

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

48 CFR Parts 301, 302, 303, 304, 305, 306, 308, 309, 311, 312, 313, 314, 315, 316, 318, 319, 322, 323, 324, 325, 326, 327, 330, 331, 332, 333, 334, 335, 336, 337, 341, 342, 343, 344, 345, 347, 352, and 370

RIN 0991-AC36

### HHS Acquisition Regulation: Regulatory Review

**AGENCY:** Department of Health and Human Services.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Health and Human Services (HHS) is proposing to amend and update its Health and Human Services Acquisition Regulation (HHSAR) to update and streamline the HHSAR. Under this initiative, all parts of the regulation were reviewed to streamline the regulation, to revise or remove policy superseded by changes in the Federal Acquisition Regulation (FAR), to remove any procedural guidance that is internal to HHS into a new HHS Acquisition Manual (HHSAM) as internal policies, guidance, and instructions. The rule would add new coverage to implement agency unique requirements. The HHSAR would also be updated to reflect organizational changes in the Department, incorporate recent statutory changes and government mandates, and to accomplish editorial revisions for clarification.

**DATES:** Comments must be received on or before December 2, 2024, to be considered in the formulation of the final rule.

**ADDRESSES:** Submit written comments in response to HHSAR Case 2023-002 through the Federal eRulemaking Portal at: <https://www.regulations.gov> by searching for “HHSAR Case 2023-002”. Select the link “Comment Now” and follow the “Submit a comment” instructions. Please include your name, company name (if any), and indicate they are submitted in response to “RIN 0991-AC36—HHS Acquisition Regulation: Regulatory Review (HHSAR Case 2023-002).”

**Warning:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to comments received.

**Inspection of Public Comments:** All comments received before the close of the comment period will be available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <https://www.regulations.gov>. Follow the search instructions on that website to view the public comments.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jarreau Vieira, Chief, Acquisition Rule-Making Branch, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources, Office of Acquisition Policy, 200 Independence Avenue SW, Washington, DC 20201. Email: [acquisition\\_policy@hhs.gov](mailto:acquisition_policy@hhs.gov), Telephone: (202) 731-4625. This is not a toll-free telephone number.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

This rulemaking is being taken under the authority of the Office of Federal Procurement Policy (OFPP) Act which provides the authority for an agency head to authorize the issuance of agency acquisition regulations that implement or supplement the FAR. The OFPP Act, as codified in 41 U.S.C. 1702, provides the authority for the FAR and for the issuance of agency acquisition regulations consistent with the FAR. This authority ensures that Government procurements are handled fairly and consistently, that the Government receives overall best value, and that the Government and contractors both operate under a known set of rules. The statute at 41 U.S.C. 1121(b) provides authority for the FAR, while 41 U.S.C. 1121(e), 1702(b)(3)(e), and 1702(c)(2), when read together, provide authority for the issuance of agency acquisition regulations consistent with the FAR. HHS issues the HHSAR under these authorities.

HHS has determined that changes to the HHSAR are necessary to align it to the FAR. As a result, the HHS Acquisition Policy Division Integrated Project Team (IPT) under the direction of the Senior Procurement Executive and composed of representatives from HHS's operating divisions (OPDIVs) and staff divisions (STAFFDIVs) and other

agency stakeholders, have participated in reviews of the regulation, resulting in a complete revision of the HHSAR. HHS conducted a comprehensive review of the HHSAR with the goal of updating obsolete coverage, streamlining policies and procedures where applicable consistent with current guidance, and moving internal policies applicable to the HHS acquisition workforce to a new HHS Acquisition Manual (HHSAM). The HHSAM will incorporate portions of the internal procedural guidance removed from the HHSAR, as well as other internal agency acquisition policy.

This proposed rule reflects changes that need to be made to the HHSAR to implement and/or supplement the FAR. HHS is proposing to substantially revise and streamline the HHSAR to update or remove references to superseded or obsolete policies, procedures, and organizations and to incorporate electronic links to FAR provisions and other matters referenced in the HHSAR. Other revisions include incorporating additional policies, solicitation provisions, and/or contract clauses into the HHSAR to implement and supplement the FAR and satisfy HHS unique mission needs and responsibilities. This includes incorporating changes in dollar and approval thresholds, definitions, and HHS position titles and offices. The reissued HHSAR proposed in this notice would correct inconsistencies, remove redundant and duplicate material already covered by the FAR, delete outdated material or information, and appropriately renumber HHSAR text, clauses, and provisions where required to comport with FAR format, numbering, and arrangement. All amendments, revisions, and removals have been reviewed and concurred with by a HHSAR revision team from each of the OPDIVs/STAFFDIVs and key agency stakeholders. This effort will create a 2024 edition of the HHSAR.

Currently, HHS is tracking a number of new FAR case proposed and final rules, as well as Executive orders (E.O.s) and directives that the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) are reviewing for potential impact to the FAR system. The Executive orders include E.O. 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (86 FR 7009; Jan. 25, 2021), E.O. 14005, “Ensuring the Future is Made in All of America by All of America’s Workers” (86 FR 7475; Jan. 28, 2021), and E.O. 14008, “Tackling the Climate Crisis at Home and Abroad” (86 FR 7619; Feb. 1, 2021). If and when FAR cases and proposed

rules are drafted and FAR final rules are published, HHS intends to examine each of these for impact to the HHSAR and any updates that may be required to maintain the HHSAR. HHS is institutionalizing an ongoing, sustained HHSAR refreshment process, so that as FAR proposed and final rules, E.O.s, and other directives are issued, HHS will initiate new HHSAR cases to bring the regulation in alignment and to avoid duplication, as necessary. HHS will examine any FAR final rules that become effective and will take into consideration such FAR changes, as appropriate, in subsequent rulemakings. When needed, HHS will also consider use of an advanced notice of proposed rulemaking (ANPRM) to obtain public input as the agency implements rulemaking to address new and emerging issues that may be identified by the Councils or by HHS as a result of E.O.s and other directives. HHS will use this public input to inform how HHS implements such guidance in the HHSAR.

The HHSAR uses the regulatory structure and arrangement of the FAR, and headings and subject areas are broken up consistent with the FAR content. The HHSAR is divided into subchapters, parts (each of which covers a separate aspect of acquisition), subparts, sections, and subsections.

When Federal agencies acquire supplies and services using appropriated funds, the purchase is governed by the FAR, set forth at title 48 Code of Federal Regulations (CFR), chapter 1, parts 1 through 53, and the agency regulations that implement and supplement the FAR. The HHSAR is set forth at 48 CFR, chapter 3, parts 301 through 370.

HHS is proposing to revise the HHSAR to add new policy or regulatory requirements and to remove any guidance that is applicable only to HHS's internal operating processes or procedures. Codified acquisition regulations may be amended and revised only through rulemaking.

### Discussion and Analysis

HHS proposes to make the following changes to the HHSAR as a part of its updating and streamlining initiative. For procedural guidance cited below that is proposed to be deleted from the HHSAR, each section cited for removal has been considered for inclusion in HHS's internal agency operating procedures in accordance with FAR 1.301(a)(2). Similarly, delegations of authorities that are removed from the HHSAR will be included in the HHSAM as internal agency guidance.

We propose to revise the following parts of the HHSAR, 48 CFR chapter 3: Parts 301, 302, 303, 304, 305, 306, 308, 309, 311, 312, 313, 314, 315, 316, 319, 322, 323, 324, 326, 327, 330, 331, 332, 333, 334, 335, 336, 337, 342, 352, and 370.

We propose to add seven (7) parts to the HHSAR: Parts 318 (Emergency Acquisitions); 325 (Foreign Acquisition); 341 (Acquisition of Utility Services); 343 (Contract Modifications); 344 (Subcontracting Policies and Procedures); 345 (Government Property); and 347 (Transportation).

And, to streamline the HHSAR and improve its use and benefit to the public, small businesses, and the HHS acquisition workforce, we propose to remove the following three (3) parts from the HHSAR: Parts 307 (Acquisition Planning); 310 (Market Research); and 317 (Special Contracting Methods). This would also move internal procedural guidance still applicable from these parts to the HHSAM, and/or remove outdated and unnecessary text or policy redundant to the FAR.

We propose to revise the authority citations cited in each HHSAR part to reflect as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304. Where additional authorities for a specific part are applicable, we identify them under that discussion of each HHSAR part later in this preamble.

We propose to retain the authority of 5 U.S.C. 301. This authority provides that the head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.

We propose to retain the authority of 40 U.S.C. 121(c) and slightly revise the reference. This authorizes the head of each executive agency to issue orders and directives that the agency head considers necessary to carry out the FAR.

We propose to include a reference to 41 U.S.C. 1121(c)(3). This provision states that the authority of an executive agency under another law to prescribe policies, regulations, procedures, and forms for procurement is subject to the authority conferred in section 1121, as well as other sections of title 41.

We propose to add an authority citation for 41 U.S.C. 1702 which addresses the acquisition planning and management responsibilities of HHS' Senior Procurement Executive.

And we propose to add the citation of "48 CFR 1.301 through 1.304" to reflect

the authority and responsibility set forth in the FAR and delegated to Federal agencies to issue agency regulations that supplement and implement the FAR.

Any other proposed changes to authorities are shown under the individual parts below.

Throughout the proposed rule (including in the discussion of each proposed revised or new HHSAR part), whenever HHS indicates that it proposes to revise and update the citation(s) to the FAR and HHSAR, it is for the purpose of comports with FAR Drafting Guidelines convention and style, and in accordance with FAR 1.105–2, Arrangement of regulations, that specifies how the FAR and by extension the HHSAR is to be referenced within the body of the regulation. References to revising and updating citations are to either correct the current citations, correct any FAR or HHSAR references to a more suitable citation, or add appropriate FAR or HHSAR citations where necessary.

### HHSAR Subchapter Headings

Under the authority of 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702, and 48 CFR 1.301 through 1.304 we propose to update the following HHSAR subchapter heading to align with the Federal Acquisition Regulation, title 48, chapter 1:

- SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING is revised to read: SUBCHAPTER B—ACQUISITION PLANNING

We propose to update the following HHSAR subchapter numbering and heading to provide a similar numbering and heading construct as other agency supplemental regulations:

- SUBCHAPTER M—HHS SUPPLEMENTATIONS is revised to read: SUBCHAPTER I—DEPARTMENT SUPPLEMENTARY REGULATIONS

### HHSAR Part 301—HHS Acquisition Regulation System

We propose to revise the authority citations for part 301, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(b), (c)(3); 41 U.S.C. 1303(a)(2); 41 U.S.C. 1702, 1707; and 48 CFR 1.301 through 1.304.

In addition to the authorities described in the Discussion and Analysis above, we propose to add the authority of the statute at 41 U.S.C. 1121(b) which provides authority for the FAR, while 41 U.S.C. 1121(e), 41 U.S.C. 1702(b)(3)(e), and 41 U.S.C. 1702(c)(2), when read together, provide authority for the issuance of agency acquisition regulations consistent with the FAR.

We also propose to add the authority of 41 U.S.C. 1303(a)(2) to HHSAR part 301. This authority provides that other regulations relating to procurement issued by an executive agency shall be limited to regulation essential to implement Government-wide policies and procedures within the agency, and additional policies and procedures required to satisfy the specific and unique needs of the agency. HHS follows these limitations on the policy and procedures promulgated in the HHSAR.

We also propose to add the authority of 41 U.S.C. 1707 to HHSAR part 301. This authority prescribes the required publication of proposed rules that HHS follows to ensure transparency and the ability of the public to comment on the unique policies and procedures HHS has identified to implement specific agency requirements to fulfill its mission and issue and administer contracts and acquisitions in accordance with the FAR.

We propose to add section 301.000, Scope of part, to prescribe general Department of Health and Human Services Acquisition Regulation (HHSAR) policies, including information regarding the maintenance and administration of the HHSAR, acquisition policies, and procedures for deviation from the HHSAR and the Federal Acquisition Regulation (FAR).

In subpart 301.1, Purpose, Authority, Issuance, we propose to revise section 301.101, Purpose, to remove scope of part language now covered in section 301.000, as well as moving the remaining language to the more appropriately placed new subpart 301.3, Agency Acquisition Regulations, section 301.301, Policy. We propose to add language that the subpart establishes uniform acquisition policies and procedures to implement and supplement the FAR, and the authorities under which the HHSAR is issued.

We propose to revise section 301.103, Authority, to prescribe the delegated authority by the Secretary of HHS to the Senior Procurement Executive (SPE) for clarity and explain the authority under which the HHSAR is issued, move the 48 CFR chapter 3 reference to new section 301.501–1, as well as other administrative edits.

We propose to add section 301.104, Applicability, to prescribe that the FAR and the HHSAR apply to all HHS acquisitions, except where expressly excluded.

We propose to add sections 301.105, Issuance, and 301.105–1, Publication and code arrangement, to identify the HHSAR issuance as 48 CFR chapter 3,

which was moved from section 301.103. We propose to add section 301.105–2 Arrangement of regulations, to prescribe the HHSAR arrangement, numbering system, and references and citations, to conform with FAR 1.105–2. We propose to add section 301.105–3, Copies, regarding access to and HHSAR availability.

We propose to revise section 301.106, OMB Approval under the Paperwork Reduction Act, to revise the title to comport with FAR 1.106, and to identify that the list of the information collection and recordkeeping requirements contained in the HHSAR, approved by the Office of Management and Budget (OMB), are revised to reflect current approved information collections. This list would be otherwise publicly available on *reginfo.gov* after a final rule pertaining to this proposed rule is published and effective.

We propose to add section 301.107, Certifications, to prescribe when a new requirement for a certification by a contractor or offeror may be included in the HHSAR, per 41 U.S.C. 1304(a)(b)(3).

We propose to remove the reserved subpart 301.2, as unnecessarily needed.

We propose to add subpart 301.3, Agency Acquisition Regulations, and section 301.301, Policy, where we propose to move the language from section 301.101 to be more appropriately placed here to describe that the HHSAR contains HHS policies governing implementation and supplementation of the FAR, including minor administrative edits.

We propose to add section 301.301–70, Amendment of the HHSAR, as an HHS supplemental section to the FAR prescribing the processes for requesting a change to the HHSAR and maintenance of HHSAR and HHSAM content and publication.

We propose to add section 301.303–70, Publication and codification—HHSAR, to prescribe that the HHSAR and HHSAM shall parallel the FAR in format, arrangement, and numbering systems. The section also establishes that HHSAR titles and numbering sequencing shall conform with the FAR to the maximum extent practicable, describes the policy, guidance and/or procedures regarding HHSAR numbering sequence when supplementing the FAR, and provides unique HHS Operating Division guidance on supplementary material numbering sequencing.

We propose to add section 301.304, Agency control and compliance procedures, which provides that the SPE is responsible for amending the HHSAR for compliance with FAR 1.304.

In subpart 301.470, Deviations from the FAR and HHSAR, we propose to remove section 301.401, Deviations, and revise the section number and title to section 301.402, Policy, and propose additional references to new sections 301.403 and 301.404, as well as administrative edits for clarification. We propose to add section 301.403, Individual deviations, to prescribe the delegated authority to the SPE. We propose to add section 301.404, Class deviations, to prescribe the delegated authority to the SPE.

In subpart 301.6, Career Development, Contracting Authority, and Responsibilities, we propose to add section 301.601, General, to prescribe the delegated authority to the Chief Acquisition Officer and the SPE, to manage the HHS contracting functions. We propose to add the authorities delegated to the SPE in paragraph (a), and the authorities the SPE may further delegate to other HHS officials, such as the heads of the contracting activities (HCAs), and that HCA's may authorize the use of ordering officers, in paragraph (b).

We propose to revise section 301.602–3, Ratification of unauthorized commitments, in paragraph (a) with administrative edits and to move agency procedural language to be appropriately placed in the HHSAM. We propose to remove paragraph (b)(2) as repetitive to the FAR and moving paragraph (c)(5) to the HHSAM as procedural language.

We propose to revise section 301.603, Selection, appointment, and termination of appointment of contracting officers, and 301.603–1, General, to establish SPE and re-delegable authority.

We propose to add section 301.603–3, Appointment, to prescribe agency policy regarding contracting officer appointments and delegations of authority, and that HCAs may delegate micro-purchase authority to HHS employees under the HHS Governmentwide Purchase Card Program.

We propose to add section 301.604, Contracting Officer's Representative (COR), and 301.604–70, Contract clause, which provides the prescription for contracting officers to insert the new clause at 352.201–70, Contracting Officer's Representative, in solicitations and contracts, when the contracting officer intends to designate a COR.

We propose to add section 301.707, Signatory authority, to state that the signature authorities for determinations and findings, when delegable in the FAR, are prescribed in the applicable HHSAR parts or corresponding HHSAM part.

*HHSAR Part 302—Definitions of Words and Terms*

We propose to revise the authority citations for part 302, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

In subpart 302.1, Definitions, and section 302.101, Definitions, we propose to add one new definition, remove one definition, and revise two existing definitions. We propose to add the definition for ordering officer, and to remove the definition for Contracting Officer's Representative as it is duplicative of the FAR. We also propose to revise the definition for agency head or head of the agency to add delegation designation clarifications, and to revise the definition for head of the contracting activity (HCA) to make minor edits and to add the HHSAR citation for HCA delegated authorities.

*HHSAR Part 303—Improper Business Practices and Personal Conflicts of Interest*

We propose to revise the authority citations for part 303, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

In subpart 303.1, Safeguards, we propose to revise the text at 303.101–3, Agency regulations, to specify employee applicability of the HHS Standards of Conduct, as found in 45 CFR part 73. We propose to remove 303.104–7, Violations or possible violations of the Procurement Integrity Act, to appropriately move the content to the HHSAM as agency procedures.

In subpart 303.2, Contractor Gratuities to Government Personnel, we propose no revisions to section 303.203, Reporting suspected violations of the Gratuities clause. We propose to add section 303.204, Treatment of violations, to provide guidance required by FAR 3.203, and to provide notice and hearing information required by FAR 3.204. The section identifies the Suspending and Debaring Official (SDO) as the official designated to make the determination whether a violation of the Gratuities clause at FAR 52.203–3 has occurred and what action will be taken under FAR 3.204(c). We also propose adding the cross reference to 309.406–3, Procedures, when the SDO determines that a violation has occurred, and that debarment is being considered.

In subpart 303.6, Contracts with Government Employees or

Organizations Owned or Controlled by Them, we propose to revise section 303.603, Exceptions, with minor administrative edits for clarification.

In subpart 303.7, Voiding and Rescinding Contracts, we propose to revise section 303.704, Policy, with a minor administrative edit.

We propose to remove subpart 303.10, Contractor Code of Business Ethics and Conduct, and section 303.1003, Requirements, to appropriately move the content to the HHSAM as agency procedures.

*HHSAR Part 304—Administrative and Information Matters*

We propose to revise the authority citations for part 304, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise the title of part 304 to “Administrative and Information Matters,” to comport with FAR part 4.

We propose to remove subpart 304.6, Contract Reporting, and section 304.6, General, and propose the content be moved to the HHSAM as agency procedures.

We propose to remove subpart 304.16, Unique Procurement Instrument Identifiers, and section 304.1600, Scope of subpart, and we propose the content be moved to the HHSAM as agency procedures.

In subpart 304.71, Review and Approval of Proposed Contract Actions, we propose to remove the underlying sections, and reserve the subpart. We propose to remove section 304.7100, Policy, and propose the content be moved to the HHSAM as agency procedures.

In subpart 304.72, Affordable Care Act Prevention and Public Health Fund—Reporting Requirements, section 304.7200, Scope of subpart, we propose to move some of the language to the retitled section 304.7201, Policy, due to the nature of the implementing language.

We propose to retitle section 304.7201 as “Policy,” and move paragraphs (a) through (c) to the HHSAM as agency procedures. We propose minor administrative edits to the remaining content and restructuring the section to accommodate the relocated from section 304.7200.

We propose to revise section 304.7202, Contract clause, to add the applicable solicitations and contract actions value of \$25,000 or more threshold, and to provide minor administrative edits.

*HHSAR Part 305—Publicizing Contract Actions*

We propose to revise the authority citations for part 305, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to remove subpart 305.3, Synopses of Contract Awards, and section 305.303, Announcement of contract awards, and propose the content be moved to the HHSAM as agency procedures.

We propose to add subpart 305.4, Release of Information, and section 305.402, General public, to state that requests from the public for specific records pertaining to contract actions shall be processed according to the Freedom of Information Act. We propose to add sections 305.470, Contractor award announcements, advertisements, and releases, and 305.470–1, Policy, to provide policy that restricts contractors from referring to its HHS contract(s) in commercial advertising in a manner that states or implies the Government approves or endorses the contractor's products or services, or considers them superior to other products and services. This section also states that HHS contractors share responsibility for protecting sensitive and classified information, and approval requirements by the contracting officer prior to the release of any contract award information by the contractor.

We propose to add section 305.470–2, Contract clause, which would also prescribe clause 352.205–70, Advertisements, Publicizing Awards, and Releases, in solicitations and contracts that exceed the simplified acquisition threshold and includes an Alternate I for contracts involving sensitive or classified information.

We propose removing subpart 305.5, Paid Advertisements, and section 305.502, Authority, and propose to move the content to the HHSAM as agency procedures.

In subpart 305.70, Publicizing Requirements Funded From the Affordable Care Act Prevention and Public Health Fund, we propose minor administrative edits for clarification to sections 305.7003, Publicizing preaward, and 305.7004, Publicizing postaward.

*HHSAR Part 306—Competition Requirements*

We propose to revise the authority citations for part 306, for the reasons set forth in the discussion and analysis

section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

In subpart 306.2, Full and Open Competition After Exclusion of Sources, we propose to revise section 306.202, Establishing or maintaining alternative sources, by redesignating paragraph (a) as paragraph (b)(1) to comport with FAR and HHSAR numbering policy, move the existing content at paragraph (b)(1) to the HHSAM as agency procedures, and provide administrative edits for clarification.

In subpart 306.3, Other Than Full and Open Competition, in section 306.302–1, Only one responsible source and no other supplies or services will satisfy agency requirements, we propose to remove the reference to FAR 6.302–1 in the title, assign paragraph designation (a)(2) to the first paragraph to comport with FAR and HHSAR numbering policy, and to add descriptive implementing language. We propose to add section 306.302–2, Unusual and compelling urgency, to prescribe delegated authority to the SPE regarding making the determination that exceptional circumstances apply when seeking a total period of performance exceeding one year, including all options, for a contract awarded or modified using the authority at FAR 6.302–2(d)(1)(ii).

In subpart 306.5, Competition Advocates, we propose to revise the title to “Advocates for Competition,” to comport with the FAR subpart title. We propose to revise section 306.501, Requirement, to prescribe the designation of the Advocate for Competition as the Director, Acquisition Policy Division, Office of Acquisitions (ASFR/APD). We also propose to add that the Director, ASFR/APD may further delegate this authority to appoint an alternate agency advocate for competition, and that the HHS Advocate for Competition shall designate procuring activity advocates for competition in accordance with FAR 6.501. We also propose to add the uniform resource locator for the location of the list of HHS procuring activity advocates for competition.

#### *HHSAR Part 307—Acquisition Planning*

We propose to remove and reserve HHSAR part 307 in its entirety including underlying section 307.105, Contents of written acquisition plans, as the language is duplicative of the FAR, and to move other content to the HHSAM as needed as agency internal procedures.

#### *HHSAR Part 308—Required Sources of Supplies and Services*

We propose to revise the authority citations for part 308, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to remove subpart 308.4, Federal Supply Schedules, and section 308.405–6, Limited source justification and approval, as duplicative to the FAR, and to move some content to the HHSAM as agency procedures.

In subpart 308.8, Acquisition of Printing and Related Supplies, we recommend removing sections 308.800, Scope of subpart, and 308.801, Definitions, as the sections contain content duplicative of the FAR, and procedural in nature. We propose to move the applicable content to the HHSAM as agency procedures. In section 308.802, Policy, we propose to revise the existing content to explicitly state that unless specifically authorized in HHS contracts, no printing by a contractor or subcontractor is authorized under an HHS contract. And we propose to add language that permits contracting officers to authorize limited printing pursuant to the clause prescribed at section 308.870. We also propose to remove the information about HHS’ designated central printing authority to the HHSAM as internal agency guidance.

We propose to revise section 308.803 by renumbering and retitling it to 308.870, Contract clause, which prescribes clause 352.208–70, Printing and Duplication, to be inserted in all solicitations, contracts, and orders for supplies or services over the simplified acquisition threshold, unless printing or increased duplication is authorized by statute.

#### *HHSAR Part 309—Contractor Qualifications*

We propose to revise the authority citations for part 309, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add subpart 309.1, Responsible Prospective Contracts, and sections 309.104, Standards, and 309.104–1, General standards, to establish that for cost-reimbursement or incentive type contracts, or contracts with progress payments, the prospective contractor’s accounting system must provide reasonable stated assurances.

In subpart 309.4, Debarment, Suspension, and Ineligibility, we

propose adding section 309.400, Scope of subpart, to establish that the subpart implements FAR subpart 9.4 and prescribes HHS procedures and related actions for the suspension and debarment of contractors.

We propose to revise section 309.403, Definitions, by adding the definition for the Suspension and Debarment (S&D) Committee introduced in revised section 309.406–3. We also propose revising the existing definition to the Suspending and Debarment Official (SDO) to comport with the FAR 9.403, as well as revising the title of the appointed HHS SDO to Deputy Assistant Secretary for Acquisitions, to reflect the current title.

We propose to remove section 309.404, System for Award Management (SAM) exclusions, as much of the content is duplicative of the FAR, and the remaining content be moved to the HHSAM as agency procedures.

We propose to revise section 309.405, Effect of listing, by removing from the section title “(compelling reason determinations),” to comport with the title at FAR 9.405, and to move the existing content in paragraph (a) to the HHSAM as agency procedures and replace the content with language to prescribe the delegation of authority to the SDO and permit further redelegation to the HCA.

We propose to add section 309.405–1, Continuation of current contracts, which authorizes the continuation of contracts for contractors debarred (or proposed to be debarred) or suspended. It also requires a written determination before the award of orders or options on existing contracts with these contractors (see FAR 9.405–1(a)(2)) and delegates authority to the SDO with further redelegation to the HCA. We also propose to add section 309.405–2, Restrictions on subcontracting, which prescribes the delegated authority to the SDO, who further redelegates the authority to the HCA to consent to a contractor’s use of a subcontractor who is suspended, proposed for debarment, or is debarred.

We propose to add section 309.406–1, General, to provide additional SDO debarment consideration and determination factors and examples.

We propose to revise section 309.406–3, Procedures, to include minor administrative edits to the existing content, and to introduce a formal Suspending and Debarment Committee (S&D Committee) to assist the SDO in the final determination for debarment. This section also provides additional public-facing debarment referral procedures and S&D Committee procedures for transparency.

We propose to add sections 309.407, Suspension, and 309.407–1, General, to prescribe the delegated authority to the SDO to determine whether to continue business dealings with a suspended contractor, and to establish the SDO as the suspending official under the Federal Management Regulation at 41 CFR 102–117.295.

We propose to revise section 309.407–3, Procedures, to include minor administrative edits to the existing content, and to introduce a formal Suspending and Debarring Committee (S&D Committee) to assist the SDO in the final determination for suspension. This section also provides additional public-facing suspension referral procedures and S&D Committee procedures for transparency.

We propose to revise section 309.470–1, Situations where reports are required, to make administrative edits in stating that the contracting officer shall report to the HCA and SDO regarding the situations listed thereafter.

We propose to add section 309.471, Fact-finding procedures, to establish procedures to resolve genuine disputes of material fact involving debarment or suspension determinations. The section provides details to include the Office of General Council, witnesses, and other factors needed to assist the SDO in a final suspension or debarment determination.

We propose to add subpart 309.5, Organizational and Consultant Conflicts of Interest, and section 309.503, Waiver, to provide that the SPE is the designee at FAR 9.403 to waive general rules or procedures of the subpart. We also propose to add section 309.507–1, Solicitation provision, which prescribes the new provision at 352.209–70, Organizational Conflicts of Interest, to be included in any solicitation for the services addressed at FAR 9.502.

#### *HHSAR Part 310—Market Research*

We propose to remove HHSAR part 310, Market Research, and reserve the part as we propose to remove the coverage currently contained at section 310.001 as duplicative of the FAR.

#### *HHSAR Part 311—Describing Agency Needs*

We propose to revise the authority citations for part 311, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add subpart 311.1, Selecting and Developing Requirement Documents, and section 311.103, Market

acceptance, to prescribe that the authority is delegated to the HCA.

We propose to add subpart 311.5, Liquidated Damages, and section 311.501, Policy, to establish that the HCA may reduce or waive the amount of liquidated damages assessed under a contract, if the Commissioner, Financial Management Service, or designee, approves.

We propose to add subpart 311.6, Priorities and Allocations, to provide information on the HHS Health Resources Priorities and Allocation System (HRPAS) that is part of the Federal Priorities and Allocations System. This subpart references guidance and procedures for use of the Defense Production Act (DPA) priorities and allocations authority with respect to health resources necessary or appropriate to promote the national defense as delegated to the Secretary of HHS.

We propose to add section 311.600, Scope of subpart, to establish that the subpart details information on the HHS HRPAS that is part of the Federal Priorities and Allocations System. This subpart references guidance and procedures for use of the DPA priorities and allocations authority with respect to health resources necessary or appropriate to promote the national defense as delegated to the Secretary.

We propose to add section 311.601, Definitions, to establish two definitions, national defense and rated order, as the definitions differ slightly from the FAR and are derived from 45 CFR part 101.

We propose to add section 311.602–70, The Health Resources Priorities and Allocation System, to reference Executive Order (E.O.) 13603, National Defense Resources Preparedness, dated March 16, 2012. This E.O. provides the Secretary the authority to require acceptance and priority performance of contracts or orders (other than contracts of employment) to promote the national defense over performance of any other contracts or orders, and to allocate materials, services, and facilities as deemed necessary or appropriate to promote the national defense, with respect to health resources is delegated to the Secretary.

We propose to add section 311.603, Procedures, and section 311.603–70, Agency program, to reference specific HHS agency procedures as set forth in the HRPAS regulations at 45 CFR part 101, which provides guidance and procedures for use of the DPA priorities and allocations authority with respect to health resources, including the use of priority rated orders, necessary or appropriate to promote the national defense.

In subpart 311.70, Section 508 Accessibility Standards, we propose to reserve the subpart, as we propose to move the content at section 311.7000, Defining electronic information technology requirements, to the HHSAM as agency procedures.

In subpart 311.71, Public Accommodations and Commercial Facilities, we propose to revise section 311.7102, Contract clause, which prescribes clause 352.211–1, Public Accommodations and Commercial Facilities, be inserted in solicitations, contracts, and orders requiring the contractor to conduct events in accordance with 311.7100(b). We propose to revise clause number to 352.211–70, to comport with FAR numbering convention of supplemental clauses.

In subpart 311.72, Conference Funding and Sponsorship, we propose minor administrative edits to section 311.7201, Funding and sponsorship. We also propose to revise section 311.7202, Contract clause, which prescribes clause 352.211–2, Conference Sponsorship Request and Conference Materials Disclaimer, be inserted in solicitations, contracts, and orders providing funding which partially or fully supports a conference. We propose to revise clause number to 352.211–71, to comport with FAR numbering convention of supplemental clauses.

In subpart 311.73, Contractor Collection of Information, we propose minor administrative edits to section 311.7300, Policy. We also propose to revise section 311.7301, Contract clause, which prescribes clause 352.211–3, Paperwork Reduction Act, be inserted in solicitations, contracts, and orders that require a contractor to collect the same information from 10 or more persons. We propose to revise the clause number to 352.211–72, to comport with FAR numbering convention of supplemental clauses.

#### *HHSAR Part 312—Acquisition of Commercial Products and Commercial Services*

We propose to revise the authority citations for part 312, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise the title of part 312 to “Acquisition of Commercial Products and Commercial Services,” to comport with the FAR part 12 title.

We propose to remove subpart 312.1, Acquisition of Commercial Items—General, and section 312.101, Policy,

moving the content to the HHSAM as agency procedures.

We propose to remove subpart 312.2, Special Requirements for the Acquisition of Commercial Items, and section 312.202, Market research and description of agency need, as the content is duplicative to the FAR.

We propose adding subpart 312.3, Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services, consisting of section 312.301, which prescribes clause 352.212–70, Gray Market and Counterfeit Items, which requires the contracting officer to insert in solicitations and contracts for new medical supplies, new medical equipment, new information technology equipment, and maintenance of medical or information technology equipment that includes replacement parts, if used, refurbished, or remanufactured parts are unacceptable, when the associated solicitation includes FAR provisions 52.212–1, Instructions to Offerors—Commercial Products and Commercial Services, and 52.212–2, Evaluation—Commercial Products and Commercial Services.

#### *HHSAR Part 313—Simplified Acquisition Procedures*

We propose to revise the authority citations for part 313, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise part 313, Simplified Acquisition Procedures, to remove one section and substantively revise subpart 313.3 to enact legislative requirements. We propose to remove section 313.003, Policy, which provides section 508 of the Rehabilitation Act of 1973 guidance for Information and Communication Technology acquisition. This guidance is also found at 339.203(a) and will be addressed in the HHSAM in part 339.

We also propose to revise subpart 313.3, Simplified Acquisition Methods, and section 313.301, Governmentwide commercial purchase card. The existing content at 313.301 is removed and placed in the HHSAM as it is more appropriate for internal agency operating procedures. We propose to redesignate the section as 313.301–70, revise the heading to read “Governmentwide commercial purchase card—purchases of PPE”, and state that the Infrastructure Investment and Jobs Act (IIJA), Public Law 117–58, Subtitle C, Make Personal Protective Equipment (PPE) in America (MPPEIA), applies to all purchases of PPE including those

transactions made using the Governmentwide commercial purchase card under the micro-purchase threshold. We are including a cross reference to subpart 325.71 for definitions, restrictions, and exceptions, when procuring PPE.

#### *HHSAR Part 314—Sealed Bidding*

We propose to revise the authority citations for part 314, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to remove subpart 314.1, Use of Sealed Bidding, and section 314.103, Policy, which states that electronic and information technology supplies and service shall comply with section 508 of the Rehabilitation Act of 1973, as the content is appropriately covered in part 339, Acquisition of Information Technology.

We propose to retain subpart 314.4, Opening of Bids and Award of Contract, and section 314.404–1, Cancellation of invitations after opening, with no change to the content. We propose to revise section 314.407–3, Other mistakes disclosed before award, to add delegation, without redelegation, language to the HCA’s authority. We also propose to revise section 314.407–4, Mistakes after award, to add delegation, without redelegation, language to the HCA’s authority.

We propose to add sections 314.408, Award, and 314.408–70, Award when only one bid is received, to provide when only one bid is received in response to an invitation for bids, such bid may be considered and accepted if the contracting officer makes a written determination, approved one level above the contracting officer, documenting the stated issues in the section, and that the determination shall be placed in the contract file.

#### *HHSAR Part 315—Contracting by Negotiation*

We propose to revise the authority citations for part 315, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

In subpart 315.2, Solicitation and Receipt of Proposals and Information, we propose to remove section 315.204–5, Part IV—Representations and instructions, as the content is repetitive to the FAR, and moving some content to the HHSAM as agency procedure.

We recommend retaining section 315.208, Submission, modification,

revision, and withdrawal of proposals, as a title with no content, and moving the current content to new section 315.208–70, Submission, modification, revision, and withdrawal of proposals—R&D acquisitions, to clarify that the content applies in the case of biomedical or behavioral research and development acquisitions only. We also propose to restructure the content into redesignated paragraph numbers. Paragraph (a) contains the original 315.208(b) text, revised for clarity. Paragraph (b) is a new proposed paragraph that sets forth the policy permitting the contracting officer to consider a proposal received concerning biomedical or behavioral research and development (R&D) acquisitions after the date specified for receipt, under certain conditions. It is based on the existing provision at 352.215–70, Late Proposals and Revisions, that pertains only to biomedical or behavioral R&D solicitations using competitive proposals. While the provision itself was previously codified, there was no corresponding policy in the HHSAR, which is now provided. Paragraph (c) contains the original 315.208(b)(2) content. We propose redesignating the paragraph as paragraph (c), removing the acronym “HCA”, and substituting it with “contracting officer” to reflect that the contracting officer will exercise this authority rather than the HCA.

We propose to add section 315.209–70, Solicitation provision, which prescribes the provision 352.215–70, Late Proposals and Revisions—R&D Solicitations, in biomedical or behavioral R&D competitive acquisition solicitations subject to the requirements of 315.208–70(a) and the authorization of the HCA.

In subpart 315.3, Source Selection, we propose to revise section 315.303–70 by incorporating administrative edits and formatting revisions to the section for clarification.

We propose to revise section 315.304, Evaluation factors and significant subfactors, by removing the term “electronic and information technology (EIT)” and replacing it with “information and communication technology (ICT)” to comport with FAR subpart 315.3 terminology. We propose to revise the section to provide clarity that the requirement is that contracting officers shall include a separate technical evaluation factor pertaining to compliance with section 508 requirements, rather than the language as now shown that appears to just require contracting officers to comply with the general tenets of section 508. We also propose to add a reference to 339.203.



We propose to revise section 315.305, Proposal evaluation, by removing the content and leaving the header with no text. We propose adding section 315.305–70, Proposal evaluation—use of non-Federal evaluators, and revising and updating the content now at 315.305(c)(1) through (2) and move it to 315.305–70. Accordingly, we propose to reformat and redesignate the text in section 315.305 from paragraphs (c)(1) and (2) to paragraphs (a) and (b) to comport with FAR numbering requirements, and to include paragraphs (b)(1) through (4), and to add a new paragraph (c) to outline HHS’s policy with respect to use of non-Federal evaluators. We also propose administrative edits in the section for clarification.

In paragraph (a), we propose to add language that add the requirement that the Source Selection Authority or the contracting officer, as applicable, make the decision to disclose proposals to non-Federal evaluators and to add a reference to FAR 15.305(c) at the end of the paragraph.

In paragraph (b), redesignated from paragraph (c)(1), we propose to add content that when an offeror’s or contractor’s proposal will be disclosed outside the Government, the provision prescribed at 315.305–71 requires that the contractor and its employees, as well as any subcontractors and their employees, agree that when performing work as an evaluator under a Government contract that they will use the data (trade secrets, business data, and technical data) contained in the proposal for evaluation purposes only. Proposed paragraphs (b)(1) through (4) provides other conditions and restrictions on use of non-Federal evaluators. In paragraph (c), it requires that the agreement shall be signed by the contractor and the assigned contractor employee, subcontractor, or consultant (*i.e.*, the non-Federal evaluator) and filed in the contract file of an offeror’s proposal.

We propose to add section 315.305–71, Solicitation provision, to prescribe the provision at 352.215–71, Use of Non-Federal Evaluators—Conditions for Evaluating Proposals, in solicitations when the Government may use non-Federal evaluators to evaluate an offeror’s or contractor’s proposals and offers.

In subpart 315.4, Contract Pricing, at section 314.404–2, Data to support proposal analysis, we propose to revise the section title to comport with the FAR section title, provide administrative edits within the section for clarification, and move some of the

content to the HHSAM as agency procedures.

In subpart 315.6, Unsolicited Proposals, we propose to add section 315.604, Agency points of contact, to establish minimum information that HHS operating divisions/staff divisions must make available to potential offerors of unsolicited proposals in accordance with FAR 15.604(a) and assigning this responsibility to the HCAs. Additionally, we propose adding a uniform resource locator to the HHS internet web page to provide the HHS point of contact information.

We propose to revise section 315.605–70, Content of unsolicited proposals—warranty by offeror, by revising the title and number of the section to redesignate it as a supplement to the FAR, and to add “—warranty by offeror,” to reflect the focus of the content, distinguishable from the FAR. We also propose minor administrative edits to comport with FAR formatting requirements.

We propose to retain section 315.606, Agency procedures, with no changes.

We propose to revise section 315.606–1, Receipt and initial review, to redesignate the paragraph number to comport with the appropriate FAR paragraph being implemented.

#### *HHSAR Part 316—Types of Contracts*

We propose to revise the authority citations for part 316, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

In subpart 316.3, Cost-Reimbursement Contracts, section 316.307, Contract clauses, we propose to revise paragraph (a)(1), which prescribes clause 352.216–70, Allowable Cost and Payment for Hospitals, and requires contracting officer to insert the clause in solicitations and contracts when a cost-reimbursement contract with a hospital (profit or non-profit) is contemplated and when the clause 52.216–7 is inserted in the contract. We propose to revise the content with administrative edits for clarification. We also propose to revise the clause content with administrative edits to remove the reference to 45 CFR part 75. We also propose to remove paragraph (a)(2), which prescribes clause 352.216–70, Additional Cost Principles for Hospitals (Profit and Non-Profit), and requires contracting officer to insert the clause when a cost-reimbursement contract with a hospital (profit or non-profit) is contemplated. We propose to appropriately move this clause to part 331, Contract Cost Principles and Procedures.

In subpart 316.5, Indefinite-Delivery Contracts, section 316.505, Ordering, we propose to revise paragraph (b)(8) to update the title of the HHS Advocate for Competition to comport with FAR usage and to designate the HHS Advocate for Competition as the task-order and delivery-order ombudsman. The section is also updated to require each HHS HCA to designate, in writing, a task-order and delivery-order ombudsman and to provide the website on the HHS internet where this is listed.

We propose to remove subpart 316.6, Time-and-Materials, Labor-Hour, and Letter Contracts, and sections 316.603, Letter contracts, and 316.303–3, Limitations, as internal operational procedures or delegations that will be moved to the HHS Acquisition Manual (HHSAM).

#### *HHSAR Part 317—Special Contracting Methods*

We propose to remove part 317, Special Contracting Methods, and reserve the part as we propose to remove the current part content.

We propose to remove subpart 317.1, Multi-Year Contracting, and section 317.104, General, moving the content to the HHSAM as agency procedure.

We propose to remove sections 317.105, Policy, and 317.105–1, Uses, moving the content to the HHSAM as agency procedure.

We propose to remove section 317.107, Options, moving the content to the HHSAM as agency procedure.

We propose to remove section 317.108, Congressional notification, moving the content to the HHSAM as agency procedures.

We propose to remove subpart 317.2, Options, and section 317.204, Contracts, removing most of the content as duplicative to the FAR, and moving the remaining content to the HHSAM as agency procedures.

#### *HHSAR Part 318—Emergency Acquisitions*

We propose to add the authority citations for part 318, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add section 318.000 to identify that part 318 will set forth additional emergency acquisition flexibilities. We also propose to add section 318.001, Definition, and section 318.001–71, Agency delegation of determination, to prescribe the delegated authority to the HCA to utilize emergency acquisition flexibilities and make the agency head determinations as



set forth in FAR part 18 and as defined in subpart 318.2.

We propose to add subpart 318.1, Available Acquisition Flexibilities, section 318.109, Priorities and allocations, and section 318.109–70, The Health Resources Priorities and Allocation System, to provide description and reference to subpart 311.6 to comport with FAR formatting.

We propose to add subpart 318.2, Emergency Acquisition Flexibilities, and section 318.202–70, Specific HHS flexibilities, to provide four specific definitions to reflect the delegated emergency authorities for: the Micro-purchase threshold; the Simplified acquisition threshold; Commercial product or commercial service treatment; and Simplified procedures for certain commercial products and commercial services.

We propose to add 318.270, Head of the agency delegations, to prescribe the delegated authority to the HCA to make the determinations in the listed FAR references, which include FAR 2.101, definitions of “Simplified acquisition threshold” and “Micro-purchase threshold, 12.102(f), 13.201(g), and 13.500(c)(1).

#### *HHSAR Part 319—Small Business Programs*

We propose to revise the authority citations for part 319, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 15 U.S.C. 631, *et seq.*; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add the authority of 15 U.S.C. 631, *et seq.* (the Small Business Act), as an authority pertaining to small business programs.

We propose to clarify subpart 319.2, Policies, by making minor administrative updates in citations, references, and titles of individuals.

We propose redesignating paragraph (d) of 319.201 as paragraph (c) to align with FAR 19.201, as the topical coverage more appropriately falls under paragraph (c). We also add “Executive” to the title for the OSDDBU Director.

We propose redesignating paragraph (e) of 319.201 as paragraph (d) to align with FAR 19.201, as the topical coverage more appropriately falls under paragraph (d). We are removing the language that dealt with SBS review of all acquisitions that are not set-aside. The matter is more appropriately addressed in internal procedural policy in the HHS Acquisition Manual (HHSAM).

In subpart 319.2, we are adding section 319.202 to provide the requirement that contracting officers

document set-aside actions and recommendation on HHS Form 653, Small Business Program Review.

We propose to remove the coverage concerning unique mentor-protégé clauses as the HHS Mentor Protégé (MP) program is no longer in effect. Therefore, references to the program and related clauses have been deleted from the HHSAR. HHS follows the SBA Federal-wide guidance.

We propose adding subpart 319.8, Contracting With the Small Business Administration (the 8(a) Program), to provide coverage for the SBA partnership agreement. Under this subpart we are adding coverage at sections 319.800, General, 319.811, Preparing the contracts, and 319.811–370, SBA Partnership Agreement and contract clauses. This subpart prescribes two new clauses to be used when an 8(a) acquisition is processed pursuant to the Partnership Agreement: 352.219–72, HHS Notification of Competition Limited to Eligible 8(a) Participants, and for noncompetitive solicitations and awards, we propose adding the clause at 352.219–73, Notification of Section 8(a) Direct Awards, instead of the prescribed FAR clauses at 52.219–11, Special 8(a) Contract Conditions; 52.219–12, Special 8(a) Subcontract Conditions; and 52.219–17, Section 8(a) Award, as it governs HHS unique agency requirements.

#### *HHSAR Part 322—Application of Labor Laws to Government Acquisitions*

We propose to revise the authority citations for part 322, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 322 by adding a new subpart 322.1 and revising the existing subpart 322.8.

We propose to add subpart 322.1, Basic Labor Policies, to provide the procedures for the admittance of union representatives to HHS facilities. Under this subpart we propose to add section 322.101, Labor relations, as a header with no underlying text. We propose to add section 322.101–70, Admittance of union representatives to HHS facilities, to provide necessary admittance policy and procedures, and reporting requirements if entry is denied. In paragraph (a) it states that it is HHS policy to admit labor union representatives of contractor employees to HHS facilities to visit work sites and transact labor union business with contractors, their employees, or union stewards pursuant to existing union collective bargaining agreements. Their

presence shall not interfere with the contractor’s work progress under an HHS contract nor violate the safety or security regulations that may be applicable to persons visiting the facility. The union representatives will not be permitted to conduct meetings, collect union dues, or make speeches concerning union matters while visiting a work site. Paragraph (b) would require that whenever a union representative is denied entry to a facility or work site, the person denying entry shall make a written report to the HHS labor coordinator, the Office of the General Counsel (OGC), or corresponding labor advisor, with a copy to the cognizant contracting officer within two working days after the request for entry is denied. The report shall include the reason(s) for the denial, the name of the representative denied entry, the union affiliation and number, and the name and title of the person that denied the entry.

We propose to revise subpart 322.8, Equal Employment Opportunity, to include a new section 322.808, Complaints. The new section would require that contractors shall, in good faith, cooperate with HHS in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614 and in accordance with clause 352.222–70 as prescribed in this subpart.

We propose to revise section 322.810, Solicitation provisions and contract clauses, to redesignate the paragraph from (h) to (e) to properly align with the FAR, and to add “and Anti-Harassment” to the title of the clause, 352.222–70, so the title of the clause would read “Contractor Cooperation in Equal Employment Opportunity and Anti-Harassment Investigations.” The clause is prescribed to be included in solicitations, contracts, and order that include the clause at FAR 52.222–26, Equal Opportunity.

#### *HHSAR Part 323—Environment, Sustainable Acquisition, and Material Safety*

We propose to revise the authority citations for part 323, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 323 by updating the header of the part to “Environment, Sustainable Acquisition, and Material Safety,” to align with the title for FAR part 23 recently updated effective May 22, 2024, via FAR Case 2022–006 (RIN 2900–AO43) final rule (89 FR 30212). Additionally, we propose

moving text from existing sections to a new subpart 323.3 to properly align with the FAR, and to redesignate existing subpart 323.71 to 323.1 as described below.

We propose to remove sections 323.7000, 323.7001, and 323.7002 and move the coverage under a new subpart 323.3 where it will align with the FAR coverage concerning hazardous material identification.

We propose to revise subpart 323.71, Sustainable Acquisition Requirements, by renumbering and retitling the header for the subpart as 323.1, Sustainable Products and Services. This aligns with the updated FAR subpart title and numbering. We propose to remove sections 323.7101 and 323.7102 as internal agency procedures that will be updated and moved to the HHSAM. The remaining sections, 323.7100 and 323.7103, would be renumbered as 323.103–70 and 323.109–70, respectively to appropriately align with the FAR.

In proposed section 323.103–70, Policy—Sustainable Acquisition Plan, the existing text is removed as unnecessary and redundant to the FAR. A new paragraph (a) is added to provide that contracting officers may, for new contracts and orders above the micro-purchase threshold, insert an evaluation factor on the offeror's Sustainable Action Plan in the solicitation. And a new paragraph (b) is added to require that offerors, when the solicitation includes the provision prescribed at 323.109–70 (*i.e.*, the newly numbered 352.223–70, Instructions to Offerors—Sustainable Acquisition Plan), offerors shall include a Sustainable Acquisition Plan in their technical proposal addressing sustainable products for services for delivery under any resulting contract, and that the contracting officer shall incorporate the final Sustainable Acquisition Plan into the contract.

In proposed section 323.109–70, Solicitation provision, the prescribed provision number is updated to reflect 352.223–70, and the title is updated to reflect “Instructions to Offerors—Sustainable Acquisition Plan.”

We propose to add subpart 323.3, Hazardous Material Identification, Material Safety Data, and Notice of Radioactive Materials, to reflect the revised FAR header at FAR subpart 23.3, and we propose to add underlying sections 323.300 and 323.304–70. The new subpart aligns with the FAR and adds updated language moved from sections 323.7000, 323.7001, and 323.7002. Section 323.300, Scope of subpart, identifies this subpart provides procedures for administering safety and health requirements. In section

323.304–70, Contract clause, clause 352.223–71, Safety and Health, is prescribed to be inserted in solicitations and contracts that involve hazardous materials or hazardous operations and details for which types of requirements.

