

warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### Environmental Review

The FAA has determined that this airspace action of amending VOR Federal airway V-187 qualifies for categorical exclusion under the National Environmental Policy Act and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5-6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5-2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

#### PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

#### § 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E,

Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

*Paragraph 6010(a) Domestic VOR Federal Airways.*

\* \* \* \* \*

#### V-187 [Amended]

From Socorow, NM; via INT Socorow 015° and Albuquerque, NM, 160° radials; Albuquerque, Rattlesnake, NM; 50 miles, 62 miles, 115 MSL, Grand Junction, CO; 75 miles, 50 miles, 112 MSL, Rock Springs, WY; 20 miles, 37 miles, 95 MSL, INT Rock Springs 026° and Riverton, WY, 180° radials; Riverton; Boysen Reservoir, WY; 9 miles, 78 miles, 105 MSL, Billings, MT; INT Billings 317° and Great Falls, MT, 122° radials; Great Falls; Missoula, MT; Nez Perce, ID; Pasco, WA; INT Pasco 321° and Ellensburg, WA, 107° radials; Ellensburg; INT Yakima 331° and Ellensburg 274° radials. From Olympia; to Astoria, OR.

\* \* \* \* \*

Issued in Washington, DC, on October 14, 2020.

**Scott M. Rosenbloom,**

*Acting Manager, Rules and Regulations Group.*

[FR Doc. 2020-23083 Filed 10-22-20; 8:45 am]

**BILLING CODE 4910-13-P**

#### AGENCY FOR INTERNATIONAL DEVELOPMENT

#### 22 CFR Part 228

RIN 0412-AB02

#### Procurement of Certain Essential Medical Supplies To Address the COVID-19 Pandemic

**AGENCY:** Agency for International Development.

**ACTION:** Temporary final rule.

**SUMMARY:** The United States Agency for International Development (USAID) is issuing a Temporary Final Rule (TFR) amending *our regulations* to allow USAID to waive “Source and Nationality” rules to provide for increased flexibility, targeting, and speed of procurement of Essential Medical Supplies (EMS) required to address the COVID-19 pandemic worldwide.

**DATES:** *Effective date:* This rule is effective October 23, 2020 through April 30, 2021.

**ADDRESSES:** You may review the docket by searching for Docket ID [AID-2020-0004], via the Federal eRulemaking Portal: <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Natalie J. Freeman (or designee), Attorney Advisor, Office of the General

Counsel, USAID, 1300 Pennsylvania Ave. NW, Washington, DC 20523, [GCFEDREGMailbox@usaid.gov](mailto:GCFEDREGMailbox@usaid.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

##### A. The Current COVID-19 Pandemic in the United States

Coronavirus Disease 2019 (COVID-19) is a highly communicable infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). On January 30, 2020, the Director-General of the World Health Organization (WHO) declared the outbreak of COVID-19 a Public Health Emergency of International Concern under the International Health Regulations. On January 31, 2020, the HHS Secretary declared COVID-19 a Public Health Emergency under Section 319 of the Public Health Service (PHS) Act. *42 U.S.C. 247d*. On March 11, 2020, the WHO declared the COVID-19 outbreak a pandemic. On March 13, 2020, the President issued a declaration of a national emergency under Sections 201 and 301 of the National Emergencies Act, *50 U.S.C. 1601-1651*, and consistent with Section 1135 of the Social Security Act, *42 U.S.C. 1320b-5*. See *Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak*.

On March 13, 2020, the President also declared a nationwide emergency under Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, *42 U.S.C. 5121-5207* (the “Stafford Act”), authorizing FEMA to provide assistance for emergency protective measures to respond to the COVID-19 pandemic. Under the Stafford Act, FEMA may direct USAID, through a Mission Assignment, to use its authorities and resources to meet domestic needs, including making available any EMS to FEMA.

As of May 21, 2020, there were over 1.5 million confirmed cases of COVID-19 in the United States, resulting in over 93,000 deaths due to the disease, with new cases and fatalities being reported daily. Worldwide, there have been over 5 million confirmed cases, resulting in over 328,000 deaths. Presently, there is no vaccine that can prevent infection with COVID-19, nor is there currently any FDA-approved post-exposure prophylaxis for people who may have been exposed to COVID-19. Treatment is limited to supportive (or palliative) care for patients who need it. Clinical management for hospitalized patients with COVID-19 is focused on supportive care for complications, including supplemental oxygen and

advanced organ support for respiratory failure, septic shock, and multi-organ failure.

### B. USAID's Response to COVID-19

USAID is responding to the COVID-19 pandemic with decisive action at home and abroad. Our priorities in the response are to protect the safety and health security of our global workforce, ensure that we can continue our life-saving mission across the world, and support partner countries in their response to COVID-19.

