



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Washington, D.C. 20201

TO: Heads of the Contracting Activities

FROM: H. Katrina Brisbon //s//
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SUBJECT: 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

DATE: February 9, 2023

EFFECTIVE DATE: Immediately.

EXPIRATION DATE: This class deviation will remain in effect until it is incorporated into the HHS Acquisition Regulation (HHSAR) or is otherwise rescinded.

PURPOSE: This memorandum approves an HHS class deviation from the HHSAR to implement 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, as follows:

- (a) Adds HHSAR Part 325, Foreign Acquisition and Subpart 325.71 – Make PPE in America Act Restrictions on Foreign Acquisition of Personal Protective Equipment (Attachment 1).
- (b) Announces one new HHSAR clause, 352.225-70 Made in America – Personal Protective Equipment (FEB 2023); and
- (c) Announces one new HHSAR provision, 352.225-71 Made in America Certificate – Personal Protective Equipment (FEB 2023).

BACKGROUND: 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, beginning 90 days after the enactment of the Act.

The Act defines “personal protective equipment” as 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.

The Act requires that any contract awarded by the covered agencies for the procurement of PPE:

- (a) Be issued for a duration of at least two years, plus all option periods necessary, to incentivize investment in the production of personal protective equipment and the materials and components thereof in the United States; and
- (b) Be for personal protective equipment, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.

Section 70953(c) of the Act authorizes HHS to issue contracts for PPE, or a component or material of PPE, *not* produced in the United States if (after first maximizing domestic sources of PPE) the HHS Secretary:

- (1) Maximizes sources for 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; and
- (2) Certifies every 120 days that it is necessary to procure personal protective equipment under alternative procedures to respond to the immediate needs of a public health emergency.

Section 70953(d) of the Act also authorizes HHS to issue contracts for PPE, or a component or material of PPE, *not* produced in the United States if the contract is for PPE, or a component or material of PPE, that:

- (1) Is, or includes, a material listed in section 25.104 of the Federal Acquisition Regulation (FAR) as one for which a non-availability determination has been made; or
- (2) 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.

When using the exception in Section 70953(d), the HHS Secretary must certify every 120 days that the exception is necessary to meet the immediate needs of a public health emergency.

AUTHORITY: This class deviation is issued under the authority of FAR 1.404 and the HHSAR 301.401.

DEVIATION:

Effective immediately, Program and Project Managers, Contracting Officers, and Government Purchase Card holders must ensure that procurements for PPE meet the requirements of the Make PPE in America Act. To implement the Act, the following shall apply to all HHS Operating and Staff Divisions:

Applicability of HHS New Clause and Provision:

(a) Made in America – Personal Protective Equipment (FEB 2023) (Attachment 2).

Contracting officers shall insert the full text of the new clause in:

- New solicitations for PPE, as defined in the Act and above the micro purchase threshold, issued after the issuance date of this class deviation;
- New contracts for PPE, as defined in the Act and above the micro purchase threshold, awarded after the issuance date of this class deviation.
- For PPE purchases made utilizing the Government Purchase Card (GPC) at or below the micro-purchase threshold, GPC cardholders shall comply with the procedures outlined in Acquisition Alert 2023-01 (as amended).

(b) Made in America Certificate – Personal Protective Equipment (FEB 2023) (Attachment 3).

Contracting officers shall insert the full text of the new provision in:

- New solicitations for PPE, as defined in the Act and regardless of dollar value, issued on or after the issuance date of this class deviation.
- For PPE purchases made utilizing the Government Purchase Card (GPC) at or below the micro-purchase threshold, GPC cardholders shall comply with the procedures outlined in Acquisition Alert 2023-01 (as amended).

Applicability of Commercial Clauses:

- (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, as defined in the Act and above the micro purchase threshold, contracting officers shall also include the full text of the new clause Made in America – Personal Protective Equipment.
- (b) When the provision at FAR 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services is included in a solicitation for PPE, as defined in the Act and above the micro purchase threshold, contracting officers shall also

include the full text of the new provision Made in America Certificate – Personal Protective Equipment.