#### *HHSAR Part 324—Protection of Privacy and Freedom of Information*

We propose to revise the authority citations for part 324, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to make only limited revisions at this time to HHSAR part 324 as this part will be updated through future rulemaking. To align with FAR numbering conventions in FAR subpart 24.1, we propose to renumber 324.103 to 324.103–70 and renumber 324.104 to 324.103–71. We propose to amend section 324.105, Contract clauses, by renumbering it to 324.104 to align with the FAR and revising paragraph (b) to add at the end of the sentence for the prescription of HHSAR clause 352.224–71, Confidential Information, the phrase “. . . and in solicitations, contracts, and orders that include the clause at 352.227–71, Rights in Data—Supplement—Exceptional Circumstances.” We also propose in this sentence to remove the word “to” in front of “third party information” so it would read “to Government or third party confidential information.”

#### *HHSAR Part 325—Foreign Acquisition*

We propose to revise the authority citations for part 325, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add HHSAR part 325 to provide agency policies and procedures and the restrictions on Make Personal Protective Equipment (PPE) in America. This rule would add subpart 325.71, Make PPE in America Act Restrictions on Foreign Acquisition of Personal Protective Equipment, and underlying sections 325.7100 through 325.7103 as described below.

In section 325.7100, Scope of subpart, it indicates that the subpart contains restrictions on the acquisition of certain personal protective equipment as required by the Make PPE in America Act (Pub. L. 117–58) for solicitations and contracts issued by HHS (among other agencies not included under the purview of this regulation). This subpart would codify the class deviation to the HHSAR issued by the HHS Senior

Procurement Executive on February 9, 2023, that implemented the Make PPE in America Act, Division G, Title IX, Subtitle C, secs. 70951–70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58), dated November 15, 2021. On November 15, 2021, the President signed, the Infrastructure Investment and Jobs Act (IIJA). As part of the IIJA, Congress enacted the Make PPE in America Act (the Act). In promulgating the Act, Congress found, among other things, that the COVID–19 pandemic exposed the vulnerability of the United States' supply chains with respect to PPE and the lack of domestic production of PPE, including the components and materials thereof. To meet the needs for a long-term investment strategy for the domestic production of PPE items critical to the U.S. national response to a public health emergency, including, but not limited to, the COVID–19 pandemic, the Act requires action by HHS, the Department of Homeland Security, and the Department of Veterans Affairs (the covered agencies). To incentivize domestic manufacturing of PPE, the Act imposes certain requirements for contracts awarded by the covered agencies for the procurement of PPE.

The class deviation issued by the Senior Procurement Executive implemented the tenets of the Act applicable to HHS in advance of rulemaking. This rule seeks public comment on the proposed language to be added to the HHSAR that HHS has been following and in effect at the agency since February 9, 2023.

In section 325.7101, Definitions, we propose six definitions to ensure common understanding and meaning as used in this part—component, domestic personal protective equipment, foreign-made domestic personal protective equipment, foreign personal protective equipment, personal protective equipment, and United States.

We propose to add section 325.7102, Restrictions on certain personal protective equipment, as a header with no text.

In section 325.7102–1, Restrictions, certain restrictions are identified that implement section 70952 of the Make PPE in America Act, and they apply to all contracts and orders for the purchase of personal protective equipment. These restrictions include the requirement for contracting officers to purchase domestic personal protective equipment (PPE), except as provided in section 325.7102–2, Exceptions. And the text provides that any contract for PPE shall have a base period of performance of at least two years, plus any option periods, as required by law.

In section 325.7102–2, Exceptions, paragraph (a) provides that acquisitions of PPE in certain categories are not subject to the restrictions in section 325.7102–1, to include PPE where the HHS Secretary has maximized sources for foreign-made domestic PPE, and where the HHS Secretary certifies every 120 days that it is necessary to procure PPE under alternative procedures to respond to the immediate needs of a public health emergency. Other exceptions set forth in paragraph (b) include an item of PPE or component thereof, including those described in paragraph (a), that is, or includes, a material listed in FAR 25.104 as one for which a nonavailability determination has been made; or to which the HHS Secretary—

- Determines that a sufficient quantity of a satisfactory quality that is grown, reprocessed, reused, or produced in the United States cannot be procured as, and when, needed at United States market prices; and
- Certifies every 120 days that it is necessary to procure PPE to respond to the immediate needs of a public health emergency.

Under paragraph (c), the HHS Secretary is authorized to make the certification in paragraphs (a) and (b) or the nonavailability or unreasonable cost determination; supporting documentation requirements and approval levels are further outlined for the public.

In section 325.7103, Solicitation provisions and contract clauses, paragraph (a), clause 352.225–70, Made in America—Personal Protective Equipment, is prescribed to be inserted in solicitations and contracts, regardless of dollar value, when procuring any item covered under 325.7102–1(a). And in paragraph (b), provision 352.225–71, Made in America Certificate—Personal Protective Equipment, would be required to be inserted in solicitations containing the clause at 352.225–70.

#### *HHSAR Part 326—Other Socioeconomic Programs*

We propose to revise the authority citations for part 326, for the reasons set forth in the discussion and analysis section and as described below, to read as follows: 5 U.S.C. 301; 25 U.S.C. 47; 25 U.S.C. 1633; 25 U.S.C. 5301 *et seq.*; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; 42 U.S.C. 2003 and 48 CFR 1.301 through 1.304. We propose to retain the existing authorities of 5 U.S.C. 301; 25 U.S.C. 47; 25 U.S.C. 1633; and 42 U.S.C. 2003 as applicable to the subject matter and requirements set forth in the part. We removed the authority citation for 41 U.S.C. 253(c)(5)

as it no longer exists. Additionally, we propose to add the authority citations for 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304 as set forth in the discussion and analysis section above, to align part 326 with the other parts set forth in 48 U.S.C. chapter 3. We propose to add one additional authority under which Public Law 93–638 was recodified: 25 U.S.C. 5301 *et seq.*, as it sets forth requirements that impact acquisitions under 25 U.S.C. chapter 46, Indian Self-Determination and Education Assistance.

We propose to make minor administrative and non-substantive technical changes to the part to update numbering conventions to FAR drafting standards, to spell out words, correct capitalization, and update references, including revising the table of contents and numbering of current subparts to properly align with the FAR and conform to FAR drafting conventions as follows:

- Revise the current subpart numbering for subpart 326.5, Indian Preference in Employment, Training, and Subcontracting Opportunities, to subpart 326.70. The underlying sections and subsections would be renumbered accordingly. Other numbering and minor administrative edits are made to comport with FAR drafting guidelines.

- Revise the current subpart numbering for subpart 326.6, Acquisitions Under the Buy Indian Act, to subpart 326.71. The underlying sections and subsections would be renumbered accordingly. Other numbering and minor administrative edits are made to comport with FAR drafting guidelines.

- Revise the current subpart numbering for subpart 326.7, Acquisitions Requiring the Native American Graves Protection and Repatriation Act, to subpart 326.72. The underlying sections and subsections would be renumbered accordingly.

We also propose to make certain limited revisions to update the part:

- In section 326.501 (proposed to be renumbered to 326.7001, we updated to the current citations.
- In section 326.502 (proposed to be renumbered and retitled to 326.7002, Additional Definitions), we propose the following changes: (1) delete section 326.502(c) and (d) as duplicative of FAR 26.101; (2) add definitions to reflect those at 25 U.S.C. 3504; (3) revised paragraph (b); (4) redesignate paragraphs (a), (b), (e), and (f), and; (4) revise this section by renumbering 326.502 as shown to comport with the FAR drafting guidelines. We propose to add the following definitions:

construction contract, construction programs, contract funding, direct program costs, indirect costs, indirect cost rate, mature contract, Secretary, self-determination contract, state education agency, Tribal organization or as relevant to the part and the usage from the cited authorities.

- In 326.505 (proposed to be renumbered to 326.7005), we propose to revise the header title to read “Contract clauses” in lieu of “Applicability” as the section prescribes two clauses: 352.226–70, Indian Preference, and 352.226–71, Indian Preference Program, and the naming convention for the header comports with the FAR.

- In subpart 326.6, Acquisitions Under the Buy Indian Act, we have made minimal revisions. *Note:* An update to subpart 326.6, Acquisitions Under the Buy Indian Act, took place recently. The update was published in the **Federal Register** on 1/13/2022, with an effective date of March 14, 2022. The rule is intended to establish Buy Indian Act acquisition policies and procedures for HHS that are consistent with rules proposed and/or adopted by the Department of the Interior (DOI). Due to the recent HHSAR changes and the tremendous collaborative effort to implement time sensitive legislative mandates, we are not proposing any substantive changes to this subpart. However, there are minor technical changes that are necessary to integrate this collaborative effort into the HHSAR update project to be FAR compliant. These changes include the following:

- We propose to revise this subpart by renumbering 326.6 as shown to comport with the FAR drafting guidelines. Specifically, we recommend this subpart be referenced as 326.71 since it is unique to HHS and has no correlation to the programs under the FAR part. Headings and references within the subpart have been updated to reflect the new numbering scheme. The underlying sections and subsections would be renumbered accordingly. Other numbering and minor administrative edits are made to comport with FAR drafting guidelines.
- In section 326.602 (proposed to be renumbered to 326.7102), we propose to revise the header title to “Applicability” and to add the text that will be moved from 326.602–1.
- We propose to remove 326.602–1, Scope of part. The placement and text for this material more properly falls under the proposed section 326.7102, Applicability.

- In section 326.604–2, Procedures for Acquisitions under the Buy Indian Act (proposed to be renumbered to 326.7104–2), we propose to remove

paragraph (e) in its entirety and move the prescriptions for clauses under a new proposed section 326.7104–5, Solicitation provisions and contract clauses, to comport with FAR drafting convention and style.

- We propose to add section 326.7104–4, Performance and payment bonds. This text is moved from a section proposed to be removed, 326.605–2, Performance and payment bonds, to reflect the requirements of 25 U.S.C. 47a and to permit contracting officers to accept alternative forms of security in lieu of performance and payment bonds if a determination is made that such forms of security provide the Government with adequate security for performance and payment.

- We propose to renumber and retitle section 326.605, Contract Requirements, to 326.7105, Solicitation provisions and contract clauses, and move the prescriptions for the existing provisions and clauses in 326.604–2(c) to this section and renumber the provisions and clauses accordingly: 352.226–73, Notice of Indian Small Business Economic Enterprise Set-Aside; 352.226–74, Notice of Indian Economic Enterprise Set-Aside; 352.226–75, Indian Economic Enterprise Subcontracting Limitations; and 352.226–76, Indian Economic Enterprise Representation; and 352.226–75, Indian Economic Enterprise Subcontracting Limitations.

- We propose to remove section 326.605–2, Performance and payment bonds. Updated text concerning the requirements under this paragraph is proposed to move to section 326.7104–4, Performance and payment bonds, as the placement earlier in the subpart is more appropriate with the last section of the subpart reflecting any prescribed provisions or clauses to comport with FAR drafting conventions.

- In section 326.606–2, Representation provision, we propose to renumber it to 326.7106–2 based on the renumbering of all sections within the subpart, and adding one requirement in paragraph (c) for the contracting officer to include the documentation in the file, when the head of the contracting activity is informed in writing of all suspected Indian Economic Enterprise (IEE) misrepresentations by an offeror or failure to provide written notification of a change in IEE eligibility.

- In subpart 326.7, Acquisitions Requiring the Native American Graves Protection and Repatriation Act, we propose to revise this subpart by renumbering it as subpart 326.72 to comport with the FAR drafting guidelines and reflect as a unique HHS supplement. The underlying sections

and subsections would be renumbered accordingly. Other numbering and minor administrative edits are made to comport with FAR drafting guidelines.

#### *HHSAR Part 327—Patents, Data, and Copyrights*

We propose to revise the authority citations for part 327, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

In subpart 327.3, Patent Rights Under Government Contracts, we propose to revise section 327.303 by renumbering it to 327.303–70 and changing the header to read “Contract clause” in lieu of “Solicitation provision and contract clause” since it prescribes only one clause. We also propose to update the text to reflect the revised numbering and title of clause 352.227–11, Patent Rights—Exceptional Circumstances, to now read, “352.227–70, Patent Rights—Supplement—Exceptional Circumstances,” and to prescribe its use in solicitations, contracts, and orders that include the FAR clause at 52.227–11, Patent Rights—Ownership by the Contractor. Instructions to the contracting officer that are internal operating procedures are removed and will be revised and moved to the HHSAM.

In subpart 327.4, Rights in Data and Copyrights, we propose to remove section 327.404–70, Solicitation provision and contract clause, as the prescription is being moved to section 327.409 where all the subpart’s prescriptions will be located.

We propose to revise section 327.409, Solicitation provision and contract clauses, by renumbering it to 327.409–70 and revising the header title to “Contract clauses” to reflect that only contract clauses are prescribed in the subpart. In paragraph (a) we propose to update the citation to the prescribed clause 352.227–14 and renumber it to “352.227–71” to comport with FAR drafting guidelines, and to retitle the clause to “Rights in Data—Supplement—Exceptional Circumstances.” We also propose to prescribe its use in solicitations, contracts, and others that include the FAR clause at 52.227–14, Rights in Data—General, and have updated the grammar and structure of the sentence to provide clarity.

We propose to add paragraph (b) to set forth the prescription for the clause moved from the removed section 327.404–70, and renumber the clause from “352.227–70, Publications and

Publicity” to “352.227–72, Publications and Publicity.”

#### *HHSAR Part 330—Cost Accounting Standards*

We propose to revise the authority citations for part 330, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

In subpart 330.2, CAS Program Requirements, in section 330.201–5, Waiver, we propose to revise his section to restructure and clarify the sentence that states the Senior Procurement Executive is authorized to exercise the waiver authority under FAR 30.201–5(a)(1) when the conditions at FAR 30.201–5(a)(1) are met. We propose to remove the coverage concerning the Operating and Staff Divisions and forwarding the waiver requests to the Senior Procurement Executive as it is internal operating procedures more appropriate to the HHS Acquisition Manual (HHSAM).

#### *HHSAR Part 331—Contract Cost Principles and Procedures*

We propose to revise the authority citations for part 331, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

In subpart 331.1, Applicability, we propose to revise section 331.101–70, Salary rate limitation, to renumber it to section 331.170, to align with FAR drafting convention numbering as there is no existing FAR section to intelligibly implement the required HHS policy and numbering as “331.170” places it appropriately as a supplement to subpart 331. We also propose to remove the paragraph (a) designation as there is no paragraph (b), and to remove the reference to a fiscal year as not necessary to the policy requirement. We also propose to revise the paragraph to update and provide the name of the Rates of Basic Pay for the Executive Schedule (EX) Level II, that is found on the Office of Personnel Management website.

We also propose to remove the designation of paragraph (b) as the text will be contained in a new proposed section. We propose to add section 331.101–70, Contract clause, to contain the prescription for clause 352.231–70, Salary Rate Limitation, that was previously contained in paragraph (b) under the prior existing section 331.101–70, and to fix sentence

construction and punctuation to provide clarity.

#### *HHSAR Part 332—Contract Funding*

We propose to revise the authority citations for part 332, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 332, Contract Financing, by adding introductory sections 332.006, 332.006–1, and 332.006–4 to align with the FAR.

We propose to add section 332.006, Reduction or suspension of contract payments upon finding of fraud, as a section header with no text to align with the FAR.

We propose to add section 332.006–1, General, paragraph (b), to provide that the Senior Procurement Executive (SPE) is authorized to make the determination there is substantial evidence that a contractor's request for advance, partial, or progress payments is based on fraud, and may direct further payments to the contractor be reduced or suspended, in accordance with FAR 32.006 and that the authority may not be redelegated.

And we propose to also add section 332.006–4, Procedures, paragraph (b), to align with the FAR and to designate the Remedy Coordination Official (RCO) for HHS as the SPE, who shall carry out the responsibilities in FAR 32.006–4(b). We add paragraph (e) under this section to implement the FAR and stipulate that the RCO is authorized to carry out the responsibilities of the agency head in FAR 32.006–4(e) to notify the contractor of the reasons for the recommended action and of its right to submit information within a reasonable period of time in response to the proposed action under FAR 32.006. In paragraph (e)(1), HHS sets forth the procedures to be followed for the notice of proposed action and the requirement to send it to the last known address of the contractor, the contractor's counsel, or agent for service of process, by certified mail, return receipt requested, or any other method that provides signed evidence of receipt. In the case of a business, the notice of proposed action may be sent to any partner, principal, officer, director, owner or co-owner, or joint venture. We also propose to set forth the due process rights for contractors to be afforded an opportunity to appear before the RCO to present information or argument in person or through a representative and to supplement the oral presentation with written information and argument. In paragraph (e)(2), additional processes and procedures for due process rights are

established including that the proceedings will be conducted in an informal manner without the requirement for a transcript. It also would state that if the RCO does not receive a reply from the contractor within 30 calendar days, the RCO will base his or her recommendations on the information available. The RCO is required to make a determination whether or not substantial evidence of fraud exists.

And, in paragraph (g) under section 332.006–4, we propose to require that the SPE shall provide a copy of each final determination and the supporting documentation to the contractor, the RCO, the contracting officer, and the HHS Office of the Inspector General (OIG).

We propose to add subpart 332.2, Commercial Product and Commercial Service Purchase Financing, and the underlying section 332.202, General, to provide that the SPE is authorized to approve actions for commercial item purchase financing pursuant to FAR 32.202.

In subpart 332.4, we propose to revise the subpart header title from “Advance Payments for Non-Commercial Items” to “Advance Payments for Other Than Commercial Acquisitions” to align with the updated title in the FAR. In section 332.402, General, we propose to revise the sentence for clarity that the head of the contracting activity (HCA) is authorized to make determinations related to advance payments and that the authority may not be redelegated. We propose to remove section 332.407, Interest, as this delegation by the agency head to the HCA to make the determination required by FAR 32.407(d) is being moved to the HHSAM.

In subpart 332.5, Progress Payments Based on Costs, we propose to correct the header title listed in the HHSAR to match the FAR by adding an “s” to the existing word “Cost.” In section 332.501–2, Unusual progress payments, we propose to revise the sentence to comport with FAR drafting guidelines and style, and rephrased the same delegation that authorizes the HCA to approve unusual progress payments and to stipulate that the authority may not be relegated.

In subpart 332.7, Contract Funding, we propose to remove section 332.702, Policy, and move it to the HHSAM as internal operational policy.

We propose to retain the underlying sections 332.703–1, General, and 332.703–71, Incrementally funded cost-reimbursement contracts, as important policy and procedures contracting officers shall follow when administering

incremental funding under an HHS contract and the considerations contracting officers must examine when approving the use of incrementally funded cost-reimbursement contracts. We also propose to redesignate 332.703–71 to 332.703–70.

We propose to revise the numbering of section 332.703–72, Incremental Funding Table, to “332.703–71” based on the redesignation of 332.703–71 to 332.703–70.

We propose to revise the header title of section 332.706, Solicitation provision and contract clauses, to “Contract clauses” to align with the FAR.

In subpart 332.70, Electronic Submission and Processing of Payment Requests, and the underlying sections 332.7001, 332.7002, and 332.7003, we make minor editorial formatting and capitalization corrections. In section 332.7003, Contract clause, we add language that states the clause at 352.232–71, Electronic Submission of Payment Requests, is to be used in all solicitations and contracts, unless an exception at HHSAR 332.7002(a) or (b) applies.

#### *HHSAR Part 333—Protests, Disputes, and Appeals*

We propose to revise the authority citations for part 333, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 333 to revise text and add sections as described below.

In subpart 333.1, Protests, we propose to revise section 333.102, General, to make minor typographical and editorial updates and remove the paragraph designation of (g)(1).

In section 333.103, Protests to the agency, we propose to substantially revise the content to provide clarity by identifying that the contracting officer prepares the determination pursuant to FAR 33.103(f)(1) and to state that the contracting activity's designated protest official control officer, in consultation with the cognizant HHS legal office, may approve the determination subject to the procedures in 333.103–70.

We propose to add section 333.103–70, Procedures—protests to HHS, paragraphs (a) through (d), to provide agency procedures on how HHS will handle protests submitted to the agency. This includes providing information on protests to the contracting officer, and a higher-level independent review or appeal of a contracting officer decision for protests files directly with the

agency. We also propose to add language at paragraph (d) that if protests are pending with the contracting officer and have not been decided yet, an independent review of a protest filed pursuant to paragraph (a)(2) will not be considered.

We propose to add section 333.103–71, Agency actions on specific protests, to provide that the following types of protests may be dismissed without consideration of the merits or may be forwarded to another agency for appropriate action:

- *Contract administration.* Disputes between a contractor and HHS are resolved under the disputes clause (see the Dispute statute, 41 U.S.C. chapter 71).

- *Small business size standards and standard industrial classification.* These are handled by the Small Business Administration.

- *Small business certificate of competency program.* A protest made under section 8(b)(7) of the Small Business Act, or in regard to any issuance of a certificate of competency or refusal to issue a certificate under that section, is not reviewed in accordance with bid protest procedures unless there is a showing of possible fraud or bad faith on the part of Government officials.

- *Decision not to set-aside under section 8(a) of the Small Business Act.* The decision to place or not to place a procurement under the 8(a) program is not subject to review unless there is a showing of possible fraud or bad faith on the part of Government officials or that regulations may have been violated (see 15 U.S.C. 637(a)).

- *Affirmative determination of responsibility by the contracting officer.* An affirmative determination of responsibility will not be reviewed unless there is a showing that such determination was made fraudulently or in bad faith or that definitive responsibility criteria in the solicitation were not met.

- *Contracts subject to FAR subpart 22.6—Contracts for Materials, Supplies, Articles, and Equipment.* Challenges concerning the legal status of a firm as a regular dealer or manufacturer within the meaning of 41 U.S.C. chapter 65 are determined solely by the procuring agency, the SBA (if a small business is involved), and the Secretary of Labor (see FAR subpart 22.6).

- *Subcontractor protests.* The contracting agency will not consider subcontractor protests except where HHS determines it is in the interest of the Government.

- *Judicial proceedings.* The contracting agency will not consider

protests where the matter involved is the subject of litigation before a court of competent jurisdiction.

- *Alternative dispute resolution.* Bidders/offerors and HHS contracting officers are encouraged to use alternative dispute resolution (ADR) procedures to resolve protests at any stage in the protest process. If ADR is used, HHS will not furnish any documentation in an ADR proceeding beyond what is required by FAR 33.103.

In subpart 333.2, Disputes and Appeals, we propose to add section 333.201, Definitions, to provide the definition for Agency board of contract appeals for HHS means the Civilian Board of Contract Appeals (CBCA).

We propose to revise section 333.203, Applicability, to make minor editorial corrections, to use the acronym CBCA, and to provide an updated address for each method of filing—e-file, U.S. Postal Service, or Overnight or Courier Delivery.

In section 333.209, Suspected fraudulent claims, we propose to add to the end of the existing sentence that the contracting officer may submit any instance of a contractor's suspected fraudulent claim for potential referral to the Department of Justice through the head of the contracting activity (HCA).

We propose to add section 333.214, Alternative dispute resolution (ADR), to state that contracting officers and contractors are encouraged to use alternative dispute resolution (ADR) procedures, and that guidance on ADR may be obtained at the U.S. Civilian Board of Contract Appeals website at <https://www.cbca.gsa.gov>.

And in section 333.215–70, Contract clauses, we propose to revise paragraph (b) to revise the phrase, “commercial item” to “commercial product or commercial service” to comport with the updated usage of the terms in the FAR.

#### *HHSAR Part 334—Major System Acquisition*

We propose to revise the authority citations for part 334, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 334 to make minor editorial changes to provide clarity to the sentence structure and to add needed references.

In section 334.201, Policy, introductory sentence, we are adding the acronym “(EVMS)” after earned value management system to permit usage of the acronym later in the section. In paragraph (b), we remove the

fully spelled out term and use the EVMS acronym.

In section 334.202, Integrated Baseline Reviews (IBRs), we remove the acronym usage in the header. In paragraph (a), we reconstructed the sentence for clarity by adding the term “Integrated Baseline Review (IBR)” and a reference to FAR 34.201(a), and we remove the phrase “normally should read” and replace it with “is usually”.

#### *HHSAR Part 335—Research and Development Contracting*

We propose to revise the authority citations for part 335, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 335 to make minor editorial changes to provide clarity, to remove material more appropriate to internal agency procedures in the HHSAM, to add needed FAR references, and to remove two sections that are unnecessary.

In section 335.070–1, Policy, paragraph (a), we propose to remove the last sentence as it contains a general statement concerning the Government's interest that is unnecessary and vague. We propose to remove paragraph (c) as more appropriate to internal agency procedures that may be revised and moved to the HHSAM.

In section 335.070–2, Amount of cost-sharing, paragraph (a), we propose to add the phrase “appropriate (see FAR 16.303 and FAR 42.707)” to provide key FAR references.

We propose to remove sections 335.071, which is reserved, and 335.072, Key personnel. Section 335.071 was reserved during a previous rulemaking and is no longer required to be reserved. Section 335.072, Key personnel, is removed as internal agency guidance more appropriate to be revised and moved to the HHSAM.

#### *HHSAR Part 336—Construction and Architect-Engineer Contracts*

We propose to revise the authority citations for part 336, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 336 to remove one subpart and add a new subpart and make other necessary editorial changes.

We propose to remove subpart 336.1, General, and the underlying section 336.104, Policy, as the information repeats the FAR and also contains a

general reference to internal agency Facilities Management guidance that is vague and more appropriate to place in the HHSAM as internal operational procedures.

We propose to add subpart 336.2, Special Aspects of Contracting for Construction, and sections 336.203 and 336.204, to provide policy on the use of Government estimates of construction costs and other policy and procedures on the disclosure of the magnitude of construction projects.

In section 336.203, Government estimate of construction costs, paragraph (a), we propose to require that the Government estimate must be designated “CUI Controlled by: HHS, [OPDIV/STAFFDIV designation]” unless the nature of the information therein requires a security classification or other classification, in which event it shall be handled in accordance with applicable security regulations. The designation would only be removed when the estimate is made public in accordance with the procedures outlined in the section. In paragraph (b), if the acquisition is by sealed bidding, a sealed copy of the detailed Government estimate must be filed with the bids until bid opening. After the bids are read and recorded, the “CUI” designation, or other classification, must be removed and the estimate read and recorded in the same detail as the bids. In paragraph (c), we propose procedures governing the use of the marking if the acquisition is by negotiation.

In section 336.204, Disclosure of the magnitude of construction projects, we propose policy that requires the contracting officer to utilize the estimated price ranges defined in FAR 36.204(a) through (e) as further supplemented in paragraphs (f) through (h) in this section when identifying the magnitude of an HHS project in advance notices and solicitations. In paragraph (f), we propose that for estimated price ranges between \$1,000,000 and \$5,000,000, the contracting officer shall identify the magnitude of an HHS project in advance notices and solicitations in terms of the following price ranges:

- Between \$1,000,000 and \$2,000,000.
- Between \$2,000,000 and \$5,000,000.

In paragraph (g), the estimated price ranges are between \$5,000,000 and \$10,000,000. And in paragraph (h), for estimated price ranges greater than \$10,000,000, the contracting officer shall identify the magnitude of an HHS project in advance notices and solicitations in terms of one of the following price ranges:

- Between \$10,000,000 and \$20,000,000.
- Between \$20,000,000 and \$50,000,000.
- Between \$50,000,000 and \$100,000,000.
- Between \$100,000,000 and \$150,000,000.
- Between \$150,000,000 and \$200,000,000.
- Between \$200,000,000 and \$250,000,000.
- More than \$250,000,000.

In subpart 336.5, Contract Clause, we propose to make minor editorial revisions and to revise the header title of the subpart to “Contract Clauses” to align with the FAR.

In section 336.570, Contract clause, paragraph (a), we remove the word “all” before “design-build requirements” as it is unnecessary. In paragraph (b), we make minor capitalization corrections. We propose to remove paragraph (c) in its entirety as internal agency guidance that will be considered for the HHSAM and is unnecessary in the HHSAR.

#### *HHSAR Part 337—Service Contracting*

We propose to revise the authority citations for part 337, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 337 to provide updated agency policy and procedures to implement specific requirements concerning performance on HHS service contracts, and to add a new subpart 337.70 that provides the policy for the clauses prescribed by this part.

We propose to revise the header title of HHSAR part 337 from “Service Contracting—General” to “Service Contracting” to align with the FAR title.

We propose to remove subpart 337.1, Service Contracting—General, which currently contains prescriptions of key clauses required to be inserted into certain HHS solicitations and contracts. This coverage is proposed to be revised and moved to another new section specifically pertaining to prescriptions for contract clauses, 337.3306, as described below, to comport with FAR drafting standards and guidance.

We propose to add subpart 337.70, Services—Special Contract Requirements, to provide the policy and procedures applicable to the clauses prescribed under this part. We propose to add sections 337.7000, 337.7001, 337.7002, 337.7003, 337.7004, 337.7005, and 337.7006 as discussed below.

We propose to add section 337.7000, Prohibition on smoking in facilities

during delivery of services to children, to detail the policy prohibition on smoking in certain facilities where certain federally funded children’s services are provided pursuant to 20 U.S.C. 7181 (Pub. L. 107–110, the Pro-Children Act of 2001 (the Act)). Contractors are required to represent to the contracting officer and agree that by submission of its bid or offer and if awarded a contract for this requirement, the contractor agrees to comply with the requirements of the Act and the prohibition of smoking in facilities as specified in paragraph (a). The contractor shall enforce the provisions of the clause prescribed in 337.7006(a), and ensure that each of its employees, subcontractors, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act. This section also outlines the penalties for failure to comply with the Act.

We propose to add section 337.7001, Reporting of child abuse by covered professionals and key definitions, to implement the requirements of Public Law 101–647, known as the Crime Control Act of 1990 (the Act) (34 U.S.C. 20341), which imposes responsibilities on certain individuals who, while engaged in a professional capacity or activity as a covered professional, as defined in the Act, on Federal land or in a federally-operated (or contracted) facility, learn of facts that give the individual reason to suspect that a child has suffered an incident of child abuse. Paragraph (c) details the reporting requirements, and paragraph (d) contains the requirement that the offeror shall represent that it understands that by submission of its bid or offer and if awarded a contract for a requirement, the Contractor agrees to comply with the requirements of the Act. Contracting officers shall ensure the requirements of clause 352.237–71 are flowed down to subcontractors at any tier.

We propose to add section 337.7002, Requirement for background checks—childcare services, to set forth the agency policy and requirement for background checks pursuant to Public Law 101–647, known as the Crime Control Act of 1990 (the Act) (34 U.S.C. 20351), requires that all individuals involved with the provision of childcare services to children under the age of 18 undergo a criminal background check. Any conviction for a sex crime, an offense involving a child victim, or a drug felony, may be grounds for denying employment or for dismissal of an employee providing any childcare services. This would require the contracting officer to provide the necessary information to the contractor



regarding the process for obtaining the background check. And it contains the representation requirement that the offeror shall represent that it understands that by submission of its bid or offer and if awarded a contract for a requirement, the contractor agrees to comply with the requirements of the Act. Contracting officers shall ensure the requirements of clause 352.237–72 are flowed down to subcontractors at any tier.

We propose to add section 337.7003, Indian Child Protection and Family Violence Act-background investigations, to ensure protection of Indian children, and to implement requirements of the Indian Child Protection and Family Violence Act, Public Law 101–630 (25 U.S.C. 3201, *et seq.*), which prohibits employment, including personal service contracts, with anyone who has been convicted of any crime of violence when performance under a contract may require duties and responsibilities of a contractor, its employees, subcontractors, or third parties providing service under the contract that involve regular contact with or control over Indian children. The Act requires that a contractor and its employees and subcontractors, at any tier, be subject to a character and background investigation. This investigation is conducted by the Indian Health Service, Office of Human Resources. This section would require that as a prerequisite to providing services under a contract involving access to Indian children, contractors shall—

- Complete and sign a declaration concerning the background of employees or subcontractors providing such services as required by the terms and conditions of the contract;
- Provide information as required by the contracting officer to ascertain such information about its employees, subcontractors, and third parties providing services under the contract;
- Report convictions of any crime of violence immediately to the contracting officer that involve such employees, subcontractors, or third parties, who may be employed or are currently employed under the contract; and
- Flow down clause the clause prescribed at 337.7006(d), 352.337–73, Indian Child Protection and Family Violence Act—Background Investigations, into all subcontracts, at any tier.

We propose to add section 337.7004, Non-discrimination in service delivery, to implement HHS policy that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the

administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). It would include a representation requirement that the offeror shall represent that it understands that by submission of its bid or offer and if awarded a contract for a requirement, the contractor agrees to comply with the requirements of the policy. Contracting officers shall ensure the requirements of clause 352.237–74 are flowed down to subcontractors at any tier.

We propose to add section 337.7005, Key personnel, to implement HHS policy on identification and use of key personnel when considered essential to work performance under an HHS contract. We propose to require contractors to provide notice if they divert proposed personnel deemed key personnel. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals in a contract to other programs or contracts, the contractor shall notify the contracting officer and submit a justification for the diversion or replacement, and request to replace the individual. It would also outline notification, justification, and replacement requirements.

We propose to add section 337.7006, Contract clauses, to provide the prescription for the use of the following clauses in both solicitations and contracts as required by each prescription:

- 352.237–70, Nonsmoking Policy—Delivery of Services to Children
- 352.237–71, Reporting of Child Abuse
- 352.237–72, Requirement for Background Checks
- 352.237–73, Indian Child Protection and Family Violence Act—Background Investigations
- 352.237–74, Non-Discrimination in Service Delivery
- 352.237–75, Key Personnel

#### *HHSAR Part 341—Acquisition of Utility Services*

We propose to add authority citations for part 341, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add HHSAR part 341, Acquisition of Utility Services, and subparts 341.1, General, and 341.5, Solicitation Provision and Contract Clauses, to provide policy on purchases of utility services from nonregulated and regulated utility suppliers, and the acquisition of energy when purchased as a commodity in accordance with FAR part 41.

We propose to add subpart 341.1, General, and section 341.102, Applicability, paragraph (a), to implement FAR 41.102(a) and to state that this part applies to purchases of utility services from nonregulated and regulated utility suppliers when a delegation of authority from GSA for those services is requested and obtained. In paragraph (b)(4), we provide the explanation that the acquisition of energy, such as electricity, and natural or manufactured gas, when purchased as a commodity is considered to be acquisitions of supplies rather than utility services as described in FAR part 41.

We propose to add subpart 341.5, Solicitation Provision and Contract Clauses, and sections 341.501 and 341.501–70. In section 341.501, Solicitation provision and contract clauses, we propose to add the section header with no text for alignment with the FAR where HHS supplements coverage in an underlying section. In section 341.501–70, Disputes—utility contracts, we propose to require contracting officers to insert the clause at 352.241–70, Disputes—Utility Contracts, in solicitations and contracts for utility services subject to the jurisdiction and regulation of a utility rate commission, to provide the notice to the contractor on specific disputes requirements concerning utilities. In the clause, it provides that the requirements of the Disputes clause at FAR 52.233–1 are supplemented to provide that matters involving the interpretation of tariffed retail rates, tariff rate schedules, and tariffed terms provided under this contract are subject to any determinations by the independent regulatory body having jurisdiction (*i.e.*, the Federal Energy Regulatory Commission, a state-wide agency, or an agency with less than state-wide jurisdiction when operating pursuant to state authority. The body has the power to fix, establish, or control the rates and services of utility suppliers.).

#### *HHSAR Part 342—Contract Administration and Audit Services*

We propose to revise the authority citations for part 342, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise HHSAR part 342 to update its header title, and to add subpart 342.2.

We propose to revise and update the header title of part 342 from “Contract Administration” to “Contract

Administration and Audit Service” to align with the FAR part title.

We propose to add subpart 342.2, Contract Administration, and sections 342.270, 342.271, and 342.272, to set forth policy and procedures with respect to the use of Contracting Officer’s Representatives (CORs) in contract administration, the Administrative Contracting Officer’s (ACO) role in contract administration and delegated functions, and prescribed agency contract clauses.

We propose to add section 342.270, Contracting Officer’s Representatives role in contract administration, to establish that a contracting officer may designate a qualified person to be the Contracting Officer’s Representative (COR) for the purpose of performing certain technical functions in administering a contract. Paragraph (b) would provide that the COR may act solely as a technical representative of the contracting officer and is not authorized to perform any function that results in a change in the scope, price, terms, or conditions of the contract, and that the designation must be in writing and a copy of the designation must be furnished to the contractor and the ACO.

We propose to add section 342.271, Administrative Contracting Officer’s role in contract administration and delegated functions, to provide the department’s use of an Administrative Contracting Officer Letter of Delegation, which means a delegation of functions as set forth in FAR 42.202 and 42.302 and this section, that is issued by a contracting officer to delegate certain contract administration or specialized support services. This section would limit the ACO’s authority to the actions detailed in the delegation, state that they shall be set forth in a written ACO Letter of Delegation issued by the contracting officer to the accepting contract administration office and designated administrative contracting officer. This section would require that the ACO Letter of Delegation shall contain the information required in FAR 42.202(a) through (c) and identify the responsibilities and limitations of the ACO. A copy of the delegation will be furnished to the contractor and the ACO.

And we propose to add section 342.272, Contract clauses, to prescribe two clauses to be used: The clause at 352.242–70, Administrative Contracting Officer, to be inserted in solicitations and contracts expected to exceed the micro-purchase threshold, when contract administration is delegated, and the clause at 352.242–71, Government Construction Contract

Administration, to be inserted in solicitations and contracts for construction expected to exceed the micro-purchase threshold, when contract administration is delegated

#### *HHSAR Part 343—Contract Modifications*

We propose to add authority citations for part 343, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add HHSAR part 343, Contract Modifications, and subpart 343.2, Change Orders, to provide agency policy on the definitization of unpriced change orders with an estimated value exceeding \$5 million.

We propose to add subpart 342.2, Change Orders, and sections 343.204, Administration; 343.204–70, Definitization; and 343.205, Contract clauses.

We propose to add section 343.204, Administration, as a section header with no text, and the underlying section 343.204–70, Definitization, to establish policy with respect to the definitization of unpriced change orders with an estimated value exceeding \$5 million. This section would require that unpriced change orders, when authorized by the contracting officer, shall contain a not-to-exceed price and requires a definitization schedules that provide for definitization by—

- The date after issuance of the change order may not exceed 180 days after the contractor submits a qualifying proposal); or
- The date on which the amount of funds paid to the contractor under the contract action is equal to more than 50 percent of the not-to-exceed price.

This section would also provide that if the contractor does not submit a timely qualifying proposal, the contracting officer may suspend or reduce progress payments under FAR 32.503–6 or take other appropriate action. The section would also provide a limitations on obligations in paragraph (b) that the Government shall not obligate more than 50 percent of the not-to-exceed price before definitization. However, if a contractor submits a qualifying proposal before 50 percent of the not-to-exceed price has been obligated by the Government, the limitation on obligations before definitization may be increased to no more than 75 percent. Exceptions are provided as authorized by the head of the contracting activity (HCA). The HCA may waive the limitations for unpriced change orders if the HCA determines

that the waiver is necessary to support an emergency acquisition operation.

We propose to add section 343.205, Contract clauses, to provide agency policy that as authorized in the introductory text of clauses FAR 52.243–1, Changes—Fixed-Price; 52.243–2, Changes—Cost-Reimbursement; and 52.243–4, Changes, and in the prescription at FAR 43.205(c) for FAR 52.243–3, Changes—Time-and-Materials or Labor-Hours, the contracting officer may vary the period within which a contractor must assert its right to an equitable adjustment, but the extended period shall not exceed 60 calendar days, unless approval is one level above the contracting officer.

#### *HHSAR Part 344—Subcontracting Policies and Procedures*

We propose to add authority citations for part 344, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add HHSAR part 344, Subcontracting Policies and Procedures, and underlying subparts 344.2, Consent to Subcontracts, and 344.3, Contractors’ Purchasing Systems Reviews.

We propose to add subpart 344.2, Consent to Subcontracts, and section 344.202–2, Considerations, paragraph (a), to require, in addition to the considerations outlined in FAR 44.202–2(a), that the contracting officer responsible for consent must review the request and supporting data submitted by the contractor and document whether the contractor adequately substantiated the selection as being fair, reasonable, and representing the best value to the Government where other than the lowest price is the basis for subcontractor selection.

We propose to add subpart 344.3, Contractors’ Purchasing Systems Reviews, and section 344.303–70, Additional contractors’ purchasing systems reviews, to identify that special attention shall also be paid to reviewing documentation of commercial products and commercial services determinations. Additionally, the section states that if the contractor has an approved purchasing system as defined in FAR 44.101, the contracting officer shall not withhold consent to subcontract without written coordination of the program manager or comparable requiring activity official. This ensures that a decision to withhold consent is made in concert with the full awareness of program officials who have overall programmatic, budget and schedule responsibilities for

acquisitions that may be impacted by a decision to withhold consent.

#### *HHSAR Part 345—Government Property*

We propose to add authority citations for part 345, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add HHSAR part 345, Government Property, and subpart 345.1, General, to provide agency policy and procedures on contractors' property management system compliance.

In subpart 345.1, General, we propose to add sections 345.105–70 and 345.107, Contract clauses. We propose to add section 345.105–70, Contractors' property management system compliance—policy and procedures, to provide definitions for acceptable property management system, property management system, and significant deficiency when complying with agency policies and procedures. In paragraph (a), policy is provided that the cognizant contracting officer, in consultation with the property administrator, shall determine the acceptability of the system and approve or disapprove the system, and pursue correction of any deficiencies. Paragraph (c) would provide that in evaluating the acceptability of a contractor's property management system, the contracting officer, in consultation with the property administrator, shall determine whether the contractor's property management system complies with the system criteria for an acceptable property management system as prescribed in the clause at 352.245–70, Contractor Property Management System Administration. The section also outlines in paragraph (d) the procedures for disposition of findings, including notification to the contractor, in writing, whether the contractor's property management system is acceptable and approved. If the contracting officer finds that there are one or more significant deficiencies (as defined in the clause at 352.245–70, Contractor Property Management System Administration) due to the contractor's failure to meet one or more of the property management system criteria in the clause at 352.245–70, the contracting officer shall—

- Promptly make an initial written determination on any significant deficiencies and notify the contractor, in writing, providing a description of each significant deficiency in sufficient detail to allow the contractor to understand the deficiency;

- Request the contractor to respond, in writing, to the initial determination within 30 days and;

- Evaluate the contractor's response to the initial determination, in consultation with the property administrator, and make a final determination.

Paragraph (d)(3) of this section also provides the procedures for final determination and notification to the contractor in writing whether acceptable and approved, whether significant deficiencies remain and the requested corrective actions, disapproval, and monitoring of the system. Paragraphs (e) and (f) provide policy and procedures on system approval, and other contracting officer notifications.

We propose to add section 345.107, Contract clauses, to prescribe the HHSAR clause at 352.245–70, Contractor Property Management System Administration, be inserted in solicitations and contracts containing the clause at FAR 52.245–1, Government Property.

#### *HHSAR Part 347—Transportation*

We propose to add authority citations for part 347, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to add part 347, Transportation, to provide unique HHS delivery information and marking requirements. Proposed underlying sections 347.303–6, F.o.b. destination; 347.303–670, Place of delivery, prescribe clause 352.247–70, Delivery Location, or a clause substantially the same as the clause at 352.247–70 in supply contracts when it is necessary to specify delivery locations.

Section 347.305, Solicitation provisions, contract clauses, and transportation factors, and its underlying section 347.305–10, Packing, marking, and consignment instructions, prescribes two clauses:

- Paragraph (a) prescribes the clause 352.247–71, Marking Deliverables, or a clause substantially the same as 352.247–71 in solicitations and contracts if special marking on deliverables is required.

- Paragraph (b) prescribes the clause at 352.247–72, Packing for Domestic Shipment, in contracts when item(s) will be delivered for immediate use to a destination in the continental United States; when the material specification or purchase description does not provide preservation, packaging, packing, and/or marking requirements; and/or when the requiring activity has

not cited a specific specification for packaging.

#### *HHSAR Part 352—Solicitation Provisions and Contract Clauses*

We propose to revise the authority citations for part 352, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise subpart 352.1, Instructions for Using Provisions and Clauses, to update the underlying sections 352.100, Scope of subpart, and 351.101–70, Application of provisions and clauses, as follows:

We propose to revise 352.100, Scope of subpart, to make a minor grammatical revision by adding the word “supplemental” before the words “provisions and clauses” in the text to provide clarity.

We propose to add a section header with no text, 352.102, Incorporating provisions and clauses, to align the supplemental HHSAR section that follows it.

And we propose to renumber section 352.101–70 to 352.102–70 as the topical coverage in the text more appropriately aligns under FAR 52.102. We propose to add the phrase “unless fill-ins are required” at the end of paragraph (a) to add a caveat to the policy that it is not necessary to also include clauses in a task order or delivery order if it is included in the overarching master instrument.

We propose to add clause 352.201–70, Contracting Officer's Representative, as prescribed in section 301.602–70, to provide that if the contracting officer designates a COR, the contractor will receive a copy of the written designation. It will specify the extent of the COR's authority to act on behalf of the contracting officer. The COR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

We propose to revise clause 352.203–70, Anti-Lobbying, as prescribed in section 303.808–70, to make minor administrative and grammatical updates, including to the prescription. This clause provides that the contractor shall not use any HHS contract funds for:

- Publicity or propaganda purposes;
- 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;

- 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.

We propose to revise clause 352.204–70, Prevention and Public Health Fund—Reporting Requirements, to update the prescription, and make minor administrative updates. In paragraph (a), we provide an updated citation to Public Law 112–74, section 220(b)(5). In paragraph (c), we correct grammar to move the word “electronic” after the words “508 compliant.” And in paragraphs (c)(2) and (5), we are removing the words “funds” and “funding” respectively for clarity since the acronym “PPHF” contains the word “fund” in its name.

We propose to add clause 352.205–70, Advertisements, Publicizing Awards, and Releases, to state that for HHS contracts and orders, the contractor shall not refer to the contract in commercial advertising or similar promotions in such a manner as to state or imply that the product or service provided is endorsed or preferred by the Federal Government or is considered by the Government to be superior to other products or services. An Alternate I version of the clause is proposed for use when a contract involves sensitive or classified information.

We propose to revise clause 352.208–70, Printing and Duplication, to update the prescription to a FAR compliant format, to move all definitions under paragraph (a), to provide context to the clause, to add headers to each paragraph to comport with FAR style and convention, to rephrase paragraphs (b) through (d) for clarity, and to add paragraph (e) to require the clause is flowed down in subcontracts.

We propose to add provision 352.209–70, Organizational Conflicts of

Interest, to include the requirement that offerors shall provide a statement with its offer which describes, in a concise manner, all relevant facts concerning any past, present, or currently planned interest (financial, contractual, organizational, or otherwise) or actual or potential organizational conflicts of interest relating to the services to be provided under this solicitation.

We propose to revise clause 352.211–1, Public Accommodations and Commercial Facilities, to renumber it to 352.211–70 to comport with FAR drafting standards, and to revise the prescription to comport with FAR style conventions.

We propose to revise clause 352.211–2, Conference Sponsorship Requests and Conference Materials Disclaimer, to renumber it to 352.211–71 to comport with FAR drafting standards, to update the prescription to comport with FAR style conventions, and to make minor grammatical updates to paragraphs (a) and (b) for clarity.

We propose to revise clause 352.211–3, Paperwork Reduction Act, to renumber it to 352.211–72, update the title so it would read: “Paperwork Reduction Act Requirements,” and update the prescription to comport with FAR style conventions.

We propose to add clause 352.212–70, Gray Market and Counterfeit Items, to provide important protection for supplies or equipment offered to the Government to prevent unauthorized items from entering the HHS supply chain. HHS’ critical mission is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. It is imperative that HHS have a high degree of fidelity in the supplies and equipment delivered to support the critical programs under its purview. This clause would importantly require that no used, refurbished, or remanufactured supplies or equipment/parts shall be provided, and that the procurement is for new Original Equipment Manufacturer (OEM) items only. As stated in paragraph (a), this clause would prohibit gray market items under the contract which are OEM goods intentionally or unintentionally sold outside an authorized sales territory or sold by non-authorized dealers in an authorized sales territory. Paragraph (b) provides that no counterfeit supplies or equipment/parts shall be provided. Counterfeit items include unlawful or unauthorized reproductions, substitutions, or alterations that have been mismarked,

misidentified, or otherwise misrepresented to be an authentic, unmodified item from the original manufacturer, or a source with the express written authority of the original manufacturer or current design activity, including an authorized aftermarket manufacturer. Unlawful or unauthorized substitutions include used items represented as new, or the false identification of grade, serial number, lot number, date code, or performance characteristics. The clause would also state in paragraph (c) that the vendor is required to be an OEM, authorized dealer, authorized distributor, or authorized reseller for the proposed equipment, verified by an authorization letter or other documents from the OEM. All software licensing, warranty and service associated with the equipment shall be in accordance with the OEM terms and conditions.

We propose to revise provision 352.215–70, Late Proposals and Revisions, by updating the title to add “- R&D Solicitations” to make clear the types of solicitations this clause involves. And we propose to update the prescription to comport with FAR style conventions, and to substantively revise the provision for clarity and standard FAR clause and provision construction that uses lists for ease of reading. This would include revising the introductory text so that it clarifies that notwithstanding the procedures contained in the provision at FAR 52.215–1, Instructions to Offerors—Competitive Acquisition, paragraph (c)(3), the contracting officer may consider a proposal received for biomedical or behavioral research and development (R&D) solicitations after the date specified for receipt if the three conditions set forth in the clause are met.

We propose to add provision 352.215–71, Use of Non-Federal Evaluators—Conditions for Evaluating Proposals, as prescribed in 315.305–71, to provide terms and conditions pertaining to the use of non-Federal evaluators when evaluating proposals and offers. We propose to require that to participate in such role as a non-Federal evaluator, the Contractor shall agree that it and its employees, as well as any subcontractors and their employees as non-Federal evaluators will use the data (trade secrets, business data, and technical data) contained in any proposals under review for evaluation purposes only. Further, the Contractor, its employees, and subcontractors and their employees may not release, in whole or in part, any material received from the Government to evaluate and must protect and secure the data against

unauthorized disclosure. The provision requires each non-Federal evaluator to insert their name, title, company, signature, and date and provide to the HHS office providing the material and the contracting officer.

We propose to remove clause 352.216–70, Additional Cost Principles for Hospitals (Profit and Non-Profit), as the requirement is being removed as a clause and placed in another part of the HHSAR—part 331. The clause number will be repurposed for a HHSAR part 316 related clause.

We propose to add clause 352.216–70, Allowable Cost and Payment for Hospitals (Profit and Non-Profit), to stipulate that payment amounts requested by the Contractor and included in invoices submitted for payment in accordance with FAR clause 52.216–7, paragraph (a)(1), must be determined allowable by the Contracting Officer in accordance with the FAR clause at 52.216–7, 45 CFR part 75, appendix IX, and FAR subpart 31.2.

We propose to remove two outdated clauses as they are no longer relevant to the HHS small business programs: 352.219–70, Mentor-Protégé Program, and 352.219–71, Mentor-Protégé Program Reporting Requirements. HHS does not currently have a mentor protégé program and the clauses are obsolete.

We propose to add two clauses related to the 8(a) partnership program under HHSAR part 319: the clause at 352.219–70, Notification of Competition Limited to Eligible 8(a) Participants, and the clause at 352.219–71, Notification of Section 8(a) Direct Award.

We propose to add clause 352.219–70, Notification of Competition Limited to Eligible 8(a) Participants, as prescribed in 319.811–370. This clause provides that when FAR 52.219–18, Notification of Competition Limited to Eligible 8(a) Participants, is utilized in conjunction with the FAR clause at 52.219–18, any award resulting from a solicitation will be made directly by the contracting officer to the successful 8(a) offeror. The contractor shall comply with the limitations on subcontracting requirements as provided in 13 CFR 125.6 and all other 8(a) program requirements, as set forth in 13 CFR part 124.

We propose to add clause 352.219–71, Notification of Section 8(a) Direct Award, as prescribed in 319.811–370. The clause alerts 8(a) firms of the direct contract authority and provides that by submission of its offer, the Offeror represents that it is in good standing and that it meets all the criteria for participation in the program in accordance with 13 CFR part 124,

including compliance with the limitations on subcontracting, and the other 8(a) program principles and administrative requirement that are still under the SBA purview.

We propose to revise clause 352.222–70, Contractor Cooperation in Equal Employment Opportunity Investigations, by revising the title to read “Contractor Cooperation in Equal Employment and Anti-Harassment Opportunity Investigations” to convey the additional important new content added to the clause. We propose to update the prescription to comport with FAR style conventions, and to substantively revise the provision for clarity and standard FAR clause and provision construction. We propose to substantively revise the flow and content of the paragraphs to provide clarity and add headers to each paragraph. We propose to retain the three definitions from the existing paragraph (a), include the header “Definitions,” and revise the definitions to comport with standard FAR drafting style and convention. We propose to redesignate the existing paragraph (a) as paragraph (b) and add the header “Cooperation with investigations.” In paragraph (b), we also add the requirement for contractors to cooperate in HHS internal Anti-Harassment investigations. We also propose to redesignate paragraph (b) as paragraph (d) and add a header of “Subcontract flowdown.” We propose to update paragraph (c) and add the header “Compliance.”

We propose to revise clause 352.223–71, Instructions to Offerors—Sustainable Acquisition, to renumber it as 352.223–70 to comport with FAR and agency supplement numbering conventions. We propose to revise the title to read: “Instructions to Offerors—Sustainable Acquisition Plan,” to identify the content of the provision more clearly. We propose to make minor updates to revise the prescription, correct a FAR citations, and make minor grammatical revisions.

We propose to revise clause 352.223–70, Safety and Health, to renumber it as 352.223–71 to comport with FAR and agency supplement numbering conventions and to make other minor updates in the prescription.

We propose to add clause 352.225–70, Made in America—Personal Protective Equipment, that provides new legislative requirements from the Make PPE in America Act (Pub. L. 117–58, sec. 70951, dated November 15, 2021). This codifies a class deviation issued by HHS, Department of Health and Human Services (HHS) Class Deviation from the Health and Human Services Acquisition

Regulation (HHSAR)—Implementation of the Make Personal Protective Equipment (PPE) in America Act Requirements, issued on February 9, 2023. The clause requires contractors to deliver only domestic personal protective equipment, unless the solicitation specifies delivery of foreign-made domestic personal protective equipment in the provision of the solicitation entitled “Made in America Certificate—Personal Protective Equipment.” The clause is to be inserted in solicitations and contracts for PPE as prescribed in 325.7103(a), above the micro-purchase threshold, when the clause at FAR 52.212–5, Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services, is included in a solicitation or contract for PPE. Contracting officers shall include the full text of the clause at 352.225–70.

We propose to add provision 352.225–71, Made in America Certificate—Personal Protective Equipment, in solicitations containing the clause at 352.225–70. The provision requires the offeror to certify that each item of personal protective equipment, except those listed in paragraph (b) of this provision, is domestic personal protective equipment. The clause also requires the offeror to list offered foreign-made domestic personal protective equipment items in paragraph (b). The provision is to be inserted in solicitations as prescribed in 325.7103(b), above the micro-purchase threshold, when the provision at FAR 52.212–3, Offeror Representations and Certifications—Commercial Products and Commercial Services is included in a solicitation for PPE. Contracting officers shall include the full text of the provision at 352.225–71.

We propose to revise clause 352.226–1, Indian Preference, to renumber the clause to 352.226–70 to comport with FAR drafting standards and to make minor updates to the clause prescription and citation.

We propose to revise clause 352.226–2, Indian Preference Program, to renumber the clause to 352.226–71 to comport with FAR drafting standards and to make minor updates to the clause prescription and citation.

We propose to revise clause 352.226–3, Native American Graves Protection and Repatriation Act, to renumber the clause to 352.226–72 to comport with FAR drafting standards and to make minor updates to the clause prescription and citation.

We propose to revise clause 352.226–4, Notice of Indian Small Business Economic Enterprise set-aside, to

renumber the clause to 352.226–73, and to capitalize “Set-Aside” in the title to comport with FAR drafting standards and to make minor updates to the clause prescription and citation. We also propose to update an HHSAR citation in the second sentence.

We propose to revise clause 352.226–5, Notice of Indian Economic Enterprise set-aside, to renumber the clause to 352.226–74, and to capitalize “Set-Aside” in the title to comport with FAR drafting standards and to make minor updates to the clause prescription and citation. We also propose to align the Public Law citation in paragraph (a), in the definition for “Alaska Native Claims Settlement Act (ANCSA)” to reflect the “Pub. L.” abbreviation and to update the HHSAR reference from the “subpart” to the “section” to standardize with FAR drafting standards. We also propose to spell out “contracting officer” in lieu of “CO” throughout the clause, as well as update any HHSAR section citations as these have been renumbered to comport with FAR standard numbering conventions.

We propose to revise clause 352.226–6, Indian Economic Enterprise Subcontracting Limitations, to renumber the clause to 352.226–75, to comport with FAR drafting standards and to make minor updates to the clause prescription and citation. We also propose to spell out “contracting officer” in lieu of “CO” throughout the clause and other minor administrative abbreviation update.

We propose to revise clause 352.226–7, Indian Economic Enterprise Representation, to renumber the clause to 352.226–76, to comport with FAR drafting standards and to make minor updates to the clause prescription and citation.

We propose to revise clause 352.227–11, Patent Rights—Exceptional Circumstances, to renumber the clause to 352.227–70, and to add the word “Supplement” in the title so it now reads: “Patent Rights—Supplement—Exceptional Circumstances,” to comport with FAR drafting standards and to make minor updates to the clause prescription and citation. We propose to remove the first introductory sentence in the clause and move it to a new paragraph (b). We propose to update the definition of “Agency” in paragraph (a) to make reference to HHS operating division or agency, and provide examples (*i.e.*, Centers for Disease Control and Prevention, Food and Drug Administration, etc.). We propose to renumber the existing paragraph (b) to (c) and update the FAR clause 52.227–11 title in paragraph (c)(2)(ii) to read “Patent Rights—Ownership by the

Contractor” to reflect the correct FAR title. We also propose to make minor grammatical and FAR citation reference updates in paragraphs (c)(2)(ii) and (c)(3), and add paragraphs (c)(3)(i) and (ii) to the existing text to appropriately break up the text for ease of reading and reference. And we propose to make other minor citation reference numbering updates in the clause to reflect the correct paragraph numbers and to correct the FAR clause referenced in paragraph (e)(2) to read “FAR 52.227–11” versus “52.227–13.” And we propose to make other minor non-substantive administrative updates, and to update HHSAR clause reference cited in the prescription for Alternate I of the clause.

We propose to revise clause 352.227–14, Rights in Data—Exceptional Circumstances, to renumber the clause to 352.227–71, and to add the word “Supplement” in the title so it now reads: “Rights in Data—Supplement—Exceptional Circumstances,” to comport with FAR drafting standards and to make minor updates to the clause prescription and citation. We propose to revise clause 352.227–14, Rights in Data—Exceptional Circumstances, as a supplemental HHSAR clause to FAR clause at 52.227–14, Rights in Data. The current clause, 352.227–14, duplicates the FAR clause at 52.227–14 except for paragraphs (d)(4) through (6). These paragraphs were added to provide HHS-specific direction when a Decision of Exceptional Circumstances was issued (paragraphs (d)(4) and (5)), and to provide additional policy at paragraph (d)(6) regarding confidential information. We propose to remove paragraphs (a) through (d)(3) as redundant to the FAR clause and unnecessary in the proposed revision to the HHS supplemental clause. We propose to retain the existing paragraphs (d)(4) and (5), with minor administrative updates to citations referenced in the text. Additionally, we propose to remove paragraphs (d)(6), (e), (f), (g), (h), and (i) and the Alternate I through V paragraphs of the existing clause.

We propose to revise clause 352.227–70, Publications and Publicity, to renumber the clause to 352.227–72, to comport with FAR drafting standards and to make minor updates to the clause prescription and citation. We propose to revise paragraph (a) to reformat the paragraph to use a list of items the contractor shall send to the contracting officer’s representative. And we propose to make minor administrative and editorial revisions in paragraphs (b) through (d) for clarity.

We propose to revise clause 352.231–70, Salary Rate Limitation, to comport with FAR drafting standards and to make minor updates to the clause prescription and citation and to include a subcontract flowdown requirements in a new paragraph (f).

We propose to revise provision 352.232–70, Incremental Funding, to comport with FAR drafting standards and to make minor updates to the provision prescription and citation.

We propose to revise clause 352.232–71, Electronic submission of payment requests, to capitalize the major words in the title and make minor updates to the clause prescription and citation to comport with FAR drafting standards.

We propose to revise clause 352.233–70, Choice of Law (Overseas), to make minor updates to the clause prescription and citation to comport with FAR drafting standards.

We propose to revise clause 352.233–71, Litigation and Claims, to make minor updates to the clause prescription and citation to comport with FAR drafting standards.

We propose to revise clause 352.236–70, Design-Build Contracts, to make minor updates to the clause prescription and citation to comport with FAR drafting standards.

We propose to revise clause 352.237–70, Pro-Children Act, to revise the title of the clause to read: Nonsmoking Policy—Delivery of Services to Children, to make substantive updates to add needed content and bring reference citations up to date, and to make minor updates to the clause prescription and citation to comport with FAR drafting standards. We propose to revise each paragraph in the clause to add headers. In paragraph (a), the paragraph is revised to make clear that smoking is prohibited in facilities where certain federally funded children’s services are provided pursuant to the Pro-Children Act, 20 U.S.C. 7181, Public Law 107–100, sec. 4301 (the Act). Other edits for grammatical clarity are made. In paragraph (b), the text is updated to make clear that the offeror represents and understands that by submission of its bid or offer and if awarded a contract for this requirement the contractor agrees to comply with the requirements of the Act and the prohibition of smoking in facilities as specified in paragraph (a) of the clause. Paragraph (c) is updated to provide information concerning penalties for each violation. And a subcontractor flowdown clause is added as paragraph (d).

We propose to revise 352.237–71, Crime Control Act—Reporting of Child Abuse, to revise the title of the clause

to read: Reporting of Child Abuse, to make substantive updates to add needed content and bring reference citations up to date, and to make minor updates to the clause prescription and citation to comport with FAR drafting standards. We propose to redesignate the existing paragraph (a) as paragraph (b) and move two existing definitions for “child abuse” and “covered professionals” from paragraph (b) into a new paragraph (a), and to add a header titled “Definitions.” We propose to add a header to the redesignated paragraph (b), Responsibility to report child abuse, and to update the statute citation. We propose to remove the existing paragraph (b) in its entirety as the definitions previously in this paragraph have been moved to paragraph (a), Definitions, to align such definition placement at the beginning of the clause to comport with FAR drafting conventions. We propose to add headers to paragraphs (c) and (d), and we propose to add a new paragraph (e) to provide subcontract flow down requirements.

We propose to revise clause 352.237–72, Crime Control Act—Requirement for Background Checks, to revise the title of the clause to read: Requirement for Background Checks, to make substantive updates to add needed content and bring reference citations up to date, and to make minor updates to the clause prescription and citation to comport with FAR drafting standards. We propose to redesignate the existing paragraph (a) as paragraph (b) and move an existing definition for “child care” from paragraph (b) into a new paragraph (a), and to add a header titled “Definition.” We propose to add a header to the redesignated paragraph (b), Requirement for background checks, and to update the statute citation. We propose to add headers to redesignated paragraphs (c) and (d), and we propose to add a new paragraph (e) to provide subcontract flow down requirements.

We propose to revise clause 352.237–73, Indian Child Protection and Family Violence Act, to revise the title of the clause to read: Indian Child Protection and Family Violence Act—Background Investigation, to make substantive updates to add needed content and bring reference citations up to date, and to make minor updates to the clause prescription and citation to comport with FAR drafting standards. We propose to redesignate the paragraphs by adding a designation for paragraph (b) to break up the existing paragraph (a), and to redesignate paragraph (b) as paragraph (c), and add a paragraph (d) to provide subcontract flow down requirements.

We propose to revise clause 352.237–74, Non-Discrimination in Service Delivery, to make substantive updates to add needed content and bring reference citations up to date, and to make minor updates to the clause prescription and citation to comport with FAR drafting standards. We propose to add paragraph designations and headers to the clause, which will now contain paragraphs (a) through (c). We propose paragraph (a), Policy, to provide the policy of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). We propose to add paragraphs (b) and (c) to provide that the offeror represents and understands that by submission of its bid or offer and if awarded a contract for this requirement the contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract in a non-discriminatory manner. And in paragraph (c) we propose to add a subcontract flow down requirement.

We propose to revise clause 352.237–75, Key Personnel, to make minor administrative and grammatical updates, and to update the clause prescription and citation to comport with FAR drafting standards.

We propose to add clause 352.241–70, Disputes—Utility Contracts, to provide that the requirements of the Disputes clause at FAR 52.233–1 are supplemented to provide that matters involving the interpretation of tariffed retail rates, tariff rate schedules, and tariffed terms provided under this contract are subject to any determinations by the independent regulatory body having jurisdiction.

We propose to add clause 352.242–70, Administrative Contracting Officer, to stipulate that the contracting officer reserves the right to designate an Administrative Contracting Officer (ACO) for the purpose of performing certain tasks/duties in the administration of the contract. It also states that such designation will be in writing through an ACO Letter of Delegation and will identify the responsibilities and limitations of the ACO, with a copy to be furnished to the contractor.

We propose to add clause 352.242–71, Government Construction Contract Administration, to detail certain delegated contract administration functions, for construction contracts, set forth in FAR 42.302 that are delegated,

if any, and to stipulate express functions that are not delegated.

We propose to add clause 352.245–70, Contractor Property Management System Administration, that would be inserted in solicitations and contracts containing the clause at FAR 52.245–1, Government Property, to require the contractor to establish and maintain an acceptable property management system and that failure to maintain an acceptable property management system, as defined in this clause, may result in disapproval of the system by the contracting officer and/or withholding of payments. The clause provides three definitions, and details what criteria will be utilized by the Government in its review of the contractor’s property management system how system deficiencies will be handled, and how the contracting officer will evaluate the contractor’s response, and the contracting officer’s notification on resolution or disapproval. The clause provides for a contracting officer’s final determination and requires the contractor to, within 45 days of receipt of final determination, either correct the significant deficiencies or submit an acceptable corrective action plan showing milestones and actions to eliminate the significant deficiencies.

We propose to add clause 352.247–70, Delivery Location, to be used in supply contracts when it is necessary to specify delivery locations and provides an insert in the clause for the address and identifying data for shipment of deliverable items other than reports.

We propose to add clause 352.247–71, Marking Deliverables, as prescribed at 347.305–10(a), Packing, marking, and consignment instructions, or a clause substantially the same as the proposed clause at 352.247–71, in solicitations and contracts if special marking on deliverables is required.

We propose to add clause 352.247–72, Packing for Domestic Shipment, as prescribed at 347.205–10(b), in contracts when item(s) will be delivered for immediate use to a destination in the continental United States; when the material specification or purchase description does not provide preservation, packaging, packing, and/or marking requirements; and/or when the requiring activity has not cited a specific specification for packaging. This clause requires that material shall be packed for shipment in such a manner that will ensure acceptance by common carriers and safe delivery at destination. Containers and closures shall comply with regulations of carriers as applicable to the mode of transportation.



We propose to revise the provisions and clauses related to HHSAR part 370, as follows, in the order currently reflected in the Code of Federal Regulations:

We propose to revise provision 352.270-4a, Notice to Offerors, Protection of Human Subjects, to make minor administrative corrections to renumber the provision to 352.270-70, revise the HHSAR citation referencing the prescription, provide the current electronic Code of Federal Regulations website address for 45 CFR part 46, update other 45 CFR part 46 citations where included in the provision, and add paragraph (h) to provide the registration processes.

We propose to revise clause 352.270-4b, Protection of Human Subjects, to make minor administrative corrections to renumber to 352.270-72 and to revise the HHSAR citation referencing the prescription.

We propose to revise 352.270-5a, Notice to Offerors of Requirement for Compliance with Public Health Service Policy on Humane Care and the Use of Laboratory Animals, to make administrative corrections. This includes revising the provision to a clause, renumbering the clause to 352.270-77, revising the title to “Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals,” and revising the HHSAR citation referencing the prescription. These revisions would add paragraph (a), Definitions, and three definitions, as well as additional content to paragraph (b) that the contract will not be awarded without the approval of the Office of Laboratory

Animal Welfare, National Institutes of Health upon receipt of the contractor’s assurance. We propose to revise paragraphs (b) and (c) to combine the current content into paragraph (b), and revise paragraph (c) to permit the contracting officer to immediately suspend, in whole or in part, work performance and further payments if the contractor is not in compliance with any of the requirements and standards in the clause.

We propose to revise clause 352.270-5b, Care of Live Vertebrate Animals, to make minor administrative corrections to renumber the clause to 352.270-78, revise the HHSAR citation referencing the prescription, remove duplicative content in paragraph (c), change the “Note” to new paragraph (e), and other minor edits for clarification.

We propose to revise clause 352.270-6, Restriction on Use of Human Subjects, to make minor administrative corrections to renumber the clause to 352.270-73, revise the HHSAR citation referencing the prescription, and other minor edits for clarification.

We propose to remove the “352.270-7—352.270-8 [Reserved]” annotation as it is no longer needed with the revision, renumbering, and retitling of the clauses and provisions under this part.

We propose to revise provision 352.270-9, Non-Discrimination for Conscience, to make minor administrative corrections to renumber the clause to 352.270-79, revise the HHSAR citation referencing the prescription, and to add “The PEPFAR Stewardship Act of 2013, and The PEPFAR Extension Act of 2018,” to paragraph (a).

We propose to revise provision 352.270-10, Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, to make minor administrative corrections to renumber the clause to 352.270-71, slightly revise the title and the HHSAR citation referencing the prescription, update the citation of the HHSAR provision number in paragraph (a), and other minor punctuation edits.

We propose to revise clause 352.270-11, Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, to make minor administrative corrections to renumber the clause to 352.270-74, revise the HHSAR citation referencing the prescription, update the citation of the HHSAR provision number in paragraph (a), and other minor punctuation edits.

We propose to revise clause 352.270-12, Needle Exchange, to make minor administrative corrections to renumber the clause to 352.270-75 and revise the HHSAR citation referencing the prescription.

We propose to revise clause 352.270-13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research, to make minor administrative corrections to renumber the clause to 352.270-76 and revise the HHSAR citation referencing the prescription.

This table reflects the above proposed revisions and renumbering of the HHSAR part 370 prescribed clauses and provisions:

Existing subpart prescription (in order of sequence)	Existing No.	Proposed No.	Proposed revised prescription for each solicitation provision and contract clause Note: (P)=Provision, (C)=Clause
370.303(a) .....	352.270-4a	352.270-70	370.304(a): 352.270-70, Notice to Offerors, Protection of Human Subjects (P). 370.304(b): 352.270-71, Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (P).
370.303(d) .....	352.270-10	352.270-71	
370.304(b) .....	352.270-6	352.270-73	370.304(d): 352.270-73, Restriction on Use of Human Subjects (C). 370.304(c): 352.270-72, Protection of Human Subjects (C). 370.304(e): 352.270-74, Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (C).
370.304(a) .....	352.270-4b	352.270-72	
370.304(c) .....	352.270-11	352.270-74	
370.304(d) .....	352.270-12	352.270-75	370.304(f): 352.270-75, Needle Exchange (C). 370.304(g): 352.270-76, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research (C).
370.304(e) .....	352.270-13	352.270-76	
370.403(a) .....	352.270-5a	352.270-77	370.403(a): 352.270-77, Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (C).
370.404 .....	352.270-5b	352.270-78	370.403(b): 352.270-78, Care of Live Vertebrate Animals (C).
370.701 .....	352.270-9	352.270-79	370.701: 352.270-79, Non-Discrimination for Conscience (P).

We propose to add subpart 352.3, Provision and Clause Matrix, and section 352.301, Solicitation provisions and contract clauses (Matrix). Section

352.301 identifies that the HHSAR matrix is not published in the Code of Federal Regulations and will be

available on the Acquisition.gov website.

*Subchapter M—HHS Supplementations*

We propose to redesignate and retitle subchapter M, HHS Supplementations, title 48, chapter 3, to subchapter I, Department Supplementary Regulations, to better align with other FAR system regulatory subchapter placements under similar agency supplements to title 48.

*HHSAR Part 370—Special Programs Affecting Acquisition*

We propose to revise the authority citations for part 370, for the reasons set forth in the discussion and analysis section, to read as follows: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

We propose to revise the title of part 370 to “Special Programs Affecting Acquisitions,” to comport with the plural usage of “Acquisitions” in the subpart titles.

In subpart 370.3, Acquisitions Involving Human Subjects, we propose in section 370.300, Scope of subpart, to add a reference to 45 CFR part 46 policy scope and update the references to the 2018 Requirements revisions. Specifically, we are adding a reference to 45 CFR 46.102, which defines the applicability of the HHS policy in general. We are also removing the reference to the old § 46.102(d) and (f), which defined “Human Subject” and “Research” respectively and replacing them with the new 2018 paragraphs (e) and (l). In section 370.301, Policy, we propose to add a reference to the 2018 exemption for certain research as set forth in 45 CFR 46.104. We also propose administrative edits in the second sentence for further clarification.

We propose in section 370.302, Federal-wide Assurance (FWA), to revise the title to “Federal-wide assurance” and make other minor edits for clarification.

In section 370.303, Notice to offerors/Provisions, we propose to revise the section title to “Notice to offerors,” moving the two provisions prescribed in paragraphs (a) and (d) to revised section 370.304, Solicitation provisions and contract clause, paragraphs (a) and (b). We also propose in section 370.303 to add a statement at paragraph (a) to reinforce the 2018 Requirements that unless exempt, no contract can start without the required certifications.

We propose in section 370.304, Contract clauses, to revise the title to “Solicitation provisions and contract clause.” The following revisions to the text under this section are proposed:

- Move provision 352.270–4a, Notice to Offerors—Protection of Human Subjects, from section 370.303,

paragraph (a), to be renumbered as 352.270–70, to comport with FAR numbering conventions. The provision is prescribed to be inserted in solicitations that involve human subjects.

- Move propose provision 352.270–10, Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, from section 370.303, paragraph (d), to be renumbered as 352.270–71, to comport with FAR numbering conventions. The provision is prescribed to be inserted in solicitations that involve human subjects when the research is subject to RIHSC review and approval.

- Redesignate the existing paragraph (a) to paragraph (c), and renumber the clause 352.270–4b, Protection of Human Subjects, to 352.270–72, to comport with FAR numbering conventions. The clause is prescribed to be inserted in solicitations, contracts, and orders involving human subjects.

- Redesignate the existing paragraph (b) to paragraph (d), and renumber the clause 352.270–6, Restriction of Use of Human Subjects, to 352.270–73, to comport with FAR numbering conventions. The clause is prescribed to be inserted in solicitations, contracts, and orders involving human subjects. In contracts and orders if the contractor has an approved FWA of compliance in place but cannot certify prior to award that an IRB registered with OHRP reviewed and approved the research, because definite plans for involvement of human subjects are not set forth in the proposal (e.g., projects in which human subjects’ involvement will depend upon completion of instruments, prior animal studies, or purification of compounds). Under these conditions, the contracting officer may make the award without the requisite certification, as long as the contracting officer includes appropriate conditions in the contract or order.

- Redesignate the existing paragraph (c) to paragraph (e), and renumber the clause 352.270–11, Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, to 352.270–74, to comport with FAR numbering conventions. The clause is prescribed to be inserted in solicitations, contracts, and orders that involve human subjects when the research is subject to RIHSC review and approval.

- Redesignate the existing paragraph (e) to paragraph (f), and renumber the clause 352.270–12, Needle Exchange, to 352.270–75, to comport with FAR

numbering conventions. The clause is prescribed to be inserted in solicitations, contracts, and orders that involve human subjects.

- Redesignate the existing paragraph (e) to paragraph (e), and renumber the clause 352.270–13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research, to 352.270–76, to comport with FAR numbering conventions. The clause is prescribed to be inserted in solicitations, contracts, and orders that involve human subjects.

In subpart 370.4, Acquisitions Involving the Use of Laboratory Animals, we propose minor edits for clarification, and to move the citation regarding the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) to new section 370.402, Policy. We propose in new section 370.401, Definitions, to define three definitions used in this subpart, “Animal,” “Animal Welfare Assurance or assurance,” and “Institutional Animal Care and Use Committee.”

We propose to redesignate section 370.401 as section 370.402 to comport with FAR conventions and have made conforming revisions in the section to comport with the revised Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, which implements Public Law 99–158. We also propose to redesignate paragraph (b) to paragraph (c), and remove content to the HHSAM as internal procedures, as well as submission requirements that have more appropriately been moved to clause 352.270.77, Compliance with the Public Health Policy on Humane Care and Use of Laboratory Animals, which is prescribed at section 370.403(a).

We propose to remove section 370.402 and move the details of the assurance and approval requirements to clause 352.270.77, Compliance with the Public Health Policy on Humane Care and Use of Laboratory Animals, which is prescribed at section 370.403(a).

We propose to rename section 370.403 as “Contract clauses,” to reflect that only clauses are prescribed in the section. The following revisions are proposed:

- In paragraph (a), change the prescription to renumbered clause 352.270–77, Compliance with the Public Health Policy on Humane Care and Use of Laboratory Animals, which comports with FAR numbering convention. The clause is prescribed to be inserted in solicitations, contracts, and orders that involve live vertebrate animals.

- Move the prescription currently at section 370.304 for clause 352.270–5b, Care of Live Vertebrate Animals, to

paragraph (b) of section 370.403, Contract clauses, and renumber the clause to 352.270–76, which comports with FAR numbering convention. The clause is prescribed to be inserted in solicitations and contracts that involve live vertebrate animals.

- Remove the remaining content in section 370.403 as the language is duplicative of the prescribed clauses.

We propose to remove section 370.404, Contract clause, as the content has been moved to section 370.403.

In subpart 370.7, Acquisitions Under the Leadership Act, we propose to revise the title of the subpart to “Acquisitions Under the President’s Emergency Plan for AIDS Relief,” as this is the more commonly used title of Public Law 108–25, in addition to the fact the short title, “Leadership Act,” is no longer widely used.

In section 370.700, Scope of subpart, we propose to add the “PEPFAR” (“President’s Emergency Plan for AIDS Relief”) acronym and update the amended public law references to include Public Law 115–305, the PEPFAR Extension Act.

In section 370.701, Solicitation provision, we propose to number provision 352.270–9, Non-Discrimination for Conscience, to 352.270–79, to comport with FAR numbering convention. We also propose to revise the prescription language at paragraphs (a) to update with the enacted PEPFAR Stewardship and Oversight Act of 2013 (Pub. L. 113–56) in lieu of the PEPFAR Extension Act of 2018 (Pub. L. 115–305). We also propose to move the content of paragraph (b) to the HHSAM as agency procedures.

## Regulatory Reviews

### *Executive Order 12866 and 13563*

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Office of Information and Regulatory Affairs has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action, and has determined

that this rule is not a significant regulatory action under E.O. 12866.

HHS’s impact analysis can be found as a supporting document at <https://www.regulations.gov>, usually within 48 hours after the rulemaking document is published.

### *Paperwork Reduction Act*

This proposed rule includes provisions constituting collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that require approval by the Office of Management and Budget (OMB). Accordingly, under 44 U.S.C. 3507(d), HHS has submitted a copy of this rulemaking action to OMB for its review.

OMB assigns control numbers to collections of information it approves. HHS may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. HHS is revising 12 currently approved collections of information proposed in this rule under the HHSAR, 48 CFR part 352, Solicitation Provisions and Contract Clauses, that are prescribed under and related to the following HHSAR parts:

- 48 CFR part 370, Special Programs Affecting Acquisition;
- 48 CFR part 327, Patents, Data, and Copyrights;
- 48 CFR part 337, Service Contracting—General; and
- 48 CFR part 311, Describing Agency Needs.

The 12 existing approved information collections followed by their currently designated numbers and titles are reflected below. (Note: The following existing section (clause or provision) numbers may be updated by number or title as reflected later in this section via a table describing the updated burden information.)

- 48 CFR 352.270–4a, Notice to Offerors, Protection of Human Subjects.
- 48 CFR 352.270–10, Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.
- 48 CFR 352.270–4b, Protection of Human Subjects.
- 48 CFR 352.270–11, Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.
- 48 CFR 352.237–73, Indian Child Protection and Family Violence Act.
- 48 CFR 352.270–5a, Notice to Offerors of Requirement for Compliance with Public Health Service Policy on

Humane Care and the Use of Laboratory Animals.

- 48 CFR 352.270–5b, Care of Live Vertebrate Animals.
- 48 CFR 352.211–1, Public Accommodations and Commercial Facilities.
- 48 CFR 352.211–2, Conference Sponsorship Request and Conference Materials Disclaimer.
- 48 CFR 352.227–11, Patent Rights—Exceptional Circumstances.
- 48 CFR 52.227–14, Rights in Data—Exceptional Circumstances.
- 48 CFR 352.237–72, Crime Control Act—Requirement for Background Checks.

Additionally, HHS is proposing to add six (6) new collections of information in this proposed rule under the HHSAR, 48 CFR part 352, Solicitation Provisions and Contract Clauses, that are prescribed under and related to the following HHSAR parts:

- 48 CFR part 304, Administrative Matters (proposed to be revised to a new header to comport with the FAR: Administrative and Information Matters);
- 48 CFR part 308, Required Sources of Supplies and Services;
- 48 CFR part 309, Contractor Qualifications;
- 48 CFR part 323, Environment, Energy and Water Efficiency, Renewable Energy Technologies, Occupational Safety, and Drug-Free Workplace (proposed to be revised to a new header to comport with the FAR: Environment, Sustainable Acquisition, and Material Safety);
- 48 CFR part 333, Protests, Disputes, and Appeals; and
- 48 CFR part 345, Government Property.

The six new proposed approved information collections are as follows (Note: Based on the number of respondents for two of the associated information collections falling under 10 that do not require OMB approval due to exception, HHS is requesting four (4) new approved OMB control numbers for items 1 through 4 as follows out of the six new identified collections of information.):

1. 48 CFR 352.204–70, Prevention and Public Health Fund—Reporting Requirements.
2. 48 CFR 352.209–70, Organizational Conflicts of Interest.
3. 48 CFR 352.208–70, Printing and Duplication.
4. 48 CFR 352.245–70, Contractor Property Management System Administration.
5. 48 CFR 352.223–70, Instructions to Offerors—Sustainable Acquisition Plan. (OMB approval not required at this time.)

6. 48 CFR 352.233–71, Litigation and Claims. (OMB approval not required at this time.)

If OMB does not approve the collections of information as requested, HHS will immediately remove the provisions containing a collection of information or take such other action as is directed by OMB.

Comments on the collections of information contained in this proposed rule should be submitted to the Office of Management and Budget, Attention: Desk Officer for the Department of Health and Human Services, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies sent by mail or hand delivery to the U.S. Department of Health and Human Services, Office of the Chief Information Officer, Attn: Sherrette Funn, 200 Independence Ave. SW, Room 336E, Washington, DC 20201; or email to [sherrette.funn@hhs.gov](mailto:sherrette.funn@hhs.gov); and email to <https://www.regulations.gov>. Comments should indicate that they are submitted in response to “RIN 0991–AC36—HHS

Acquisition Regulation: Regulatory Review (HHSAR Case 2023–002).”

OMB is required to make a decision concerning the collections of information contained in this proposed rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the proposed rule.

The Department considers comments by the public on proposed collections of information in—

- Evaluating whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department’s estimate of the burden of the proposed collections of information, including the validity of the methodology and assumptions used;

- Enhancing the quality, usefulness, and clarity of the information to be collected; and

- Minimizing the burden of the collections of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

The collection of information on currently approved OMB control numbers can be accessed on [reginfo.gov](http://reginfo.gov). The following table provides a summary of the proposed revisions of the 12 currently approved collections of information. The proposed revisions do not change information collection requirements and the estimated burden hours. But the proposed revision made changes in the Information Collection Instruments/Instructions. HHS has submitted them to OMB for review and approval.

Existing clause/provision number and header title	Approved OMB control number	Proposed clause/provision number and header title	Proposed other changes	Burden hours
352.270–4a, Notice to Offerors, Protection of Human Subjects.	0990–0431	352.270–70, Notice to Offerors—Protection of Human Subjects.	Revise the HHSAR citation referencing the prescription.	450
352.270–10 Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.	0990–0431	352.270–71, Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.	N/A .....	450
352.270–4b, Protection of Human Subjects.	0990–0431	352.270–72, Protection of Human Subjects.	Revise the HHSAR citation referencing the prescription.	450
352.270–11 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.	0990–0431	352.270–74 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.	Revise the HHSAR citation referencing the prescription.	450
352.237–72, Crime Control Act—Requirement for Background Checks.	0990–0430	352.237–72, Requirement for Background Checks.	Update the prescription and the title.	160
352.270–5a, Notice to Offerors of Requirement for Compliance with Public Health Service Policy on Humane Care and the Use of Laboratory Animals.	0990–0432	352.270–77, Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.	Revise the title and HHSAR citation referencing the prescription. Adding new content.	54
352.270–5b, Care of Live Vertebrate Animals.	0990–0432	352.270–78, Care of Live Vertebrate Animals.	Revise the HHSAR citation referencing the prescription and remove duplicative content.	54
352.211–1, Public Accommodations and Commercial Facilities.	0990–0434	352.211–70, Public Accommodations and Commercial Facilities.	Revise the prescription to comport with FAR style conventions.	533.5
352.211–2, Conference Sponsorship Request and Conference Materials Disclaimer.	0990–0434	352.211–71, Conference Sponsorship Requests and Conference Materials Disclaimer.	Update the prescription to comport with FAR style conventions.	533.5
352.227–11, Patent Rights—Exceptional Circumstances.	0990–0419	352.227–70, Patent Rights—Supplement—Exceptional Circumstances.	Make minor updates to the clause prescription and citation.	5,449.5
352.227–14, Rights in Data—Exceptional Circumstances.	0990–0419	352.227–71, Rights in Data—Supplement—Exceptional Circumstances.	Make minor updates to the clause prescription and citation and remove duplicate content.	5,449.5

Existing clause/provision number and header title	Approved OMB control number	Proposed clause/provision number and header title	Proposed other changes	Burden hours
352.237–73, Indian Child Protection and Family Violence Act.	0990–0433	352.237–73, Indian Child Protection and Family Violence Act—Background Investigations.	Revise title of the clause. Add needed content and bring reference citations up to date. Updates to the clause prescription and citation.	67

HHSAR parts 308, 309, 304, 323, 333, and 345 related new collections of information: Individual summaries of collection of information, description of need for information and proposed use

of information, along with supporting estimated data are described below. The following table summarizes HHS request for four (4) new OMB control numbers for the four proposed clauses/

provisions containing collections of information with burdens on the public.

OMB control # requesting	HHSAR clause provision	Estimated hour	BLS hourly wage rate	Estimated cost to the public
1 .....	352.208–70	500	\$42.89	\$21,445
1 .....	352.209–70	150	42.89	6,434
N/A * .....	352.233–71	N/A	42.89	N/A
N/A * .....	352.223–70	N/A	42.89	N/A
1 .....	352.204–70	260	42.89	11,151
1 .....	352.245–70	66	42.89	2,831

\* No OMB Control Number is requested because currently, the estimated number of respondents falls below 10. While HHS will collect information it does not meet the threshold for submitting to OMB for approval. As HHS captures more information in the future when the rule is published as final, HHS will continue to examine how much the proposed new collections of information are utilized in HHS procurements.

The Bureau of Labor Statistics (BLS) gathers information on full-time wage and salary workers. The BLS hourly wage rate is using the latest (May 2023) available BLS data, the mean hourly wage is \$31.48 on BLS wage code—“00–0000 All Occupations” plus 36.25% fringe benefits per OMB Memo M–08–13 dated March 11, 2008.

The 6 new clauses/provisions containing collections of information are described below:

- The first new OMB Control number request is for 352.208–70, Printing and Duplication.

The collection of information contained in section 308.870, Contract clauses, and part 352 at proposed clause 352.208–70, is described immediately following this paragraph.

*Summary of collection of information:* We propose the use of 352.208–70,

Printing and Duplication, as prescribed at 308.870, Contract clauses.

The proposed HHSAR clause 352.208–70, Printing and Duplication, is required in all solicitations and contracts for supplies or services over the simplified acquisition threshold, unless printing or increased duplication is authorized by statute. It is intended to prohibit contractors and subcontractors from performing printing, to acquire related supplies, or to provide other printing-related services without prior authorization from the contracting officer. When printing supplies or services are required, and specified under the contract, the Contractor shall submit camera-ready copies of such deliverables to the Contracting Officer’s Representative for printing. The information collection requirement is

necessary to ensure deliverables are not duplicated and/or printed without prior approval from the contracting officer.

*Description of need for information and proposed use of information:* Public Law 90–620, (44 U.S.C. 101), Public Printing and Document, was passed to centralize in the United States Government Publishing Office the printing, binding, and distribution of U.S. Government documents.

To comply with Public Law 90–620, and to establish parameters on allowable printing under HHS contracts, HHS developed clause 352.208–70, Printing and Duplication. The clause contains the following information collection requirements: the contractor shall submit camera-ready copies of such deliverables to the Contracting Officer’s Representative for printing.

**BURDEN HOUR CALCULATION**

Number of respondents	× Number of responses per respondent	× Number of minutes	+ by 60 min/hour	Number of burden hours
5,000 .....	1	10	.....	500

- The second new OMB control number request is for 352.209–70, Organizational Conflicts of Interest.

The collection of information contained in section 309.507–1, Solicitation provision, and part 352 at proposed provision 352.209–70, is

described immediately following this paragraph.

*Summary of collection of information:* We propose to add 352.209–70, Organizational Conflicts of Interest, as prescribed at 309.507–1, Solicitation provision.

The proposed rule HHSAR provision 352.209–70, Organizational Conflicts of Interest, is required in all solicitations for the services addressed at FAR 9.502 and is intended to avoid situations which might create an organizational conflict of interest or where the offeror’s

performance of work under the contract may provide the contractor with an unfair competitive advantage. HHS would use the information collection requirements to assess whether an organizational conflict of interest exists with the contractor. The information collection requirement is necessary to ensure that the offeror's performance of work under the contract may not provide the contractor with an unfair competitive advantage.

*Description of need for information and proposed use of information:* Under

Public Law 117–324, Preventing Organizational Conflicts of Interest in Federal Acquisition Act, each agency of the Federal Government must prevent organizational conflicts of interest in Federal acquisitions. To comply, HHS developed provision 352.209–70, Organizational Conflicts of Interest. The provision contains the following information collection requirements: The offeror shall provide (1) a statement with its offer which describes all relevant facts concerning any past, present, or currently planned interest

(financial, contractual, organizational, or otherwise) or actual or potential organizational conflicts of interest relating to the services to be provided under this solicitation; (2) same information as (1) for any consultants and subcontractors identified in its proposal and which will provide services under the solicitation; (3) relevant facts that show how its organizational and/or management system or other actions would avoid or mitigate any actual or potential organizational conflicts of interest.

BURDEN HOUR CALCULATION

Number of respondents	× Number of responses per respondent	× Number of minutes	+ by 60 min/hour	Number of Burden Hours
150 .....	1	60	.....	150

- The third information collection added in the rule is for 352.233–71, Litigation and Claims. Due to the estimated projected respondents falling under 10, a new OMB control number will not be requested at this time. The information on the collection of information that falls within the exception is provided here for the public's information and use. HHS will continue to examine in the future after publication of a final rule whether or not the use of the clause increases over 10 in a given fiscal year and proceed with requesting OMB approval if needed at that time.

The collection of information contained in section 333.215–70, Contract clauses, and part 352 at proposed clause 352.233–71, is described immediately following this paragraph.

*Summary of collection of information:* We propose to add 352.233–71, Litigation and Claims, as prescribed at 333.215–70, Contract clauses.

The proposed rule HHSAR clause 352.233–71, Litigation and Claims, is required in solicitations and contracts when a cost-reimbursement, time-and-materials, or labor-hour contract is contemplated and is intended to require contractors to notify the Department of Health and Human Services (HHS) immediately for any litigation or claims that may be filed against the contractor arising out of the performance of the contract. The information collection requirement is necessary to determine the need of assigning representatives of HHS to settle or defend any such action or claim.

*Description of need for information and proposed use of information:* To ensure HHS is not liable for the expense

of defending any action or for any costs resulting from the loss thereof to the extent that the contractor would have been compensated by insurance due to the contractor failing to secure, through its own fault or negligence, appropriate insurance coverage, HHS developed clause 352.233–71, Litigation and Claims. The clause contains the following information collection requirements: (1) The contractor shall provide written notification immediately to the contracting officer of any action, including any proceeding before an administrative agency, filed against the contractor arising out of the performance of this contract; (2) the contractor shall furnish immediately to the contracting officer copies of all pertinent documents received by the contractor with respect to such action or claim.

BURDEN HOUR CALCULATION

Number of respondents	× Number of responses per respondent	× Number of minutes	+ by 60 min/hour	Number of burden hours
2 (N/A) * .....	2 (N/A)	60	.....	2 (N/A)

\* Note: Due to the estimated low number of projected respondents, no formal OMB information collection approval is required at this time. HHS will continue monitoring the use of the clause after publication of the final rule.

- The fourth information collection added in the rule is for 352.223–70, Instructions to Offerors—Sustainable Acquisition Plan.

The collection of information contained in section 323.109–70, Solicitation provision, and part 352 at proposed provision 352.223–70, is described immediately following this paragraph.

*Summary of collection of information:* We propose to add 352.223–70, Instructions to Offerors—Sustainable Acquisition Plan, as prescribed at 323.109–70, Solicitation provision.

The proposed rule would add HHSAR provision 352.223–70, Instructions to Offerors—Sustainable Acquisition Plan. It is required in solicitations above the micro-purchase threshold when acquiring a product or service that

include sustainable acquisition attributes and is intended to apply FAR subpart 23.1, Sustainable Products and Services. The information collection requirement is necessary to comply with the requirements of Executive Order 13423.

*Description of need for information and proposed use of information:* Executive Order (E.O.) 13423 requires in agency acquisitions of goods and

services (i) the use of sustainable environmental practices, including acquisition of biobased, environmentally preferable, energy-efficient, water-efficient, and recycled-content products, and (ii) the use of

paper of at least 30 percent post-consumer fiber content. To comply with E.O. 13423, HHS developed provision 352.223–70, Instructions to Offerors—Sustainable Acquisition Plan. The provision contains the following

information collection requirements: Offerors shall include a Sustainable Acquisition Plan in their technical proposals.

BURDEN HOUR CALCULATION

Number of respondents	× Number of responses per respondent	× Number of minutes	÷ by 60 min/hour	Number of burden hours
6 (N/A) *	1 (N/A)	120	.....	12 (N/A)

\* Note: Due to the estimated low number of projected respondents, no formal OMB information collection approval is required at this time. HHS will continue monitoring the use of the clause after publication of the final rule.

• The fifth new information collection, and third request for an OMB control number is for 352.204–70, Prevention and Public Health Fund—Reporting Requirements.

The collection of information contained in section 304.7202, Contract clause, and part 352 at proposed clause 352.204–70, is described immediately following this paragraph.

*Summary of collection of information:* We propose to add of 352.204–70, Prevention and Public Health Fund—Reporting Requirements, as prescribed at 304.7202, Contract clause.

Proposed rule added HHSAR clause 352.204–70, Prevention and Public Health Fund—Reporting Requirements,

is required in all solicitations and contract actions with a value of \$25,000 or more funded in whole or in part with Prevention and Public Health Funds (PPHFs), except classified solicitations and contracts and is intended to implement section 220 of Public Law 112–74, FY 2012 Labor, HHS and Education Appropriations Act. The information collection requirement is necessary to comply with the requirements of semi-annual reporting on the use of funds from the Prevention and Public Health Fund (PPHF), Public Law 111–148, sec. 4002.

*Description of need for information and proposed use of information:* Under

Public Law 112–74, Consolidated Appropriations Act, 2012, section 220(b)(5), requires each contractor to report on its use of Prevention and Public Health Fund under the contract. To comply with the public law, HHS developed clause 352.204–70, Prevention and Public Health Fund—Reporting Requirements. The clause contains the following information collection requirements: Semi-annual reports from the contractor for all work funded, in whole or in part, by the PPHF, are due no later than 20 days following the end of each 6-month period.

BURDEN HOUR CALCULATION

Number of respondents	× Number of responses per respondent	× Number of minutes	÷ by 60 min/hour	Number of burden hours
260	2	30	.....	260

• The sixth new information collection requirement is for 352.245–70, Contractor Property Management System Administration.

The collection of information contained in section 345.107, Contract clauses, and part 352 at proposed clause 352.245–70, Contractor Property Management System Administration, is described immediately following this paragraph.

*Summary of collection of information:* We propose to add 352.245–70, Contractor Property Management System Administration, as prescribed at 345.107, Contract clauses.

Proposed rule added HHSAR clause 352.245–70, Contractor Property Management System Administration, is

required in solicitations and contracts containing the clause at FAR 52.245–1, Government Property, and is intended to protect HHS’s property. The information collection requirement is necessary to ensure the Contractor’s system or systems for managing and controlling Government property is acceptable by HHS.

*Description of need for information and proposed use of information:* To ensure the contractor is establishing and maintaining an acceptable property management system, HHS developed clause 352.245–70, Contractor Property Management System Administration. The clause contains the following information collection requirements: The contractor shall respond within 30

days to a written initial determination from the contracting officer that identifies significant deficiencies in the contractor’s property management system. HHS estimates that of the 26,128 total contract actions over the Simplified Acquisition Threshold during FY 2018–FY 2022, that no more than 5% (1,306) would require the required contractor property management system administration, and no more than 10% of that subset (131) would be submitting information in any one fiscal year during performance under the contract. We have entered the data below and as HHS obtains more data for future renewals, we will update the estimated burden.



BURDEN HOUR CALCULATION

Number of respondents	× Number of responses per respondent	× Number of minutes	+ by 60 min/hour	Number of Burden Hours
131 .....	1	30	.....	66

*Regulatory Flexibility Act*

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

HHS expects that the overall impact of the proposed rule would benefit small businesses because HHS proposes to update the HHSAR to, among other things, revise outdated information, remove extraneous procedural information that applies only to HHS’s internal operating procedures, and remove policy or procedures duplicative of FAR requirements. Any additional costs associated with the rule, such as costs to implement the substantive new and revised requirements concerning Made in America Act, can be factored into the contract price. On this basis, the Secretary hereby certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of sections 603 and 604 do not apply.

While based on the foregoing, HHS has determined that the agency is not required to prepare an Initial Regulatory Flexibility Analysis (IRFA), HHS has prepared an IRFA that is summarized here. Comments are solicited from small businesses and other interested parties

and will be considered in the development of the final rule.

*Initial Regulatory Flexibility Analysis*

This Initial Regulatory Flexibility Analysis has been prepared consistent with 5 U.S.C. 603.

1. Description of the Reasons why the Action is Being Taken

This proposed rule would amend the Health and Human Services Acquisition Regulation (HHSAR) to implement updates to the HHSAR, remove extraneous procedural information that applies only to HHS’s internal operating procedures, and remove policy or procedures duplicative of FAR requirements. The proposed rule also includes substantive new and revised requirements concerning due process rights on debarments and suspensions. Based on a review of the potential impact on small business entities, HHS has determined that the requirements specified in the proposed rule are inherent to successful performance on any Federal contract and are required for both large and small businesses.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

In addition to updating the HHSAR to remove outdated information, remove extraneous procedural information that applies only to HHS’s internal operating procedures, and to remove policy or procedures duplicative of FAR requirements, the proposed rule implements important agency policies and procedures to implement Executive orders and specific requirements of the FAR specified for agency implementation. This must be

implemented in the HHSAR in accordance with 41 U.S.C. 1707 and FAR subpart 1.5, which require publication of a proposed rule for public comment.

3. Description of and, Where Feasible, Estimate of the Number of Small Entities to Which the Proposed Rule Will Apply

This proposed rule will impact small businesses that provide supplies, services, and construction to HHS as prime contractors or subcontractors, as well as those small business entities that would like to support HHS and who submit quotations, offers and proposals to compete for future opportunities. To estimate the number of small businesses that could potentially be impacted by the proposed rule, HHS focused on those contract award actions over the Simplified Acquisition Threshold (SAT) (in most instances the SAT was \$150,000 before June 1, 2018, and \$250,000 after June 1, 2018, when the SAT was increased). This is because it is likely that the most impact to small business entities as a result of this important HHSAR update would be at the SAT or above, as the FAR already provides agencies more streamlined policies and procedures under the SAT to ease the burden, both on the public as well as the acquisition workforce, for actions that fall under the SAT. Across the thirteen main Operating Divisions and Staff Divisions we examined the Federal Procurement Data System for HHS contract award actions over the SAT for Fiscal Years (FY) 2018–2022. This data reflects the following HHS contract awards to small business entities as shown in the table below:

HHS CONTRACT ACTION AWARDS TO SMALL BUSINESS ENTITIES OVER THE SAT: FY 2018–FY 2022

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	Total	Average
Total .....	2536	2405	2502	2426	2551	12,420	2484

As shown, HHS awarded over 12,420 contracts to small business entities over the SAT during the period FY 2018 through FY 2022. Using this figure to project the potential impact to small business entities that may be affected by the proposed rule, the Department estimates that on average each fiscal year, 2,484 small business entities or more may perform under HHS contracts and be impacted by the acquisition regulations contained in this rulemaking.