Attachments:

- Attachment 1: HHSAR Part 325, Foreign Acquisition and Subpart 325.71, Make PPE in America Act Restrictions on Foreign Acquisition of Personal Protective Equipment
- Attachment 2: New HHSAR Clause “352.225-70, Made in America – Personal Protective Equipment”
- Attachment 3: New HHSAR Provision “352.225-71, Made in America Certificate – Personal Protective Equipment”

Please contact the HHS Acquisition Policy Division with any questions at OAP@hhs.gov .

Attachment 1: HHSAR Part 325, Foreign Acquisition and Subpart 325.71, Make PPE in America Act Restrictions on Foreign Acquisition of Personal Protective Equipment

325.7100	Scope of subpart.
325.7101	Definitions.
325.7102	Restrictions on certain personal protective equipment.
325.7102-1	Restrictions.
325.7102-2	Exceptions.
325.7102-3	Specific application of the Buy American Act and Trade Agreements Act.
325.7103	Solicitation provisions and contract clauses.

Subpart 325.71—Make PPE in America Act Restrictions on Foreign Acquisition of Personal Protective Equipment

This subpart contains restrictions on the acquisition of certain personal protective equipment imposed by the Make PPE in America Act (Pub. L. 117-58) on new solicitations and contracts.

325.7101 Definitions.

As used in this subpart -

- (a) *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.
- (b) *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.
- (c) *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.
- (d) *Foreign personal protective equipment* means personal protective equipment other than domestic personal protective equipment or foreign-made domestic personal protective equipment.
- (e) *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.
- (f) *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 personal protective equipment.

- (a) Except as provided in subsection 325.7102-2, contracting officers shall purchase domestic personal protective equipment.
- (b) Any contract for personal protective equipment shall have a base period of performance of at least two years, plus any option periods.

325.7102-2 Exceptions.

Acquisitions of personal protective equipment in the following categories are not subject to the restrictions in 325.7102-1:

- (a) Acquisitions of an item of personal protective equipment, or component thereof, otherwise covered by 325.7102-1 when the HHS Secretary:
 - (1) Maximizes sources for foreign-made domestic personal protective equipment; and
 - (2) Certifies every 120 days that it is necessary to procure personal protective equipment under alternative procedures to respond to the immediate needs of a public health emergency.
- (b) Acquisitions of an item of personal protective equipment, or component thereof, including those described in paragraph (a) —
 - (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 personal protective equipment to respond to the immediate needs of a public health emergency.
- (c) When either of the exceptions in the paragraphs (a) or (b) are used:
 - (1) Only the HHS Secretary is authorized to make the certification in paragraphs (a)(2) and (b)(3) or the nonavailability or unreasonable cost determination in paragraph (b).
 - (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), 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 from the Head of the Contracting Activity before submission to the Senior Procurement Executive.
- (ii) For the nonavailability or unreasonable cost determination in paragraph (b), 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 Head of the Contracting Activity before submission to the Senior Procurement Executive.

325.7102-3 Specific application of the Buy American Act and Trade Agreements Act.

If the HHS Secretary determines neither domestic personal protective equipment nor foreign-made domestic personal protective equipment are available due to nonavailability or unreasonable cost, the contracting officer shall insert either –

- (a) The clause at Federal Acquisition Regulation (FAR) 52.225-1, Buy American – Supplies, and the provision at FAR 52.225-2, Buy American Certificate;
- (b) The clause at FAR 52.225-3, Buy American – Free Trade Agreements – Israeli Trade Act, and the provision at FAR 52.225-4, Buy American – Free Trade Agreements – Israeli Trade Act Certificate; or
- (c) The clause at FAR 52.225-5, Trade Agreements, and the provision at FAR 52.225-6, Trade Agreements Certificate, as applicable.

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, regardless of dollar value, when procuring any item covered under 325.7102-1(a).
- (b) Insert the provision at 352.225-71, Made in America—Personal Protective Equipment, in solicitations containing the clause at 352.225-70.

Attachment 2: New HHSAR Clause “352.225-70, Made in America – Personal Protective Equipment”

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 (FEB 2023)

(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 used 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) 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)

Attachment 3: New HHSAR Provision “352.225-71, Made in America Certificate – Personal Protective Equipment”

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 (FEB 2023)

(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]

(End of provision)