4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report Or Record

The proposed rule includes reporting or recordkeeping requirements. The revised record keeping and reporting requirements and estimated impacts are described in the Paperwork Reduction Act section of the rulemaking.

5. Identification, to the Extent Practicable, of all Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

6. Description of any Significant Alternatives to the Proposed Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Rule on Small Entities

HHS considered whether any other alternatives would reduce the impact on small businesses but concluded that the proposed rule was necessary for consistency with the FAR, for compliance with new statutes such as Made in America, and to ensure the protection of children entrusted under the care of HHS through unique agency acquisition requirements with respect to important issues such as compliance with reporting of child abuse, non-smoking, and required background checks.

Comments on the Economic Impacts of the Proposed Rule

HHS has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. HHS will consider comments from small entities concerning the affected HHSAR parts that pertain to this proposed rule. Interested parties should cite 5 U.S.C 601, et seq. and reference

“RIN 0991–AC36—HHS Acquisition Regulation: Regulatory Review (HHSAR Case 2023–002),” in comments on the certification or the IRFA presented in this proposed rule.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. HHS has determined that this proposed rule would have no such effect on State, local, and Tribal governments or on the private sector. Therefore, the analytical requirements of UMRA do not apply.

List of Subjects

48 CFR Parts 301, 302, 303, 304, 305, 306, 308, 309, 311, 312, 313, 314, 315, 316, 318, 319, 322, 323, 324, 327, 330, 331, 332, 333, 334, 335, 336, 337, 343, 345, 352, and 370

Government procurement.

48 CFR Part 325

Customs duties and inspection, Foreign currencies, Foreign trade, Government procurement.

48 CFR Part 326

Government procurement, Indians, Indians-business and finance, Reporting and recordkeeping requirements.

48 CFR Part 341

Government procurement, Reporting and recordkeeping requirements, Utilities.

48 CFR Parts 342 and 344

Government procurement, Reporting and recordkeeping requirements.

48 CFR Part 347

Freight, Government procurement, Reporting and recordkeeping requirements, Transportation.

Xavier Becerra,

Secretary, Department of Health and Human Services.

For the reasons set out in the preamble, HHS proposes to amend 48 CFR chapter 3 as follows:

■ 1. Revise parts 301 through 303 to read as follows:

\* \* \* \* \*

PART 301 HHS ACQUISITION REGULATION SYSTEM
PART 302 DEFINITIONS OF WORDS AND TERMS

PART 303 IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

\* \* \* \* \*

PART 301—HHS ACQUISITION REGULATION SYSTEM

Sec.

301.000 Scope of part.

Subpart 301.1—Purpose, Authority, Issuance

- 301.101 Purpose.
301.103 Authority.
301.104 Applicability.
301.105 Issuance.
301.105–1 Publication and code arrangement.
301.105–2 Arrangement of regulations.
301.105–3 Copies.
301.106 OMB approval under the Paperwork Reduction Act.
301.107 Certifications.

Subpart 301.3—Agency Acquisition Regulations

- 301.301 Policy.
301.301–70 Amendment of the HHSAR.
301.303–70 Publication and codification—HHSAR.
301.304 Agency control and compliance procedures.

Subpart 301.470—Deviations from the FAR and HHSAR

- 301.402 Policy.
301.403 Individual deviations.
301.404 Class deviations.

Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

- 301.601 General.
301.602 Contracting officers.
301.602–3 Ratification of unauthorized commitments.
301.603 Selection, appointment, and termination of appointment of contracting officers.
301.603–1 General.
301.603–3 Appointment.
301.604 Contracting Officer’s Representative (COR).
301.604–70 Contract clause.

Subpart 301.7—Determination and Findings

301.707 Signatory authority.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(b), (c)(3); 41 U.S.C. 1303(a)(2); 41 U.S.C. 1702, 1707; and 48 CFR 1.301 through 1.304.

301.000 Scope of part.

This part sets out general Department of Health and Human Services Acquisition Regulation (HHSAR) policies, including information regarding the purpose, authority, issuance, arrangement, applicability, numbering, implementation, supplementation, and maintenance and administration of the HHSAR. The HHSAR is an integral part of the Federal Acquisition Regulations System. It also includes Health and Human Services

(HHS) acquisition policies and procedures for deviation from the HHSAR and the Federal Acquisition Regulation (FAR).

**Subpart 301.1—Purpose, Authority, Issuance**

**301.101 Purpose.**

The HHSAR establishes uniform acquisition policies and procedures, which implement and supplement the Federal Acquisition Regulation (FAR). This subpart also provides the explanation of the authorities under which the HHSAR is issued.

**301.103 Authority.**

(b) The Senior Procurement Executive (SPE), as delegated by the Secretary of HHS, prescribes the HHSAR under the authority of 41 U.S.C. 1707, 5 U.S.C. 301, section 205(c) of the Federal Property and Administrative Services Act of 1949, 40 U.S.C. 121(c)(2), FAR 1.301 through 1.304, and other authorities as cited.

**301.104 Applicability.**

The FAR and the HHSAR apply to all HHS acquisitions as defined in FAR 2.101.

**301.105 Issuance.**

**301.105-1 Publication and code arrangement.**

(b) The HHSAR is issued as chapter 3 of title 48 in the Code of Federal Regulations (CFR) and referenced as 48 CFR chapter 3.

**301.105-2 Arrangement of regulations.**

(a) *General.* The HHSAR conforms with the arrangement and numbering system prescribed by FAR 1.105-2.

(b) *Numbering.* (1) The numbering illustrations at FAR 1.105-2(b) apply to the HHSAR. Coverage in the HHSAR is identified by the prefix “3” followed by the complete HHSAR citation. For example, 301.105-2(b).

(2) Subdivisions below the section or subsection level follow the FAR in this sequence: (a)(1)(i)(A)(1)(i).

(c) *References and citations.* (1) Cross reference to the FAR in the HHSAR will be cited by “FAR” followed by the FAR numbered citation. References to specific citations with the HHSAR will be referenced by the numbered citation only, e.g., 301.105-2.

(2) This chapter may be referred to as the Health and Human Services Acquisition Regulation or the HHSAR.

(3) Using the HHSAR coverage at 301.105-2(b) as a typical illustration, reference to the—

(i) Part would be “HHSAR part 301” outside the HHSAR and “part 301” within the HHSAR.

(ii) Subpart would be “HHSAR subpart 301.1” outside the HHSAR and “subpart 301.1” within the HHSAR.

(iii) Section would be “HHSAR 301.105” outside the HHSAR and “301.105” within the HHSAR.

(iv) Subsection would be “HHSAR 301.105-1” outside the HHSAR and “301.105-1” within the HHSAR.

(v) Paragraph would be “HHSAR 301.105-1(b)” outside the HHSAR and “301.105-1(b)” within the HHSAR.

**301.105-3 Copies.**

The HHSAR is available on the internet at <https://www.ecfr.gov/current/title-48/chapter-3> or <https://acquisition.gov>.

HHSAR segment	OMB Control No.
304.7202 .....	0990-XXXX
308.870 .....	0990-XXXX
309.507-1 .....	0990-XXXX
311.7102 .....	0990-0434
311.7202 .....	0990-0434
327.303-70 .....	0990-0419
327.407-70 .....	0990-0419
337.7006 .....	0990-0430, 0990-0433
345.107 .....	0990-XXXX
370.304 .....	0990-0431
370.403 .....	0990-0432
352.204-70 .....	0990-XXXX
352.208-70 .....	0990-XXXX
352.209-70 .....	0990-XXXX
352.211-70 .....	0990-0434
352.211-71 .....	0990-0434
352.227-70 .....	0990-0419
352.227-71 .....	0990-0419
352.237-72 .....	0990-0430
352.237-73 .....	0990-0433
352.245-70 .....	0990-XXXX
352.270-70 .....	0990-0431
352.270-71 .....	0990-0431
352.270-72 .....	0990-0431
352.270-74 .....	0990-0431
352.270-77 .....	0990-0432
352.270-78 .....	0990-0432

**301.106 OMB approval under the Paperwork Reduction Act.**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521), the Office of Management and Budget (OMB) has approved the reporting or recordkeeping provisions that are included in the HHSAR and has given HHS the following approval numbers:

**301.107 Certifications.**

In accordance with 41 U.S.C. 1304, a new requirement for a certification by a contractor or offeror may not be included in the HHSAR unless—

- (a) The certification is specifically imposed by statute; or
- (b) Written justification for the certification requirement is provided to the Secretary of HHS by the SPE, and

the Secretary of HHS approves, in writing, the inclusion of such certification requirement.

**Subpart 301.3—Agency Acquisition Regulations**

**301.301 Policy.**

(a)(1) HHS implementation and supplementation of the FAR is issued in the HHSAR under authorization and subject to the authority, direction, and control of the HHS Secretary. The HHSAR contains HHS policies that govern the acquisition process or otherwise control acquisition relationships between HHS’ contracting activities and contractors. The HHSAR contains—

- (i) Requirements of law;
- (ii) HHS-wide policies;
- (iii) Deviations from FAR requirements; and
- (iv) Policies that have a significant effect beyond the internal procedures of HHS or a significant cost or administrative impact on contractors or offerors.

(2) Relevant internal policy, procedures, guidance, and instructions not meeting the criteria in paragraph (a)(1) of this section are issued by HHS in the HHSAM. The HHSAM contains internal operating procedures providing supplementary guidance and instructions for carrying out FAR and HHSAR requirements and contains references to other agency policy and guidance issuances.

**301.301-70 Amendment of the HHSAR.**

(a) Changes to the HHSAR may be the result of recommendations from HHS personnel, other Government agencies, or the public. Proposed changes shall be submitted in the following format to the Assistant Secretary for Financial Resources, Office of Acquisitions, Acquisition Policy Division, U.S. Department of Health and Human Services, 200 Independence Ave. SW, Washington, DC 20201:

(1) *Problem.* Succinctly state the problems created by current HHSAR language and describe the factual or legal reasons necessitating regulatory change.

(2) *Recommendation.* Identify the recommended change by using the current language (if applicable) and striking through the proposed deleted words with a horizontal line. Insert proposed language in bold and brackets. If the change is extensive, reflect proposed deleted language in strikethrough and proposed new or revised language with complete paragraphs in bold and brackets.

(3) *Discussion.* Explain why the change is necessary and how it will

solve the problem. Address any cost or administrative impact on Government activities, offerors, and contractors, to include potential impact to small businesses. Provide any other information and documents, such as statutes, legal decisions, regulations, and reports, that may be helpful.

(4) *Point of contact.* Provide a point of contact who can answer questions regarding the recommendation, including an email and telephone number.

(b) The HHSAR is maintained by the SPE through the HHSAR and HHSAM change process. This process consists of input from various HHS staff and operating divisions specifically designated to formulate Departmental acquisition policies and procedures.

(c) HHSAR Acquisition Circulars will be used to publish updates to the HHSAR throughout HHS.

### 301.303–70 Publication and codification—HHSAR.

(a) *Codification.* The HHSAR is codified under chapter 3 in title 48, Code of Federal Regulations. The HHSAR shall parallel the FAR in format, arrangement, and numbering system in accordance with FAR 1.303(a). The HHSAM is non-codified but will also parallel the FAR and the HHSAR in format, arrangement, and numbering system.

(b) *Implementing the FAR.* This paragraph (b) describes language and coverage in the HHSAR that relates to coverage in a FAR part, subpart, section, or subsection. The HHSAR titles and numbering shall conform with the FAR to the maximum extent practicable. Coverage in the HHSAR that implements the FAR uses the identical number sequence and caption of the FAR subpart, section, or subsection being implemented, which may be to the paragraph level. Paragraph numbers and letters are not always shown sequentially but may be shown by the specific FAR paragraph implemented. For example, HHSAR 301.105–1 contains only paragraph (b) because only this paragraph, correlated with the FAR, is implemented in the HHSAR.

(c) *Supplementing the FAR.* This paragraph (c) describes policy, guidance, and/or procedures that are placed in the HHSAR for which there is no direct counterpart in the FAR (potentially no corresponding specific part, subpart, section, or subsection of the FAR and associated titles). Coverage in the HHSAR that supplements the FAR will use part, subpart, section, and subsection numbers ending in “70” or higher, sequentially. A series of numbers beginning with “70” is used

for provisions and clauses. For example, HHSAR text supplementing FAR 1.301 would be numbered 301.301–70. See table 1 to this section.

TABLE 1 TO 301.303–70—HHSAR NUMBERING

FAR	Is implemented as	Is supplemented as
19 .....	319	319.70
19.5 .....	319.5	319.570
19.501 .....	319.501	319.501–70
19.501–1 ...	319.501–1	319.501–170

### 301.304 Agency control and compliance procedures.

The SPE is responsible for amending the HHSAR for compliance with FAR 1.304.

### Subpart 301.470—Deviations From the FAR and HHSAR

#### 301.402 Policy.

Contracting officers shall not deviate from the FAR or HHSAR without obtaining written approval in accordance with 301.403 and 301.404. With full acknowledgement of FAR 1.102(d) regarding innovative approaches, any deviation from the FAR or the HHSAR requires SPE approval.

#### 301.403 Individual deviations.

Authority to authorize individual deviations from the FAR and HHSAR is delegated to the SPE.

#### 301.404 Class deviations.

(a) Authority to authorize class deviations from the FAR and HHSAR is delegated to the SPE. The SPE may authorize class deviations from the FAR and HHSAR when a class deviation is in the best interest of the Government. The SPE must comply with the provisions of FAR 1.404.

### Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

#### 301.601 General.

(a) The Secretary has delegated to the Chief Acquisition Officer and the SPE (see definitions at 302.101) broad authority to manage HHS’ contracting functions. Except as otherwise provided by statute, HHS regulations, the FAR or the HHSAR, or other specific delegations that may be issued by the Secretary, the authority vested in the Secretary to do the following is delegated to the SPE:

(1) Ensure compliance with the FAR and Office of Management and Budget guidance.

(2) Develop, implement, update, and distribute the HHSAR and other acquisition policies, procedures, and guidance.

(3) Serve as Department’s functional manager for acquisition, including acquisition guidance, internal controls, systems, training and certification, major investments, reviews, audits, and interagency acquisitions issued under the authority of FAR subpart 17.5 or 17.7.

(4) Approve the selection of heads of the contracting activities (HCAs) and issue contracting officer warrants to HCAs.

(5) Revoke HCA acquisition authority.

(6) Manage HHS Acquisition Workforce Development Program and implement the Office of Federal Procurement Policy (OFPP) Act and Federal Acquisition Institute training and certification programs.

(7) Redirect Operating and Staff Division acquisition staff to support the preparation for, or response to, potential or actual emergencies, e.g., terrorist strike, natural disaster, epidemic.

(8) The SPE may further delegate authority to execute, award, and administer contracts, purchase orders, and other agreements to other HHS officials, such as HCAs and contracting officers. At HHS, delegation of certain contract functions and management of the contracting activities of the agency within their approved delegations is made to designated HCAs. A list of HCAs is available at <https://www.hhs.gov/grants/grants-business-contacts/hca-and-key-managers/index.html>.

(9) HCAs may authorize the use of ordering officers to order supplies and services in accordance with the ordering limits identified in the contract or agreement or the specific ordering guide.

#### 301.602 Contracting officers.

#### 301.602–3 Ratification of unauthorized commitments.

(b) *Policy.* (1) The Government is not bound by agreements with, or contractual commitments made to, prospective contractors by individuals who do not have delegated contracting authority. Unauthorized commitments do not follow the appropriate process for the expenditure of Government funds. Consequently, the Government may not be able to ratify certain actions, putting a contractor at risk for taking direction from a Federal official other than the contracting officer (see FAR 1.602–1). Government employees responsible for unauthorized commitments are subject to disciplinary

action. Contractors perform at their own risk when accepting direction from unauthorized officials. Acquisitions can only be made by a contracting officer having authority to enter into such acquisitions. Acquisitions made by other than authorized personnel are contrary to departmental policy and may be considered matters of serious misconduct on the part of an employee making an unauthorized commitment and may result in disciplinary action being taken against an employee who makes an unauthorized commitment.

(2) The HCA is the official authorized to ratify an unauthorized commitment. No other re-delegations are authorized.

### **301.603 Selection, appointment, and termination of appointment of contracting officers.**

#### **301.603–1 General.**

The agency head has delegated broad authority to the Chief Acquisition Officer, who in turn has further delegated this authority to the SPE. The SPE has redelegated specific acquisition authority to the Operating and Staff Division heads and the HCAs to select, appoint, and terminate the appointment of contracting officers. This authority is non-delegable.

#### **301.603–3 Appointment.**

(a) All contracting officer appointments and delegations of authority will be made in writing. To ensure proper control of redelegated acquisition authorities, HCAs shall maintain a file containing successive delegations of HCA authority through the contracting officer level.

(b) HCAs may delegate micro-purchase authority to HHS employees under the HHS Governmentwide Purchase Card Program in accordance with agency procedures.

#### **301.604 Contracting Officer's Representative (COR).**

#### **301.604–70 Contract clause.**

When the contracting officer intends to designate a representative under this section for a solicitation or contract, the contracting officer must include the clause at 352.201–70, Contracting Officer's Representative, in the solicitation and contract.

### **Subpart 301.7—Determinations and Findings**

#### **301.707 Signatory authority.**

Signature authority for determination and findings, when delegable in the FAR, are prescribed in applicable HHSAR parts or the corresponding HHSAM part.

## **PART 302—DEFINITIONS OF WORDS AND TERMS**

Sec.

302.000 Scope of part.

### **Subpart 302.1—Definitions**

302.101 Definitions.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### **302.000 Scope of part.**

(a) This part—

(1) Defines words and terms that are frequently used in the HHSAR;

(2) Provides cross-references to other definitions in the HHSAR of the same word or term; and

(3) Provides for the incorporation of these definitions in solicitations and contracts by reference.

(b) Other parts, subparts, and sections of this chapter may define other words or terms and those definitions only apply to the part, subpart, or section where the word or term is defined.

### **Subpart 302.1—Definitions**

#### **302.101 Definitions.**

As used in this chapter—

*Agency head* or *head of the agency*, unless otherwise stated, means the Secretary of Health and Human Services or specified designee. When delegated by the Secretary, the specific designee will be reflected in the specific part, subpart, or section where a specified designee other than the Secretary has been designated.

*Chief Acquisition Officer (CAO)* means the Assistant Secretary for Financial Resources.

*Head of the contracting activity (HCA)* means an official having overall responsibility for managing a contracting activity, *i.e.*, the organization within an Operating Division (OPDIV) or Staff Division (STAFFDIV) or other HHS organization which has been delegated broad authority regarding the conduct of acquisition functions (see 301.603–1).

*Ordering officer* means the HHS official authorized to order supplies and services against a FAR-based contract or agreement in accordance with 301.601(a)(10) and agency procedures.

*Senior Procurement Officer (SPE)* means the Deputy Assistant Secretary for Acquisitions. The SPE is responsible for the management and oversight of the acquisition function for the Department.

## **PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST**

### **Subpart 303.1—Safeguards**

Sec.

303.101 Standards of conduct.

303.101–3 Agency regulations.

### **Subpart 303.2—Contractor Gratuities to Government Personnel**

303.203 Reporting suspected violations of the Gratuities clause.

303.204 Treatment of violations.

### **Subpart 303.6—Contracts With Government Employees or Organizations Owned or Controlled by Them**

303.602 Exceptions.

### **Subpart 303.7—Voiding and Rescinding Contracts**

303.704 Policy.

### **Subpart 303.8—Limitation on the Payment of Funds to Influence Federal Transactions**

303.808–70 Solicitation provision and contract clause.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### **Subpart 303.1—Safeguards**

#### **303.101 Standards of conduct.**

#### **303.101–3 Agency regulations.**

(a) The HHS Standards of Conduct are prescribed in 45 CFR part 73, which apply to all employees of the Department and to special Government employees to the extent described therein.

### **Subpart 303.2—Contractor Gratuities to Government Personnel**

#### **303.203 Reporting suspected violations of the Gratuities clause.**

HHS personnel shall report suspected violations of the clause at FAR 52.203–3, Gratuities, to the contracting officer, who will in turn report the matter to the Office of General Counsel (OGC), Ethics Division for disposition.

#### **303.204 Treatment of violations.**

(a) The Suspending and Debarring Official (SDO) shall determine whether or not a violation of the Gratuities clause, FAR 52.203–3, has occurred and what action will be taken under FAR 3.204(c).

(c) When the SDO determines that a violation has occurred and that debarment is being considered, the SDO shall follow procedures at 309.406–3.

### **Subpart 303.6—Contracts With Government Employees or Organizations Owned or Controlled by Them**

#### **303.602 Exceptions.**

The head of contracting activity (HCA) is the official authorized to approve an exception to the policy stated in FAR 3.601. This authority is non-delegable.

### Subpart 303.7—Voiding and Rescinding Contracts

#### 303.704 Policy.

(a) The Senior Procurement Executive is delegated the authority to declare void and rescind contracts in accordance with FAR 3.704. This authority is further delegated to the HCA.

### Subpart 303.8—Limitation on the Payment of Funds To Influence Federal Transactions

#### 303.808–70 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.203–70, Anti-Lobbying, in solicitations and contracts that exceed the simplified acquisition threshold.

### PART 304—ADMINISTRATIVE AND INFORMATION MATTERS

■ 2. The authority citation for part 304 is revised to read as follows:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

■ 3. Revise the heading for part 304 to read as set forth above.

#### Subparts 304.6 and 304.16 [Removed]

■ 4. Remove subparts 304.6 and 304.16.

#### Subpart 304.71 [Removed and Reserved]

■ 5. Remove and reserve subpart 304.71.

■ 6. Revise subpart 304.72 to read as follows:

#### Subpart 304.72—Affordable Care Act Prevention and Public Health Fund—Reporting Requirements

Sec.

304.7200 Scope of subpart.

304.7201 Policy.

304.7202 Contract clause.

#### Subpart 304.72—Affordable Care Act Prevention and Public Health Fund—Reporting Requirements

##### 304.7200 Scope of subpart.

This subpart implements section 220 of Pub. L. 112–74, FY 2012 Labor, HHS and Education Appropriations Act, which requires, semi-annual reporting on the use of funds from the Prevention and Public Health Fund (PPHF), Pub. L. 111–148, sec. 4002.

##### 304.7201 Policy.

Contractors that receive awards (or modifications to existing awards) with a value of \$25,000 or more funded, in whole or in part, from the PPHF, shall report information specified in the clause at 352.204–70, Prevention and

Public Health Fund—Reporting Requirements, including, but not limited to—

(a) The dollar amount of contractor invoices;

(b) The supplies delivered and services performed; and

(c) Specific information on subcontracts with a value of \$25,000 or more.

(d) The contracting officer shall make the contractor's failure to comply with the reporting requirements in this section a part of the contractor's performance information under FAR subpart 42.15.

##### 304.7202 Contract clause.

Insert the clause at 352.204–70, Prevention and Public Health Fund—Reporting Requirements, in all solicitations and contract actions with a value of \$25,000 or more funded in whole or in part with Prevention and Public Health Funds (PPHFs), except classified solicitations and contracts. This includes, but is not limited to, awarding, or modifying orders against existing or new contracts issued under FAR subparts 8.4 and 16.5 that will be funded with PPHFs. Contracting officers shall include this clause in any existing contract or order that will be funded with PPHFs. This clause is not required for any contract or order which contains a prior version of the clause at 352.204–70.

■ 7. Revise subchapters B and C to read as follows:

### SUBCHAPTER B—ACQUISITION PLANNING

#### PART 305 PUBLICIZING CONTRACT ACTIONS

#### PART 306 COMPETITION REQUIREMENTS

#### PART 307 [RESERVED]

#### PART 308 REQUIRED SOURCES OF SUPPLIES AND SERVICES

#### PART 309 CONTRACTOR QUALIFICATIONS

#### PART 310 [RESERVED]

#### PART 311 DESCRIBING AGENCY NEEDS

#### PART 312 ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

### SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

#### PART 313 SIMPLIFIED ACQUISITION PROCEDURES

#### PART 314 SEALED BIDDING

#### PART 315 CONTRACTING BY NEGOTIATION

#### PART 316 TYPES OF CONTRACTS

#### PART 317 [RESERVED]

#### PART 318 EMERGENCY ACQUISITIONS

### SUBCHAPTER B—ACQUISITION PLANNING

#### PART 305—PUBLICIZING CONTRACT ACTIONS

##### Subpart 305.4—Release of Information

Sec.

305.402 General public.

305.470 Contractor award announcements, advertisements, and releases.

305.470–1 Policy.

305.470–2 Contract clause.

##### Subpart 305.70—Publicizing Requirements Funded From the Affordable Care Act Prevention and Public Health Fund

305.7001 Scope.

305.7002 Applicability.

305.7003 Publicizing preaward.

305.7004 Publicizing postaward.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

##### Subpart 305.4—Release of Information

##### 305.402 General public.

Requests from the public for specific records pertaining to contract actions shall be processed according to the Freedom of Information Act (FOIA), 5 U.S.C. 552.

##### 305.470 Contractor award announcements, advertisements, and releases.

##### 305.470–1 Policy.

(a) Contracting officers should restrict contractors from referring to its HHS contract(s) in its commercial advertising in a manner that states or implies the Government approves or endorses the contractor's products or services or considers them superior to other products or services. The intent of this policy is to prevent the appearance of Government bias toward any product or service.

(b) The Department's contractors share the responsibility for protecting sensitive and classified information related to efforts under their contracts. For any contract that involves sensitive or classified information, prior to the release of any contract award announcement, advertisement, or other information pertaining to the contract, the contractor must obtain the approval of the responsible contracting officer.

##### 305.470–2 Contract clause.

(a) Insert the clause at 352.205–70, Advertisements, Publicizing Awards, and Releases, in all solicitations and contracts that exceed the simplified acquisition threshold.

(b) If the contract involves sensitive or classified information, use the clause at 352.205–70 with its Alternate I.

### Subpart 305.70—Publicizing Requirements Funded From the Affordable Care Act Prevention and Public Health Fund

#### 305.7001 Scope.

Pursuant to appropriations acts, this subpart prescribes requirements for posting presolicitation and award notices for actions funded in whole or in part from the Prevention and Public Health Fund (PPHF). The requirements of this subpart enhance transparency to the public.

#### 305.7002 Applicability.

This subpart applies to all actions funded in whole or in part by the PPHF.

#### 305.7003 Publicizing preaward.

Notices of all proposed contract actions, funded in whole or in part by the PPHF, shall be identified on HHS' Prevention and Public Health Fund website at <https://www.hhs.gov/open/prevention/index.html> no later than one business day after issuance of the solicitation or other request for proposal or quotation document. When applicable, the notice shall provide a link to the full text; for example, a link to the Contract Opportunities notice required by FAR 5.201.

#### 305.7004 Publicizing postaward.

Notices of contract actions valued at or above \$25,000, funded in whole or in part by the PPHF, shall be identified on HHS' PPHF website at <https://www.hhs.gov/open/prevention/index.html> no later than five business days after the contract action occurs.

## PART 306—COMPETITION REQUIREMENTS

### Subpart 306.2—Full and Open Competition After Exclusion of Sources

Sec.

306.202 Establishing or maintaining alternative sources.

### Subpart 306.3—Other Than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.

306.302-1 Only one responsible source and no other supplies or services will satisfy agency requirements.

306.302-2 Unusual and compelling urgency.

### Subpart 306.5—Advocates for Competition

306.501 Requirement.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 306.2—Full and Open Competition After Exclusion of Sources

306.202 Establishing or maintaining alternative sources.

(b)(1) The Senior Procurement Executive (SPE) is designated to make the required determination and sign the determination and findings (D&F) pursuant to FAR 6.202(b).

### Subpart 306.3—Other Than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.

306.302-1 Only one responsible source and no other supplies or services will satisfy agency requirements.

(a)(2) For acquisitions covered by 42 U.S.C. 247d-6a(b)(2)(A) concerning conducting and supporting countermeasure research and development activities, "available from only one responsible source" shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

306.302-2 Unusual and compelling urgency.

(d)(1)(ii) The period of performance shall be limited to the minimum period necessary to meet the urgent and compelling requirements of the work to be performed and to enter into another contract for the required goods or services through the use of competitive procedures, but in no event shall the period of performance exceed one year, including all options pursuant to FAR 6.302-2(d)(1)(ii), unless the Secretary determines that exceptional circumstances apply, approving the determination and the written justifications and approvals described in FAR 6.303 and 6.304 (see FAR 6.303-2(c)) and HHS internal procedures.

### Subpart 306.5—Advocates for Competition

306.501 Requirement.

The Executive Director, Acquisition Policy, Legislation, Oversight & Workforce, Assistant Secretary for Financial Resources (ASFR), Office of Acquisitions is designated as the HHS Advocate for Competition. The Executive Director may further delegate this authority and appoint an alternate agency advocate for competition. The Executive Director shall designate procuring activity advocates for competition in accordance with FAR 6.501. A complete list of HHS procuring activity advocates for competition can be found at: <https://www.hhs.gov/>

[grants/grants-business-contacts/competition-advocates/index.html](https://www.hhs.gov/grants/grants-business-contacts/competition-advocates/index.html).

## PART 307 [RESERVED]

## PART 308—REQUIRED SOURCES OF SUPPLIES AND SERVICES

### Subpart 308.8—Acquisition of Printing and Related Supplies

Sec.

308.802 Policy.

308.870 Contract clause.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 308.8—Acquisition of Printing and Related Supplies

308.802 Policy.

Government printing must be done by or through the Government Publishing Office (GPO) in accordance with FAR 8.802. Unless specifically authorized in HHS contracts, no printing by the Contractor or any subcontractor is authorized under HHS contracts, whether to support Government printing, to acquire related supplies, or to provide other printing-related services. Contracting officers may authorize limited printing under HHS contracts pursuant to the clause prescribed at 308.870 within the stated limits in the clause.

308.870 Contract clause.

The contracting officer shall insert the clause at 352.208-70, Printing and Duplication, in all solicitations, contracts, and orders for supplies or services over the simplified acquisition threshold, unless printing or increased duplication is authorized by statute.

## PART 309—CONTRACTOR QUALIFICATIONS

### Subpart 309.1—Responsible Prospective Contracts

Sec.

309.104 Standards.

309.104-1 General standards.

### Subpart 309.4—Debarment, Suspension, and Ineligibility

309.400 Scope of subpart.

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309.503 Waiver.

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309.507–1 Solicitation provisions.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

**Subpart 309.1—Responsible Prospective Contracts**

**309.104 Standards.**

**309.104–1 General standards.**

(e) For cost-reimbursement or incentive type contracts, or contracts which provide for progress payments based on costs or on a percentage or stage of completion, the prospective contractor's accounting system and related internal controls must provide reasonable assurance that—

(1) Applicable laws and regulations are complied with;

(2) The accounting system and cost data are reliable;

(3) Risk of misallocations and mischarges are minimized; and

(4) Contract allocations and charges are consistent with invoice procedures.

**Subpart 309.4—Debarment, Suspension, and Ineligibility**

**309.400 Scope of subpart.**

This subpart implements FAR subpart 9.4 and prescribes HHS procedures and related actions for the suspension and debarment of contractors.

**309.403 Definitions.**

As used in this subpart:

*Suspending and Debarment Official (SDO)* means the individual responsible for final decisions regarding suspension and debarment, as appointed by the agency. The HHS SDO is the Deputy Assistant Secretary for Acquisitions, and Senior Procurement Executive.

*Suspension & Debarment (S&D) Committee* means a committee authorized by the SDO to assist the SDO with suspension and debarment related matters.

**309.405 Effect of listing.**

(a) The authority under FAR 9.405(a) and (e)(2) and (3) to determine where to solicit from, evaluate bids or proposals from, or award contracts to contractors with active exclusions in the System for Award Management (SAM) is delegated to the SDO. This authority is further delegated to the HCA.

**309.405–1 Continuation of current contracts.**

(a) Notwithstanding the suspensions, proposed debarment, or debarment of a contractor, HHS may continue contracts or subcontracts in existence at the time the contractor was suspended, proposed for debarment, or debarred, unless the cognizant HCA directs otherwise.

(b) Authority to make the determinations under FAR 9.405–1(a)(2) is delegated to the SDO and is further delegated to the HCA. The HCA must make a written determination of the compelling reasons in accordance with FAR 9.405–1(a)(2). Compelling reasons for the purposes of FAR 9.405–1(a)(2) include, but are not limited to, urgency of the need for new or continued work and/or, lengthy period to acquire the new work from other sources.

**309.405–2 Restrictions on subcontracting.**

Authority to make the written determination required under FAR 9.405–2 consenting to a contractor's use of a subcontractor who is suspended, proposed for debarment, or debarred is delegated to the SDO. This authority is further delegated to the HCA.

**309.406 Debarment.**

**309.406–1 General.**

(a) In addition to the factors listed in FAR 9.406–1, the SDO may consider the following additional factors before arriving at a debarment decision:

(1) Whether the contractor had a mechanism, such as a hotline, by which employees could have reported suspected instances of improper conduct, and instructions in place that encouraged employees to make such reports; or

(2) Whether the contractor conducted periodic reviews of company business practices, procedures, policies, and internal controls for compliance with standards of conduct and the special requirements of Government contracting.

(c) As provided in FAR 9.406–1(c), authority to determine whether to continue business dealings between HHS and a contractor suspended, proposed for debarment, or debarred is delegated to the SDO.

**309.406–3 Procedures.**

(a) HHS procedures are set forth in the HHS Discretionary Suspension and Debarment Handbook for Contracts and Grants (S&D Handbook) at (Link To Be Determined (TBD)). The procedures in this subpart supplement HHS' internal operational procedures. Any individual may submit a referral to debar an individual or contractor to the SDO or to the S&D Committee. The S&D

Committee is an advisory committee to the SDO who retains the final approval authority to debar.

(1) The referral for debarment shall be supported with evidence of a cause for debarment listed in FAR 9.406–2.

(2) The SDO shall forward referrals for debarment to the S&D Committee. If the referring individual is an HHS employee and the referral for debarment is based on possible criminal or fraudulent activities, the HHS employee shall also refer the matter to the HHS Office of Inspector General.

(b) When the S&D Committee finds preponderance of the evidence for a cause for debarment, as listed in FAR 9.406–2, it shall prepare a recommendation and draft notice of proposed debarment for the SDO's consideration.

(c) The notice of proposal to debar shall be issued by the SDO to the contractor and any specifically named affiliates. A notice of proposed debarment shall be issued by the SDO in accordance with FAR 9.406–3(c), by certified mail, return receipt requested, unless one of the flexible procedures set forth in this paragraph (c) is necessary to meet emergency or exigent circumstances which shall be documented in the file. In such cases as approved by the SDO—

(1) The written notice shall be sent—

(i) By mail, to the last known street address;

(ii) To the last known facsimile number; or

(iii) To the last known email address.

(2) The notice shall be sent—

(i) To the contractor, the contractor's identified counsel for purposes of the administrative proceedings, or the contractor's agent for service of protest. If sent by email, it shall be sent to the last known email address for all three, if known; and

(ii) For each specifically named affiliate, to the affiliate itself, the affiliate's identified counsel for purposes of the administrative proceedings, or the affiliate's agent for service of process. If sent by email, it shall be sent to the last known email addresses for all three, if known.

(3) The notice shall include the requirements set forth in FAR 9.406–3(c)(1) through (7). Additionally, in the case of a contractor, HHS may send the notice of proposed debarment to any partner, principal, officer, director, owner or co-owner, or joint venture. The S&D Committee shall concurrently list the appropriate parties as excluded in the SAM in accordance with FAR 9.404.

(d) If HHS does not receive a reply from the contractor within 30 days after sending the notice of proposed

debarment, the S&D Committee shall prepare a recommendation and refer the case to the SDO for a decision on whether or not to debar based on the information available.

(e) If HHS receives a reply from the contractor within 30 days after sending the notice of proposed debarment, the S&D Committee shall consider the information in the reply before the S&D Committee makes its recommendation to the SDO.

(f) The S&D Committee, upon the request of the contractor proposed for debarment, shall, as soon as practicable, allow the contractor an opportunity to appear before the S&D Committee to present information or argument personally or through a representative. The contractor may supplement the oral presentation with written information and argument. HHS shall conduct the proceedings in an informal manner and without requirement for a transcript.

(g) The S&D Committee will review the contractor's or individual's submission in opposition to the proposed debarment to determine whether it raises a genuine dispute over facts material to the proposed debarment and the debarment action is not based on a conviction or civil judgment. The S&D Committee will submit its analyses to the SDO for review. If the SDO finds there is a genuine dispute of material facts, the SDO shall refer the dispute to a designee for a resolution pursuant to 309.470. The SDO shall provide the contractor or individual with the disputed material fact(s).

### **309.407 Suspension.**

#### **309.407-1 General.**

(a) As provided in FAR 9.407-1(d), authority to determine whether to continue business dealings between HHS and a suspended contractor is delegated to the SDO. Compelling reasons include, but are not limited to, urgency of the need for new or continued work, lengthy time period to acquire the new work from other sources and meeting estimated quantities for requirements contracts.

(b) For the purposes of FAR 9.407-1, the SDO is the suspending official.

#### **309.407-3 Procedures.**

(a) HHS procedures are set forth in the HHS Discretionary Suspension and Debarment Handbook for Contracts and Grants (S&D Handbook) at (Link TBD). The procedures in this subpart supplement HHS' internal operational procedures. Any individual may submit a referral to suspend an individual or contractor to the SDO or to the S&D

Committee. The S&D Committee is an advisory committee to the SDO who retains the final approval authority to issue suspensions. Referrals shall include supporting evidence of a cause for suspension listed in FAR 9.407-2. The SDO will forward the referral to the S&D Committee for analysis. If the referring individual is an HHS employee and the referral for suspension is based on possible criminal or fraudulent activities, the HHS employee shall also refer the matter to the HHS Office of Inspector General.

(b) The S&D Committee will forward its analyses to the SDO. When the SDO finds adequate evidence of a cause for suspension, as listed in FAR 9.407-2, the S&D Committee will prepare a recommendation and draft notice of suspension for the SDO's consideration and approval.

(c) In accordance with FAR 9.407-3(c) regarding the notice of suspension, when a contractor or any specifically named affiliates are suspended, they shall be immediately advised by means of delivery set forth in FAR 9.406-3(c) and 309.406-3(c). In the case of a contractor, HHS may send a notice of suspension to any partner, principal, officer, director, owner or co-owner, or joint venture. The S&D Committee concurrently shall list the appropriate parties as excluded in SAM in accordance with FAR 9.404.

(d) If HHS receives a reply from the contractor within 30 days after receipt of the notice of suspension, the S&D Committee shall consider the information in the reply before the Committee makes further recommendations to the SDO. The S&D Committee, upon the request of a suspended contractor, shall, as soon as practicable, allow the contractor an opportunity to appear before the S&D Committee to present information or argument personally or through a representative. The contractor may supplement the oral presentation with written information and argument. The proceedings will be conducted in an informal manner and without requirement for a transcript.

(e) For the purposes of FAR 9.407-3(b)(2), in actions not based on an indictment, if the SDO finds that the contractor's submission in opposition to the suspension raises a genuine dispute over facts material to the suspension, the S&D Committee will submit to the SDO the information received establishing the dispute of material facts. However, the SDO may first coordinate any further proceeding regarding the material facts in dispute with the Department of Justice or with a State prosecuting authority in a case

involving a State jurisdiction. HHS shall take no further action to determine disputed material facts pursuant to this section or 309.470 if the Department of Justice or a State prosecuting authority advises HHS in writing that additional proceedings to make such a determination would prejudice Federal or State legal proceedings.

(f) If the SDO finds that there is a genuine dispute of material facts, the SDO shall refer the dispute to the designee for resolution pursuant to 309.470.

### **309.470 Reporting of suspected causes for debarment or suspension or the taking of evasive actions.**

#### **309.470-1 Situations where reports are required.**

The contracting officer shall report to the HCA and the SDO whenever the contracting officer—

(a) Knows or suspects that a contractor is committing or has committed any of the acts described in FAR 9.406-2 or 9.407-2; or

(b) Suspects a contractor is attempting to evade the prohibitions of debarment or suspension imposed under FAR 9.405, or any other comparable regulation, by changes of address, multiple addresses, formation of new companies, or by other devices.

#### **309.471 Fact-finding procedures.**

The provisions of this section constitute the procedures to be used to resolve genuine disputes of material fact pursuant to 309.406-3 and 309.407-3. The SDO shall appoint a designee to conduct the fact-finding. The proceedings before the fact-finder will be limited to a finding of the facts in dispute, as determined by the SDO. The fact-finder shall establish the date for the fact-finding hearing, normally to be held within 30 days after the S&D Committee notifies the contractor or individual that the SDO has established a genuine dispute of material fact(s) exists.

(a) The Government's representative and the contractor will have an opportunity to present evidence relevant to the material fact(s) identified by the SDO. The contractor or individual may appear in person or through a representative at the fact-finding hearing. The contractor or individual may submit documentary evidence, present witnesses, and confront any person the agency presents.

(b) Witnesses may testify in person. Witnesses will be reminded of the official nature of the proceedings and that any false testimony given is subject to criminal prosecution. Witnesses are

subject to cross-examination. Hearsay evidence may be presented and will be given appropriate weight by the fact-finder.

(c) The proceedings shall be transcribed, and a copy of the transcript shall be made available at cost to the contractor upon request, unless the contractor and the fact-finder, by mutual agreement, waive the requirement for a transcript.

(d) The fact-finder shall determine the disputed fact(s) by a preponderance of the evidence for proposed debarments, and by adequate evidence for suspensions. Written findings of fact shall be prepared by the fact-finder. A copy of the findings of fact shall be provided to the SDO, the Government's representative, and the contractor or individual. The SDO will consider the written findings of fact in the decision regarding the suspension or proposed debarment.

### Subpart 309.5—Organizational and Consultant Conflicts of Interest

#### 309.503 Waiver.

The Senior Procurement Executive is the designee under FAR 9.503.

#### 309.507 Solicitation provisions and contract clause.

#### 309.507-1 Solicitation provisions.

(a) While conflicts of interest may not presently exist, award of certain types of contracts may create potential future organizational conflicts of interest (see FAR 9.508 for examples). If a solicitation may create a potential future organizational conflict of interest, the contracting officer shall insert a provision in the solicitation imposing an appropriate restraint on the contractor's eligibility for award of contracts in the future. Under FAR 9.507-1, the restraint must be appropriate to the nature of the conflict and may exclude the contractor from award of one or more contracts in the future.

(b) The provision at 352.209-70, Organizational Conflicts of Interest, must be included in any solicitation for the services addressed in FAR 9.502.

## PART 310 [RESERVED]

## PART 311—DESCRIBING AGENCY NEEDS

### Subpart 311.1—Selecting and Developing Requirements Documents

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311.7300 Policy.

311.7301 Contract clause.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 311.1—Selecting and Developing Requirement Documents

#### 311.103 Market acceptance.

(a) The head of the contracting activity (HCA) is delegated this authority.

### Subpart 311.5—Liquidated Damages

#### 311.501 Policy.

(d) The HCA may reduce or waive the amount of liquidated damages assessed under a contract, if the Commissioner, Financial Management Service, or designee approves.

### Subpart 311.6—Priorities and Allocations

#### 311.600 Scope of subpart.

This subpart details information on the Health and Human Services (HHS') Health Resources Priorities and Allocation System (HRPAS) that is part of the Federal Priorities and Allocations System. This subpart references guidance and procedures for use of the Defense Production Act (DPA) priorities and allocations authority with respect to health resources necessary or appropriate to promote the national defense as delegated to the Secretary of HHS.

#### 311.601 Definitions.

As used in this subpart—  
*National defense* means programs for military and health resources production or construction, military or critical infrastructure assistance to any foreign nation, homeland security,

stockpiling, space, and any directly related activity. Such term includes emergency preparedness activities conducted pursuant to title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5195, *et seq.*) and critical infrastructure protection and restoration. The term *national defense* is defined broadly and can include critical infrastructure protection and restoration, emergency preparedness and response, and recovery from natural and man-made disasters.

*Rated order* means a prime contract, a subcontract, or a purchase order in support of an approved program issued in accordance with the provisions of this part.

#### 311.602 General.

#### 311.602-70 The Health Resources Priorities and Allocation System.

As set forth in Executive Order 13603, National Defense Resources Preparedness, March 16, 2012, the authority to require acceptance and priority performance of contracts or orders (other than contracts of employment) to promote the national defense over performance of any other contracts or orders, and to allocate materials, services, and facilities as deemed necessary or appropriate to promote the national defense, with respect to health resources is delegated to the Secretary of HHS.

#### 311.603 Procedures.

#### 311.603-70 Agency program.

Agency procedures are set forth in the HRPAS regulations at 45 CFR part 101. The regulation provides guidance and procedures for use of the DPA priorities and allocations authority with respect to health resources, including the use of priority rated orders, necessary or appropriate to promote the national defense.

### Subpart 311.70—[Reserved]

### Subpart 311.71—Public Accommodations and Commercial Facilities

#### 311.7100 Policy.

(a) It is HHS policy that all contractors comply with current and any future changes to 28 CFR part 36. For the purpose of this subpart, *accessibility* is defined as both physical access to public accommodations and commercial facilities, and access to aids and services enabling individuals with sensory disabilities to fully participate in events in public accommodations and commercial facilities.

(b) This subpart applies to all contracts requiring contractors to conduct events in public accommodations and commercial facilities open to the public or involving HHS personnel, but not ad hoc meetings necessary or incidental to contract performance.

#### **311.7101 Responsibilities.**

The contractor shall submit a plan assuring that any event held will meet or exceed the minimum accessibility standards set forth in 28 CFR part 36. A consolidated or master plan for contracts requiring numerous events in public accommodations and commercial facilities is acceptable.

#### **311.7102 Contract clause.**

The contracting officer shall insert the clause at 352.211–70, Public Accommodations and Commercial Facilities, in solicitations, contracts, and orders requiring the contractor to conduct events in accordance with 311.7100(b).

#### **Subpart 311.72—Conference Funding and Sponsorship**

##### **311.7200 Policy.**

HHS policy requires that all conferences the agency funds or sponsors shall be consistent with HHS missions, objectives, and policies; represent an efficient and effective use of taxpayer funds; and withstand public scrutiny.

##### **311.7201 Funding and sponsorship.**

A conference funded through an HHS contract does not automatically imply HHS sponsorship, unless the conference is funded entirely by the agency. Also, HHS staff attendance or participation at a conference does not imply HHS conference sponsorship. Accordingly, for non-conference contracts funded entirely by HHS prior to a contractor claiming HHS sponsorship, the contractor must provide the contracting officer a written request for permission to designate HHS the conference sponsor. The operating division or staff division head, or designee, shall approve such requests. The determination on what constitutes a “conference contract” or a “non-conference contract” shall be made by the contracting officer.

##### **311.7202 Contract clause.**

To ensure that a contractor:

(a) Properly requests approval to designate HHS the conference sponsor, where HHS is not the sole provider of conference funding; and

(b) The contracting officer shall include the clause at 352.211–71,

Conference Sponsorship Request and Conference Materials Disclaimer, in solicitations, contracts, and orders providing funding which partially or fully supports a conference.

#### **Subpart 311.73—Contractor Collection of Information**

##### **311.7300 Policy.**

In accordance with the Paperwork Reduction Act, contractors shall not proceed with collecting information from surveys, questionnaires, or interviews until the contracting officer’s representative obtains an Office of Management and Budget (OMB) clearance and the contracting officer issues written approval to proceed. For any contract involving a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal Government or disclosure to third parties, the contracting officer must comply with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

##### **311.7301 Contract clause.**

The contracting officer shall insert the clause at 352.211–72, Paperwork Reduction Act Requirements, in solicitations, contracts, and orders that require a contractor to collect the same information from 10 or more persons.

### **PART 312—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES**

#### **Subpart 312.3—Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services**

Sec.

312.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### **Subpart 312.3—Solicitation Provisions and Contract Clauses for the Acquisition of Commercial Products and Commercial Services**

**312.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.**

(f) Contracting officers shall insert the clause 352.212–70, Gray Market and Counterfeit Items, in solicitations and contracts for new medical supplies, new medical equipment, new information

technology equipment, and maintenance of medical or information technology equipment that includes replacement parts, if used, refurbished, or remanufactured parts are unacceptable, when the associated solicitation includes the provisions at FAR 52.212–1, Instructions to Offerors—Commercial Products and Commercial Services, and 52.212–2, Evaluation—Commercial Products and Commercial Services.

### **SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES**

#### **PART 313—SIMPLIFIED ACQUISITION PROCEDURES**

##### **Subpart 313.3—Simplified Acquisition Methods**

Sec.

313.301–70 Governmentwide commercial purchase card—purchases of PPE.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

##### **Subpart 313.3—Simplified Acquisition Methods**

**313.301–70 Governmentwide commercial purchase card—purchases of PPE.**

The Infrastructure Investment and Jobs Act (IIJA), Pub. L. 117–58, Subtitle C, Make Personal Protective Equipment (PPE) in America (MPPEIA), applies to all purchases of PPE including those transactions made using the Governmentwide commercial purchase card (GPC) under the micro-purchase threshold. See subpart 325.71 for definitions, restrictions, and exceptions when procuring PPE.

### **PART 314—SEALED BIDDING**

#### **Subpart 314.4—Opening of Bids and Award of Contract**

Sec.

314.404 Rejection of bids.

314.404–1 Cancellation of invitations after opening.

314.407 Mistakes in bids.

314.407–3 Other mistakes disclosed before award.

314.407–4 Mistakes after award.

314.408 Award.

314.408–70 Award when only one bid is received.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### **Subpart 314.4—Opening of Bids and Award of Contract**

**314.404 Rejection of bids.**

**314.404–1 Cancellation of invitations after opening.**

(c) The head of the contracting activity (HCA) shall make the

determinations specified in FAR 14.404–1(c).

#### 314.407 Mistakes in bids.

##### 314.407–3 Other mistakes disclosed before award.

(e) The HCA is delegated, without redelegation, the authority to make determinations under FAR 14.407–3(a) through (d).

##### 314.407–4 Mistakes after award.

(c) The HCA is delegated, without redelegation, the authority to make administrative determinations in connection with alleged post-award mistakes.

#### 314.408 Award.

##### 314.408–70 Award when only one bid is received.

When only one bid is received in response to an invitation for bids, such bid may be considered and accepted if the contracting officer makes a written determination, approved one level above the contracting officer, and documents the contract file that—

(a) The specifications were clear and not unduly restrictive;

(b) Adequate competition was solicited, and it could have been reasonably assumed that more than one bid would have been submitted;

(c) The price is fair and reasonable; and

(d) The bid is otherwise in accordance with the invitation for bids. Such a determination shall be placed in the file.

## PART 315—CONTRACTING BY NEGOTIATION

### Subpart 315.2—Solicitation and Receipt of Proposals and Information

Sec.

315.208 Submission, modification, revision, and withdrawal of proposals.

315.208–70 Submission, modification, revision, and withdrawal of proposals—R&D acquisitions.

315.209–70 Solicitation provision.

### Subpart 315.3—Source Selection

315.303–70 Policy.

315.304 Evaluation factors and significant subfactors.

315.305 Proposal evaluation.

315.305–70 Proposal evaluation—use of non-Federal evaluators.

315.305–71 Solicitation provision.

### Subpart 315.4—Contract Pricing

315.404 Proposal analysis.

315.404–2 Data to support proposal analysis.

### Subpart 315.6—Unsolicited Proposals

315.604 Agency points of contact.

315.605–70 Content of unsolicited proposals—warranty by offeror.

315.606 Agency procedures.

315.606–1 Receipt and initial review.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 315.2—Solicitation and Receipt of Proposals and Information

#### 315.208 Submission, modification, revision, and withdrawal of proposals.

##### 315.208–70 Submission, modification, revision, and withdrawal of proposals—R&D acquisitions.

(a) The provision prescribed at 315.209–70 may be used in competitive solicitations when—

(1) The head of contracting activity (HCA) determines that biomedical or behavioral research and development acquisitions may be subject to conditions that could impact timely submission and receipt of proposals other than those specified in FAR 52.215–1(c)(3);

(2) Use of the provision is authorized by the HCA; and

(3) The provision at FAR 52.215–1, Instructions to Offerors—Competitive Acquisition, is included in the solicitation.

(b) When the provision at 315.209–70 is inserted in the solicitation, notwithstanding the procedures contained in the provision at FAR 52.215–1(c)(3), Instructions to Offerors—Competitive Acquisition, the contracting officer may consider a proposal received concerning biomedical or behavioral research and development (R&D) acquisitions after the date specified for receipt if—

(1) It appears to offer significant cost or technical advantage to the Government; and

(2) It was received before proposals were distributed for evaluation; or

(3) It was received within five calendar days after the exact time specified for receipt, whichever is earlier.

(c) When the provision at 352.215–70 is included in the solicitation and if the contracting officer intends to consider a proposal or proposals received after the exact time specified for receipt, the contracting officer, with the assistance of cost or technical personnel as appropriate, shall determine in writing that the proposal(s) meets the requirements of the provision at 352.215–70.

#### 315.209–70 Solicitation provision.

The contracting officer shall insert the provision at 352.215–70, Late Proposals and Revisions—R&D Solicitations, in biomedical or behavioral R&D competitive acquisition solicitations

subject to the requirements of 315.208–70(a) and the authorization of the HCA.

### Subpart 315.3—Source Selection

#### 315.303–70 Policy.

(a) When an operating division (OPDIV) of the Department of Health and Human Services (HHS) is required by statute to use peer review for technical review of proposals, the requirements of those statutes, any implementing regulatory requirements, and the Federal Advisory Committee Act (5 U.S.C. chapter 10), takes precedence over the otherwise applicable requirements of this subpart.

(b) The applicable OPDIV peer review and implementing regulations include—

(1) National Institutes of Health—42 U.S.C. 289a and 42 CFR part 52h;

(2) Substance Abuse and Mental Health Services Administration—42 U.S.C. 290aa-3; and

(3) Agency for Healthcare Research and Quality—42 U.S.C. 299c-1.

#### 315.304 Evaluation factors and significant subfactors.

When acquiring information and communication technology (ICT) supplies and services using negotiated procedures, contracting officers shall include a separate technical evaluation factor, or subfactor, concerning compliance with section 508 of the Rehabilitation Act of 1973, as amended (see 339.203).

#### 315.305 Proposal evaluation.

##### 315.305–70 Proposal evaluation—use of non-Federal evaluators.

(a) Except when peer review is required by statute as provided in 315.303–70, decisions to disclose proposals to non-Federal evaluators shall be made by the Source Selection Authority or the contracting officer, as applicable, responsible for appointing Source Selection Evaluation Team members in accordance with agency procedures. The avoidance of organizational and personal conflicts of interest must be taken into consideration when making the decision to use non-Federal evaluators (see FAR 15.305(c)).

(b) When an offeror's or contractor's proposal will be disclosed outside the Government to a contractor or a contractor employee for evaluation purposes, the provision prescribed at 315.305–71 requires that the contractor and its employees, as well as any subcontractors and their employees, to agree that when performing work as an evaluator under a Government contract that they will use the data (trade secrets, business data, and technical data)

contained in the proposal for evaluation purposes only.

(1) This paragraph (b) does not apply to data obtained from another source without restriction.

(2) Upon completion of the evaluation, the non-Federal evaluator shall return to the Government the furnished copy of the proposal or abstract, and all copies thereof, to the HHS office which initially furnished the proposal for evaluation.

(3) All electronic records of proposals or proposal-related material shall be provided to the Government and immediately be destroyed and/or deleted from all electronic media.

(4) Evaluators shall not contact the offeror concerning any aspects of a proposal's contents.

(c) The agreement shall be signed by the contractor and the assigned contractor employee, subcontractor, or consultant (*i.e.*, the non-Federal evaluator) and filed in the contract file prior to disclosure of an offeror's proposal.

#### **315.305–71 Solicitation provision.**

Insert the provision at 352.215–71, Use of Non-Federal Evaluators—Conditions for Evaluating Proposals, in solicitations when the Government may use non-Federal evaluators to evaluate an offeror's or contractor's proposals and offers.

#### **Subpart 315.4—Contract Pricing**

##### **315.404 Proposal analysis.**

##### **315.404–2 Data to support proposal analysis.**

(a)(2) When some or all information sufficient to determine the reasonableness of the proposed cost or price is already available or can be obtained from the cognizant audit agency, or by other means including data obtained through market research (see FAR part 10) the contracting officer may request partial field pricing support as outlined in FAR 15.404–2(a)(2).

#### **Subpart 315.6—Unsolicited Proposals**

##### **315.604 Agency points of contact.**

(a) Each HCA is responsible for disseminating the information required at FAR 15.604(a).

##### **315.605–70 Content of unsolicited proposals—warranty by offeror.**

(a) To ensure against contacts between HHS personnel and prospective offerors that would exceed the limits of advance guidance set forth in FAR 15.604 and potentially result in an unfair advantage to an offeror, the prospective offeror of an unsolicited proposal must include a

supporting document in the form of a warranty statement in accordance with paragraph (c) of this section with any unsolicited proposal.

(b) Unsolicited proposals submitted without the warranty statement will not be processed by the Government. Contracting officers receiving an unsolicited proposal without this warranty shall not process the proposal until the offeror is notified of the missing language and given an opportunity to submit the supporting documentation. If no warranty statement is provided in a reasonable time, the contracting officer shall reject the unsolicited proposal, notify the offeror of the rejection, and document the actions in the file.

(c) Prospective offerors shall submit a supporting document with any submitted unsolicited proposal in the form of a warranty statement as follows:

#### **UNSOLICITED PROPOSAL—WARRANTY BY OFFEROR**

This is to warrant that—

(a) This proposal has not been prepared under Government supervision;

(b) The methods and approaches stated in the proposal were developed by this offeror;

(c) Any contact with HHS personnel has been within the limits of appropriate advance guidance set forth in FAR 15.604;

(d) No prior commitments were received from HHS personnel regarding acceptance of this proposal; and

(e) This proposal was not previously submitted for an HHS grant award consideration that was rejected for lack of scientific merit.

Date: \_\_\_\_\_  
Organization: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

*[This warranty shall be signed by a responsible management official of the proposing organization who is a person authorized to contractually obligate the organization.]*

##### **315.606 Agency procedures.**

(a) The HCA is responsible for establishing procedures to comply with FAR 15.606(a).

(b) The HCA or designee shall be the point of contact for coordinating the receipt and processing of unsolicited proposals.

##### **315.606–1 Receipt and initial review.**

(a)(2) Operating Divisions (OPDIVs) may consider an unsolicited proposal for award of a contract even though an organization initially submitted it as a grant application. However, contracting

officers shall not award contracts based on unsolicited proposals that have been rejected for grant awards due to lack of scientific merit.

#### **PART 316—TYPES OF CONTRACTS**

##### **Subpart 316.3—Cost-Reimbursement Contracts**

Sec.

316.307 Contract clauses.

##### **Subpart 316.5—Indefinite-Delivery Contracts**

316.505 Ordering.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

##### **Subpart 316.3—Cost-Reimbursement Contracts**

##### **316.307 Contract clauses.**

(a)(1) The contracting officer shall insert the clause at 352.216–70, Allowable Cost and Payment for Hospitals (Profit and Non-Profit), in solicitations and contracts, when a cost-reimbursement contract with a hospital (profit or non-profit) is contemplated and when the clause at FAR 52.216–7 is inserted in the contract.

##### **Subpart 316.5—Indefinite-Delivery Contracts**

##### **316.505 Ordering.**

(b)(8) The Department of Health and Human Services Advocate for Competition is designated as the task-order and delivery-order ombudsman. Each HHS HCA shall designate, in writing, a task-order and delivery-order ombudsman. The list of HHS Task-order and Delivery-order ombudsmen is at <https://www.hhs.gov/grants/grants-business-contacts/competition-advocates/index.html>.

#### **PART 317—[RESERVED]**

#### **PART 318—EMERGENCY ACQUISITIONS**

Sec.

318.000 Scope of part.

318.001 Definition.

318.001–70 Agency delegation of determination.

##### **Subpart 318.1—Available Acquisition Flexibilities**

318.109 Priorities and allocations.

318.109–70 The Health Resources Priorities and Allocation System.

##### **Subpart 318.2—Emergency Acquisition Flexibilities**

318.202 Defense or recovery from certain events.

318.202–70 Specific HHS flexibilities.

318.270 Head of the agency delegations.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### 318.000 Scope of part.

This part sets forth additional emergency acquisition flexibilities found in FAR part 18.

### 318.001 Definition.

#### 318.001–70 Agency delegation of determination.

The Secretary delegates to the head of the contracting activity (HCA) the authority to utilize emergency acquisition flexibilities and make the agency head determinations as set forth in FAR part 18 and as defined in subpart 318.2.

### Subpart 318.1—Available Acquisition Flexibilities

#### 318.109 Priorities and allocations.

#### 318.109–70 The Health Resources Priorities and Allocation System.

The HHS Health Resources Priorities and Allocation System was established to require acceptance and priority performance of contracts or orders (other than contracts of employment) to promote the national defense over performance of any other contracts or orders, and to allocate materials, services, and facilities as deemed necessary or appropriate to promote the national defense, with respect to health resources. (See subpart 311.6.)

### Subpart 318.2—Emergency Acquisition Flexibilities

#### 318.202 Defense or recovery from certain events.

#### 318.202–70 Specific HHS flexibilities.

(a) *Micro-purchase threshold.* The threshold increases when the SPE determines the supplies or services are to be used to facilitate defense against or recovery from cyber, nuclear, biological, chemical, or radiological attack; to facilitate provision of international disaster assistance; or to support response to an emergency or major disaster. (See FAR 2.101.)

(b) *Simplified acquisition threshold.* The threshold increases when the SPE determines the supplies or services are to be used to facilitate defense against or recovery from cyber, nuclear, biological, chemical, or radiological attack; to facilitate provision of international disaster assistance; or to support response to an emergency or major disaster. (See FAR 2.101.)

(c) *Commercial product or commercial service treatment.* Contracting officers may treat any acquisition of supplies or services as an

acquisition of commercial products or commercial services if the SPE determines the acquisition is to be used to facilitate the defense against or recovery from cyber, nuclear, biological, chemical, or radiological attack. (See FAR 12.102(f)(1) and 13.500(c)(2).)

(d) *Simplified procedures for certain commercial products and commercial services.* The threshold limits authorized for use of this authority may be increased when it is determined by the SPE the acquisition is to facilitate defense against or recovery from cyber, nuclear, biological, chemical, or radiological attack; to facilitate provision of international disaster assistance; or to support response to an emergency or major disaster. (See FAR 13.500(c).)

#### 318.270 Head of the agency delegations.

The Secretary delegates to the SPE the authority to make the determinations identified in the following FAR references:

- (a) FAR 2.101, definitions of “Simplified acquisition threshold” and “Micro-purchase threshold”;
- (b) FAR 12.102(f);
- (c) FAR 13.201(g); and
- (d) FAR 13.500(c)(1).

■ 8. Revise parts 319 through 323 to read as follows:

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* * * * *
PART 319 SMALL BUSINESS PROGRAMS
PARTS 320–321 [RESERVED]
PART 322 APPLICATION OF LABOR
LAW TO GOVERNMENT
ACQUISITIONS
PART 323 ENVIRONMENT,
SUSTAINABLE ACQUISITION, AND
MATERIAL SAFETY
* * * * *
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### PART 319—SMALL BUSINESS PROGRAMS

#### Subpart 319.2—Policies

Sec.

319.201 General policy.

319.202 Specific policies.

#### Subpart 319.7—The Small Business Subcontracting Program

319.705 Responsibilities of the contracting officer under the subcontracting assistance program.

319.705–6 Postaward responsibilities of the contracting officer.

#### Subpart 319.8—Contracting With the Small Business Administration (the 8(a) Program)

319.800 General.

319.811 Preparing the contracts.

319.811–370 SBA Partnership Agreement and contract clauses.

**Authority:** 5 U.S.C. 301; 15 U.S.C. 631, *et seq.*; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 319.2—Policies

#### 319.201 General policy.

(c) The functional management responsibilities for the Department of Health and Human Services’ (HHS) small business program are delegated to the Office of Small and Disadvantaged Business Utilization (OSDBU) Executive Director.

(d)(1) The HHS OSDBU Executive Director shall exercise full management authority over the small business program and appoints small business specialists (SBS). The SBS shall review and make set-aside recommendations in accordance with Federal Acquisition Regulation (FAR) 19.502, and OSDBU guidance and agency procedures. The review must take place prior to issuing the solicitation.

(2) Within the Indian Health Service (IHS), the primary SBS is responsible for IHS’ overall implementation of the HHS small business program; however, each IHS contracting office will assign a small business technical advisor (SBTA) to perform those functions and responsibilities necessary to implement the small business program. The primary IHS SBS shall assist and provide guidance to respective SBTAs.

#### 319.202 Specific policies.

Contracting officers shall use HHS Form 653, Small Business Program Review, to document set-aside decisions in accordance with agency procedures.

### Subpart 319.7—The Small Business Subcontracting Program

#### 319.705 Responsibilities of the contracting officer under the subcontracting assistance program.

#### 319.705–6 Postaward responsibilities of the contracting officer.

(h) The contracting officer shall coordinate with the small business specialist assigned to the contracting activity (and the SBA procurement center representative (PCR), if one is assigned) on all potential determinations to assess liquidated damages pursuant to FAR 19.705–7(a) and (b). OSDBU should also be alerted prior to a final determination.

### Subpart 319.8—Contracting With the Small Business Administration (the 8(a) Program)

#### 319.800 General.

(e) The Small Business Administration (SBA) and HHS have entered into a Partnership Agreement delegating SBA’s contract execution and administrative functions to HHS. Contracting officers shall follow the



alternate procedures in the Partnership Agreement and this subpart, as applicable, to award an 8(a) contract. In the event the Partnership Agreement ceases to be in effect, contracting officers shall follow the procedures in FAR subpart 19.8.

#### 319.811 Preparing the contracts.

#### 319.811–370 SBA Partnership Agreement and contract clauses.

When an 8(a) acquisition is processed pursuant to the Partnership Agreement, the contracting officer shall:

(a) For competitive solicitations and awards, use the clause at FAR 52.219–18, Notification of Competition Limited to Eligible 8(a) Participants, and clause 352.219–70, Notification of Competition Limited to Eligible 8(a) Participants, substituting paragraph (c) of FAR 52.219–18 with paragraph (c) contained in 352.219–70.

(b) For noncompetitive solicitations and awards insert the clause at 352.219–71, Notification of Section 8(a) Direct Awards, instead of the prescribed clauses at FAR 52.219–11, Special 8(a) Contract Conditions; 52.219–12, Special 8(a) Subcontract Conditions; and 52.219–17, Section 8(a) Award.

(c) In all instances, include the clause at FAR 52.219–14, Limitations on Subcontracting, or if applicable 52.219–33, Nonmanufacturer Rule.

### PARTS 320–321 [RESERVED]

## PART 322—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

### Subpart 322.1—Basic Labor Policies

Sec.

322.101 Labor relations.

322.101–70 Admittance of union representatives to HHS facilities.

### Subpart 322.8—Equal Employment Opportunity

322.808 Complaints.

322.810 Solicitation provisions and contract clauses.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 322.1—Basic Labor Policies

#### 322.101 Labor relations.

#### 322.101–70 Admittance of union representatives to HHS facilities.

(a) *Admittance policy and procedures.* It is HHS policy to admit labor union representatives of contractor employees to HHS facilities to visit work sites and transact labor union business with contractors, their employees, or union stewards pursuant to existing union collective bargaining agreements. Their

presence shall not interfere with the contractor's work progress under an HHS contract, nor violate the safety or security regulations that may be applicable to persons visiting the facility. The union representatives will not be permitted to conduct meetings, collect union dues, or make speeches concerning union matters while visiting a work site.

(b) *Denied entry reporting.* Whenever a union representative is denied entry to a facility or work site, the person denying entry shall make a written report to the HHS labor coordinator, the Office of the General Counsel (OGC), or corresponding labor advisor, with a copy to the cognizant contracting officer within two working days after the request for entry is denied. The report shall include the reason(s) for the denial, the name of the representative denied entry, the union affiliation and number, and the name and title of the person that denied the entry.

### Subpart 322.8—Equal Employment Opportunity

#### 322.808 Complaints.

Contractors shall, in good faith, cooperate with the Department of Health and Human Services (HHS) in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614 and in accordance with clause 352.222–70 as prescribed in this subpart.

#### 322.810 Solicitation provisions and contract clauses.

(e) The contracting officer shall insert the clause at 352.222–70, Contractor Cooperation in Equal Employment Opportunity and Anti-Harassment Investigations, in solicitations, contracts, and orders that include the clause at FAR 52.222–26, Equal Opportunity.

## PART 323—ENVIRONMENT, SUSTAINABLE ACQUISITION, AND MATERIAL SAFETY

### Subpart 323.1—Sustainable Products and Services

Sec.

323.103–70 Policy—Sustainable Acquisition Plan.

323.109–70 Solicitation provision.

### Subpart 323.3—Hazardous Material Identification, Material Safety Data, and Notice of Radioactive Materials

323.300 Scope of subpart.

323.304–70 Contract clause.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 323.1—Sustainable Products and Services

#### 323.103–70 Policy—Sustainable Acquisition Plan.

(a) For new contracts and orders above the micro-purchase threshold, contracting officers shall insert an evaluation factor on the offeror's Sustainable Action Plan in the solicitation, when a Sustainable Action Plan is required.

(b) When a solicitation includes the provision at 352.223–70, Instructions to Offerors—Sustainable Acquisition Plan, offerors shall include a Sustainable Acquisition Plan in their technical proposal addressing sustainable products for services for delivery under any resulting contract.

(c) The contracting officer shall incorporate the final Sustainable Acquisition Plan into the contract.

#### 323.109–70 Solicitation provision.

The contracting officer shall insert the provision at 352.223–70, Instructions to Offerors—Sustainable Acquisition Plan, in solicitations above the micro-purchase threshold when acquiring a product or service that include sustainable acquisition attributes.

### Subpart 323.3—Hazardous Material Identification, Material Safety Data, and Notice of Radioactive Materials

#### 323.300 Scope of subpart.

This subpart provides procedures for administering safety and health requirements.

#### 323.304–70 Contract clause.

Insert the clause at 352.223–71, Safety and Health, in solicitations and contracts that involve hazardous materials or hazardous operations for the following types of requirements:

- (a) Services or products.
- (b) Research, development, or test projects.
- (c) Transportation of hazardous materials.
- (d) Construction, including construction of facilities on the contractor's premises.

## PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

■ 9. The authority citation for part 324 is revised to read as follows:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 324.1—Protection of Individual Privacy

#### 324.103, 324.104, and 324.105

[Redesignated as 324.103–70, 324.103–71, and 324.104]

- 10. Redesignate sections 324.103, 324.104, and 324.105 as sections 324.103–70, 324.103–71, and 324.104.
- 11. Amend newly redesignated section 324.104 by revising paragraph (b) to read as follows:

#### 324.104 Contract clauses.

\* \* \* \* \*

(b) The contracting officer shall insert the clause at 352.224–71, Confidential Information, in solicitations, contracts, and orders that require access to Government or third party confidential information, and in solicitations, contracts, and orders that include the clause at 352.227–71, Rights in Data—Supplement—Exceptional Circumstances.

- 12. Add part 325 to read as follows:

### PART 325—FOREIGN ACQUISITION

#### Subpart 325.71—Make PPE in America Act Restrictions on Foreign Acquisition of Personal Protective Equipment

Sec.

- 325.7100 Scope of subpart.
- 325.7101 Definitions.
- 325.7102 Restrictions on certain personal protective equipment.
- 325.7102–1 Restrictions.
- 325.7102–2 Exceptions.
- 325.7103 Solicitation provisions and contract clauses.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### Subpart 325.71—Make PPE in America Act Restrictions on Foreign Acquisition of Personal Protective Equipment

##### 325.7100 Scope of subpart.

This subpart contains restrictions on the acquisition of certain personal protective equipment (PPE) as required by the Make PPE in America Act (Pub. L. 117–58) for applicable solicitations and contracts issued by HHS.

##### 325.7101 Definitions.

As used in this subpart—

*Component*, as applied to an item described in 325.7102–1, means an article, material, or supply incorporated directly into an item of personal protective equipment.

*Domestic personal protective equipment*, as applied to an item described in 325.7102–1, means personal protective equipment, including the materials and components thereof, that is grown, reprocessed,

reused, or produced in the United States.

*Foreign-made domestic personal protective equipment*, as applied to an item described in 325.7102–2, means personal protective equipment that is assembled outside the United States containing only materials and components that are grown, reprocessed, reused, or produced in the United States.

*Foreign personal protective equipment* means personal protective equipment other than domestic personal protective equipment or foreign-made domestic personal protective equipment.

*Personal protective equipment*, as applied to an item described in 325.7102–1, means surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease.

*United States*, as applied to an item described in 325.7102–1, means the 50 States, the District of Columbia, and the possessions of the United States.

##### 325.7102 Restrictions on certain personal protective equipment.

###### 325.7102–1 Restrictions.

The following restrictions implement section 70953 of the Make PPE in America Act, and they apply to all contracts and orders for the purchase of PPE.

(a) Except as provided in subsection 325.7102–2, contracting officers shall purchase domestic PPE.

(b) Any contract for PPE shall have a base period of performance of at least two years, plus any option periods.

###### 325.7102–2 Exceptions.

Acquisitions of PPE in the following categories are not subject to the restrictions in 325.7102–1:

(a) Acquisitions of an item of PPE, or component thereof, otherwise covered by 325.7102–1 when the HHS Secretary:

- (1) Maximizes sources for foreign-made domestic PPE; and
- (2) Certifies every 120 days that it is necessary to procure PPE under alternative procedures to respond to the immediate needs of a public health emergency.

(b) Acquisitions of an item of PPE, or component thereof, including those described in paragraph (a) of this section—

- (1) That is, or that includes, a material listed in FAR 25.104 as one for which

a nonavailability determination has been made; or

(2) As to which the HHS Secretary—

- (i) Determines that a sufficient quantity of a satisfactory quality that is grown, reprocessed, reused, or produced in the United States cannot be procured as, and when, needed at United States market prices; and

- (ii) Certifies every 120 days that it is necessary to procure PPE to respond to the immediate needs of a public health emergency.

(c) When either of the exceptions in paragraph (a) or (b) of this section are used:

(1) Only the HHS Secretary is authorized to make the certification in paragraphs (a)(2) and (b)(2)(ii) or the nonavailability or unreasonable cost determination in paragraph (b) of this section.

(2) The supporting documentation for the Senior Procurement Executive shall be prepared by the HHS Operating or Staff Division and—

(i) For the certification in paragraphs (a)(2) and (b)(2)(ii) of this section, the contracting officer shall—

(A) Include a written justification documenting the immediate public health emergency requiring use of alternative procedures; and

(B) Obtain written approval of the justification from the head of the contracting activity (HCA) before submission to the Senior Procurement Executive.

(ii) For the nonavailability or unreasonable cost determination in paragraph (b) of this section, the contracting officer shall—

(A) Include a written justification documenting why a nonavailability or unreasonable cost exception is required; and

(B) Obtain written approval of the justification from the HCA before submission to the Senior Procurement Executive.

##### 325.7103 Solicitation provisions and contract clauses.

(a) Insert the clause at 352.225–70, Made in America—Personal Protective Equipment, in solicitations and contracts, above the micro-purchase threshold, when procuring any item covered under 325.7102–1(a). When the clause at FAR 52.212–5, Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services, is included in a solicitation or contract for PPE, contracting officers shall include the full text of the clause at 352.225–70.

(b) Insert the provision at 352.225–71, Made in America Certificate—Personal

Protective Equipment, in solicitations containing the clause at 352.225–70. When the provision at FAR 52.212–3, Offeror Representations and Certifications—Commercial Products and Commercial Services, is included in a solicitation for PPE, contracting officers shall include the full text of the provision at 352.225–71.

■ 13. Revise part 326 to read as follows:

#### **PART 326—OTHER SOCIOECONOMIC PROGRAMS**

##### **Subpart 326.70—Indian Preference in Employment, Training, and Subcontracting Opportunities**

Sec.

- 326.7001 Statutory requirements.
- 326.7002 Additional definitions.
- 326.7003 Compliance enforcement.
- 326.7004 Tribal preference requirements.
- 326.7005 Contract clauses.

##### **Subpart 326.71—Acquisitions Under the Buy Indian Act**

- 326.7100 General.
  - 326.7100–1 Scope of subpart.
  - 326.7100–2 Buy Indian Act acquisition regulations.
- 326.7101 Definitions.
- 326.7102 Applicability.
  - 326.7102–1 Restrictions on the use of the Buy Indian Act.
- 326.7103 Policy.
  - 326.7103–1 Requirement to give preference to Indian Economic Enterprises.
  - 326.7103–2 Delegations and responsibility.
- 326.7103–3 Deviations.
- 326.7104 Procedures.
  - 326.7104–1 General.
  - 326.7104–2 Procedures for acquisitions under the Buy Indian Act.
  - 326.7104–3 Debarment and suspension.
  - 326.7104–4 Performance and payment bonds.
- 326.7105 Solicitation provisions and contract clauses.
- 326.7106 Representation by an Indian Economic Enterprise offeror.
  - 326.7106–1 General.
  - 326.7106–2 Representation provision.
  - 326.7106–3 Representation process.
- 326.7107 Challenges to representation.
  - 326.7107–1 Procedure.
  - 326.7107–2 Receipt of challenge.
  - 326.7107–3 Award in the face of challenge.
  - 326.7107–4 Challenge not timely.

##### **Subpart 326.72—Acquisitions Requiring the Native American Graves Protection and Repatriation Act**

- 326.7200 Scope of subpart.
- 326.7201 Contract clauses.

**Authority:** 5 U.S.C. 301, 25 U.S.C. 47, 25 U.S.C. 1633, 25 U.S.C. 5301 *et seq.*; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; 42 U.S.C. 2003; and 48 CFR 1.301 through 1.304.

##### **Subpart 326.70—Indian Preference in Employment, Training, and Subcontracting Opportunities**

###### **326.7001 Statutory requirements.**

Any contract or subcontract pursuant to 25 U.S.C. chapter 46, the Act of April 16, 1934 (48 Stat. 596), as amended (25 U.S.C. 5301, *et seq.*), or any other Act authorizing Federal contracts with or grants to Indian organizations or for the benefit of Indians, shall, to the greatest extent feasible, comply with section 7(b) of the Indian Self-Determination and Education Assistance Act, Public Law 93–638, 88 Stat. 2205 (25 U.S.C. 5307(b)), which provides preferences and opportunities for training and employment in connection with the administration of such contracts, and preference in the award of subcontracts in connection with the administration of such contracts to Indian organizations and to Indian-owned economic enterprises as defined in 25 U.S.C. 1452.

###### **326.7002 Additional definitions.**

As used in this subpart—

(a) *Construction contract* means a fixed-price or cost-reimbursement self-determination contract for a construction project, except that such term does not include any contract—

- (1) That is limited to providing planning services and construction management services (or a combination of such services);
- (2) For the Housing Improvement Program or roads maintenance program of the Bureau of Indian Affairs administered by the Secretary of the Interior; or
- (3) For the health facility maintenance and improvement program administered by the Secretary of Health and Human Services. (Pub. L. 116–180, title II, sec. 201(a), 134 Stat. 878.)

(b) *Contract funding base* means the base level from which contract funding needs are determined, including all contract costs.

(c) *Indian* means a person who is a member of an Indian Tribe. If the contractor has reason to doubt that a person seeking employment preference is an Indian, the contractor shall grant the preference but shall require the individual provide evidence within 30 days from the Tribe concerned that the person is a member of the Tribe.

(d) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601 *et seq.*).

(e) *Indian Tribe* means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601 *et seq.*), which is recognized as eligible for special programs and services provided by the United States to Indians because of their status as Indians.

(f) *Indirect costs* means costs incurred for a common or joint purpose benefiting more than one contract objective, or which are not readily assignable to the contract objectives specifically benefited without effort disproportionate to the results achieved.

(g) *On or near an Indian reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably commute to and from in the course of a work day.

(h) *Secretary*, unless otherwise designated, means either the Secretary of Health and Human Services or the Secretary of the Interior or both.

(i) *Self-determination contract* means a contract entered into under 25 U.S.C. subchapter I (or a grant or cooperative agreement used under 25 U.S.C. 5308) between a Tribal organization and the appropriate Secretary for the planning, conduct, and administration of programs or services that are otherwise provided to Indian Tribes and members of Indian Tribes pursuant to Federal law, subject to the condition that, except as provided in 25 U.S.C. 5324(a)(3), no contract entered into under 25 U.S.C. subchapter I (or grant or cooperative agreement used under 25 U.S.C. 5308) shall be—

(1) Considered to be a procurement contract; or

(2) Except as provided in 25 U.S.C. 5328(a)(1), subject to any Federal procurement law (including regulations).

(j) *Tribal organization* means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided, that in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe

shall be a prerequisite to the letting or making of such contract or grant.

### 326.7003 Compliance enforcement.

The contracting officer shall promptly investigate and resolve written complaints of noncompliance with the requirements of the clauses at 352.226–70, Indian Preference, and 352.226–71, Indian Preference Program, filed with the contracting activity.

### 326.7004 Tribal preference requirements.

(a) When the contractor will perform work under a contract on an Indian reservation, the contracting officer may supplement the clause at 352.226–71, Indian Preference Program, by adding specific Indian preference requirements of the Tribe on whose reservation the contractor will work. The contracting activity and the Tribe shall jointly develop supplemental requirements for the contract. Supplemental preference requirements shall represent a further implementation of the requirements of section 7(b) of Public Law 93–638 and require the approval of the affected program director and the appropriate legal office, or a regional attorney, before the contracting officer adds them to a solicitation and resultant contract. Any supplemental preference requirements the contracting officer adds to the clause at 352.226–71, Indian Preference Program shall also clearly identify in the solicitation the additional requirements.

(b) Nothing in this subpart shall preclude Tribes from independently developing and enforcing their own Tribal preference requirements. Such independently-developed Tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this subpart, and shall not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

### 326.7005 Contract clauses.

The contracting officer shall insert the clause at 352.226–70, Indian Preference, and the clause at 352.226–71, Indian Preference Program, in solicitations and contracts to implement section 7(b) of Public Law 93–638 for all Department of Health and Human Services (HHS) offices. Contracting officers shall use the clauses as follows, except for those exempted solicitations and contracts issued and/or awarded pursuant to title I of Public Law 93–638 (25 U.S.C. 450 *et seq.*):

(a) The contracting officer shall insert the clause at 352.226–70, Indian

Preference, in solicitations, contracts, and orders when—

(1) The award is (or will be) pursuant to an act specifically authorizing such awards with Indian organizations; or

(2) The work is specifically for the benefit of Indians and is in addition to any incidental benefits which might otherwise accrue to the general public.

(b) The contracting officer shall insert the clause at 352.226–71, Indian Preference Program, in solicitations, contracts, and orders when—

(1) The dollar amount of the acquisition is expected to equal or exceed \$750,000 for non-construction work or \$1.5 million for construction work;

(2) The solicitation, contract, or order includes the clause at 352.226–70; and

(3) The contracting officer makes the determination, prior to solicitation, that performance will take place in whole or in substantial part on or near an Indian reservation(s). In addition, the contracting officer may insert the clause at 352.226–71 in solicitations, contracts, and orders below the \$750,000 threshold or \$1.5 million threshold level for non-construction or construction contracts, respectively, but which meet the requirements of paragraphs (b)(2) and (3) of this section, and in the opinion of the contracting officer, offer substantial opportunities for Indian employment, training, and subcontracting.

### Subpart 326.71—Acquisitions Under the Buy Indian Act

#### 326.7100 General.

##### 326.7100–1 Scope of subpart.

This subpart implements policies and procedures for the procurement of supplies, general services, architect-engineer (A–E) services, or construction while giving preference to Indian Economic Enterprises under authority of the Buy Indian Act (25 U.S.C. 47).

##### 326.7100–2 Buy Indian Act acquisition regulations.

(a) This subpart supplements Federal Acquisition Regulation (FAR) and Health and Human Services Acquisition Regulation (HHSAR) requirements to meet the needs of the Department of Health and Human Services (HHS), Indian Health Service (IHS) in implementing the Buy Indian Act.

(b) This subpart is under the direct oversight and control of the head of contracting activity (HCA), within the Office of Management Services (OMS)—IHS, HHS. The HCA, in consultation with the Assistant Secretary for Financial Resources (ASFR) and the Senior Procurement Executive (SPE), is

responsible for promulgating this subpart, and following its enactment, will be primarily responsible for implementing its terms.

(c) Acquisitions conducted under this subpart are subject to all applicable requirements of the FAR and HHSAR, as well as internal policies, procedures, or instructions issued by IHS. After the FAR, this subpart would take precedence over any inconsistent IHS policies, procedures, or instructions.

#### 326.7101 Definitions.

As used in this subpart—

*Alaska Native Claims Settlement Act (ANCSA)* means Public Law 92–203, 85 Stat. 688, codified at 43 U.S.C. 1601–1629h.

*Alaska Native Corporation* means any Regional Corporation, any Village Corporation, any Urban Corporation, and any Group Corporation as those terms are defined by ANCSA.

*Buy Indian Act* means section 23 of the Act of June 25, 1910, codified at 25 U.S.C. 47.

*Chief Contracting Officer (CCO)* means a person with authority to enter into, administer, or terminate contracts and make related determinations and findings on behalf of the U.S. Government for the respective IHS Areas.

*Construction* means the planning, design, construction and renovation, including associated architecture and engineering services, of IHS facilities pursuant to 25 U.S.C. 1631 and in the construction of safe water and sanitary waste disposal facilities pursuant to 25 U.S.C. 1632.

*Deviation* means an exception to the requirement to use the Buy Indian Act in fulfilling an acquisition requirement subject to the Buy Indian Act.

*Fair market price* means a price based on reasonable costs under normal competitive conditions and not on lowest possible cost, as determined in accordance with FAR 19.202–6(a).

*Indian* means a person who is an enrolled member of an Indian Tribe or “Native” as defined in the Alaska Native Claims Settlement Act.

*Indian Economic Enterprise (IEE)* means any business activity owned by one or more Indians or Indian Tribes that is established for the purpose of profit provided that: The combined Indian or Indian Tribe ownership must constitute not less than 51 percent of the enterprise; the Indians or Indian Tribes must, together, receive at least a majority of the earnings from the contract; and the management and daily business operations of an enterprise must be controlled by one or more individuals who are Indians. To ensure

actual control over the enterprise, the individuals must possess requisite management or technical capabilities directly related to the primary industry in which the enterprise conducts business. The enterprise must meet these requirements throughout the following time periods:

- (1) At the time an offer is made in response to a written solicitation;
- (2) At the time of the contract award; and
- (3) During the full term of the contract.

*Indian Health Service (IHS)* means operations at all administrative levels of IHS, including Headquarters, Area Offices, and Service Units (inclusive of clinics).

*Indian Small Business Economic Enterprise (ISBEE)* means an IEE that is also a small business concern established in accordance with the criteria and size standards of 13 CFR part 121.

*Indian Tribe* means an Indian Tribe, band, nation, or other recognized group or community that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians, including any Alaska Native village or regional or village corporation under the Alaska Native Claims Settlement Act (Pub. L. 92–203, 85 Stat. 688; 43 U.S.C. 1601).

*Interested party* means an IEE that is an actual or prospective offeror whose direct economic interest would be affected by the proposed or actual award of a particular contract set-aside pursuant the Buy Indian Act.

*List of Federally Recognized Tribes* means the list published annually in the **Federal Register** identifying Indian entities that are recognized by and eligible to receive services from the United States Department of the Interior (DOI), Bureau of Indian Affairs (BIA).

*Transfer Act of 1954* means the authority of transferred responsibility and other health care “functions, responsibilities, authorities and duties of the Department of the Interior” (including the Snyder Act) to Health, Education and Welfare, the predecessor of the HHS (see Pub. L. 83–568, 68 Stat. 674 (1954) (codified at 42 U.S.C. 2001 *et seq.*)). The Transfer Act authorizes IHS to use the Buy Indian Act (25 U.S.C. 47) to carry out its health care responsibilities.

### 326.7102 Applicability.

Except as provided in 326.7102–1, this subpart applies to all acquisitions above the micro-purchase threshold, including simplified acquisitions, made by IHS, and any HHS operating or staff

divisions or agency outside of HHS conducting acquisitions on behalf of IHS.

### 326.7102–1 Restrictions on the use of the Buy Indian Act.

(a) IHS may not use the authority of the Buy Indian Act and the procedures contained in this subpart to award intergovernmental contracts to Tribal organizations to plan, operate, or administer authorized IHS programs (or parts thereof) that are within the scope and intent of the Indian Self-Determination and Education Assistance Act (ISDEAA) (Pub. L. 93–638). IHS must use the Buy Indian Act solely to award procurement contracts to IEEs. Contracts subject to ISDEAA are not covered under the FAR and are codified separately under 25 CFR part 900 and 42 CFR part 137.

(b) Contract health services (referred to administratively as Purchased/Referred Care services) are defined at 25 U.S.C. 1603 as excluding services provided by Buy Indian Act contractors. Accordingly, the Buy Indian Act may not be used to obtain services through the Purchased/Referred Care program (previously Contract Health Services). Purchase orders for care authorized pursuant to 42 CFR part 136, subpart C, may be issued without regard to the provisions of this subpart.

### 326.7103 Policy.

#### 326.7103–1 Requirement to give preference to Indian Economic Enterprises.

(a) Except as provided by 25 U.S.C. 1633, IHS must use the negotiation authority of the Buy Indian Act to give preference to IEEs whenever the use of that authority is practicable. Thus, IHS may use the Buy Indian Act to give preference to IEEs through set-asides when acquiring supplies, general services, architect-engineer (A–E) services, or construction to meet IHS needs and requirements. The Buy Indian Act does not apply when mandatory government sources are available, as required by FAR 8.002.

(b) Contract awards under the authority of the Buy Indian Act can be pursued via the acquisition procedures prescribed in this subpart in conjunction with the procedures from FAR parts 12, 13, 14, 15 and/or 16.

(c) The contracting officer will give priority to ISBEEs for all purchases, regardless of dollar value, by utilizing ISBEE set-aside to the maximum extent possible. Contracting officers when prioritizing ISBEEs may consider either—

- (1) A set-aside for ISBEEs; or
- (2) A sole source award to an ISBEE, as authorized under the FAR.

(d) If the contracting officer determines after market research that there is no reasonable expectation of obtaining offers from two or more ISBEEs that will be competitive in terms of market price, product quality, and delivery capability, the contracting officer may consider either—

- (1) A set-aside for IEEs; or
- (2) A sole source award to an IEE, as authorized under the FAR.

(e) If the contracting officer determines after market research that there is no reasonable expectation of obtaining two or more offers that will be competitive in terms of market price, product quality, and delivery capability, from ISBEEs and/or IEEs, then the contracting officer shall follow the Deviation process under 326.7103–3.

(f) Price analysis technique(s) provided in FAR 15.404–1(b) shall be used in determination of price fair and reasonableness when only one offer is received from a responsible ISBEE or IEE in response to an acquisition set-aside under paragraph (c)(1) or (d)(1) of this section:

(1) If the offer meets the technical capability requirements and is not at a reasonable and fair market price, then the contracting officer may negotiate with that enterprise for a reasonable and fair market price, as authorized under the FAR.

(2) If the offer meets the technical capability requirements and is at a reasonable and fair market price, then the contracting officer must—

- (i) Make an award to that enterprise;
- (ii) Document the reason only one offer was considered; and
- (iii) Initiate action to increase competition in future solicitations.

(g) If the offers received in response to an acquisition set-aside under paragraph (c) or (d) of this section are determined to be unreasonable or otherwise unacceptable upon price and/or technical evaluations, then the contracting officer must follow the Deviation process under 326.7103–3. The contracting officer must document in the deviation determination the reasons why the IEE offeror(s) were not reasonable or otherwise unacceptable.

(1) If a deviation determination is approved, the contracting officer must cancel the current ISBEE or IEE set-aside solicitation and inform all offerors in writing.

(2) If a deviation determination is approved, the contracting officer must identify, based on current available market research, an alternate set-aside or procurement method.

(3) When the solicitation of the same requirement is posted, the contracting

officer must inform all previous offerors in writing of the solicitation number.

(h) With respect to construction, the provisions of 25 U.S.C. 1633 shall apply. Under 25 U.S.C. 1633, IHS may give a preference to an IEE unless the agency finds, after considering the evaluation criteria listed in 25 U.S.C. 1633, that the project to be contracted for will not be satisfactory or cannot be properly completed or maintained under the proposed contract.

**326.7103–2 Delegations and responsibility.**

(a) The Director, IHS—exercises the authority of the Buy Indian Act pursuant to the Transfer Act of 1954, as delegated pursuant to 25 U.S.C. 1661. Under 25 U.S.C. 1661, the Director is authorized to enter into contracts for the procurement of goods and services to carry out the functions of the IHS. IHS exercises this authority in support of its mission and program activities and as a means of fostering Indian employment and economic development.

(b) The IHS HCA is responsible for ensuring that all IHS acquisitions under the Buy Indian Act comply with the requirements of this subpart.

**326.7103–3 Deviations.**

(a) There are certain instances where the application of the Buy Indian Act to an acquisition may not be appropriate. In these instances, the contracting officer must detail the reasons in writing or via email and make a deviation determination.

(b) Some acquisitions by their very nature would make such a written determination unnecessary. For example, any order or call placed against an indefinite delivery vehicle that already has an approved deviation from the requirements of the Buy Indian Act.

(c) Deviation determinations shall be required for all other acquisitions where the Buy Indian Act is applicable and must be approved as follows:

TABLE 1 TO 326.7103–3(c)

For a proposed contract action	The following official may authorize a deviation
Exceeding the micro-purchase threshold and up to \$25,000.	Contracting Officer.
Exceeding \$25,000 but not exceeding \$750,000.	Chief Contracting Officer (CCO) (or the IHS Division of Acquisition Policy (DAP) Director, absent a CCO).

TABLE 1 TO 326.7103–3(c)—  
Continued

For a proposed contract action	The following official may authorize a deviation
Exceeding \$750,000 but not exceeding \$15 million.	IHS Advocate for Competition.
Exceeding \$15 million but not exceeding \$75 million.	Head of Contracting Activity.
Exceeding \$75 million.	HHS Office of Small & Disadvantaged Business Utilization (OSDBU), Office of the General Counsel (OGC), HHS Department Advocate for Competition and the HHS Senior Procurement Executive.

(d) Deviations may be authorized prior to issuing the solicitation when the contracting officer makes the following determinations and takes the following actions:

(1) The contracting officer determines after market research that there is no reasonable expectation of obtaining offers that will be competitive in terms of market price, quality, and delivery from two or more responsible ISBEEs or IEEs.

(2) The deviation determination is authorized by the official listed at paragraph (c) of this section for the applicable contract action.

(e) If a deviation determination has been approved, the contracting officer must follow the FAR and HHSAR unless specified otherwise.

(f) Acquisitions made under an authorized deviation from the requirements of the Buy Indian Act must be made in conformance with the order of precedence required by FAR 8.002.

**326.7104 Procedures.**

**326.7104–1 General.**

All acquisitions under the authority of the Buy Indian Act, must conform to all applicable requirements of the FAR and HHSAR.

**326.7104–2 Procedures for acquisitions under the Buy Indian Act.**

(a) Each acquisition of commercial products, commercial services and construction that is subject to FAR part 12 or 13 must be set-aside exclusively for ISBEEs, except as otherwise set forth in this subpart. IHS will use ISBEE commercial products and commercial services, or simplified acquisition set-asides to accomplish this preference action.

(b) Commercial products and commercial services, or simplified acquisitions under this section must conform to the competition and price reasonableness documentation requirements of FAR 12.209 for commercial products and commercial services acquisitions and FAR 13.106 for simplified acquisitions.

(c) When acquiring construction and architect-engineer (A–E) services, solicit proposals and evaluate potential contractors in accordance with FAR part 36.

(d) This paragraph (d) applies to solicitations that are not restricted to participation of IEEs.

(1) If an interested IEE is identified after a solicitation has been issued, but before the date established for receipt of offers, the contracting office must provide a copy of the solicitation to this enterprise. In this case, the contracting officer:

(i) Will not give preference under the Buy Indian Act to the IEE; and

(ii) May extend the date for receipt of offers when practical.

(2) If more than one IEE is identified after issuing a solicitation, but prior to the date established for receipt of offers, the contracting officer may cancel the solicitation and re-compete it as an IEE set-aside.

**326.7104–3 Debarment and suspension.**

A misrepresentation by an offeror of its status as an IEE, failure to notify the contracting officer of any change in IEE status that would make the contractor ineligible as an IEE, or any violation of the regulations in this subpart by an offeror or an awardee may lead to debarment or suspension in accordance with FAR 9.406 and 9.407 and 309.406 and 309.407.

**326.7104–4 Performance and payment bonds.**

Solicitations requiring performance and payment bonds must conform to FAR part 28 and authorize use of any of the types of security acceptable in accordance with FAR subpart 28.2 or section 11 of Public Law 98–449, the Indian Financing Act Amendments of 1984 (25 U.S.C. 47a). In accordance with FAR 28.102 and 25 U.S.C. 47a, the contracting officer may accept alternative forms of security in lieu of performance and payment bonds if a determination is made that such forms of security provide the Government with adequate security for performance and payment.

**326.7105 Solicitation provisions and contract clauses.**

(a) The contracting officer shall insert the provision at 352.226–73, Notice of

Indian Small Business Economic Enterprise Set-Aside, in solicitations for acquisitions that are set-aside to ISBEE concerns under 326.7103-1(c).

(b) The contracting officer shall insert the provision at 352.226-74, Notice of Indian Economic Enterprise Set-Aside, in solicitations for acquisitions that are set-aside to IEE concerns in accordance with 326.7103-1(d).

(c) The contracting officer shall insert the clause at 352.226-75, Indian Economic Enterprise Subcontracting Limitations, in all solicitations and contracts when the contract award is to be made under the authority of the Buy Indian Act.

(d) The contracting officer shall insert the provision at 352.226-76, Indian Economic Enterprise Representation, in all solicitations when the contract award is to be made under the authority of the Buy Indian Act.

(e) The contracting officer shall insert the clause at FAR 52.219-14, Limitations on Subcontracting, as prescribed at FAR 19.507(e), in solicitations and contracts for supplies, services, and construction, if any portion of the requirement is to be set-aside for ISBEEs and IEEs.

(f) The contracting officer must also insert the clause 352.226-76, Indian Economic Enterprise Subcontracting Limitations, in all awards to ISBEEs and IEEs pursuant to this subpart.

### **326.7106 Representation by an Indian Economic Enterprise offeror.**

#### **326.7106-1 General.**

(a) The contracting officer must insert the provision at 352.226-76, Indian Economic Enterprise Representation, in all solicitations regardless of dollar value solicited under 326.7103-1(c) or (d) and in accordance with this subpart.

(b) To be considered for an award under 326.7103-1(c) or (d), an offeror must—

(1) Certify that it meets the definition of *Indian Economic Enterprise* in response to a specific solicitation set-aside in accordance with the Buy Indian Act and this subpart; and

(2) Identify the Indian Tribe(s) upon which the offeror relies for its IEE status.

(c) The enterprise must meet the definition of *Indian Economic Enterprise* throughout the following time periods—

(1) At the time an offer is made in response to a solicitation;

(2) At the time of contract award; and

(3) During the full term of the contract.

(d) If, after award, a contractor no longer meets the eligibility requirements

as it has certified and as set forth in this section, then the contractor must provide the contracting officer with written notification within 3 calendar days of its failure to comply with the eligibility requirements. The notification must include—

(1) Full disclosure of circumstances causing the contractor to lose eligibility status; and

(2) A description of actions, if any, that must be taken to regain eligibility.

(e) Failure to maintain eligibility under the Buy Indian Act or to provide written notification required by paragraph (d) of this section means that—

(1) The contractor may be declared ineligible for future contract awards under this subpart;

(2) The contracting officer may consider termination for default of the ongoing contract; and

(3) The contracting officer may pursue debarment or suspension of the contractor.

(f) The contracting officer will review the offeror's representation that it is an IEE in a specific bid or proposal and verify that the Indian Tribe(s) that the offeror identified in the representation is either on the List of Federally Recognized Tribes or is an Alaska Native Corporation. A contracting officer will also investigate the representation if an interested party challenges the IEE representation or if the contracting officer has any other reason to question the representation. The contracting officer may ask the offeror for more information to substantiate the representation. Challenges of and questions concerning a specific representation must be referred to the contracting officer or CCO in accordance with 326.7107.

(g) Participation in the Mentor-Protégé Program established under section 831 of the National Defense Authorization Act for Fiscal Year 1991 (25 U.S.C. 47 note) does not render an IEE ineligible for contracts awarded under the Buy Indian Act.

#### **326.7106-2 Representation provision.**

(a) Contracting offices must provide copies of the awardees' IEE representation to any interested parties upon written request. IHS will make awardees' IEE representations available via IHS public sites and/or other means.

(b) Any false or misleading information submitted by an enterprise when submitting an offer in consideration for an award set-aside under the Buy Indian Act may be a violation of the law punishable under 18 U.S.C. 1001. False claims submitted as part of contract performance may be

subject to the penalties enumerated in 31 U.S.C. 3729 to 3731 and 18 U.S.C. 287.

(c) The contracting officer shall inform the head of the contracting activity, in writing, within 10 business days, of all suspected IEE misrepresentation by an offeror or failure to provide written notification of a change in IEE eligibility. This shall be included in the contract file.

### **326.7106-3 Representation process.**

(a) Only IEEs may participate in acquisitions set-aside in accordance with the Buy Indian Act and this subpart. The procedures in this subpart are intended to support responsible IEEs and prevent circumvention or abuse of the Buy Indian Act.

(b) The contracting officer shall review the ownership information furnished under 352.226-76(b) and verify that the Indian Tribe(s) identified is either on the List of Federally Recognized Tribes or is an Alaska Native Corporation.

(c) If the contracting officer cannot verify from the offeror submission that the Indian Tribe(s) identified is either on the List of Federally Recognized Tribes or is an Alaska Native Corporation, the contracting officer must allow the offeror to correct information submitted under 352.226-76(b). The contracting officer should make every effort to allow the offeror to correct the information. If the requirement is time sensitive the contracting officer must specify to the offeror the time and date by which a response is required.

(1) If the contracting officer determines the offeror is not responsive, the contracting officer must document the circumstances and inform the offeror of the determination.

(2) The contracting officer may ask the appropriate regional Office of the General Counsel to review the IEE representation.

(3) The IEE representation does not relieve the contracting officer of the obligation for determining contractor responsibility, as required by FAR subpart 9.1.

### **326.7107 Challenges to representation.**

#### **326.7107-1 Procedure.**

(a) The contracting officer can accept an offeror's written representation of being an ISBEE or IEE (as defined in 326.7101) only when it is submitted in response to a Sources Sought Notice, Request for Information (RFI) or with an offer in response to a solicitation under the Buy Indian Act. Another interested party may challenge the representation



of an offeror or awardee by filing a written challenge.

(b) Upon receipt of the challenge, the contracting officer shall re-verify the representation of the offeror or awardee in accordance with the requirements of this subpart, including the provisions of 326.7106.

#### **326.7107–2 Receipt of challenge.**

(a) An interested party must file any challenges against an offeror's representation with the cognizant contracting officer.

(b) The challenge must be in writing and must contain the basis for the challenge with accurate, complete, specific, and detailed evidence. The evidence must support the allegation that the offeror fails to meet the definition of *Indian Economic Enterprise* or *Indian Small Business Economic Enterprise* as defined in 326.7101 or is otherwise ineligible. The contracting officer will dismiss any challenge that is deemed frivolous or that does not meet the conditions in this section.

(c) To be considered timely, a challenge must be received by the contracting officer no later than 10 calendar days after the basis of challenge is known or should have been known, whichever is earlier.

(1) A challenge may be made orally if it is confirmed in writing within the 10-day period after the basis of challenge is known or should have been known, whichever is earlier.

(2) A written challenge may be delivered by hand, email, or letter postmarked within the 10-day period after the basis of challenge is known or should have been known, whichever is earlier.

(3) A contracting officer's challenge to a certification is always considered timely, whether filed before or after award.

(d) Upon receiving a timely challenge, the contracting officer must:

(1) Notify the challenger of the date it was received, and that the representation of the enterprise being challenged is under consideration; and

(2) Furnish to the offeror (whose representation is being challenged) a request to provide detailed information on its eligibility by certified mail, return receipt requested or email.

(e) Within 3 calendar days after receiving a copy of the challenge and the contracting officer's request for detailed information, the challenged offeror must file, as specified at paragraph (d)(2) of this section, with the contracting officer a complete statement answering the allegations in the challenge and furnish evidence to

support its position on representation. If the offeror does not submit the required material within the 3 calendar days, or another period of time granted by the contracting officer, the contracting officer may assume that the offeror does not intend to dispute the challenge and must not award to the challenged offeror.

(f) Within 10 calendar days after receiving a challenge, the challenged offeror's response, and any other pertinent information, the contracting officer must determine the representation status of the challenged offeror and notify the challenger and the challenged offeror of the decision by certified mail, return receipt requested or email, and make known to all parties the option to appeal the determination to IHS DAP.

(g) If the representation accompanying an offer is challenged and subsequently upheld by DAP, the written notification of this action must state the reason(s).

#### **326.7107–3 Award in the face of challenge.**

(a) Award of a contract in the face of challenge only may be made on the basis of the contracting officer's written determination that the challenged offeror's representation is valid.

(1) This determination is final unless it is appealed to DAP, and the contracting officer is notified of the appeal before award.

(2) If an award was made before the contracting officer received notice of appeal, the contract is presumed to be valid.

(b) After receiving a challenge involving an offeror being considered for award, the contracting officer must not award the contract until the contracting officer has determined the validity of the representation. Award may be made in the face of a timely challenge when the contracting officer determines in writing that an award must be made to protect the public interest, is urgently required, or a prompt award will otherwise be advantageous to the Government.

(c) If a timely challenge on representation is filed with the contracting officer and received before award in response to a specific offer and solicitation, the contracting officer must notify eligible offerors within one day that the award will be withheld. The contracting officer also may ask eligible offerors to extend the period for acceptance of their proposals.

(d) If a challenge on representation is filed with the contracting officer and received after award in response to a specific offer and solicitation, the contracting officer need not suspend contract performance or terminate the

awarded contract unless the contracting officer believes that an award may be invalidated, and a delay would prejudice the Government's interest. However, if contract performance is to be suspended, the contracting officer would follow those guidelines as outlined in FAR part 49.

#### **326.7107–4 Challenge not timely.**

If a contracting officer receives an untimely filed challenge of a representation, the contracting officer must notify the challenger that the challenge cannot be considered on the instant acquisition but will be considered in any future actions. However, the contracting officer may question at any time, before or after award, the representation of an IEE.

### **Subpart 326.72—Acquisitions Requiring the Native American Graves Protection and Repatriation Act**

#### **326.7200 Scope of subpart.**

Public Law 101–601, dated November 16, 1990, also known as the Native American Graves Protection and Repatriation Act, imposes certain responsibilities on individuals and organizations when they discover Native American cultural items (including human remains) on Federal or Tribal lands.

#### **326.7201 Contract clauses.**

The contracting officer shall insert the clause at 352.226–72, Native American Graves Protection and Repatriation Act, in solicitations, contracts, and orders requiring performance on Tribal lands or those for construction projects on Federal or Tribal lands.

■ 14. Revise subchapter E to read as follows:

#### **SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS**

PART 327 PATENTS, DATA, AND COPYRIGHTS

PARTS 328–329 [RESERVED]

PART 330 COST ACCOUNTING STANDARDS ADMINISTRATION

PART 331 CONTRACT COST PRINCIPLES AND PROCEDURES

PART 332 CONTRACT FINANCING

PART 333 PROTESTS, DISPUTES, AND APPEALS

#### **PART 327—PATENTS, DATA, AND COPYRIGHTS**

##### **Subpart 327.3—Patent Rights Under Government Contracts**

Sec.

327.303–70 Contract clause.

##### **Subpart 327.4—Rights in Data and Copyrights**

327.409–70 Contract clauses.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 327.3—Patent Rights Under Government Contracts

#### 327.303–70 Contract clause.

The contracting officer shall insert the clause at 352.227–70, Patent Rights—Supplement—Exceptional Circumstances, in solicitations, contracts, and orders that include the clause at FAR 52.227–11, Patent Rights—Ownership by the Contractor, and a Determination of Exceptional Circumstances (DEC) involving the provision of materials has been executed and Agency policies and procedures prescribe its use.

### Subpart 327.4—Rights in Data and Copyrights

#### 327.409–70 Contract clauses.

(a) The contracting officer shall insert the clause at 352.227–71, Rights in Data—Supplement—Exceptional Circumstances, in solicitations, contracts, and orders that include the clause at FAR 52.227–14, Rights in Data—General, a Determination of Exceptional Circumstances (DEC) has been executed and agency policies and procedures prescribe its use.

(b) The contracting officer shall insert the clause at 352.227–72, Publications and Publicity, in solicitations, contracts, and orders involving requirements which could lead to the contractor publishing the results of its work under the contract.

## PARTS 328–329 [RESERVED]

## PART 330—COST ACCOUNTING STANDARDS

### Subpart 330.2—CAS Program Requirements

Sec.  
330.201 Contract requirements.  
330.201–5 Waiver.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 330.2—CAS Program Requirements

#### 330.201 Contract requirements.

#### 330.201–5 Waiver.

The Senior Procurement Executive is authorized to exercise the waiver authority under FAR 30.201–5(a)(1) when the conditions at FAR 30.201–5(a)(1) are met. This authority cannot be redelegated.

## PART 331—CONTRACT COST PRINCIPLES AND PROCEDURES

### Subpart 331.1—Applicability

Sec.  
331.170 Salary rate limitation.  
331.171 Contract clause.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 331.1—Applicability

#### 331.170 Salary rate limitation.

Congress has stipulated in the Department of Health and Human Services appropriations acts and continuing resolutions that, under certain contracts (and subcontracts thereunder), appropriated funds cannot be used to pay the direct salary of an individual above the Rates of Basic Pay for the Executive Schedule (EX), Level II, contained on the Office of Personnel Management website. The applicable rates for each year are identified in the EX Salary Table found at [www.opm.gov](http://www.opm.gov).

#### 331.171 Contract clause.

The contracting officer shall insert the clause at 352.231–70, Salary Rate Limitation, in solicitations and contracts when a cost-reimbursement, fixed-price level-of-effort, time-and-materials, or labor-hour contract is contemplated.

## PART 332—CONTRACT FINANCING

Sec.  
332.006 Reduction or suspension of contract payments upon finding of fraud.  
332.006–1 General.  
332.006–4 Procedures.

### Subpart 332.2—Commercial Product and Commercial Service Purchase Financing

332.202 General.

### Subpart 332.4—Advance Payments for Other Than Commercial Acquisitions

332.402 General.

### Subpart 332.5—Progress Payments Based on Costs

332.501 General.  
332.501–2 Unusual progress payments.

### Subpart 332.7—Contract Funding

332.703 Contract funding requirements.  
332.703–1 General.  
332.703–70 Incrementally funded cost-reimbursement contracts.  
332.703–71 Incremental funding table.  
332.706 Contract clauses.  
332.706–2 Clauses for limitation of cost or funds.

### Subpart 332.70—Electronic Submission and Processing of Payment Requests

332.7000 Scope of subpart.  
332.7001 Definition.  
332.7002 Policy.  
332.7003 Contract clause.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### 332.006 Reduction or suspension of contract payments upon finding of fraud.

#### 332.006–1 General.

(b) The Senior Procurement Executive (SPE) is authorized to make the determination there is substantial evidence that a contractor's request for advance, partial, or progress payments is based on fraud, and may direct further payments to the contractor be reduced or suspended, in accordance with FAR 32.006. This authority may not be redelegated.

#### 332.006–4 Procedures.

(b) The Remedy Coordination Official (RCO) for HHS is the SPE, who shall carry out the responsibilities in FAR 32.006–4(b).

(e) The RCO shall carry out the responsibilities of the agency head in FAR 32.006–4(e) to notify the contractor of the reasons for the recommended action and of its right to submit information within a reasonable period of time in response to the proposed action under FAR 32.006.

(1) The notice of proposed action will be sent to the last known address of the contractor, the contractor's counsel, or agent for service of process, by certified mail, return receipt requested, or any other method that provides signed evidence of receipt. In the case of a business, the notice of proposed action may be sent to any partner, principal, officer, director, owner or co-owner, or joint venture. The contractor will be afforded an opportunity to appear before the RCO to present information or argument in person or through a representative and may supplement the oral presentation with written information and argument.

(2) The proceedings will be conducted in an informal manner and without the requirement for a transcript. If the RCO does not receive a reply from the contractor within 30 calendar days, the RCO will base his or her recommendations on the information available. Any recommendation of the RCO under FAR 31.006–4(a) and paragraph (b) of this section, must address the results of this notification and the information, if any, provided by the contractor. After reviewing all the information, the RCO shall make a determination whether or not substantial evidence of fraud exists.

(g) In addition to following the procedures in FAR 32.006–4, the SPE shall provide a copy of each final determination and the supporting documentation to the contractor, the

RCO, the contracting officer, and the HHS Office of the Inspector General (OIG). The contracting officer will place a copy of the determination and the supporting documentation in the contract file.

**Subpart 332.2—Commercial Product and Commercial Service Purchase Financing**

**332.202 General.**

The SPE is authorized to approve actions for commercial item purchase financing pursuant to FAR 32.202.

**Subpart 332.4—Advance Payments for Other Than Commercial Acquisitions**

**332.402 General.**

(e) The head of the contracting activity (HCA) is authorized to make determinations related to advanced payments and shall ensure compliance with FAR 32.402. This authority may not be redelegated.

**Subpart 332.5—Progress Payments Based on Costs**

**332.501 General.**

**332.501–2 Unusual progress payments.**

(a)(3) The HCA is authorized to approve unusual progress payments. This authority may not be redelegated.

**Subpart 332.7—Contract Funding**

**332.703 Contract funding requirements.**

**332.703–1 General.**

(b) The following requirements govern all solicitations and contracts using incremental funding, as appropriate:

(1) The contracting officer shall consider the estimated total cost of the contract, including all planned increments of performance when determining the requirements that must

be met before contract execution (e.g., Justification and Approvals, clearances, and approvals).

(2) The solicitation and resultant contract shall include a statement of work or performance work statement that describes the total project, covers all proposed increments of performance, and contains a schedule of planned increments of performance. No funding increment may exceed 1 year, and the services rendered during each increment of performance must provide a specific material benefit that can stand alone if the remaining effort is not funded. The resultant contract shall also include the corresponding amount of funds planned for obligation for each increment of performance.

(3) The contracting officer shall request that offerors respond to the solicitation with technical and cost proposals for the entire project, and shall require distinct technical and cost break-outs of the planned increments of performance.

(4) Proposals shall be evaluated, and any discussions and negotiations shall be conducted based upon the total project, including all planned increments of performance.

**332.703–70 Incrementally funded cost-reimbursement contracts.**

Incremental funding may be used in cost-reimbursement contracts for severable services only when all of the following circumstances are present:

(a) Funding of increments after the initial increment of performance is provided from the appropriation account available for obligation at that time;

(b) The project represents a bona fide need of the fiscal year in which the contract is awarded and initially funded (i.e., the initial increment of performance) and is also a bona fide

need of each subsequent fiscal year whose appropriation will be used; and  
 (c) The project’s significance provides reasonable assurance that subsequent year appropriations will be made available to fund the project’s continuation and completion.

**332.703–71 Incremental funding table.**

(a) The contracting officer shall insert substantially the language in figure 1 to this section in “Section B: Supplies or Services and Prices or Costs,” “Table 1,” in all cost-reimbursement contracts for severable services using incremental funding. The language requires the contracting officer to:

(1) Insert the initial funding obligated by the award;

(2) Identify the increment of performance covered by the funding provided; and

(3) Specify the start and end dates for each increment of performance, as required by the “Limitation of Funds” clause at FAR 52.232–22.

(b) Modification of the language is permitted to fit specific circumstances of the contract, including but not limited to language necessary to reflect the specific type of cost reimbursement contract awarded, but the language may not be omitted completely.

**Figure 1 to 332.703–71—Incremental Funding Table**

**Table 1–B. Estimated Cost—Incrementally Funded Contract**

(a) The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is \$ \_\_ [insert full amount].

(b) The following represents the schedule\* by which the Government expects to allot funds to this contract:

CLIN, task number, or description	Start date of increment of performance	End date of increment of performance	Estimated cost (\$)	Fee (\$ (as appropriate))	Estimated cost plus fee (\$ (as appropriate))
.....	.....	.....	[Total]	[Total]	[Total]

\* To be inserted after negotiation  
 (c) Total funds currently obligated and available for payment under this contract are \$ \_\_ [insert amount funded to date].

(d) The contracting officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs (b) and/or (c) above.

(e) Until this contract is fully funded, the requirements of the clause at FAR 52.232–22, *Limitation of Funds*, shall

govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232–20, *Limitation of Cost*, govern.

**332.706 Contract clauses.**

**332.706–2 Clauses for limitation of cost or funds.**

(b) In addition to the clause at FAR 52.232–22, *Limitation of Funds*, the contracting officer shall insert the provision at 352.232–70, *Incremental*

Funding, in all solicitations when a cost-reimbursement contract for severable services using incremental funding is contemplated. The provision requires the contracting officer to insert a specific increment of performance that the initial funding is expected to cover.

### Subpart 332.70—Electronic Submission and Processing of Payment Requests

#### 332.7000 Scope of subpart.

This subpart prescribes policies and procedures for electronic submission and processing of payment requests.

#### 332.7001 Definition.

As used in this subpart, *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) and the applicable Payment clause included in the contract.

#### 332.7002 Policy.

(a) Contracts shall require the electronic submission of payment requests, except for—

(1) Purchases paid for with a Governmentwide commercial purchase card; and

(2) Classified contracts or purchases when electronic submission and processing of payment requests could compromise classified information or national security.

(b) Where a contract otherwise requires the electronic submission of invoices, the contracting officer may authorize alternate procedures only if the contracting officer makes a written determination that—

(1) The Department of Health and Human Services (HHS) is unable to receive electronic payment requests or provide acceptance electronically;

(2) The contractor has demonstrated that electronic submission would be unduly burdensome; or

(3) The contractor is in the process of transitioning to electronic submission of payment requests but needs additional time to complete such transition.

Authorizations granted on the basis of this paragraph (b)(3) must specify a date by which the contractor will transition to electronic submission.

(c) Except as provided in paragraphs (a) and (b) of this section, HHS officials shall process electronic payment submissions through the Department of the Treasury Invoice Processing Platform or successor system.

(d) If the requirement for electronic submission of payment requests is waived under paragraph (a)(2) or (b) of this section, the contract or alternate payment authorization, as applicable, shall specify the form and method of payment request submission.

#### 332.7003 Contract clause.

Except as provided in 332.7002(a), use the clause at 352.232–71, Electronic

Submission of Payment Requests, in all solicitations and contracts, unless an exception at 332.7002(a) or (b) applies.

### PART 333—PROTESTS, DISPUTES, AND APPEALS

#### Subpart 333.1—Protests

Sec.

333.102 General.

333.103 Protests to the agency.

333.103–70 Procedures—protests to HHS.

333.103–71 Agency action on specific protests.

#### Subpart 333.2—Disputes and Appeals

333.201 Definitions.

333.203 Applicability.

333.209 Suspected fraudulent claims.

333.214 Alternative dispute resolution (ADR).

333.215–70 Contract clauses.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### Subpart 333.1—Protests

##### 333.102 General.

The Office of General Counsel-General Law Division serves as the liaison for protests lodged with the Government Accountability Office (GAO), is designated as the office responsible for all protests within the Department of Health and Human Services and serves as the notification point with GAO for all protests.

##### 333.103 Protests to the agency.

(f)(1) The contracting officer prepares the determination pursuant to FAR 33.103(f)(1), to award a contract notwithstanding the protest. The contracting activity's designated protest official, in consultation with the cognizant HHS legal office, may approve the determination subject to the procedures in 333.103–70.

##### 333.103–70 Procedures—protests to HHS.

(a) *Agency protests.* Pursuant to FAR 33.103(d)(4), an interested party may protest to the contracting officer or, as an alternative, may request an independent review at a level above the contracting officer as provided in this section. An interested party may also appeal to HHS a contracting officer's decision on a protest.

(1) *Protests to the contracting officer.* Protests to the contracting officer shall be in writing and shall be addressed where the offer/bid is to be submitted or as indicated in the solicitation.

(2) *Independent review or appeal of a contracting officer decision—protest filed directly with the agency.* Protests requesting an independent review one level above the contracting officer and appeals within HHS to a designated

official above the level of the contracting officer, shall be addressed to the applicable designated official specified, and as instructed, in the solicitation.

(b) *Pending protests filed with contracting officer not considered.* An independent review of a protest filed pursuant to paragraph (a)(2) of this section will not be considered if the interested party has a protest on the same or similar issues pending with the contracting officer.

##### 333.103–71 Agency actions on specific protests.

(a) *Agency actions on specific types of protests.* The following types of protests may be dismissed without consideration of the merits or may be forwarded to another agency for appropriate action:

(1) *Contract administration.* Disputes between a contractor and HHS are resolved under the disputes clause (see the Dispute statute, 41 U.S.C. chapter 71).

(2) *Small business size standards and standard industrial classification.* Challenges of established size standards, ownership and control, or the size status of particular firm, and challenges of the selected standard industrial classification are for review solely by the Small Business Administration (SBA) (see 15 U.S.C. 637(b)(6); 13 CFR 121.1002).

(3) *Small business certificate of competency program.* A protest made under section 8(b)(7) of the Small Business Act, or in regard to any issuance of a certificate of competency or refusal to issue a certificate under that section, is not reviewed in accordance with bid protest procedures unless there is a showing of possible fraud or bad faith on the part of Government officials.

(4) *Decision not to set-aside under section 8(a) of the Small Business Act.* The decision to place or not to place a procurement under the 8(a) program is not subject to review unless there is a showing of possible fraud or bad faith on the part of Government officials or that regulations may have been violated (see 15 U.S.C. 637(a)).

(5) *Affirmative determination of responsibility by the contracting officer.* An affirmative determination of responsibility will not be reviewed unless there is a showing that such determination was made fraudulently or in bad faith or that definitive responsibility criteria in the solicitation were not met.

(6) *Contracts subject to FAR subpart 22.6.* Challenges concerning the legal status of a firm as a regular dealer or manufacturer within the meaning of 41

U.S.C. chapter 65 are determined solely by the procuring agency, the SBA (if a small business is involved), and the Secretary of Labor (see FAR subpart 22.6).

(7) *Subcontractor protests.* The contracting agency will not consider subcontractor protests except where HHS determines it is in the interest of the Government.

(8) *Judicial proceedings.* The contracting agency will not consider protests where the matter involved is the subject of litigation before a court of competent jurisdiction.

(b) *Alternative dispute resolution.* Bidders/offerors and HHS contracting officers are encouraged to use alternative dispute resolution (ADR) procedures to resolve protests at any stage in the protest process. If ADR is used, HHS will not furnish any documentation in an ADR proceeding beyond what is required by FAR 33.103.

## Subpart 333.2—Disputes and Appeals

### 333.201 Definitions.

*Agency board of contract appeals for HHS* means the Civilian Board of Contract Appeals (CBCA) (see <https://cbca.gov>).

### 333.203 Applicability.

(c) The CBCA is the authorized board to hear and determine disputes for the Department. All filings must be submitted to the Clerk of the Board. Filings may be made in the following ways and the board's address for each method of filing is as follows (the public should verify current operating procedures and delivery instructions with the CBCA, found at <https://cbca.gov/howto/filing.html#where>):

(1) In person or by courier: These filings should be made in the Clerk's office, located in room 6006, 6th Floor, of 1800 M Street NW, Washington, DC 20036. Check with the Clerk of the Board for any impacts due to national emergencies or other exigent circumstances to confirm whether in-person deliveries are accepted.

(2) By United States Postal Service mail: 1800 F Street NW, Washington, DC 20405.

(3) By facsimile transmission: These filings should be sent to the Clerk at (202) 606-0019.

(4) By electronic mail (e-file): [cbca.efile@cbca.gov](mailto:cbca.efile@cbca.gov). Specific e-file instructions and prohibitions can be found at <https://cbca.gov/howto/efiling.html>.

### 333.209 Suspected fraudulent claims.

The contracting officer shall submit any instance of a contractor's suspected

fraudulent claim to the Office of Inspector General for investigation and potential referral to the Department of Justice through the head of the contracting activity (HCA).

### 333.214 Alternative dispute resolution (ADR).

Contracting officers and contractors are encouraged to use alternative dispute resolution (ADR) procedures. Guidance on ADR may be obtained at the U.S. Civilian Board of Contract Appeals website at <https://www.cbca.gsa.gov>.

### 333.215–70 Contract clauses.

(a) The contracting officer shall insert the clause at 352.233–70, Choice of Law (Overseas), in solicitations and contracts when performance will be outside the United States, its possessions, and Puerto Rico, except as otherwise provided in a government-to-government agreement.

(b) The contracting officer shall insert the clause at 352.233–71, Litigation and Claims, in solicitations and contracts when a cost-reimbursement, time-and-materials, or labor-hour contract is contemplated (other than a contract for a commercial product or commercial service).

■ 15. Revise parts 334 through 337 to read as follows:

\* \* \* \* \*

PART 334 MAJOR SYSTEM ACQUISITION

PART 335 RESEARCH AND DEVELOPMENT CONTRACTING

PART 336 CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

PART 337 SERVICE CONTRACTING

\* \* \* \* \*

## PART 334—MAJOR SYSTEM ACQUISITION

### Subpart 334.2—Earned Value Management System

Sec.

334.201 Policy.

334.202 Integrated Baseline Reviews.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 334.2—Earned Value Management System

#### 334.201 Policy.

The Department of Health and Human Services applies the earned value management system (EVMS) requirement as follows:

(a) For cost or incentive contracts and subcontracts valued at \$20 million or more, the contractor's earned value

management system shall comply with the guidelines in the American National Standards Institute/Electronic Industries Alliance Standard 748, Earned Value Management Systems (ANSI/EIA-748).

(b) For cost or incentive contracts and subcontracts valued at \$50 million or more, the contractor shall have an EVMS that has been determined by the cognizant Federal agency to be in compliance with the guidelines in ANSI/EIA-748.

(c) For cost or incentive contracts and subcontracts valued at less than \$20 million—

(1) The application of earned value management is optional at the discretion of the program/project manager and is a risk-based decision that must be supported by a cost/benefit analysis; and

(2) A decision to apply earned value management shall be documented in the contract file.

(d) For firm-fixed-price contracts and subcontracts of any dollar value the application of earned value management is discouraged.

### 334.202 Integrated Baseline Reviews.

(a) An Integrated Baseline Review (IBR) is usually conducted as a post-award activity when an EVMS is required in accordance with FAR 34.201(a). A pre-award IBR may be conducted only if—

(1) The acquisition plan contains documentation that demonstrates the need and rationale for a pre-award IBR, including an assessment of the impact on the source selection schedule and the expected benefits;

(2) The use of a pre-award IBR is approved in writing by the head of the contracting activity prior to the issuance of the solicitation;

(3) The source selection plan and solicitation specifically address how the results of a pre-award IBR will be used during source selection, including any weight to be given to it in source evaluation; and

(4) Specific arrangements are made, and budget authority is provided, to compensate all offerors who prepare for or participate in a pre-award IBR; and the solicitation informs prospective offerors of the means for and conditions of such compensation.

## PART 335—RESEARCH AND DEVELOPMENT CONTRACTING

Sec.

335.070 Cost-sharing.

335.070–1 Policy.

335.070–2 Amount of cost-sharing.

335.070–3 Method of cost-sharing.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### 335.070 Cost-sharing.

#### 335.070–1 Policy.

(a) Contracting activities should encourage contractors to contribute to the cost of performing research and development (R&D), through the use of cost-sharing contracts, where there is a probability that the contractor will receive present or future benefits from participation as described in Federal Acquisition Regulation (FAR) 16.303. Examples include increased technical know-how, training for employees, acquisition of goods or services, development of a commercially viable product that can be sold in the commercial market and use of background knowledge in future contracts. Cost-sharing is intended to serve the mutual interests of the Government and its contractors by helping to ensure efficient utilization of the resources available for the conduct of R&D projects and by promoting sound planning and prudent fiscal policies of the contractor.

(b) The contracting officer should use a cost-sharing contract for R&D contracts unless the contracting officer determines that a request for cost-sharing would not be appropriate.

#### 335.070–2 Amount of cost-sharing.

When cost-sharing is appropriate, the contracting officer shall use the following guidelines to determine the amount of cost participation by the contractor:

(a) The amount of cost participation depends on the extent to which the R&D effort or results are likely to enhance the contractor's capability, expertise, or competitive position, and the value of this enhancement to the contractor. Therefore, contractor cost participation could reasonably range from as little as one percent or less of the total project cost to more than 50 percent of the total project cost. Ultimately, cost-sharing is a negotiable item. As such, the amount of cost-sharing shall be proportional to the anticipated value of the contractor's gain.

(b) If the contractor will not acquire title to, or the right to use, inventions, patents, or technical information resulting from the R&D project, it is normally appropriate to obtain less cost-sharing than in cases in which the contractor acquires these rights.

(c) If the R&D is expected to be of only minor value to the contractor, and if a statute does not require cost-sharing, it may be appropriate for the contractor to make a contribution in the form of a

reduced fee or profit rather than sharing costs of the project. Alternatively, a limitation on indirect cost rates might be appropriate (see FAR 16.303 and 42.707).

(d) The contractor's participation may be considered over the total term of the project, so that a relatively high contribution in one year may be offset by a relatively low contribution in another. Care must be exercised that the intent to cost-share in future years does not become illusory. Redetermination of the cost sharing arrangement might be appropriate depending on future circumstances.

(e) A relatively low degree of cost-sharing may be appropriate if an area of R&D requires special stimulus in the national interest.

#### 335.070–3 Method of cost-sharing.

Cost-sharing on individual contracts may be accomplished either by a contribution of part or all of one or more elements of allowable cost of the work being performed or by a fixed amount or stated percentage of the total allowable costs of the project. Contractors shall not charge costs contributed to the Government under any other instrument (e.g., grant or contract), including allocations to other instruments as part of any independent R&D program.

## PART 336—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

### Subpart 336.2—Special Aspects of Contracting for Construction

Sec.

336.203 Government estimate of construction costs.

336.204 Disclosure of the magnitude of construction projects.

#### Subpart 336.5—Contract Clauses

336.570 Contract clause.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### Subpart 336.2—Special Aspects of Contracting for Construction

#### 336.203 Government estimate of construction costs.

(a) The Government estimate must be designated "CUI Controlled by: HHS, [OPDIV/STAFFDIV]" unless the nature of the information therein requires a security classification or other classification, in which event it shall be handled in accordance with applicable security regulations. The "CUI Controlled by: HHS, [OPDIV/STAFFDIV]" designation, or other classification, must be removed only when the estimate is made public in

accordance with the instructions in paragraphs (b) and (c) of this section.

(b) If the acquisition is by sealed bidding, a sealed copy of the detailed Government estimate must be filed with the bids until bid opening. After the bids are read and recorded, the "CUI Controlled by: HHS, [OPDIV/STAFFDIV]" designation, or other classification, must be removed and the estimate read and recorded in the same detail as the bids.

(c) If the acquisition is by negotiation, the following procedures apply:

(1) The overall amount of the Government estimate must not be disclosed prior to award;

(2) At the time of award, the "CUI Controlled by: HHS, [OPDIV/STAFFDIV]" designation, or other classification, on the Government estimate must be removed; and

(3) After award, the Government estimate may be revealed, upon request, at the discretion of the contracting officer.

#### 336.204 Disclosure of the magnitude of construction projects.

The contracting officer shall utilize the estimated price ranges defined in FAR 36.204(a) through (e) as further supplemented by paragraphs (f) through (h) of this section when identifying the magnitude of an HHS project in advance notices and solicitations:

(f) For estimated price ranges between \$1,000,000 and \$5,000,000, the contracting officer shall identify the magnitude of an HHS project in advance notices and solicitations in terms of the following price ranges:

(1) Between \$1,000,000 and \$2,000,000.

(2) Between \$2,000,000 and \$5,000,000.

(g) Between \$5,000,000 and \$10,000,000.

(h) For estimated price ranges greater than \$10,000,000, the contracting officer shall identify the magnitude of an HHS project in advance notices and solicitations in terms of one of the following price ranges:

(1) Between \$10,000,000 and \$20,000,000.

(2) Between \$20,000,000 and \$50,000,000.

(3) Between \$50,000,000 and \$100,000,000.

(4) Between \$100,000,000 and \$150,000,000.

(5) Between \$150,000,000 and \$200,000,000.

(6) Between \$200,000,000 and \$250,000,000.

(7) More than \$250,000,000.

**Subpart 336.5—Contract Clauses****336.570 Contract clause.**

(a) The contracting officer shall insert the clause at 352.236–70, Design-Build Contracts, in all solicitations and contracts for design-build requirements.

(b) The contracting officer shall use Alternate I to the clause at 352.236–70, Design-Build Contracts, in all solicitations and contracts for construction when fast-track procedures are being used.

**PART 337—SERVICE CONTRACTING****Subpart 337.70—Services—Special Contract Requirements**

Sec.

337.7000 Prohibition on smoking in facilities during delivery of services to children.

337.7001 Reporting of child abuse by covered professionals.

337.7002 Requirement for background checks—childcare services.

337.7003 Indian Child Protection and Family Violence Act—background investigations.

337.7004 Non-discrimination in service delivery.

337.7005 Key personnel.

337.7006 Contract clauses.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

**Subpart 337.70—Services—Special Contract Requirements****337.7000 Prohibition on smoking in facilities during delivery of services to children.**

(a) *Policy-prohibition on smoking in certain facilities where certain federally funded children's services are provided.* When performing services under contracts awarded by the U.S. Department of Health and Human Services (HHS) where children's services are provided, contractors including employees, subcontractors, and third-parties performing services on behalf of a contractor are prohibited from smoking in facilities where certain federally funded children's services are provided pursuant to 20 U.S.C. 7181 (Pub. L. 107–110, the Pro-Children Act of 2001 (the Act)). Smoking is prohibited within any indoor facility (or portion thereof), whether owned, leased, or contracted for, or involving indoor facilities that are constructed, operated, or maintained with Federal funds, that is used for the routine or regular provision of—

(1) Kindergarten, elementary, or secondary education or library services; or

(2) Health or day care services that are provided to children under the age of 18.

(b) *Representation and agreement.* Contractors are required to represent to the contracting officer and agree that by submission of its bid or offer and if awarded a contract, the contractor agrees to comply with the requirements of the Act and the prohibition of smoking in facilities as specified in paragraph (a) of this section. The contractor shall enforce the provisions of the clause prescribed in 337.7006(a), and ensure that each of its employees, subcontractors, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act.

(c) *Penalties.* Failure to comply with the Act may result in the imposition of a civil monetary penalty in an amount not to exceed \$1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity after proper notice in accordance with agency procedures.

**337.7001 Reporting of child abuse by covered professionals.**

(a) *Definitions.* As used in this subpart—

*Child abuse* means the physical or mental injury, sexual abuse or exploitation, or negligent treatment of a child.

*Covered professionals* means those persons engaged in professions and activities in eight different categories including, but not limited to, teachers, social workers, physicians, dentists, medical residents or interns, hospital personnel and administrators, nurses, health care practitioners, chiropractors, osteopaths, pharmacists, optometrists, podiatrists, emergency medical technicians, ambulance drivers, alcohol or drug treatment personnel, psychologists, psychiatrists, mental health professionals, childcare workers and administrators, and commercial film and photo processors.

(b) *Responsibility to report child abuse.* Public Law 101–647, known as the Crime Control Act of 1990 (the Act) (34 U.S.C. 20341), imposes responsibilities on certain individuals who, while engaged in a professional capacity or activity as a covered professional, as defined in the Act, on Federal land or in a federally-operated (or contracted) facility, learn of facts that give the individual reason to suspect that a child has suffered an incident of child abuse.

(c) *Reporting requirements.* Accordingly, any person engaged in a covered profession or activity under an HHS contract or subcontract (*i.e.*, a

covered professional), regardless of the purpose of the contract or subcontract, shall immediately report a suspected child abuse incident in accordance with the provisions of the Act. If a child is suspected of being harmed, the appropriate State Child Abuse Hotline, local child protective services (CPS), or law enforcement agency shall be contacted. For more information about where and how to file a report, Contractors may contact the Childhelp USA, National Child Abuse Hotline (1–800–4–A–CHILD). Any covered professional failing to make a timely report of such incident shall be guilty of a Class B misdemeanor.

(d) *Representation.* The offeror shall represent that it understands that by submission of its bid or offer and if awarded a contract for a requirement, the Contractor agrees to comply with the requirements of the Act. Contracting officers shall ensure the requirements of clause 352.237–71 are flowed down to subcontractors at any tier.

**337.7002 Requirement for background checks—childcare services.**

(a) *Definition.* As used in this subpart, *childcare services* means and include, but are not limited to, social services, health and mental health care, child (day) care, education (whether or not directly involved in teaching), and rehabilitative programs.

(b) *Requirement for background checks.* Public Law 101–647, known as the Crime Control Act of 1990 (the Act) (34 U.S.C. 20351), requires that all individuals involved with the provision of childcare services to children under the age of 18 undergo a criminal background check. Any conviction for a sex crime, an offense involving a child victim, or a drug felony, may be grounds for denying employment or for dismissal of an employee providing any childcare services.

(c) *Background check protocols.* The contracting officer will provide the necessary information to the contractor regarding the process for obtaining the background check. The contractor may hire a staff person provisionally prior to the completion of a background check, if at all times prior to the receipt of the background check during which children are in the care of the newly-hired person, the person is within the sight and under the supervision of a previously investigated staff person.

(d) *Representation.* The offeror shall represent that it understands that by submission of its bid or offer and if awarded a contract for a requirement, the contractor agrees to comply with the requirements of the Act. Contracting officers shall ensure the requirements of



clause 352.237–72 are flowed down to subcontractors at any tier.

**337.7003 Indian Child Protection and Family Violence Act—background investigations.**

(a) To ensure protection of Indian children, the Indian Child Protection and Family Violence Act, Public Law 101–630 (25 U.S.C. 3201, *et seq.*), prohibits employment, including personal service contracts, with anyone who has been convicted of any crime of violence when performance under a contract may require duties and responsibilities of a contractor, its employees, subcontractors, or third parties providing service under the contract that involve regular contact with or control over Indian children. The Act requires that a contractor and its employees and subcontractors, at any tier, be subject to a character and background investigation. This investigation is conducted by the Indian Health Service, Office of Human Resources.

(b) Until such time as the contractor or its employees and subcontractors have been notified of completion of the investigation, the contractor and its employees and subcontractors shall have no unsupervised contact with Indian children. In order to initiate this background investigation, the contractor and its employees and subcontractors must provide information as required in the contract or as directed by the contracting officer.

(c) As a prerequisite to providing services under a contract involving access to Indian children, contractors shall—

(1) Complete and sign a declaration concerning the background of employees or subcontractors providing such services as required by the terms and conditions of the contract;

(2) Provide information as required by the contracting officer to ascertain such information about its employees, subcontractors, and third parties providing services under the contract;

(3) Report convictions of any crime of violence immediately to the contracting officer that involve such employees, subcontractors, or third parties, who may be employed or are currently employed under the contract; and

(4) Flow down clause the clause prescribed at 337.7006(d), 352.337–73, Indian Child Protection and Family Violence Act—Background Investigations, into all subcontracts, at any tier.

**337.7004 Non-discrimination in service delivery.**

(a) *Policy.* It is the policy of the HHS that no person otherwise eligible will be

excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental).

(b) *Representation.* The offeror shall represent that it understands that by submission of its bid or offer and if awarded a contract for a requirement, the contractor agrees to comply with the requirements of the policy. Contracting officers shall ensure the requirements of clause 352.237–74 are flowed down to subcontractors at any tier.

**337.7005 Key personnel.**

(a) To ensure successful performance under an HHS contract, it may be necessary for the contracting officer to require contractors to identify certain positions as key personnel when considered to be essential to work performance.

(b) Contractors must provide notice if they divert proposed personnel deemed key personnel. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals in a contract to other programs or contracts, the contractor shall notify the contracting officer and submit a justification for the diversion or replacement, and request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract. The contract should be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(c) If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than 30 days' notice, the contractor must provide the maximum notice practicable under the circumstances. The contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the contracting officer.

**337.7006 Contract clauses.**

(a) The contracting officer shall insert the clause at 352.237–70, Nonsmoking Policy—Delivery of Services to Children, in solicitations, contracts, and orders that involve health or daycare services that are provided to children under the age of 18 on a routine or regular basis pursuant to the Pro-Children Act of 2001 as set forth in 337.7000.

(b) The contracting officer shall insert the clause at 352.237–71, Reporting of Child Abuse, in solicitations, contracts,

and orders that require performance on Federal land or in a federally operated (or contracted) facility and involve “covered professionals” performed by persons specified in the Crime Control Act of 1990 (34 U.S.C. 20341) engaged in a covered profession or activity under an HHS contract or subcontract, regardless of the purpose of the contract or subcontract, including, but not limited to those performed by—

- (1) Teachers;
- (2) Social workers;
- (3) Physicians, nurses, dentists, health care practitioners, optometrists, psychologists, emergency medical technicians, alcohol or drug treatment personnel; and
- (4) Childcare workers and administrators, emergency medical technicians and ambulance drivers.

(c) The contracting officer shall insert the clause at 352.237–72, Requirement for Background Checks, in solicitations, contracts, and orders that involve providing childcare services to children under the age of 18, including social services, health and mental health care, child-(day) care, education (whether or not directly involved in teaching), and rehabilitative programs covered under the Crime Control Act of 1990 (34 U.S.C. 20351).

(d) The contracting officer shall insert the clause at 352.237–73, Indian Child Protection and Family Violence Act—Background Investigations, in all solicitations, contracts, and orders when performance of the contract may involve regular contact with or control over Indian children. The required declaration shall also be included in section J of the solicitation and contract. This clause shall be included by all contracting officers supporting the Indian Health Service, whether issued by IHS or through or by use of an interagency agreement.

(e) The contracting officer shall insert the clause at 352.237–74, Non-Discrimination in Service Delivery, in solicitations, contracts, and orders involving delivery of services under HHS' programs directly to the public.

(f) The contracting officer shall insert the clause at 352.237–75, Key Personnel, in solicitations, contracts, and orders when the contracting officer will require the contractor to designate contractor key personnel.

**PART 338 [ADDED AND RESERVED]**

■ 16. Add reserved part 338 to subchapter F.

**PART 340 [ADDED AND RESERVED]**

■ 17. Add reserved part 340 to subchapter F.

■ 18. Add part 341 to subchapter F to read as follows:

## **PART 341—ACQUISITION OF UTILITY SERVICES**

### **Subpart 341.1—General**

Sec.

341.102 Applicability.

### **Subpart 341.5—Solicitation Provision and Contract Clauses**

341.501 Solicitation provision and contract clauses.

341.501–70 Disputes—utility contracts.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### **Subpart 341.1—General**

#### **341.102 Applicability.**

(a) This part applies to purchases of utility services from nonregulated and regulated utility suppliers when a delegation of authority from the General Services Administration (GSA) for those services is requested and obtained.

(b)(4) The acquisition of energy, such as electricity, and natural or manufactured gas, when purchased as a commodity is considered to be acquisitions of supplies rather than utility services as described in FAR part 41.

### **Subpart 341.5—Solicitation Provision and Contract Clauses**

341.501 Solicitation provision and contract clauses.

341.501–70 Disputes—utility contracts.

The contracting officer shall insert the clause at 352.241–70, Disputes—Utility Contracts, in solicitations and contracts for utility services subject to the jurisdiction and regulation of a utility rate commission.

■ 19. Revise subchapter G to read as follows:

## **SUBCHAPTER G—CONTRACT MANAGEMENT**

PART 342 CONTRACT ADMINISTRATION AND AUDIT SERVICES

PART 343 CONTRACT MODIFICATIONS

PART 344 SUBCONTRACTING POLICIES AND PROCEDURES

PART 345 GOVERNMENT PROPERTY

PART 346 [RESERVED]

PART 347 TRANSPORTATION

PARTS 348–351 [RESERVED]

## **SUBCHAPTER G—CONTRACT MANAGEMENT**

### **PART 342—CONTRACT ADMINISTRATION AND AUDIT SERVICES**

#### **Subpart 342.2—Contract Administration**

Sec.

342.270 Contracting Officer's Representatives role in contract administration.

342.271 Administrative Contracting Officer's role in contract administration and delegated functions.

342.272 Contract clauses.

#### **Subpart 342.7—Indirect Cost Rates**

342.705 Final indirect cost rates.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c)(2); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### **Subpart 342.2—Contract Administration**

**342.270 Contracting Officer's Representatives role in contract administration. (a) A contracting officer may designate a qualified person to be the Contracting Officer's Representative (COR) for the purpose of performing certain technical functions in administering a contract.**

(b) The COR acts solely as a technical representative of the contracting officer and is not authorized to perform any function that results in a change in the scope, price, terms, or conditions of the contract.

(c) A COR designation must be made in writing by the contracting officer. The designation shall identify the responsibilities and limitations of the COR. A copy of the designation must be furnished to the contractor and the Administrative Contracting Officer (ACO), when applicable.

**342.271 Administrative Contracting Officer's role in contract administration and delegated functions.**

(a) As used in this subpart, *Administrative Contracting Officer (ACO) Letter of Delegation* means a delegation of functions as set forth in FAR 42.202 and 42.302 and this section that is issued by a contracting officer to delegate certain contract administration or specialized support services.

(b) Contracting officers are authorized to delegate certain contract administration or specialized support services in accordance with FAR 42.202 and 42.302 to ACOs.

(c) The ACO's authority is limited to the actions detailed in the delegation.

(d) The delegations of authority shall be set forth in a written ACO Letter of Delegation issued by the contracting officer to the accepting contract administration office and designated administrative contracting officer. The ACO Letter of Delegation shall contain the information required in FAR 42.202(a) through (c) and identify the responsibilities and limitations of the ACO. A copy of the delegation will be furnished to the contractor and the ACO.

### **342.272 Contract clauses.**

(a) The contracting officer shall insert the clause at 352.242–70, Administrative Contracting Officer, in solicitations and contracts expected to exceed the micro-purchase threshold, when contract administration is delegated.

(b) The contracting officer shall insert the clause at 352.242–71, Government Construction Contract Administration, in solicitations and contracts for construction expected to exceed the micro-purchase threshold, when contract administration is delegated.

### **Subpart 342.7—Indirect Cost Rates**

#### **342.705 Final indirect cost rates.**

Contract actions for which the Department of Health and Human Services is the cognizant Federal agency:

(a) The Financial Management Services, Division of Cost Allocation, Program Support Center, shall establish facilities and administration costs, also known as indirect cost rates, research patient care rates, and, as necessary, fringe benefits, computer, and other special costing rates for use in contracts awarded to State and local governments, colleges and universities, hospitals, and other nonprofit organizations.

(b) The National Institute of Health, Division of Financial Advisory Services, shall establish indirect cost rates and similar rates for use in contracts awarded to for profit organizations.

## **PART 343—CONTRACT MODIFICATIONS**

### **Subpart 343.2—Change Orders**

Sec.

343.204 Administration.

343.204–70 Definitization.

343.205 Contract clauses.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

### **Subpart 343.2—Change Orders**

#### **343.204 Administration.**

#### **343.204–70 Definitization.**

(a) *Applicability.* This section applies to unpriced change orders with an estimated value exceeding \$5 million.

(b) *Price ceiling.* Unpriced change orders shall include a not-to-exceed price.

(c) *Definitization schedule.* (1) Unpriced change orders shall contain definitization schedules that provide for definitization by—

(i) The date after issuance of the change order may not exceed 180 days after the contractor submits a qualifying proposal); or

(ii) The date on which the amount of funds paid to the contractor under the contract action is equal to more than 50 percent of the not-to-exceed price.

(2) Submission of a qualifying proposal in accordance with the definitization schedule is a material element of the contract. If the contractor does not submit a timely qualifying proposal, the contracting officer may suspend or reduce progress payments under FAR 32.503-6 or take other appropriate action.

(d) *Limitations on obligations.* (1) The Government shall not obligate more than 50 percent of the not-to-exceed price before definitization. However, if a contractor submits a qualifying proposal before 50 percent of the not-to-exceed price has been obligated by the Government, the limitation on obligations before definitization may be increased to no more than 75 percent.

(2) Obligations should be consistent with the contractor's requirements for the undefinitized period.

(e) *Exception.* The head of the contracting activity (HCA) may waive the limitations in paragraph (c) of this section for unpriced change orders if the HCA determines that the waiver is necessary to support an emergency acquisition operation.

#### 343.205 Contract clauses.

As authorized in the introductory text of clauses at FAR 52.243-1, Changes—Fixed-Price; 52.243-2, Changes—Cost-Reimbursement; and 52.243-4, Changes, and in the prescription at FAR 43.205(c) for FAR 52.243-3, Changes—Time-and-Materials or Labor-Hours, the contracting officer may vary the period within which a contractor must assert its right to an equitable adjustment, but the extended period shall not exceed 60 calendar days, unless approval is one level above the contracting officer.

### PART 344—SUBCONTRACTING POLICIES AND PROCEDURES

#### Subpart 344.2—Consent to Subcontracts

Sec.

344.201 Consent and advance notification requirements.

344.201-1 Consent requirements.

344.202 Contracting officer's evaluation.

344.202-2 Considerations.

#### Subpart 344.3—Contractors' Purchasing Systems Reviews

344.303-70 Additional contractors' purchasing system review considerations.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### Subpart 344.2—Consent to Subcontracts

##### 344.201 Consent and advance notification requirements.

###### 344.201-1 Consent requirements.

(a) In accordance with section 824 of the National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232), notwithstanding the requirements in FAR 44.201-1(a), the contracting officer shall not withhold consent to subcontract without the written approval of the contracting officer's representative, if the contractor has an approved purchasing system, as defined in FAR 44.101.

##### 344.202 Contracting officer's evaluation.

###### 344.202-2 Considerations.

(a) In addition to the considerations outlined in FAR 44.202-2(a), the contracting officer responsible for consent must review the request and supporting data and document in writing whether the contractor adequately substantiated the selection as being fair, reasonable, and representing the best value to the Government where other than the lowest price is the basis for subcontractor selection.

#### Subpart 344.3—Contractors' Purchasing Systems Reviews

##### 344.303-70 Additional contractors' purchasing system review considerations.

(a) During contractor purchasing systems reviews (CPSRs), special attention shall also be paid to reviewing documentation of commercial products and commercial services determinations to ensure compliance with the definition of commercial products and commercial services in FAR 2.101.

(b) The contracting officer shall not withhold consent to subcontract without the written coordination of the program manager, or comparable requiring activity official exercising program management responsibilities, if the contractor has an approved purchasing system as defined in FAR 44.101.

### PART 345—GOVERNMENT PROPERTY

#### Subpart 345.1—General

Sec.

345.105-70 Contractors' property management system compliance—policy and procedures.

345.107 Contract clauses.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### Subpart 345.1—General

##### 345.105-70 Contractors' property management system compliance—policy and procedures.

(a) *Definitions.* As used in this part—  
*Acceptable property management system* means a property system that complies with the system criteria in accordance with paragraph (f) of the clause at FAR 52.245-1.

*Property management system* means the contractor's system or systems for managing and controlling Government property.

*Significant deficiency* means a shortcoming in the system that materially affects the ability of officials of the Department of Health and Human Services to rely upon information produced by the system that is needed for management purposes.

(b) *Policy.* The cognizant contracting officer, in consultation with the property administrator, shall—

(1) Determine the acceptability of the system and approve or disapprove the system; and

(2) Pursue correction of any deficiencies.

(c) *Acceptable property management system.* In evaluating the acceptability of a contractor's property management system, the contracting officer, in consultation with the property administrator, shall determine whether the contractor's property management system complies with the system criteria for an acceptable property management system as prescribed in the clause at 352.245-70, Contractor Property Management System Administration.

(d) *Disposition of findings—(1) Reporting of findings.* The property administrator shall document findings and recommendations in a report to the contracting officer. If the property administrator identifies any significant property system deficiencies, the report shall describe the deficiencies in sufficient detail to allow the contracting officer to understand the deficiencies.

(2) *Initial determination.* (i) The contracting officer shall review findings and recommendations and, if there are no significant deficiencies, shall promptly notify the contractor, in writing, that the contractor's property management system is acceptable and approved; or

(ii) If the contracting officer finds that there are one or more significant deficiencies (as defined in the clause at 352.245-70, Contractor Property Management System Administration) due to the contractor's failure to meet one or more of the property management system criteria in the

clause at 352.245–70, the contracting officer shall—

(A) Promptly make an initial written determination on any significant deficiencies and notify the contractor, in writing, providing a description of each significant deficiency in sufficient detail to allow the contractor to understand the deficiency;

(B) Request the contractor to respond, in writing, to the initial determination within 30 days; and

(C) Evaluate the contractor's response to the initial determination, in consultation with the property administrator, and make a final determination.

(3) *Final determination.* (i) The contracting officer shall make a final determination and notify the contractor, in writing, that—

(A) The contractor's property management system is acceptable and approved, and no significant deficiencies remain; or

(B) Significant deficiencies remain. The notice shall identify any remaining significant deficiencies, and indicate the adequacy of any proposed or completed corrective action. The contracting officer shall—

(1) Request that the contractor, within 45 days of receipt of the final determination, either correct the deficiencies or submit an acceptable corrective action plan showing milestones and actions to eliminate the deficiencies;

(2) Disapprove the system in accordance with the clause at 352.245–70, Contractor Property Management System Administration; and

(3) Take other remedies such as withholding payments as appropriate in accordance with the terms and conditions of the contract.

(ii) Monitor a contractor's corrective action and the correction of significant deficiencies.

(e) *System approval.* The contracting officer shall promptly approve a previously disapproved property management system and notify the contractor when the contracting officer determines, in consultation with the property administrator, that there are no remaining significant deficiencies.

(f) *Contracting officer notifications.* The cognizant contracting officer shall promptly distribute copies of a determination to approve a system, disapprove a system and withhold payments, or approve a previously disapproved system and release withheld payments to the auditor; payment office; affected contracting officers at the buying activities; and cognizant contracting officers in

contract administration activities, as appropriate.

#### **345.107 Contract clauses.**

The contracting officer shall insert the clause at 352.245–70, Contractor Property Management System Administration, in solicitations and contracts containing the clause at FAR 52.245–1, Government Property.

### **PART 346 [RESERVED]**

### **PART 347—TRANSPORTATION**

#### **Subpart 347.3—Transportation in Supply Contracts**

Sec.

347.303–6 F.o.b. destination.

347.303–670 Place of delivery.

347.305 Solicitation provisions, contract clauses, and transportation factors.

347.305–10 Packing, marking, and consignment instructions.

347.306 Transportation factors in the evaluation of offers.

347.306–70 Records of claims.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### **Subpart 347.3—Transportation in Supply Contracts**

**347.303–6 F.o.b. destination.**

**347.303–670 Place of delivery.**

The contracting officer shall insert clause 352.247–70, Delivery Location, or a clause substantially the same as the clause at 352.247–70, in supply contracts when it is necessary to specify delivery locations. If necessary, the clause may reference an attachment which lists various delivery locations and other delivery details (*e.g.*, quantities to be delivered to each location, etc.).

**347.305 Solicitation provisions, contract clauses, and transportation factors.**

**347.305–10 Packing, marking, and consignment instructions.**

(a) The contracting officer shall insert clause 352.247–71, Marking Deliverables, or a clause substantially the same as 352.247–71, in solicitations and contracts if special marking on deliverables is required.

(b) The contracting officer shall insert the clause at 352.247–72, Packing for Domestic Shipment, in contracts when item(s) will be delivered for immediate use to a destination in the continental United States; when the material specification or purchase description does not provide preservation, packaging, packing, and/or marking requirements; and/or when the requiring activity has not cited a specific specification for packaging.

**347.306 Transportation factors in the evaluation of offers.**

**347.306–70 Records of claims.**

When contracting for transportation, and consistent with FAR 15.304, contracting officers should consider using offerors' record of claims involving loss or damage as an evaluation factor or subfactor.

### **PARTS 348–351 [RESERVED]**

### **PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES**

■ 20. The authority citation for part 352 is revised to read as follows:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

■ 21. Revise subpart 352.1 to read as follows:

#### **Subpart 352.1—Instructions for Using Provisions and Clauses**

Sec.

352.100 Scope of subpart.

352.102 Incorporating provisions and clauses.

352.102–70 Application of provisions and clauses.

#### **Subpart 352.1—Instructions for Using Provisions and Clauses**

**352.100 Scope of subpart.**

This subpart provides guidance for applying the Department of Health and Human Services supplemental provisions and clauses in solicitations, contracts, and orders.

**352.102 Incorporating provisions and clauses.**

**352.102–70 Application of provisions and clauses.**

(a) If a clause is included in the master instrument (*e.g.*, in an indefinite-delivery, indefinite-quantity contract, or a blanket purchase agreement), it is not necessary to also include the clause in a task order or delivery order thereunder, unless fill-ins are required.

(b) When a dollar amount or dollar threshold is specified (*e.g.*, \$25 million or simplified acquisition threshold), the dollar amount of the award (contract or order) includes any options thereunder.

#### **Subpart 352.2—Text of Provisions and Clauses**

■ 22. Add section 352.201–70 to read as follows:

**352.201–70 Contracting Officer's Representative.**

As prescribed in 301.604–70, insert the following clause:

Contracting Officer's Representative (DATE)

(a) *Definition.* Contracting officer's representative (COR) means an individual designated in accordance with FAR 1.602–2(d) and authorized in writing by the Contracting Officer to perform specific technical or administrative functions.

(b) If the Contracting Officer designates a COR, the Contractor will receive a copy of the written designation. It will specify the extent of the COR's authority to act on behalf of the Contracting Officer. The COR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

(End of clause)

■ 23. Revise sections 352.203–70 and 352.204–70 to read as follows:

**352.203–70 Anti-Lobbying.**

As prescribed in 303.808–70, insert the following clause:

Anti-Lobbying (DATE)

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 paragraphs (a), (b), and (c) 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)

**352.204–70 Prevention and Public Health Fund—Reporting Requirements.**

As prescribed in 304.7202, insert the following clause:

Prevention and Public Health Fund—Reporting Requirements (DATE)

(a) Pursuant to public law this contract requires the contractor to provide products or services or both that are funded from the Prevention and Public Health Fund (PPHF), Public Law 111–148, sec. 4002. Public Law 112–74, section 220(b)(5), requires each contractor to report on its use of these funds under this contract. These reports will be made available to the public.

(b) Semi-annual reports from the Contractor for all work funded, in whole or in part, by the PPHF, are due no later than 20 days following the end of each 6-month period. The 6-month reporting periods are January through June and July through December. The first report is due no later than 20 days after the end of the 6-month period following contract award. Subsequent reports are due no later than 20 days after the end of each reporting period. If applicable, the Contractor shall submit its final report for the remainder of the contract period no later than 20 days after the end of the reporting period in which the contract ended.

(c) The Contractor shall provide the following information in a Section 508 compliant electronic format to the Contracting Officer.

- (1) The Government contract and order number, as applicable.
- (2) The amount of PPHFs invoiced by the contractor for the reporting period and the cumulative amount invoiced for the contract or order.
- (3) A list of all significant services performed, or supplies delivered, including construction, for which the contractor invoiced in the reporting period.
- (4) Program or project title, if any.
- (5) The Contractor shall report any subcontract funded in whole or in part with PPHFs valued at \$25,000 or more. The Contractor shall advise the subcontractor that the information will be made available to the public. The Contractor shall report:
  - (i) Name and address of the subcontractor.
  - (ii) Amount of the subcontract award.
  - (iii) Date of the subcontract award.
  - (iv) A description of the products or services (including construction) being provided under the subcontract.

(End of clause)

■ 24. Add section 352.205–70 to read as follows:

**352.205–70 Advertisements, Publicizing Awards, and Releases.**

As prescribed in 305.470–2, insert the following clause:

Advertisements, Publicizing Awards, and Releases (DATE)

The Contractor shall not refer to this contract in commercial advertising or similar promotions in such a manner as to state or imply that the product or service provided is endorsed or preferred by the Federal Government or is considered by the Government to be superior to other products or services.

(End of clause)

*Alternate I* (DATE). If a contract involves sensitive or classified

information, designate the paragraph in the base clause as (a) and add the following paragraph (b) to the clause:

(b) All advertisements, releases, announcements, or other publication regarding this contract or the agency programs and projects covered under it, or the results or conclusions made pursuant to performance, must be approved by the Contracting Officer. Under no circumstances shall the Contractor, or anyone acting on behalf of the Contractor, refer to the supplies, services, or equipment furnished pursuant to the provisions of this contract in any publicity, release, or commercial advertising without first obtaining explicit written consent to do so from the Contracting Officer.

■ 25. Revise section 352.208–70 to read as follows:

**352.208–70 Printing and Duplication.**

As prescribed in 308.870, insert the following clause:

Printing and Duplication (DATE)

(a) *Definitions.* As used in this clause—  
*Duplicating/copying* means the term as defined in the Government Printing and Binding Regulations published by the Joint Committee on Printing, U.S. Congress, Title I: Definitions.

*Government printing* means printing, binding, and blank book work for the use of an executive department, independent agency, or establishment of the Government (see Government Printing and Binding Regulations published by the Joint Committee on Printing, U.S. Congress, Title I: Definitions).

*Printing* means the term as defined in the Government Printing and Binding Regulations published by the Joint Committee on Printing, U.S. Congress, Title I: Definitions.

*Related supplies* means supplies that are used and equipment that is usable in printing and binding operations.

*Other printing-related services* means composition, platemaking, presswork, binding, and micrographics when used as a substitute for printing.

(b) *Prohibitions.* Unless otherwise specified, no printing by the Contractor or any subcontractor is authorized for performance under the contract, whether to support Government printing, to acquire related supplies, or to provide other printing-related services. When printing supplies or services are required, and specified under the contract, the Contractor shall submit camera-ready copies of such deliverables to the Contracting Officer's Representative for printing through, or by the Government Printing Office, except as authorized by the Contracting Officer.

(c) *Limited printing authorized.* If necessary for performance of the contract, the Contractor may duplicate or copy less than 5,000 production units of any one page, or less than 25,000 production units in the aggregate of multiple pages for the use of a department or agency. A production unit is

defined as one sheet, size 8.5 x 11 inches, one side only, and one color. The pages may not exceed a maximum image size of 10 3/4 by 14 1/4 inches. This page limit applies to each printing requirement and not for all printing requirements under the entire contract.

(d) *Approval procedures for printing, duplication, and other printing-related services.* Contractors must obtain approval from the Contracting Officer for all printing, as well as duplicating/copying in excess of the limited printing authorized stated limits in paragraph (c). The cost of any unauthorized printing or duplicating/copying under this contract is unallowable and the Contractor will not be reimbursed.

(e) *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (e), in subcontracts under this contract (including subcontracts for the acquisition of commercial products and commercial services).

(End of clause)

■ 26. Add section 352.209–70 to read as follows:

**352.209–70 Organizational Conflicts of Interest.**

As prescribed in 309.507–1(b), insert the following provision:

Organizational Conflicts of Interest (DATE)

(a) It is in the best interest of the Government to avoid situations which might create an organizational conflict of interest or where the Offeror's performance of work under the contract may provide the Contractor with an unfair competitive advantage. The term "organizational conflict of interest" means that because of other activities or relationships with other persons, a person is unable to render impartial assistance or advice to the Government, or the person's objectivity in performing the contract work is or might be otherwise impaired, or the person has an unfair competitive advantage.

(b) The Offeror shall provide a statement with its offer which describes, in a concise manner, all relevant facts concerning any past, present, or currently planned interest (financial, contractual, organizational, or otherwise) or actual or potential organizational conflicts of interest relating to the services to be provided under this solicitation. The Offeror shall also provide statements with its offer containing the same information for any consultants and subcontractors identified in its proposal and which will provide services under the solicitation. The Offeror may also provide relevant facts that show how its organizational and/or management system or other actions would avoid or mitigate any actual or potential organizational conflicts of interest.

(c) Based on this information and any other information solicited or obtained by the Contracting Officer, the Contracting Officer may determine that an organizational conflict of interest exists which would warrant disqualifying the Contractor for award of the contract unless the organizational conflict of interest can be mitigated to the Contracting Officer's satisfaction by negotiating terms and

conditions of the contract to that effect. If the conflict of interest cannot be mitigated and if the Contracting Officer finds that it is in the best interest of the United States to award the contract, the Contracting Officer shall request a waiver in accordance with FAR 9.503.

(d) Nondisclosure or misrepresentation of actual or potential organizational conflicts of interest at the time of the offer or arising as a result of a modification to the contract, may result in the termination of the contract at no expense to the Government.

(End of provision)

**352.211–1 through 352.211–3 [Redesignated as 352.211–70 through 352.211–72]**

■ 27. Redesignate sections 352.211–1 through 352.211–3 as sections 352.211–70 through 352.211–72.

■ 28. Revise newly redesignated sections 352.211–70 through 352.211–72 to read as follows:

**352.211–70 Public Accommodations and Commercial Facilities.**

As prescribed in 311.7102, insert the following clause:

Public Accommodations and Commercial Facilities (DATE)

The Contractor agrees as follows:

(a) Except for ad hoc meetings necessary or incidental to contract performance, the Contractor shall develop a plan to assure that any event held pursuant to this contract will meet or exceed the minimum accessibility standards set forth in 28 CFR part 36—Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities. The Contractor shall submit the plan to the Contracting Officer and must receive approval prior to the event. The Contractor may submit a consolidated or master plan for contracts requiring numerous events in lieu of separate plans.

(b) The Contractor shall manage the contract in accordance with the standards set forth in 28 CFR part 36.

(End of clause)

**352.211–71 Conference Sponsorship Requests and Conference Materials Disclaimer.**

As prescribed in 311.7202, insert the following clause:

Conference Sponsorship Request and Conference Materials Disclaimer (DATE)

(a) If HHS is not the sole provider of funding under this contract, then the Contractor shall submit a written request (including rationale) to the Contracting Officer for permission to claim such HHS sponsorship, prior to the Contractor claiming HHS conference sponsorship.

(b) The Contractor shall include the following statement on conference materials, including promotional materials, agendas, and websites, whether or not HHS is the conference sponsor:

"This conference was funded, in whole or in part, through a contract (insert contract number) with the Department of Health and

Human Services (HHS) (insert name of OPDIV or STAFFDIV). The views expressed in written conference materials and by speakers and moderators at this conference, do not necessarily reflect the official policies of HHS, nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government."

(c) Unless authorized in writing by the Contracting Officer, the Contractor shall not display the HHS logo on any conference materials.

(End of clause)

**352.211–72 Paperwork Reduction Act Requirements.**

As prescribed in 311.7301, insert the following clause:

Paperwork Reduction Act Requirements (DATE)

(a) This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Representative shall be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall not expend any funds or begin any data collection until the Contracting Officer provides the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

(End of clause)

■ 29. Add section 352.212–70 to read as follows:

**352.212–70 Gray Market and Counterfeit Items.**

As prescribed in 312.301(f), insert the following clause:

Gray Market and Counterfeit Items (DATE)

(a) No used, refurbished, or remanufactured supplies or equipment/parts shall be provided. This procurement is for new Original Equipment Manufacturer (OEM) items only. No gray market items shall be provided. Gray market items are OEM goods intentionally or unintentionally sold outside an authorized sales territory or sold

by non-authorized dealers in an authorized sales territory.

(b) No counterfeit supplies or equipment/parts shall be provided. Counterfeit items include unlawful or unauthorized reproductions, substitutions, or alterations that have been mismarked, misidentified, or otherwise misrepresented to be an authentic, unmodified item from the original manufacturer, or a source with the express written authority of the original manufacturer or current design activity, including an authorized aftermarket manufacturer. Unlawful or unauthorized substitutions include used items represented as new, or the false identification of grade, serial number, lot number, date code, or performance characteristics.

(c) The vendor shall be an OEM, authorized dealer, authorized distributor or authorized reseller for the proposed equipment/system, verified by an authorization letter or other documents from the OEM. All software licensing, warranty and service associated with the equipment/system shall be in accordance with the OEM terms and conditions.

(End of clause)

■ 30. Revise section 352.215–70 to read as follows:

**352.215–70 Late Proposals and Revisions—R&D Solicitations.**

As prescribed in 315.209–70, insert the following provision:

Late Proposals and Revisions—R&D Solicitations (DATE)

Notwithstanding the procedures contained in the provision at FAR 52.215–1, Instructions to Offerors—Competitive Acquisition, paragraph (c)(3), the Contracting Officer may consider a proposal received for biomedical or behavioral research and development (R&D) solicitations after the date specified for receipt if—

(a) It appears to offer significant cost or technical advantage to the Government; and

(b) It was received before proposals were distributed for evaluation; or

(c) It was received within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

■ 31. Add section 352.215–71 to read as follows:

**352.215–71 Use of Non-Federal Evaluators—Conditions for Evaluating Proposals.**

As prescribed in 315.305–71, insert the following provision:

Non-Federal Evaluators—Conditions for Evaluating Proposals (DATE)

(a) *Prohibition on the use and release of proposal data.* The contractor agrees that it and its employees, as well as any subcontractors and their employees as non-Federal evaluators will use the data (trade secrets, business data, and technical data) contained in any proposals under review for evaluation purposes only. Further, the contractor, its employees, and subcontractors and their employees may not release, in

whole or in part, any material received from the Government to evaluate and must protect and secure the data against unauthorized disclosure. This does not apply to data obtained from another source without restriction.

(b) *Notices, legends, and return of materials.* Any notice or legend placed on the proposal by either HHS, or the offeror shall be applied to any reproduction or abstract provided to the evaluator or made by the evaluator. Upon completion of the evaluation, the evaluator shall return the furnished copy of the proposal or abstract furnished by the Government, and all copies thereof, to the HHS office which initially furnished the proposal for evaluation.

(c) *Electronic records.* All electronic records of proposals or proposal-related material shall be provided to the Government and immediately be destroyed and/or deleted from all electronic media.

(d) *Non-contact with offerors of proposals under evaluation.* The evaluator shall not contact the offeror concerning any aspects of a proposal's contents.

(e) *Requirement to sign agreement.* Each non-Federal evaluator shall complete, sign, and provide to the HHS office furnishing the proposal for review and the Contracting Officer, a signed acknowledgement of this agreement and insert the name, title, company, signature, and date set forth in paragraph (f) of this clause.

(f) *Agreement.* By signing the agreement as shown in this paragraph, the non-Federal evaluator agrees, in order to participate under an HHS contract providing services to HHS as a non-Federal evaluator, to adhere to the terms and conditions set forth in paragraphs (a)–(e) of this provision. The agreement will be retained by the HHS office providing the proposal data and the Contracting Officer.

Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Company: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Date: \_\_\_\_\_

(End of provision)

■ 32. Revise section 352.216–70 to read as follows:

**352.216–70 Allowable Cost and Payment for Hospitals (Profit and Non-Profit).**

As prescribed in 316.307(a)(1), insert the following clause:

Allowable Cost and Payment for Hospitals (Profit and Non-Profit) (DATE)

Payment amounts requested by the Contractor and included in invoices submitted for payment in accordance with Federal Acquisition Regulation (FAR) clause 52.216–7, paragraph (a)(1), must be determined allowable by the Contracting Officer in accordance with the FAR clause at 52.216–7, 45 CFR part 75, appendix IX, and FAR subpart 31.2, in effect on the date of this contract and in accordance with the terms of this contract.

(End of clause)

■ 33. Revise sections 352.219–70 and 352.219–71 to read as follows:

**352.219–70 Notification of Competition Limited to Eligible 8(a) Participants.**

As prescribed in 319.811–370(a), insert the following clause and use in conjunction with the clause at FAR 52.219–18:

Notification of Competition Limited to Eligible 8(a) Participants (DATE)

Substitute paragraph (c) in FAR Clause 52.219–18 as follows:

(c) Any award resulting from this solicitation will be made directly by the Contracting Officer to the successful 8(a) offeror. Although SBA is not identified as such in the award form, SBA is still the Prime Contractor. Contractor shall comply with the limitations on subcontracting as provided in 13 CFR 125.6 and all other 8(a) program requirements, as set forth in 13 CFR part 124.

(End of clause)

**352.219–71 Notification of Section 8(a) Direct Award.**

As prescribed in 319.811–70(b), insert the following clause:

Notification of Section 8(a) Direct Award (DATE)

(a) Offers are solicited only from small business concerns expressly certified by the Small Business Administration (SBA) for participation in the SBA's 8(a) Program. By submission of its offer, the Offeror represents that it is in good standing and that it meets all of the criteria for participation in the program in accordance with 13 CFR part 124.

(b) Any award resulting from this solicitation will be made directly by the Contracting Officer to the successful 8(a) offeror. Although SBA is not identified as such in the award form, SBA is still the Prime Contractor.

(c) This contract is issued as a direct award between the contracting activity and the 8(a) Contractor pursuant to the Partnership Agreement (PA) between the Small Business Administration (SBA) and the Department of Health and Human Services.

(d) SBA retains responsibility for 8(a) certification, 8(a) eligibility determinations and related issues, and providing counseling and assistance to the 8(a) Contractor under the 8(a) program. The cognizant SBA district office is: \_\_\_\_\_ [To be completed by the Contracting Officer at the time of award].

(e) The contracting activity is responsible for administering the contract and taking any action on behalf of the Government under the terms and conditions of the contract. However, the contracting activity shall give advance notice to the SBA before it issues a final notice terminating performance, either in whole or in part, under the contract. The contracting activity shall obtain SBA's approval prior to processing any novation agreement(s). The contracting activity may assign contract administration functions to a contract administration office.

(f) The Contractor agrees:

(1) To notify the Contracting Officer, simultaneous with its notification to SBA (as required by SBA's 8(a) regulations), when the owner or owners upon whom 8(a) eligibility



is based plan to relinquish ownership or control of the concern.

(2) Consistent with 15 U.S.C. 637(a)(21), transfer of ownership or control shall result in termination of the contract for convenience, unless SBA waives the requirement for termination prior to the actual relinquishing of ownership and control.

(3) It will adhere to the requirements of FAR 52.219-14, Limitations of Subcontracting, and other requirements in 13 CFR part 124 and 13 CFR 125.6, as applicable

(g) Any proposed joint venture involving an 8(a) Participant must be approved by SBA before contracts are awarded.

(End of clause)

■ 34. Revise section 352.222-70 to read as follows:

**352.222-70 Contractor Cooperation in Equal Employment Opportunity and Anti-Harassment Investigations.**

As prescribed in 322.810(e), insert the following clause:

Contractor Cooperation in Equal Employment Opportunity and Anti-Harassment Investigations (DATE)

(a) *Definitions.* As used in this clause—*Complaint* means a formal or informal complaint that has been filed with Health and Human Services (HHS), HHS agency Equal Employment Opportunity (EEO) officials, the Equal Employment Opportunity Commission (EEOC), the Office of Federal Contract Compliance Programs (OFCCP) or a court of competent jurisdiction.

*Contractor employee* means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide HHS with that employee's last known mailing address, email address, and telephone number, if that employee has been identified as a witness in an EEO or Anti-Harassment complaint or investigation.

*Good faith cooperation* means, but is not limited to, making Contractor employees available, with the presence or assistance of counsel as deemed appropriate by the Contractor, for—

(1) Formal and informal interviews by EEO counselors, the OFCCP, or other Agency officials processing EEO or Anti-Harassment complaints;

(2) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;

(3) Reviewing and signing appropriate affidavits or declarations summarizing statements provided by such Contractor employees during EEO or Anti-Harassment investigations;

(4) Producing documents requested by EEO counselors, EEO investigators, OFCCP investigators, Agency employees, or the

EEOC in connection with a pending EEO or Anti-Harassment complaint; and

(5) Preparing for and providing testimony in depositions or in hearings before the Merit Systems Protection Board, EEOC, OFCCP, and U.S. District Court.

(b) *Cooperation with investigations.* In addition to complying with the clause at FAR 52.222-26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Health and Human Services (HHS) in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614 and internal Anti-Harassment investigations.

(c) *Compliance.* Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default (or for cause when using FAR part 12 procedures) in accordance with the termination clause contained in the contract.

(d) *Subcontract flowdown.* The Contractor shall include the terms and conditions of this clause in its entirety in all subcontract solicitations and subcontracts awarded, at any tier, under this contract.

(End of clause)

■ 35. Revise sections 352.223-70 and 352.223-71 to read as follows:

**352.223-70 Instructions to Offerors—Sustainable Acquisition Plan.**

As prescribed in 323.109-70, insert the following provision:

Instructions to Offerors—Sustainable Acquisition Plan (DATE)

Offerors shall include a Sustainable Acquisition Plan in their technical proposals. The Plan must describe their approach and the quality assurance mechanisms in place for applying FAR subpart 23.1, Sustainable Products and Services, and other Federal laws, regulations and Executive Orders governing sustainable acquisition. The Plan shall clearly identify those products and services included in Federal sustainable acquisition preference programs by categorizing them along with their respective price/cost in the following eight groups: Recycled Content, Energy Efficient, Biobased, Environmentally Preferable, Electronic Product Environment Assessment Tool, Water-Efficient, Non-Ozone Depleting Substances, and Alternative Fuel Vehicle and Alternative Fuels.

(End of provision)

**352.223-71 Safety and Health.**

As prescribed in 323.304-70, insert the following clause:

Safety and Health (DATE)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/

enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at <https://www.osha.gov/>.

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 *et seq.*). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at <https://www.cdc.gov/biosafety/publications/index.htm>.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street NW, Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at <https://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-han>.

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable "Changes" clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice

of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

■ 36. Add sections 352.225–70 and 352.225–71 to read as follows:

**352.225–70 Made in America—Personal Protective Equipment.**

As prescribed in 325.7103(a), insert the following clause:

Made in America—Personal Protective Equipment (DATE)

(a) *Definitions.* As used in this clause—*Component*, as applied to an item described in subsection (b) of this clause, means an article, material, or supply incorporated directly into personal protective equipment.

*Domestic personal protective equipment*, as applied to an item described in subsection (b) of this clause, means personal protective equipment, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.

*Foreign-made domestic personal protective equipment*, as applied to an item described in subsection (b) of this clause, means personal protective equipment that is assembled outside the United States containing only materials and components that are grown, reprocessed, reused, or produced in the United States.

*Foreign personal protective equipment* means personal protective equipment other than domestic personal protective equipment or foreign-made domestic personal protective equipment.

*Personal protective equipment*, as applied to an item described in subsection (b) of this clause, means surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing

to protect an individual from the transmission of disease.

*United States*, as applied to an item described in subsection (b) of this clause, means the 50 States, the District of Columbia, and the possessions of the United States.

(b) *Requirement.* The Contractor shall deliver only domestic personal protective equipment, unless it specified delivery of foreign-made domestic personal protective equipment in the provision of the solicitation entitled “Made in America Certificate—Personal Protective Equipment.”

(End of clause)

**352.225–71 Made in America Certificate—Personal Protective Equipment.**

As prescribed in 325.7103(b), insert the following provision:

Made In America Certificate—Personal Protective Equipment (DATE)

(a)(1) The Offeror certifies that each item of personal protective equipment, except those listed in paragraph (b) of this provision, is domestic personal protective equipment.

(2) The Offeror shall list offered foreign-made domestic personal protective equipment items in paragraph (b).

(3) The terms “domestic personal protective equipment,” “foreign-made domestic personal protective equipment,” “foreign personal protective equipment,” and “personal protective equipment,” are defined in the clause of this solicitation entitled “Made in America—Personal Protective Equipment.”

(b) Foreign-made Domestic Personal Protective Equipment:

Line-Item No.	Country of origin
[List as necessary]	

[List as necessary]

(End of provision)

**352.226–1 through 352.226–7 [Redesignated as 352.226–70 through 352.226–76]**

■ 37. Redesignate sections 352.226–1 through 352.226–7 as sections 352.226–70 through 352.226–76.

■ 38. Revise newly redesignated sections 352.226–70 through 352.226–76 to read as follows:

*	*	*	*	*
352.226–70	Indian Preference.			
352.226–71	Indian Preference Program.			
352.226–72	Native American Graves Protection and Repatriation Act.			
352.226–73	Notice of Indian Small Business Economic Enterprise Set-Aside.			
352.226–74	Notice of Indian Economic Enterprise Set-Aside.			
352.226–75	Indian Economic Enterprise Subcontracting Limitations.			
352.226–76	Indian Economic Enterprise Representation.			
*	*	*	*	*

**352.226–70 Indian Preference.**

As prescribed in 326.7005(a), insert the following clause:

Indian Preference (DATE)

(a) The Contractor agrees to give preference in employment opportunities under this contract to Indians who can perform required work, regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. To the extent feasible and consistent with the efficient performance of this contract, the Contractor further agrees to give preference in employment and training opportunities under this contract to Indians who are not fully qualified to perform regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. The Contractor also agrees to give preference to Indian organizations and Indian-owned economic enterprises in the awarding of any subcontracts to the extent feasible and consistent with the efficient performance of this contract. The Contractor shall maintain the necessary statistical records to demonstrate compliance with this paragraph.

(b) In connection with the Indian employment preference requirements of this clause, the Contractor shall provide reasonable opportunities for training, incident to such employment. Such training shall include on-the-job, classroom, or apprenticeship training designed to increase the vocational effectiveness of an Indian employee.

(c) If the Contractor is unable to fill its employment and training opportunities after giving full consideration to Indians as required by this clause, the Contractor may satisfy those needs by selecting non-Indian persons in accordance with the clause of this contract entitled “Equal Opportunity.”

(d) If no Indian organizations or Indian-owned economic enterprises are available under reasonable terms and conditions, including price, for awarding of subcontracts in connection with the work performed under this contract, the Contractor agrees to comply with the provisions of this contract involving utilization of small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; women-owned small businesses; or small disadvantaged businesses.

(e) As used in this clause,

(1) *Indian* means a person who is a member of an Indian tribe. If the Contractor has reason to doubt that a person seeking employment preference is an Indian, the Contractor shall grant the preference but shall require the individual provide evidence within 30 days from the tribe concerned that the person is a member of the tribe.

(2) *Indian tribe* means an Indian tribe, pueblo, band, nation, or other organized group or community, including Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601) which the United States recognizes as eligible for the special programs and services provided to Indians because of its status as Indians.

(3) *Indian organization* means the governing body of any Indian Tribe or entity

established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77; 25 U.S.C. 1451).

(4) *Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and that ownership shall encompass active operation and control of the enterprise.

(f) The Contractor agrees to include the provisions of this clause, including this paragraph (f), in each subcontract awarded at any tier under this contract.

(g) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may pursue any other remedies authorized by law or by other provisions of the contract.

(End of clause)

### 352.226–71 Indian Preference Program.

As prescribed in 326.7005(b), insert the following clause:

Indian Preference Program (DATE)

(a) In addition to the requirements of the clause of this contract entitled “Indian Preference,” the Contractor agrees to establish and conduct an Indian preference program which will expand opportunities for Indians to receive preference for employment and training in connection with the work performed under this contract, and which will expand the opportunities for Indian organizations and Indian-owned economic enterprises to receive a preference in the awarding of subcontracts. In this connection, the Contractor shall perform the following:

(1) Designate a liaison officer who will maintain liaison with the Government and the Tribe(s) on Indian preference matters; supervise compliance with the provisions of this clause; and administer the Contractor’s Indian preference program.

(2) Advise its recruitment sources in writing and include a statement in all employment advertisements that Indian applicants receive preference in employment and training incident to such employment.

(3) Not more than 20 calendar days after award of the contract, post a written notice setting forth the Contractor’s employment needs and related training opportunities in the tribal office of any reservations on or near the contract work location. The notice shall include the approximate numbers and types of employees needed; the approximate dates of employment; any experience or special skills required for employment; training opportunities available; and other pertinent information necessary to advise prospective employees of any other employment requirements. The Contractor shall also request the tribe(s) on or near whose reservation(s) the Contractor will perform contract work to provide assistance filling its employment needs and training opportunities. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact regarding the posting of notices and requests for Tribal assistance.

(4) Establish and conduct a subcontracting program which gives preference to Indian

organizations and Indian-owned economic enterprises as subcontractors (including suppliers) under this contract. The Contractor shall give public notice of existing subcontracting opportunities and, to the extent feasible and consistent with the efficient performance of this contract, shall solicit bids or proposals from Indian organizations or Indian-owned economic enterprises only. The Contractor shall request assistance and information on Indian firms qualified as subcontractors (including suppliers) from the Tribe(s) on or near whose reservation(s) the Contractor will perform contract work. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact regarding the request for assistance and information. Public notices and solicitations for existing subcontracting opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including—

(i) A clear description of the supplies or services required, including quantities, specifications, and delivery schedules that facilitate the participation of Indian firms;

(ii) A statement indicating that Indian organizations and Indian-owned economic enterprises will receive preference in accordance with section 7(b) of Public Law 93–638; 88 Stat. 2205; 25 U.S.C. 450e(b);

(iii) Definitions for the terms “Indian organization” and “Indian-owned economic enterprise” prescribed under the “Indian Preference” clause of this contract;

(iv) A statement that the bidder or offeror shall complete certifying that it is an Indian organization or Indian-owned economic enterprise; and

(v) A closing date for receipt of bids or proposals which provides sufficient time for preparation and submission of a bid or proposal. If, after soliciting bids or proposals from Indian organizations and Indian-owned economic enterprises, the Contractor receives no responsive bid or acceptable proposal, the Contractor shall comply with the requirements of paragraph (d) of the “Indian Preference” clause of this contract. If the Contractor receives one or more responsive bids or conforming proposals, the Contractor shall award the contract to the low, responsive, responsible bidder or conforming offer from a responsible offeror if the price is reasonable. If the Contractor determines the low responsive bid or conforming proposal’s price is unreasonable, the Contractor shall attempt to negotiate a reasonable price and award a subcontract. If parties cannot agree on a reasonable price, the Contractor shall comply with the requirements of paragraph (d) of the “Indian Preference” clause of this contract.

(5) Maintain written records under this contract which demonstrate—

(i) The numbers of Indians seeking employment for each employment position available under this contract;

(ii) The number and types of positions filled by Indians and non-Indians;

(iii) The total number of Indians employed under this contract;

(iv) For those positions having both Indian and non-Indian applicants, and a non-Indian is selected for employment, the reason(s)

why the Contractor did not select the Indian applicant;

(v) Actions taken to give preference to Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract;

(vi) Reasons why Indian subcontractors and or suppliers did not receive preference for each requirement where the Contractor determined that such preference was inconsistent with efficient contract performance; and

(vii) The number of Indian organizations and Indian-owned economic enterprises contacted, and the number receiving subcontract awards under this contract.

(6) Submit to the Contracting Officer for approval a quarterly report summarizing the Contractor’s Indian preference program and indicating the number and types of available positions filled by Indians and non-Indians, and the dollar amounts of all subcontracts awarded to Indian organizations and Indian-owned economic enterprises, and to all other firms.

(7) Maintain records pursuant to this clause and keep them available for review by the Government for one year after final payment under this contract, or for such longer period in accordance with requirements of any other clause of this contract or by applicable law or regulation.

(b) For purposes of this clause, the following definitions of terms shall apply:

(1) The terms *Indian*, *Indian tribe*, *Indian organization*, and *Indian-owned economic enterprise* are defined in the clause of this contract entitled *Indian Preference*.

(2) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601 *et seq.*)

(3) *On or near an Indian reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably expect to commute to and from in the course of a work day.

(c) Nothing in the requirements of this clause shall preclude Indian tribes from independently developing and enforcing their own Indian preference requirements. Such requirements must not conflict with any Federal statutory or regulatory requirement dealing with the award and administration of contracts.

(d) The Contractor agrees to include the provisions of this clause, including this paragraph (d), in each subcontract awarded at any tier under this contract and to notify the Contracting Officer of such subcontracts.

(e) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may pursue any other remedies authorized by law or by other provisions of the contract.

(End of clause)

**352.226–72 Native American Graves Protection and Repatriation Act.**

As prescribed in 326.7201, insert the following clause:

Native American Graves Protection and Repatriation Act (DATE)

(a) Public Law 101–601, dated November 16, 1990, also known as the Native American Graves Protection and Repatriation Act, imposes certain responsibilities on individuals and organizations when they discover Native American cultural items (including human remains) on Federal or tribal lands.

(b) In the event the Contractor discovers Native American cultural items (including human remains, associated funerary objects, unassociated funerary objects, sacred objects and cultural patrimony), as defined in the Act during contract performance, the Contractor shall—

(1) Immediately cease activity in the area of the discovery;

(2) Notify the Contracting Officer of the discovery; and

(3) Make a reasonable effort to protect the items discovered before resuming such activity. Upon receipt of the Contractor's discovery notice, the Contracting Officer will notify the appropriate authorities as required by the Act.

(c) Unless otherwise specified by the Contracting Officer, the Contractor may resume activity in the area on the 31st calendar day following the date that the appropriate authorities certify receipt of the discovery notice. The Contracting Officer shall provide to the Contractor the date that the appropriate authorities certify receipt of the discovery notice and the date on which the Contractor may resume activities.

(End of clause)

**352.226–73 Notice of Indian Small Business Economic Enterprise Set-Aside.**

As prescribed in 326.7105(a), and in lieu of the requirements of 48 CFR 19.508, insert the following provision:

Notice of Indian Small Business Economic Enterprise Set-Aside (DATE)

Under the Buy Indian Act, 25 U.S.C. 47, offers are solicited only from Indian Economic Enterprises (see 326.7106) that are also small business concerns. Any acquisition resulting from this solicitation will be from such a concern. As required by 352.226–76(b), offerors shall include a completed Indian Economic Enterprise Representation form in response to Sources Sought Notices, Request for Information (RFI) and as part of the proposal submission. The Indian Economic Enterprise Representation form, available on the IHS DAP public website ([www.IHS.gov/DAP](http://www.IHS.gov/DAP)), shall be included in synopses, presolicitation notices, and solicitations for the acquisitions under the Buy Indian Act. Offers received from enterprises that are not both Indian Economic Enterprises and small business concerns will not be considered and will be rejected.

(End of clause)

**352.226–74 Notice of Indian Economic Enterprise Set-Aside.**

As prescribed in 326.7105(b), insert the following clause:

Notice of Indian Economic Enterprise Set-Aside (DATE)

(a) *Definitions.* As used in this clause: *Alaska Native Claims Settlement Act (ANCSA)* means Pub. L. 92–203 (December 18, 1971), 85 Stat. 688, codified at 43 U.S.C. 1601–1629h.

*Indian* means a person who is an enrolled member of an Indian Tribe or “Native” as defined in the Alaska Native Claims Settlement Act.

*Indian Economic Enterprise* means any business activity owned by one or more Indians or Indian Tribes that is established for the purpose of profit provided that: The combined Indian or Indian Tribe ownership must constitute not less than 51 percent of the enterprise; the Indians or Indian Tribes must, together, receive at least a majority of the earnings from the contract; and the management and daily business operations of an enterprise must be controlled by one or more individuals who are Indians. To ensure actual control over the enterprise, the individuals must possess requisite management or technical capabilities directly related to the primary industry in which the enterprise conducts business. The enterprise must meet these requirements throughout the following time periods—

(1) At the time an offer is made in response to a written solicitation;

(2) At the time of the contract award; and

(3) During the full term of the contract.

*Indian Tribe* means an Indian Tribe, band, nation, or other recognized group or community that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians, including any Alaska Native village or regional or village corporation under the Alaska Native Claims Settlement Act (Pub. L. 92–203, 85 Stat. 688; 43 U.S.C. 1601).

*Representation* means the positive statement by an enterprise of its eligibility for preferential consideration and participation for acquisitions conducted under the Buy Indian Act, 25 U.S.C. 47, in accordance with the procedures in section 326.7106.

(b) *General.* (1) Under the Buy Indian Act, offers are solicited only from Indian Economic Enterprises.

(2) The Contracting Officer will reject all offers received from ineligible enterprises.

(3) Any award resulting from this solicitation will be made to an Indian Economic Enterprise, as defined in paragraph (a) of this clause.

(c) *Required submissions.* In response to this solicitation, an offeror must also provide the following:

(1) A description of the required percentage of the work/costs to be provided by the offeror over the contract term as required by the clause at 352.226–75, Subcontracting Limitations; and

(2) Qualifications of the key personnel (if any) that will be assigned to the contract.

(d) *Required assurance.* The offeror must provide written assurance to the Contracting

Officer that the offeror is and will remain in compliance with the requirements of this clause. It must do this before the Contracting Officer awards the Buy Indian Act contract and upon successful and timely completion of the contract, but before the Contracting Officer accepts the work or product.

(e) *Non-responsiveness.* Failure to provide the information required by paragraphs (c) and (d) of this clause may cause the Contracting Officer to find an offer non-responsive and reject it.

(f) *Eligibility.* (1) Participation in the Mentor-Protégé Program established under section 831 of the National Defense Authorization Act for Fiscal Year 1991 (25 U.S.C. 47 note) does not render an Indian Economic Enterprise ineligible for contracts awarded under the Buy Indian Act.

(2) If a contractor no longer meets the definition of an Indian Economic Enterprise after award, the contractor must notify the Contracting Officer immediately and in writing. The notification must include full disclosure of circumstances causing the contractor to lose eligibility status and a description of any actions that the contractor will take to regain eligibility. Failure to give the Contracting Officer immediate written notification means that:

(i) The economic enterprise may be declared ineligible for future contract awards under this part; and

(ii) The Contracting Officer may consider termination for default if it is in the best interest of the government.

(g) *Representation.* Under the Buy Indian Act, 25 U.S.C. 47, offers are solicited only from Indian Economic Enterprises (see 326.7106). As required by 352.226–76(b), offerors shall include a completed Indian Economic Enterprise Representation form in response to Sources Sought Notices, Request for Information (RFI) and as part of the proposal submission. The Indian Economic Enterprise Representation form, available on the IHS DAP public website ([www.IHS.gov/DAP](http://www.IHS.gov/DAP)), shall be included in synopses, presolicitation notices, and solicitations for the acquisitions under the Buy Indian Act. Offers received from enterprises that are not Indian Economic Enterprises shall not be considered.

(End of clause)

**352.226–75 Indian Economic Enterprise Subcontracting Limitations.**

As prescribed in 326.7105(c), insert the following clause:

Indian Economic Enterprise Subcontracting Limitations (DATE)

(a) *Definitions.* As used in this clause—

(1) *Indian Economic Enterprise* means any business activity owned by one or more Indians or Indian Tribes that is established for the purpose of profit provided that: The combined Indian or Indian Tribe ownership must constitute not less than 51 percent of the enterprise; the Indians or Indian Tribes must, together, receive at least a majority of the earnings from the contract; and the management and daily business operations of an enterprise must be controlled by one or more individuals who are Indians. To ensure actual control over the enterprise, the

individuals must possess requisite management or technical capabilities directly related to the primary industry in which the enterprise conducts business. The enterprise must meet these requirements throughout the following time periods:

(i) At the time an offer is made in response to a written solicitation;

(ii) At the time of the contract award; and

(iii) During the full term of the contract.

(2) *Subcontract* means any contract, as defined in FAR subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contractor or subcontractor. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(3) *Subcontractor* means any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a prime contractor or another subcontractor.

(b) *Required percentages of work by the concern*. The contractor must comply with FAR 52.219-14, Limitations on Subcontracting, clause in allocating what percentage of work to subcontract. The contractor shall not subcontract work exceeding the subcontract limitations in FAR 52.219-14 to a concern other than a responsible Indian Economic Enterprise.

(c) *Work performed by non-IEE subcontractor employees*. Any work that an IEE subcontractor does not perform with its own employee shall be considered subcontracted work for the purpose of calculating percentages of subcontract work in accordance with FAR 52.219-14, Limitations on Subcontracting.

(d) *Cooperation*. The Contractor must—

(1) Carry out the requirements of this clause to the fullest extent; and

(2) Cooperate in any study or survey that the Contracting Officer, Indian Health Service or its agents may conduct to verify the contractor's compliance with this clause.

(e) *Incorporation in subcontracts*. The contractor must incorporate the substance of this clause, including this paragraph (e), in all subcontracts for general services, architect-engineer (A-E) services and construction awarded under this contract.

(End of clause)

### 352.226-76 Indian Economic Enterprise Representation.

As prescribed in 326.7105(d), insert the following provision:

Indian Economic Enterprise Representation  
(DATE)

(a) The offeror must represent as part of its offer that it does meet the definition of Indian Economic Enterprise (IEE) as defined in 326.7101 and that it intends to meet the definition of an IEE throughout the performance of the contract. The offeror must notify the contracting officer immediately, via email, if there is any ownership change affecting compliance with this representation.

(b) The representation must be made on the designated IHS Indian Economic Enterprise Representation form or any successor forms through which the offeror will certify that the ownership requirements defined by 326.7101 are met.

(c) Any false or misleading information submitted by an enterprise when submitting an offer in consideration for an award set-aside under the Buy Indian Act is a violation of the law punishable under 18 U.S.C. 1001. False claims submitted as part of contract performance are subject to the penalties enumerated in 31 U.S.C. 3729 to 3731 and 18 U.S.C. 287.

(End of provision)

### 352.227-11, 352.227-14, and 352.227-70 [Redesignated as 352.227-70, 352.227-71, and 352.227-72]

■ 39. Redesignate sections 352.227-11, 352.227-14, and 352.227-70 as sections 352.227-70, 352.227-71, and 352.227-72.

■ 40. Revise newly redesignated sections 352.227-70 through 352.227-72 to read as follows:

### 352.227-70 Patent Rights—Supplement—Exceptional Circumstances.

As prescribed in 327.303-70, insert the following clause:

Patent Rights—Supplement—Exceptional Circumstances (DATE)

(a) *Definitions*. As used in this clause—  
*Agency* means the U.S. Department of Health and Human Services operating division or agency (*i.e.*, Centers for Disease Control and Prevention, Food and Drug Administration, etc.) that is entering into this contract.

*Class 1 Subject Invention* means a Subject Invention described and defined in the Determination of Exceptional Circumstances (DEC) that will be assigned to a third party assignee, or assigned as directed by the Agency.

*Class 2 Subject Invention* means a Subject Invention described and defined in the DEC.

*Class 3 Subject Invention* means a Subject Invention that does not fall into Class 1 or Class 2 as defined in this clause.

*DEC* means the Determination of Exceptional Circumstances signed by \_\_\_\_\_ [insert approving official] on \_\_\_\_\_ [insert date] and titled “\_\_\_\_\_ [insert description].”

*Invention* means any invention or discovery, which is or may be patentable or otherwise protectable under Title 35 of United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, *et seq.*)

*Made* means, when used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of such invention; or when used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

*Material* means any proprietary material, method, product, composition, compound, or device, whether patented or unpatented, which is provided to the Contractor under this contract.

*Nonprofit organization* means a university or other institution of higher education or an organization of the type described in section

501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

*Practical application* means to manufacture, in the case of a composition or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

*Small business firm* means a small business concern as defined at section 2 of Public Law 85-536, 15 U.S.C. 632 *et seq.*, and FAR 19.102. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.401 through 413, will be used.

*Subject invention* means any invention of the Contractor made in the performance of work under this contract.

*Third party assignee* means any entity or organization that may, as described in the DEC, be assigned Class 1 inventions.

(b) *General*. This clause applies to all Contractor and subcontractor (at all tiers) Subject Inventions.

(c) *Allocation of principal rights*. (1)

*Retention of pre-existing rights*. Third party assignees shall retain all preexisting rights to Material in which the third party assignee has a proprietary interest.

(2) *Allocation of Subject Invention rights*. (i) *Disposition of Class 1 Subject Inventions*.

(A) Assignment to the third party assignee or as directed by the Agency. The Contractor shall assign to the third party assignee designated by the Agency the entire right, title, and interest throughout the world to each Subject Invention, or otherwise dispose of or transfer those rights as directed by the Agency, except to the extent that rights are retained by the Contractor under paragraph (c)(3) of this clause. Any such assignment or other disposition or transfer of rights will be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the U.S. Government to practice or have practiced the Subject Invention for or on behalf of the U.S. throughout the world. Any assignment shall additionally be subject to the “March-in rights” of 35 U.S.C. 203. If the Contractor is a U.S. nonprofit organization it may retain a royalty free, nonexclusive, nontransferable license to practice the invention for all nonprofit research including for educational purposes, and to permit other U.S. nonprofit organizations to do so.

(B) [Reserved]

(ii) *Disposition of Class 2 and 3 Subject Inventions*. Class 2 Subject Inventions shall be governed by FAR clause 52.227-11, Patent Rights-Ownership by the Contractor. However, the Contractor shall grant a license in the Class 2 Subject Inventions to the provider of the Material or other party designated by the Agency as set forth in Alternate I of this clause, if incorporated.

(iii) Class 3 Subject Inventions shall be governed by FAR clause 52.227–11, Patent Rights—Ownership by the Contractor.

(3) *Greater rights determinations.* The Contractor, or an employee-inventor after consultation by the Agency with the Contractor, may request greater rights than are provided in paragraph (c)(1) of this clause in accordance with the procedures of FAR 27.304–1(c). In addition to the considerations set forth in FAR 27.304–1(c), the Agency may consider whether granting the requested greater rights will interfere with rights of the Government or any third party assignee or otherwise impede the ability of the Government or the third party assignee to, for example, develop and commercialize new compounds, dosage forms, therapies, preventative measures, technologies, or other approaches with potential for the diagnosis, prognosis, prevention, and treatment of human diseases.

(i) A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (d)(1) of this clause, and in accordance with the procedures of FAR 27.304–1(c) or not later than 8 months thereafter, unless a longer period is requested in writing by the Contractor and authorized in writing by the Contracting Officer for good cause. Each determination of greater rights under this contract shall be subject to FAR clause 52.227–13, paragraph (c) and to any reservations and conditions deemed to be appropriate by the Agency such as the requirement to assign or exclusively license the rights to Subject Inventions to the third party assignee.

(ii) A determination by the Agency denying a request by the Contractor for greater rights in a Subject Invention may be appealed within 30 days of the date the Contractor is notified of the determination to an Agency official at a level above the individual who made the determination. If greater rights are granted, the Contractor must file a patent application on the invention. Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any Subject Invention in any country for which the Contractor has retained title. Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(d) *Invention disclosure by Contractor.* The Contractor shall disclose in writing each Subject Invention to the Contracting Officer and to the Director, Division of Extramural Inventions and Technology Resources (DETR), if directed by the Contracting Officer, as provided in paragraph (j) of this clause within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters.

(1) The disclosure to the Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was made and all inventors. It

shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication, and if so, whether it has been accepted for publication at the time of disclosure.

(2) In addition, after disclosure to the Agency, the Contractor will promptly notify the Contracting Officer and DETR of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the Contractor. If the Contractor assigns a Subject Invention to the third party assignee, then the Contractor and its employee inventors shall assist the third party assignee in securing patent protection. All costs of securing the patent, including the cost of the Contractor's assistance, are at the third party's expense. Any assistance provided by the Contractor and its employee inventors to the third party assignee or other costs incurred in securing patent protection shall be solely at the third party's expense and not billable to the contract.

(e) *Contractor action to protect the third party assignee's and the Government's interest.* (1) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: Establish or confirm the rights the Government has throughout the world in Subject Inventions pursuant to paragraph (c) of this clause; convey title to a third party assignee in accordance with paragraph (b) of this clause; and enable the third party assignee to obtain patent protection throughout the world in that Subject Invention.

(2) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention “made” under contract in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on Subject Inventions and to establish the Government's rights or a third party assignee's rights in the Subject Inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) If the Contractor is granted greater rights, the Contractor agrees to include, within the specification of any United States non-provisional patent application it files, and any patent issuing thereon, covering a Subject Invention the following statement:

“This invention was made with Government support under (identify the Contract) awarded by (identify the specific Agency). The Government has certain rights in the invention.”

(4) The Contractor agrees to provide a final invention statement and certification prior to the closeout of the contract listing all Subject Inventions or stating that there were none.

(f) *Subcontracts.* (1) The Contractor shall include this clause in all subcontracts, regardless of tier, for experimental, developmental, or research work. At all tiers, the clause must be modified to identify the parties with the statement: “References to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause.” The Contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's Subject Inventions.

(2) In subcontracts, at any tier, the Agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (k)(1)(4) of FAR clause 52.227–11.

(g) *Reporting on utilization of Subject Inventions in the event greater rights are granted to the Contractor.* The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under paragraph (c)(3) has been granted by the Agency. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data and information as the Agency may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by the Agency in connection with any march-in proceeding undertaken by the Agency in accordance with paragraph (h) of this clause. As required by 35 U.S.C. 202(c)(5), the Agency agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

(h) *Preference for United States industry in the event greater rights are granted to the Contractor.* Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United

States or that under the circumstances domestic manufacture is not commercially feasible.

(i) *March-in rights in the event greater rights are granted to the Contractor.* The Contractor acknowledges that, with respect to any Subject Invention in which it has acquired ownership through the exercise of the rights specified in paragraph (c)(3) of this clause, the Agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of Agency in effect on the date of contract award.

(j) Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the Contractor. If the Contractor is a nonprofit organization, it shall—

(1) Not assign rights to a Subject Invention in the United States without the written approval of the Agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a Subject Invention with the inventor, including Federal employee co-inventors (but through their Agency if the Agency deems it appropriate) when the Subject Invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to Subject Inventions, after payment of expenses (including payments to inventors) incidental to the administration of Subject Inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of Subject Inventions that are small business concerns, and give a preference to a small business concern when licensing a Subject Invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(k) *Communications.* All invention disclosures and requests for greater rights shall be sent to the Agency Contracting Officer, as directed by the Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the

Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to:

[\_\_\_\_\_] *Insert Agency Address*  
Agency Invention Reporting website: <https://public.era.nih.gov/iedison>.

(End of clause)

*Alternate I* (DATE). As prescribed in 327.303–70, the license to Class 2 inventions recited in 352.227–70(c)(2)(ii) is as follows:

[\_\_\_\_\_] *Insert description of license to Class 2 inventions*

**352.227–71 Rights in Data—Supplement—Exceptional Circumstances.**

As prescribed in 327.409–70(a), insert the following clause:

Rights in Data—Supplement—Exceptional Circumstances (DATE)

(a) In addition to any other provisions, set forth in this contract, the Contractor shall ensure that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions. Accordingly, the Contractor will provide the Contracting Officer a copy of any publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure. Upon the Contracting Officer's request, the Contractor agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with HHSAR clause at 352.227–70, Patent Rights—Supplement—Exceptional Circumstances. (See FAR clause at 52.227–14, Rights in Data-General.)

(b) The Contractor agrees that in accordance with FAR clause 52.214–14, paragraph (d)(2), proprietary data on material(s) provided to the Contractor under or through this contract shall be used only for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(End of clause)

**352.227–72 Publications and Publicity.**

As prescribed in 327.409–70(b), insert the following clause:

Publications and Publicity (DATE)

(a) Unless otherwise specified in this contract, the Contractor may publish the results of its work under this contract. The Contractor shall promptly send to the Contracting Officer's Representative—

(1) A copy of each article submitted for publication;

(2) Information of when the article or other publication is published; and,

(3) A copy of the published article.

(b) Unless authorized in writing by the Contracting Officer, the Contractor shall not display the HHS logo or the official HHS seal, including HHS Operating Division or Staff Division logos, on any publications.

(c) The Contractor shall not reference the product(s) or service(s) awarded under this contract in advertising, as defined in FAR 31.205–1, in any manner which states or implies HHS approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause in all subcontracts where the subcontractor may propose publishing the results of its work under a subcontract.

(End of clause)

■ 41. Revise sections 352.231–70 through 352.237–75 to read as follows:

*	*	*	*	*
Sec.				
352.231–70	Salary Rate Limitation.			
352.232–70	Incremental Funding.			
352.232–71	Electronic Submission of Payment Requests.			
352.233–70	Choice of Law (Overseas).			
352.233–71	Litigation and Claims.			
352.236–70	Design-Build Contracts.			
352.237–70	Nonsmoking Policy—Delivery of Services to Children.			
352.237–71	Reporting of Child Abuse.			
352.237–72	Requirement for Background Checks.			
352.237–73	Indian Child Protection and Family Violence Act—Background Investigations.			
352.237–74	Non-Discrimination in Service Delivery.			
352.237–75	Key Personnel.			
*	*	*	*	*

**352.231–70 Salary Rate Limitation.**

As prescribed in 331.171, insert the following clause:

Salary Rate Limitation (DATE)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the contract was awarded.

(b) For purposes of the salary rate limitation, the terms “direct salary,” “salary,” and “institutional base salary,” have the same meaning and are collectively referred to as “direct salary,” in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.



(e) See the salaries and wages pay tables on the Office of Personnel Management website for Federal Executive Schedule salary levels.

(f) Contractors shall flow down this clause into any resulting subcontract(s).

(End of clause)

### 352.232-70 Incremental Funding.

As prescribed in 332.706-2(b), insert the following provision:

Incremental Funding (DATE)

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clause at FAR 52.232-22, "Limitation of Funds". The initial obligation of funds under the contract is expected to cover

[insert the appropriate increment of performance]. The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining periods of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

### 352.232-71 Electronic Submission of Payment Requests.

As prescribed in 332.7003, insert the following clause:

Electronic Submission of Payment Requests (DATE)

(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) *Submission instructions.* 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](http://www.ipp.gov) or any successor site.

(c) *Alternate submission procedures.* 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) *Submission of alternate payment procedures authorization.* 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)

### 352.233-70 Choice of Law (Overseas).

As prescribed in 333.215-70(a), insert the following clause:

Choice of Law (Overseas) (DATE)

This contract shall be construed in accordance with the substantive laws of the United States of America. By the execution of this contract, the Contractor expressly agrees to waive any rights to invoke the jurisdiction of local national courts where this contract is performed and agrees to accept the exclusive jurisdiction of the United States Civilian Board of Contract Appeals or the United States Court of Federal Claims for hearing and determination of any and all disputes that may arise under the Disputes clause of this contract.

(End of clause)

### 352.233-71 Litigation and Claims.

As prescribed in 333.215-70(b), insert the following clause:

Litigation and Claims (DATE)

(a) The Contractor shall provide written notification immediately to the Contracting Officer of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled "Allowable Cost and Payment."

(b) Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent documents received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action.

(c) If the Government undertakes a settlement or defense of an action or claim, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by other terms or conditions of this contract, by law or regulation, or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Government shall not reimburse or indemnify the Contractor for any liability loss, cost, or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to

real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

### 352.236-70 Design-Build Contracts.

As prescribed in 336.570(a), insert the following clause:

Design-Build Contracts (DATE)

(a) *General.* (1) The contract constitutes and defines the entire agreement between the Contractor and the Government. This contract includes the standard or special contract clauses and schedules included at the time of award. This contract incorporates by reference:

(i) The solicitation in its entirety (with the exception of instructions to offerors and evaluation criteria which do not become part of the award document);

(ii) The specifications and statement of work;

(iii) All drawings, cuts and illustrations, included in the solicitation and any amendments during all proposal phases leading up to award;

(iv) Exhibits and other attachments; and

(v) The successful Offeror's accepted proposal.

(2) In the event of conflict or inconsistency between any of the requirements of the various portions of this contract, precedence shall be given in the following order:

(i) Betterments: Any portions of the Offeror's proposal which exceed the requirements of the solicitation and which go beyond repair and improve the value of the property.

(ii) The contract clauses and schedules included during the solicitation or at the time of award.

(iii) All requirements (other than betterments) of the accepted proposal.

(iv) Any design products, including but not limited to plans, specifications, engineering studies and analyses, shop drawings, equipment installation drawings, etc. These are "deliverables" under the contract and are not part of the contract itself.

(3) Design products must conform to all requirements of the contract, in the order of precedence stated here.

(b) *Responsibility of the contractor for design.* (1) The Contractor shall be responsible for the professional quality, technical accuracy, and the coordination of all designs, drawings, specifications, and other non-construction services furnished by the Contractor under this contract. The Contractor shall, without additional compensation, correct or revise any errors or deficiency in its designs, drawings, specifications, and other non-construction services and perform any necessary rework or modifications, including any damage to real or personal property, resulting from the design error or omission.

(2) Neither the Government's review, approval or acceptance of, nor payment for, the services required under this contract shall be construed to operate as a waiver of any rights under this contract or of any cause of action arising out of the performance of this contract. The Contractor shall be and remain liable to the Government in

accordance with applicable law for all damages to the Government caused by the Contractor's negligent performance of any of these services furnished under this contract.

(3) The rights and remedies of the Government provided for under this contract are in addition to any other rights and remedies provided by law.

(4) If the Contractor is comprised of more than one legal entity each such entity shall be jointly and severally liable with respect to all rights and remedies of the Government.

(c) *Sequence of design—construction.* (1) After receipt of the Contract Award, the Contractor shall initiate design, comply with all design submission requirements, and obtain Government review of each submission. No construction may be started until the Government reviews the Final Design submission and determines it satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

(2) If the Government allows the Contractor to proceed with limited construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any completed or in-progress construction related to the pending revisions until they are completed, resubmitted, and are satisfactory to the Government.

(3) No payment will be made for any completed or in-progress construction until all required submittals have been made, reviewed, and are satisfactory to the Government.

(d) *Constructor's role during design.* The Contractor's construction management key personnel shall be actively involved during the design process to effectively integrate the design and construction requirements of this contract. In addition to the typical required construction activities, the constructor's involvement includes, but is not limited to actions such as: integrating the design schedule into the Master Schedule to maximize the effectiveness of fast-tracking design and construction (within the limits, if any, allowed in the contract), ensuring constructability and economy of the design, integrating the shop drawing and installation drawing process into the design, executing the material and equipment acquisition programs to meet critical schedules, effectively interfacing the construction Quality Control (QC) program with the design QC program, and maintaining and providing the design team with accurate, up-to-date redline and as-built documentation. The Contractor shall require and manage the active involvement of key trade subcontractors in the above activities.

(e) *Preconstruction conference.* (1) A preconstruction conference will be arranged by the Contracting Officer after award of contract and before commencement of work. The Contracting Officer or designated representative will notify the Contractor of the time, date, and location for the meeting.

At this conference, the Contractor shall be oriented with respect to Government procedures and line of authority, contractual, administrative, and construction matters.

(2) The Contractor shall bring to this conference, in completed form, a Certificate of Insurance, plus the following items in either completed or draft form—

- (i) Accident Prevention Plan;
- (ii) Quality Control Plan;
- (iii) Letter Appointing Superintendent;
- (iv) Transmittal Register;
- (v) Power of Attorney and Certified Copy of Resolution;
- (vi) Network Analysis System, (when identified in the contract schedule as applicable);
- (vii) List of Subcontractors;
- (viii) SF 1413;
- (ix) Performance and Payment Bonds; and
- (x) Schedule of Values.

(3) A letter of record will be written documenting all items discussed at the conference, and a copy will be furnished by the Contracting Officer to all in attendance.

(f) *Payment for design under fixed-price design-build contracts.* (1) The Contracting Officer may approve progress payments for work performed during the project design phase up to the maximum amount of \_\_\_\_\_ [Contracting Officer to insert percent figure up to 6%.] If none stated, the amount is four (4) percent of the contract price.

(2) Contractor invoices for payment must be accompanied by satisfactory documentation supporting the amounts for which payments are requested. Progress payments approved by the Contracting Officer during the project design phase in no way constitute an acceptance of functional and aesthetic design elements nor acceptance of a final settlement amount in the event of a buy-out nor a waiver of any contractual requirements.

(g) *Unscheduled jobsite shutdowns.* Due to security reasons during the life of this contract the Government may on an unscheduled basis require the contractor to shut down its jobsite for two days per year at no additional cost. This shall not constitute a suspension of work under FAR 52.242-14, Suspension of Work.

(End of clause)

*Alternate I* (DATE). When fast track procedures are being used, replace paragraph (c) of the basic clause with the following:

(c) *Sequence of design build.* (1) After receipt of the Contract Award the Contractor shall initiate design, comply with all design submissions requirements and obtain Government review of each submission. The contractor may begin construction on portions of the work for which the Government has reviewed the final design submission and has determined satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal

required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

(2) If the Government allows the Contractor to proceed with the construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any in-place construction related to the pending revisions until they are completed, resubmitted, and are satisfactory to the Government.

(3) No payment will be made for any in-place construction until all required submittals have been made, reviewed, and are satisfactory to the Government.

### **352.237-70 Nonsmoking Policy—Delivery of Services to Children.**

As prescribed in 337.7006(a), insert the following clause:

Nonsmoking Policy—Delivery of Services to Children (DATE)

(a) *Prohibition.* Smoking is prohibited in facilities where certain federally funded children's services are provided pursuant to the Pro-Children Act of 2001 (20 U.S.C. 7181, Public Law 107-110, sec. 4301 (the Act)). Accordingly, smoking is prohibited within any indoor facility (or portion thereof), whether owned, leased, or contracted for, or involving indoor facilities that are constructed, operated, or maintained with Federal funds, that is used for the routine or regular provision of—

(1) Kindergarten, elementary, or secondary education or library services, or

(2) Health or day care services that are provided to children under the age of 18.

(b) *Agreement.* The offeror represents and understands that by submission of its bid or offer and if awarded a contract for this requirement, the Contractor agrees to comply with the requirements of the Act and the prohibition of smoking in facilities as specified in paragraph (a) of this clause. The Contractor shall enforce the provisions of this clause and ensure that each of its employees, subcontractors and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act.

(c) *Penalties.* Failure to comply with the Act may result in the imposition of a civil monetary penalty in an amount not to exceed \$1,000 for each violation and/or the imposition of an administrative compliance order on the responsible party. Each day a violation continues constitutes a separate violation. In the case of any civil penalty assessed, the total amount shall not exceed 50 percent of the amount of Federal funds received by the Contractor for the fiscal year in which the continuing violation occurred. Penalties will be imposed only after appropriate written notice, or an administrative compliance order may be issued by the designated HHS official only after an opportunity for a hearing in accordance with 5 U.S.C. 554. Before making such assessment or issuing such order, or both, the Secretary of HHS or designee shall

give written notice of the assessment or order to the Contractor by certified mail with return receipt and provide information in the notice of an opportunity to request in writing, not later than 30 days after the date of receipt of such notice, such hearing. Notwithstanding any specific civil penalties and compliance orders referenced herein, the Contracting Officer may take other remedies under the contract for failure to comply with the terms and conditions of the contract.

(d) *Subcontract flow down.* The Contractor shall insert the text of this clause, including this paragraph (d), in subcontracts at any tier. The Contractor shall be responsible for compliance by any subcontractor or lower-tier subcontractor with the provisions set forth in paragraphs (a) through (c) of this clause.

(End of clause)

### 352.237-71 Reporting of Child Abuse.

As prescribed in 337.7006(b), insert the following clause:

Reporting of Child Abuse (DATE)

(a) *Definitions.* As used in this clause—

*Child abuse* means the physical or mental injury, sexual abuse or exploitation, or negligent treatment of a child.

*Covered professionals* means those persons engaged in professions and activities in eight different categories including, but not limited to, teachers, social workers, physicians, dentists, medical residents or interns, hospital personnel and administrators, nurses, health care practitioners, chiropractors, osteopaths, pharmacists, optometrists, podiatrists, emergency medical technicians, ambulance drivers, alcohol or drug treatment personnel, psychologists, psychiatrists, mental health professionals, child care workers and administrators, and commercial film and photo processors.

(b) *Responsibility to report child abuse.* Public Law 101-647, known as the Crime Control Act of 1990 (the Act) (34 U.S.C. 20341), imposes responsibilities on certain individuals (*i.e.*, covered professionals) to report child abuse who, while engaged in a professional capacity or activity, as defined in the Act, on Federal land or in a federally-operated (or contracted) facility, learn of facts that give the individual reason to suspect that a child has suffered an incident of child abuse.

(c) *Reporting protocols.* Accordingly, any person engaged in a covered profession or activity under an HHS contract or subcontract, regardless of the purpose of the contract or subcontract, shall immediately report a suspected child abuse incident in accordance with the provisions of the Act. If a child is suspected of being harmed, the appropriate State Child Abuse Hotline, local child protective services (CPS), or law enforcement agency shall be contacted. For more information about where and how to file a report, contact the Childhelp USA, National Child Abuse Hotline (1-800-4-A-CHILD). Any covered professional failing to make a timely report of such incident shall be guilty of a Class B misdemeanor.

(d) *Agreement.* The offeror represents and understands that by submission of its bid or offer and if awarded a contract for this

requirement, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all applicable subcontracts awarded under this contract. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act.

(e) *Subcontract flow down.* The Contractor shall insert the text of this clause, including this paragraph (d), in subcontracts at any tier. The Contractor shall be responsible for compliance by any subcontractor or lower-tier subcontractor with the provisions set forth in paragraphs (a) through (d) of this clause.

(End of clause)

### 352.237-72 Requirement for Background Checks.

As prescribed in 337.7006(c), insert the following clause:

Requirement for Background Checks (DATE)

(a) *Definition.* As used in this clause—

*Child care services* means and include, but are not limited to, social services, health and mental health care, child (day) care, education (whether or not directly involved in teaching), and rehabilitative programs.

(b) *Requirement for background checks.* Public Law 101-647, known as the Crime Control Act of 1990 (the Act) (34 U.S.C. 20351), requires that all individuals involved with the provision of child care services to children under the age of 18 undergo a criminal background check. Any conviction for a sex crime, an offense involving a child victim, or a drug felony, may be grounds for denying employment or for dismissal of an employee providing any child care services.

(c) *Background check protocols.* The Contracting Officer will provide the necessary information to the Contractor regarding the process for obtaining the background check. The Contractor may hire a staff person provisionally prior to the completion of a background check, if at all times prior to the receipt of the background check during which children are in the care of the newly-hired person, the person is within the sight and under the supervision of a previously investigated staff person.

(d) *Agreement.* The offeror represents and understands that by submission of its bid or offer and if awarded a contract for this requirement, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all applicable subcontracts awarded under this contract. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act.

(e) *Subcontract flow down.* The Contractor shall insert the text of this clause, including this paragraph (d), in subcontracts at any tier. The Contractor shall be responsible for compliance by any subcontractor or lower-tier subcontractor with the provisions set forth in paragraphs (a) through (d) of this clause.

(End of clause)

### 352.237-73 Indian Child Protection and Family Violence Act—Background Investigations.

As prescribed in 337.7006(d), insert the following clause:

Indian Child Protection and Family Violence Act—Background Investigations (DATE)

(a) *Requirement for background checks.* This contract is subject to the Indian Child Protection and Family Violence Act, Public Law 101-630 (25 U.S.C. 3201, *et seq.*). The duties and responsibilities required by this contract may involve regular contact with or control over Indian children. Public Law 101-630 prohibits employment, including Personal Service Contracts, with anyone who has been convicted of any crime of violence. Any such conviction should immediately be brought to the attention of the Contracting Officer. Performance under this contract requires a Contractor and its employees and subcontractors to be subject to a background investigation.

(b) *Background check protocols.* The Contractor and its employees and subcontractors, at any tier, will be subject to a character and background investigation, conducted by the Indian Health Service, Office of Human Resources. Until such time as the Contractor or its employees and subcontractors have been notified of completion of the investigation, the Contractor and its employees and subcontractors shall have no unsupervised contact with Indian children. In order to initiate this background investigation, the Contractor and its employees and subcontractors must provide information as required in this contract or as directed by the Contracting Officer.

(c) *Signed declaration prerequisite.* As a prerequisite to providing services under this contract, the Contractor is required to complete and sign the declaration found in Section J of this contract.

(d) *Subcontract flow down.* The Contractor shall insert the text of this clause, including this paragraph (d), in subcontracts at any tier. The Contractor shall be responsible for compliance by any subcontractor or lower-tier subcontractor with the provisions set forth in paragraphs (a) through (c) of this clause.

(End of clause)

### 352.237-74 Non-Discrimination in Service Delivery.

As prescribed in 337.7006(e), insert the following clause:

Non-Discrimination In Service Delivery (DATE)

(a) *Policy.* It is the policy of the Department of Health and Human Services (HHS) that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). This includes the requirement for non-discrimination in contracts involving delivery of services under HHS' programs directly to the public.

(b) *Agreement*. The offeror represents and understands that by submission of its bid or offer and if awarded a contract for this requirement, the Contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract in a non-discriminatory manner. The contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with this policy.

(c) *Subcontract flow down*. The Contractor shall insert the text of this clause, including this paragraph (c), in subcontracts at any tier, in subcontracts that support or perform the specified program and services. The Contractor shall be responsible for compliance by any subcontractor or lower-tier subcontractor with the provisions set forth in paragraphs (a) through (c) of this clause.

(End of clause)

### 352.237–75 Key Personnel.

As prescribed in 337.7006(f), insert the following clause:

Key Personnel (DATE)

The key personnel specified in this contract are essential to work performance under the contract. At least 30 days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts, the Contractor shall notify the Contracting Officer and submit a justification for the diversion or replacement and request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract. If the employee of the contractor is terminated for cause or separates from the Contractor voluntarily with less than 30 days' notice, the Contractor must provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract should be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of clause)

■ 42. Add sections 352.241–70, 352.242–70, 352.242–71, 352.245–70, 352.247–70, 352.247–71, and 352.247–72 to read as follows:

\* \* \* \* \*

Sec.

352.241–70 Disputes—Utility Contracts.  
352.242–70 Administrative Contracting Officer.  
352.242–71 Government Construction Contract Administration.  
352.245–70 Contractor Property Management System Administration.  
352.247–70 Delivery Location.  
352.247–71 Marking Deliverables.  
352.247–72 Packing for Domestic Shipment.

\* \* \* \* \*

### 352.241–70 Disputes—Utility Contracts.

As prescribed in 341.501–70, insert the following clause:

Disputes—Utility Contracts (DATE)

(a) *Definition*. As used in this clause, *Independent regulatory body* means the Federal Energy Regulatory Commission, a state-wide agency, or an agency with less than state-wide jurisdiction when operating pursuant to state authority. The body has the power to fix, establish, or control the rates and services of utility suppliers.

(b) *Independent Regulatory Body determinations*. The requirements of the Disputes clause at FAR 52.233–1 are supplemented to provide that matters involving the interpretation of tariffed retail rates, tariff rate schedules, and tariffed terms provided under this contract are subject to any determinations by the independent regulatory body having jurisdiction.

(End of clause)

### 352.242–70 Administrative Contracting Officer.

As prescribed in 342.272(a), insert the following clause:

Administrative Contracting Officer (DATE)

The Contracting Officer reserves the right to designate an Administrative Contracting Officer (ACO) for the purpose of performing certain tasks/duties in the administration of the contract. Such designation will be in writing through an ACO Letter of Delegation and will identify the responsibilities and limitations of the ACO. A copy of the ACO Letter of Delegation will be furnished to the Contractor.

(End of clause)

### 352.242–71 Government Construction Contract Administration.

As prescribed in 342.272(b), insert the following clause. This is a fill-in clause.

Government Construction Contract Administration (DATE)

(a) Contract administration functions set forth in FAR 42.302 are hereby delegated to:

\_\_\_\_\_ [Insert name and office address of Administrative Contracting Officer (ACO)]

(b) The following functions will be retained by the Contracting Officer and are not redelegable:

\_\_\_\_\_ [Contracting Officer to list all functions set forth in FAR 42.302 that are not redelegable to the ACO, revise the following or enter "None," when applicable]

(1) Award of contract modifications either through supplemental agreements or change orders that exceed the ACO's appointed warrant limitations.

(2) Issuance of default letters.

(3) Issuance of Cure or Show-Cause Notices.

(4) Suspension of work letters and/or modifications.

(5) Issuance of Contracting Officer final determination letters.

(6) Issuance of termination notices.

(7) Authorization of final payment.

(c) The work will be under the direction Contracting Officer or delegated

Administrative Contracting Officer as identified in paragraph (a), who may further delegate support services responsibilities to a Contracting Officer's Representative (COR), as identified below. A copy of the COR Appointment Letter shall be furnished to the Contractor:

\_\_\_\_\_ [Contracting Officer or ACO to insert name and office address of COR and list the COR's delegated authority.]

(End of clause)

### 352.245–70 Contractor Property Management System Administration.

As prescribed in 345.107, insert the following clause:

Contractor Property Management System Administration (DATE)

(a) *Definitions*. As used in this clause—  
*Acceptable property management system* means a property system that complies with the system criteria in paragraph (c) of this clause.

*Property management system* means the Contractor's system or systems for managing and controlling Government property.

*Significant deficiency* means a shortcoming in the system that materially affects the ability of officials of the Department of Health and Human Services to rely upon information produced by the system that is needed for management purposes.

(b) *General*. The Contractor shall establish and maintain an acceptable property management system. Failure to maintain an acceptable property management system, as defined in this clause, may result in disapproval of the system by the Contracting Officer and/or withholding of payments.

(c) *System criteria*. The Contractor's property management system shall be in accordance with paragraph (f) of the contract clause at Federal Acquisition Regulation 52.245–1.

(d) *Significant deficiencies*. (1) The Contracting Officer will provide an initial determination to the Contractor, in writing, of any significant deficiencies. The initial determination will describe the deficiency in sufficient detail to allow the Contractor to understand the deficiency.

(2) The Contractor shall respond within 30 days to a written initial determination from the Contracting Officer that identifies significant deficiencies in the Contractor's property management system. If the Contractor disagrees with the initial determination, the Contractor shall state, in writing, its rationale for disagreeing.

(3) The Contracting Officer will evaluate the Contractor's response and notify the Contractor, in writing, of the Contracting Officer's final determination concerning—

(i) Remaining significant deficiencies;

(ii) The adequacy of any proposed or completed corrective action; and

(iii) System disapproval, if the Contracting Officer determines that one or more significant deficiencies remain.

(e) *Contracting Officer's final determination*. If the Contractor receives the Contracting Officer's final determination of significant deficiencies, the Contractor shall, within 45 days of receipt of the final determination, either correct the significant

deficiencies or submit an acceptable corrective action plan showing milestones and actions to eliminate the significant deficiencies.

(End of clause)

**352.247-70 Delivery Location.**

As prescribed in 347.303-670, insert a clause substantially the same as the following:

Delivery Location (DATE)

Shipment of deliverable items, other than reports, shall be to: \_\_\_\_\_ [Contracting Officer shall insert appropriate identifying data].

(End of clause)

**352.247-71 Marking Deliverables.**

As prescribed in 347.305-10(a) insert a clause substantially the same as the following:

Marking Deliverables (DATE)

(a) The contract number shall be placed on or adjacent to all exterior mailing or shipping labels of deliverable items called for by the contract.

(b) Mark deliverables, except reports, for: \_\_\_\_\_ [Contracting Officer shall insert appropriate identifying data].

(End of clause)

**352.247-72 Packing for Domestic Shipment.**

As prescribed in 347.305-10(b), insert a clause substantially the same as the following:

Packing for Domestic Shipment (DATE)

Material shall be packed for shipment in such a manner that will ensure acceptance by common carriers and safe delivery at destination. Containers and closures shall comply with regulations of carriers as applicable to the mode of transportation.

(End of clause)

**352.270-1 through 352.270-3 [Removed]**

■ 43. Remove reserved sections 352.270-1 through 352.270-3.

**352.270-4a, 352.270-4b, 352.270-5a, 352.270-5b, 352.270-6, 352.270-9, 352.270-10, 352.270-11, 352.270-12, and 352.270-13 [Redesignated]**

■ 44. Redesignate sections 352.270-4a, 352.270-4b, 352.270-5a, 352.270-5b, 352.270-6, 352.270-9, 352.270-10, 352.270-11, 352.270-12, and 352.270-13 as follows:

Old section	New section
352.270-4a .....	352.270-70
352.270-4b .....	352.270-72
352.270-5a .....	352.270-77
352.270-5b .....	352.270-78
352.270-6 .....	352.270-73
352.270-9 .....	352.270-79
352.270-10 .....	352.270-71
352.270-11 .....	352.270-74
352.270-12 .....	352.270-75

Old section	New section
352.270-13 .....	352.270-76

**352.270-7 and 352.270-8 [Removed]**

■ 45. Remove reserved sections 352.270-7 and 352.270-8.

■ 46. Revise newly redesignated sections 352.270-70 through 352.270-79 to read as follows:

\* \* \* \* \*

Sec.

352.270-70 Notice to Offerors—Protection of Human Subjects.

352.270-71 Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.

352.270-72 Protection of Human Subjects.

352.270-73 Restriction on Use of Human Subjects.

352.270-74 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.

352.270-75 Needle Exchange.

352.270-76 Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

352.270-77 Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

352.270-78 Care of Live Vertebrate Animals.

352.270-79 Non-Discrimination from Conscience.

\* \* \* \* \*

**352.270-70 Notice to Offerors—Protection of Human Subjects.**

As prescribed in 370.304(a), insert the following provision:

Notice to Offerors—Protection of Human Subjects (DATE)

(a) The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) website at: <https://www.hhs.gov/ohrp/index.html>. These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS. The regulation is also available at <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46>.

(b) The regulations at 45 CFR 46.102, among other things, define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human

subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

(c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.104, Exempt research, are exempt from complying with 45 CFR part 46. See <https://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

(e) In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see 45 CFR 46.111 at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revise-common-rule-regulatory-text/index.html#46.111> for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP website (at <https://www.hhs.gov/ohrp/assurances/index.html>).

(f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. Only the contracting officer may offer information concerning a solicitation.

(g) The offeror shall document in its proposal the approved FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research. If the offeror does not have an approved FWA from OHRP, the offeror must obtain an FWA before the deadline for proposal submission. When possible, the offeror shall also certify the IRB's review and approval of the research. If the offeror cannot obtain this certification by the time of proposal submission they must include an explanation in their proposal. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(h) Registering an IRB and obtaining an FWA are related but separate processes. The web page for electronic submission of new IRB registrations and FWAs, or update/

renewal of existing IORGs/IRBs and FWAs is at <https://ohrp.cit.nih.gov/efile/Default.aspx>.  
(End of provision)

*Alternate I (DATE)*. As prescribed in 370.304(a), the Contracting Officer shall substitute the following paragraph (g) for paragraph (g) of the basic provision.

(g) The offeror's proposal shall document that it has an approved or active FWA from OHRP, related to the designated IRB reviewing and overseeing the research.

(1) When possible, the offeror shall also certify the IRB has reviewed and approved the research. If the offeror cannot make this certification at the time of proposal submission, its proposal must include an explanation. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(2) If the offeror does not have an active FWA from OHRP, the offeror shall take all necessary steps to obtain an FWA prior to the deadline for proposal submission. If the offeror cannot obtain an FWA before the proposal submission date, the proposal shall indicate the steps/actions the offeror will take to obtain OHRP approval within *[Contracting Officer must insert a time period in which the FWA must be obtained]*. Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

**352.270-71 Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.**

As prescribed in 370.304(b), insert the following provision:

Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (DATE)

(a) All Offerors proposing research expected to involve human subjects shall comply with the regulations set forth in 45 CFR part 46, and with the provision at HHSAR 352.270-70.

(b) The Offeror shall have an acceptable Assurance of Compliance on file with the Office for Human Research Protections (OHRP), whenever it submits a proposal to the FDA for research expected to involve human subjects. Direct questions regarding Federal-wide Assurance to OHRP. The Offeror's proposal shall include a copy of the acceptable Assurance of Compliance.

(c) After the contract has been awarded, the Contractor shall take the following actions:

(1) The Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance, hereafter referred to as "the local IRB," shall review the proposed research protocol. A letter from the local IRB stating that the proposed research protocol has been reviewed and approved, and thus adequately protects the rights and welfare of

human subjects involved, or a letter stating that the proposed research is exempt under 45 CFR 46.101(b) shall be submitted to the Contracting Officer.

(2) Upon award, the successful Offeror, hereafter "the Contractor," shall submit its proposed research protocol to the FDA's Research Involving Human Subjects Committee (RIHSC). The RIHSC or its designee will review and approve the research protocol to assure it adequately protects the rights and welfare of human subjects involved. The RIHSC or designee will also determine whether the proposed research is exempt under 45 CFR 46.101(b). The Contractor shall submit, to the Contracting Officer of record, a copy of the RIHSC's or its designee's letter stating that it reviewed and approved the proposed research protocol.

(d) The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects until RIHSC or its designee reviews and approves its research. The Contractor may begin other limited aspects of contract performance prior to receiving RIHSC's or designee's approval of the proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC's or designee's approval; however, the Contractor shall submit a copy of RIHSC's or its designee's approval to the Contracting Officer within three business days of its receipt.

(e) A Contractor's failure to obtain RIHSC's or its designee's approval of its proposed research may result in termination of its contract. However, failure to obtain RIHSC's or its designee's approval during initial review will not automatically result in termination of the contract. Instead, the Contractor may correct any deficiencies identified during the initial RIHSC or designee review and resubmit the proposed research protocol to RIHSC or its designee for a second review. The Contractor is encouraged to solicit the RIHSC's or its designee's input during the resubmission process.

(f) The Contractor shall seek RIHSC's or its designee's and local IRB review and approval whenever making modifications, amendments, or other changes to the research protocol. Such modifications, amendments and changes include, but are not limited to changes in investigators, informed consent forms, and recruitment advertisements. The Contractor may institute changes immediately after receiving both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject); however, the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

(End of provision)

**352.270-72 Protection of Human Subjects.**

As prescribed in 370.304(c), insert the following clause:

Protection of Human Subjects (DATE)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

(c) Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fw-as/index.html>).

(d) If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause)

**352.270-73 Restriction on Use of Human Subjects.**

As prescribed in 370.304(d), insert the following clause:

Restriction on Use of Human Subjects (DATE)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board registered with the Office for Human Research Protections (OHRP). This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

**352.270-74 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.**

As prescribed in 370.304(e), insert the following clause:

Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (DATE)

(a) The Contractor agrees to protect the rights and welfare of human subjects involved in research under this contract by complying with 45 CFR part 46 and the clause at HHSAR 352.270-72.

(b) Initial proof of compliance with 45 CFR part 46 shall consist of -

(1) A copy of a current Federal-wide Assurance on file with OHRP. The copy of a current Federal-wide Assurance shall be included with the Contractor's proposal;

(2) A letter from the Contractor's local IRB (the Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance) stating that it has reviewed and approved the proposed research protocol. The letter from the local IRB shall be submitted to the Contracting Officer; and

(3) A copy of a letter from the RIHSC stating that it or its designee has reviewed and approved the proposed research protocol. This shall be submitted to the Contracting Officer within three business days of its issuance. The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects under this contract, until RIHSC has reviewed and approved its research. The Contractor may commence other limited aspects of contract performance prior to receiving RIHSC or its designee approval of its proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC or its designee approval; however, the Contractor shall submit a copy of RIHSC's or its designee's letter of approval to the Contracting Officer within three business days of its receipt. Failure to obtain RIHSC or its designee approval of proposed research protocols may result in the termination of this contract.

(c) The Contractor further agrees that:

(1) The Contractor will provide a letter from RIHSC, at least annually, stating that RIHSC or its designee has reviewed and approved the research protocols for research performed under this contract. This shall be

submitted to the Contracting Officer for inclusion in the contract file.

(2) The Contractor will submit all proposed modifications and amendments to research protocols for research performed under this contract to RIHSC for review and approval. Modifications and amendments include, but are not limited, to changes to consent forms and advertising materials, and the addition or deletion of investigators. Changes may be instituted immediately after the Contractor has received both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject); however, the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

(End of clause)

**352.270-75 Needle Exchange.**

As prescribed in 370.304(f), insert the following clause:

Needle Exchange (DATE)

The Contractor shall not use any funds obligated under this contract to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

(End of clause)

**352.270-76 Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.**

As prescribed in 370.304(g), insert the following clause:

Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research (DATE)

(a) The Contractor shall not use any funds obligated under this contract for any abortion.

(b) The Contractor shall not use any funds obligated under this contract for the following—

(1) The creation of a human embryo or embryos for research purposes; or

(2) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(c) The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.

(d) The Contractor shall not use any Federal funds for the cloning of human beings.

(End of clause)

**352.270-77 Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.**

As prescribed in 370.403(a), insert the following clause:

Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (DATE)

(a) *Definitions.*

*Animal* means any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing for related purposes.

*Animal Welfare Assurance or Assurance* means the documentation from an institution assuring institutional compliance with the Public Health Service Policy on Human Care and Use of Laboratory Animals available at <https://olaw.nih.gov/policies-laws/phs-policy.htm>.

*Institutional Animal Care and Use Committee (IACUC)* means an intended generic term for a committee whose function is to ensure that the care and use of animals in PHS-conducted or supported activities are appropriate and humane in accordance with this Policy. However, each institution may identify the committee by whatever name it chooses. An appropriate IACUC performs the functions described in the Public Health Service Policy on Human Care and Use of Laboratory Animals, section IV, paragraph B.

(b) *Requirement for Written Animal Welfare Assurance and IACUC approval.* This contract includes research, research training, biological testing, housing and maintenance, and other activities involving live vertebrate animals and is subject to the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy establishes a number of requirements for research activities involving animals. The contract will not be awarded without the approval of the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH) on the successful offeror's written Animal Welfare Assurance and verification of the proposed institution(s) IACUC approval.

(1) Offerors shall include in their proposal a written Animal Welfare Assurance (assurance), committing the proposed institution(s) to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC).

(2) Pursuant to the PHS Policy, section IV.A.3., offerors shall establish an IACUC, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors shall provide verification of IACUC approval in their proposals. Offerors shall review and comply with the PHS Policy details regarding assurance and IACUC requirements.

(3) The contract will not be awarded without OLAW approval of the successful offeror's written Animal Welfare Assurance.

(c) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OLAW, NIH, that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work performance and further payments under this contract until the noncompliance is corrected. Notice of the suspension may be



communicated by telephone and confirmed in writing. If the Contractor fails to come into compliance within the period of time designated by the Contracting Officer, the Contracting Officer may, in consultation with OLAW, NIH, terminate the contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

(End of clause)

### **352.270–78 Care of Live Vertebrate Animals.**

As prescribed in 370.403(b), insert the following clause:

#### Care of Live Vertebrate Animals (DATE)

(a) Before performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 through 2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor shall comply with USDA pertinent laws and regulations of the USDA (*see* 7 U.S.C. 2131 *et seq.* and 9 CFR chapter I, subchapter A, parts 1 through 4). Where a conflict exists within the standards, the more stringent standard shall govern.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare, National Institutes of Health, that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work performance and further payments under this contract until the noncompliance is corrected. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to come into compliance within the period of time designated by the Contracting Officer, the Contracting Officer may, in consultation with OLAW, NIH, terminate the contract in whole or in part.

(e) The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (email: [ace@aphis.usda.gov](mailto:ace@aphis.usda.gov); website: <https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare>).

(End of clause)

### **352.270–79 Non-Discrimination for Conscience.**

As prescribed in 370.701, insert the following provision:

#### Non-Discrimination for Conscience (DATE)

(a) Section 301(d) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, as amended, provides that an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961, under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, The PEPFAR Stewardship Act of 2013, and The PEPFAR Extension Act of 2018, or under any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care—

(1) Shall not be required, as a condition of receiving such assistance, to—

(i) Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(ii) Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.

(2) Shall not be discriminated against under the provisions of law in paragraph (a) for refusing to meet any requirement described in paragraph (a)(1) in this solicitation.

(b) Accordingly, an offeror who believes this solicitation contains work requirements requiring it endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS, or endorse, utilize, make referral to, become integrated with, or otherwise participate in a program or activity to which it has a religious or moral objection, shall identify those work requirements it excluded in its technical proposal.

(c) The Government acknowledges that an offeror has specific rights, as cited in paragraph (b), to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right to not make an award to an offeror whose proposal does not comply with the salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

(End of provision)

■ 47. Add subpart 352.3 to read as follows:

### **Subpart 352.3—Provision and Clause Matrix**

#### **352.301 Solicitation provisions and contract clauses (Matrix).**

The HHSAR matrix is not published in the CFR. It is available on the *Acquisition.gov* website at <https://www.acquisition.gov/hhsar>.

### **PART 353—[REMOVED AND RESERVED]**

■ 48. Remove and reserve part 353.

### **PARTS 354 through 369 [ADDED AND RESERVED]**

■ 49. Add reserved parts 354 through 369 to subchapter H.

### **Subchapter M [Redesignated as Subchapter I]**

■ 50. Redesignate subchapter M as subchapter I.

■ 51. Revise newly redesignated subchapter I to read as follows:

#### **SUBCHAPTER I—DEPARTMENT SUPPLEMENTARY REGULATIONS**

PART 370 SPECIAL PROGRAMS AFFECTING ACQUISITIONS  
PARTS 371–399 [RESERVED]

### **PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITIONS**

#### **Subparts 370.1–370.2 [Reserved]**

#### **Subpart 370.3—Acquisitions Involving Human Subjects**

Sec.

370.300 Scope of subpart.

370.301 Policy.

370.302 Federal-wide assurance.

370.303 Notice to offerors.

370.304 Solicitation provisions and contract clauses.

#### **Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals**

370.400 Scope of subpart.

370.401 Definitions.

370.402 Policy.

370.403 Contract clauses.

#### **Subparts 370.5–370.6 [Reserved]**

#### **Subpart 370.7—Acquisitions Under the President's Emergency Plan for AIDS Relief**

370.700 Scope of subpart.

370.701 Solicitation provision.

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

#### **Subparts 370.1–370.2 [Reserved]**

#### **Subpart 370.3—Acquisitions Involving Human Subjects**

**370.300 Scope of subpart.**

This subpart implements the Basic HHS Policy for Protection of Human Research Subjects under 45 CFR part 46 and applies to all research activities conducted under contracts involving human subjects. See 45 CFR 46.101 (for scope of the policy) and 46.102(e) and (l) (for pertinent definitions).

**370.301 Policy.**

It is the Department of Health and Human Services (HHS) policy that the contracting officer shall not award a contract involving human subjects until the prospective contractor provides assurance that the activity will undergo initial and continuing review by an appropriate Institutional Review Board (IRB) in accordance with HHS regulations at 45 CFR 46.103. Except for research eligible for exemption under 45 CFR 46.104, the contracting officer shall require a Federal-wide assurance (FWA) of each, approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or institution engaged in human subjects research in performance of a contract. OHRP administers the assurance covering all HHS-supported or HHS-conducted activities involving human subjects.

**370.302 Federal-wide assurance.**

(a) OHRP-Approved FWAs are found at the following website: <https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc>.

(b) Normally a contractor, subcontractor, or institution must provide approval of a FWA before a contract is awarded. If a contractor, subcontractor, or institution does not currently hold an approved FWA, it shall submit an explanation with its proposal and an FWA application prior to submitting a proposal. The contracting officer, on a case-by-case basis, may make award without an approved assurance in consultation with OHRP.

(c) A contractor, subcontractor, or institution must submit all FWAs, including new FWAs, using the electronic submission system available through the OHRP website at <https://ohrp.cit.nih.gov/efile/>, unless an institution lacks the ability to do so electronically. If an institution believes it lacks the ability to submit its FWA electronically, it must contact OHRP by telephone or email (see <https://www.hhs.gov/ohrp/assurances/index.html>) and explain why it is unable to submit its FWA electronically.

**370.303 Notice to offerors.**

(a) The contracting officer shall notify offerors of the HHS Basic Policy for Protection of Human Subjects and required certifications. Unless otherwise exempted by 45 CFR part 46, no contract involving human subjects may start without these certifications. See 370.304 for applicable provisions and clauses.

(b) Institutions having an OHRP-approved FWA shall certify IRB

approval of submitted proposals in the manner required by instructions for completion of the contract proposal; by completion of an OMB Form No. 0990–0263, Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule); or by letter indicating the institution's OHRP-assigned FWA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

(c) The contracting officer generally will not request FWAs for contractors, subcontractors, or institutions prior to selecting a contract proposal for negotiation. When a contractor submits an FWA, it provides certification for the initial contract period; no additional documentation is required. If the contract provides for additional years to complete the project, the contractor shall certify annually in the manner described in paragraph (a) of this section.

**370.304 Solicitation provisions and contract clauses.**

(a) The contracting officer shall insert the provision at 352.270–70, Notice to Offerors—Protection of Human Subjects, in solicitations that involve human subjects. The contracting officer shall use the clause with its Alternate I when the agency is prescribing a date later than the proposal submission by which the offeror must have an approved FWA.

(b) For the Food and Drug Administration (FDA), the contracting officer shall insert the provision at 352.270–71, Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, in solicitations that involve human subjects when the research is subject to RIHSC review and approval.

(c) The contracting officer shall insert the clause at 352.270–72, Protection of Human Subjects, in solicitations, contracts and orders involving human subjects.

(d) The contracting officer shall insert the clause at 352.270–73, Restriction on Use of Human Subjects, in contracts and orders if the contractor has an approved FWA of compliance in place, but cannot certify prior to award that an IRB registered with OHRP reviewed and approved the research, because definite plans for involvement of human subjects are not set forth in the proposal (e.g., projects in which human subjects' involvement will depend upon completion of instruments, prior animal

studies, or purification of compounds). Under these conditions, the contracting officer may make the award without the requisite certification, as long as the contracting officer includes appropriate conditions in the contract or order.

(e) For FDA, the contracting officer shall insert the clause at 352.270–74, Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, in contracts and orders that involve human subjects when the research is subject to RIHSC review and approval.

(f) The contracting officer shall insert the clause at 352.270–75, Needle Exchange, in solicitations, contracts, and orders involving human subjects.

(g) The contracting officer shall insert the clause at 352.270–76, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research, in solicitations, contracts, and orders involving human subjects.

**Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals****370.400 Scope of subpart.**

This subpart applies to HHS contracts that include research, research training, biological testing, housing and maintenance, and other activities involving live vertebrate animals.

**370.401 Definitions.**

As used in this subpart—

*Animal* means any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing for related purposes.

*Animal Welfare Assurance* or *assurance* means the documentation from an institution assuring institutional compliance with the Public Health Service Policy on Human Care and Use of Laboratory Animals at <https://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>.

*Institutional Animal Care and Use Committee (IACUC)* means an intended generic term for a committee whose function is to ensure that the care and use of animals in PHS-conducted or supported activities are appropriate and humane in accordance with the policy in 370.402. However, each institution may identify the committee by whatever name it chooses. An appropriate IACUC performs the functions described in the Public Health Service Policy on Human Care and Use of Laboratory Animals, section IV, paragraph B.

**370.402 Policy.**

(a) Proposals submitted in response to solicitations involving research on

animals administered by the National Institutes of Health (NIH) or any national research institute shall include satisfactory assurances from the offeror or submitter to the Government, pursuant to the Health Research Extension Act of 1975 (Pub. L. 99–158, sec. 495(c)), that the contract work will be subject to initial and continuing review by an appropriate IACUC. See the Public Health Service Policy on Human Care and Use of Laboratory Animals at <https://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf> implements (Pub. L. 99–158) for additional information.

(b) The contracting officer shall ensure that offerors and contractors comply with the assurance and review requirements of the Public Health Service Policy on Human Care and Use of Laboratory Animals on all actions involving research on animals.

(c) The contracting officer shall not award a contract involving research on animals without an applicable Animal Welfare Assurance approved by the

Office of Laboratory Animal Welfare (OLAW), NIH, for any institution proposed involved in research on animals to be performed under the contract.

**370.403 Contract clauses.**

(a) The contracting officer shall insert the clause at 352.270–77, Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, in solicitations and contracts involving live vertebrate animals.

(b) The contracting officer shall insert the clause at 352.270–78, Care of Live Vertebrate Animals, in solicitations and contracts that involve live vertebrate animals.

**Subparts 370.5–370.6 [Reserved]**

**Subpart 370.7—Acquisitions Under the President’s Emergency Plan for AIDS Relief**

**370.700 Scope of subpart.**

This subpart applies to contracts involving Human Immunodeficiency

Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) programs under the President’s Emergency Plan for AIDS Relief (PEPFAR) as established by the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended (Pub. L. 108–25, Pub. L. 110–293, Pub. L. 113–56, and Pub. L. 115–305).

**370.701 Solicitation provision.**

The contracting officer shall insert the provision at 352.270–79, Non-Discrimination for Conscience, in solicitations valued at more than the micro-purchase threshold, which include work associated with the implementation of HIV/AIDS programs under PEPFAR.

**PARTS 371–399 [RESERVED]**

**Subchapters J through L [Removed]**

■ 52. Remove reserved subchapters J through L.

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