USAID, together with the Department of State, launched the Strategy for Supplemental Funding to Prevent, Prepare for, and Respond to Coronavirus Abroad. Under Pillar 2 of this Strategy, USAID addresses three components—the emergency health response, strengthening health security capacities in affected countries, and helping to rebuild health systems as part of addressing the second order health effects of the pandemic. As of April 24, the USAID Bureau for Global Health (GH), in response to the pandemic, obligated \$99 million from the Emergency Reserve Fund for Infectious Disease Outbreaks, and another approximately \$90 million of the total \$435 million Global Health Programs COVID-19 supplemental. GH programming has focused on the following technical areas: Risk communication and community engagement; surveillance, rapid response teams, and contact tracing; port of entry; infection prevention and control; laboratory systems; case management; and response operations and coordination. The provision of commodities is critical for the laboratory systems, case management, and infection prevention and control components. Under Pillar 3 of the Strategy, USAID will prevent, prepare for, and respond to COVID-19 in existing complex emergency responses and address potential humanitarian consequences of the pandemic. Further, under Pillar 4 of the Strategy, USAID will prepare for, mitigate and address second order economic, civilian security, stabilization, and governance effects of COVID-19. The provision of commodities will be components of these activities. In total, USAID estimates that approximately \$137 million may be used for providing Essential Medical Supplies for overseas use.

### C. Authorities

USAID is issuing this temporary final rule as part of its response to the COVID-19 pandemic. The Administrative Procedure Act (“APA”)

generally requires an agency to publish a notice of proposed rulemaking in the **Federal Register** and provide an opportunity for public comment. This requirement does not apply, however, if the agency “for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 *U.S.C. 553(b)(3)(B)*. The APA also generally requires that an agency publish an adopted rule in the **Federal Register** at least 30 days before it becomes effective. This requirement does not apply, however, if the agency finds good cause for making the rule effective sooner. *Section 553(d)(3)*.

The rates of COVID-19 infections and the number of deaths caused by COVID-19 are significantly increasing on a daily basis worldwide. The demand for EMS is increasing worldwide given the rising number of infections. Second and possibly third waves are expected according to the medical experts. The courts have recognized that concern for public safety can constitute good cause to bypass notice and comment procedures. (See, *Jifry v. F.A.A.*, 370 F.3d 1174, 1179–80 (D.C. Cir. 2004).) The courts have further found that immediate threats to human life and physical security typically constitute an important enough interest to justify use of the good cause exception. (See, *Hawaii Helicopter Operators Ass'n v. Federal Aviation Administration*, 51 F.3d 212 (9th Cir. 1995).) This rule is intended to help protect the public from this immediate health threat by providing USAID increased flexibility, targeting, and speed of procurement of EMS required to address the COVID-19 pandemic worldwide. Given the temporary nature of this rule, its narrow application to EMS, and the significant and immediate threat to public health and safety in the United States and worldwide, the Agency finds that this emergency is sufficiently compelling to constitute good cause to forgo notice and comment. It would be contrary to the interest of public health and contrary to our national security and foreign policy interests to delay this rule.

The rule is issued accordance with section 604 of the Foreign Assistance Act (FAA) of 1961, as amended, 22 *U.S.C. 2354*.

Under the authority of the FAA and the APA, USAID issues this temporary final rule.

### II. Provisions of Temporary Final Rule

USAID is working directly with governments, multilateral organizations, NGOs, the private sector, and other organizations responding on the ground

to combat this dangerous pathogen. This includes working with front-line workers to slow the spread, care for those affected by, and equip local communities with the tools needed to fight back against COVID-19. Pandemics know no borders, and therefore international cooperation is vital. We will not successfully defeat this pandemic threat, and avoid a second or third wave, unless we fight it around the world. That is why our approach must include the necessary tools and resources to protect the safety and interests of Americans and ensure the United States continues to lead on the global response. The United States industry is uniquely positioned to produce EMS to support the achievement of COVID-19 domestic and international objectives. USAID's primary reliance on these sources ensures the availability of these critical supplies to assist countries affected by COVID-19. This temporary final rule allows flexibility to ensure those in need around the world will have access to lifesaving EMS to address COVID-19 when and where they need it. The measures described in this rule are being issued on a temporary basis from October 23, 2020 through April 30, 2021.

Current regulations authorize the following:

22 *CFR 228.03(a)* authorizes purchases from Geographic Code 937, which is defined as the United States, the cooperating/recipient country, and developing countries other than advanced developing countries, and excluding prohibited sources.

It further allows for certain purchases from Geographic Code 935, which is defined as any area or country except prohibited countries, based on additional statutory authority or otherwise approved via a waiver in accordance with Subpart D. *Section 228.03(b)*.

For purchases under Support for Economic and Democratic Development of the Independent States of the Former Soviet Union, § 228.03(c), the authorized principal geographic codes are Code 937 and Code 110 (New Independent States).

Under the current provisions of 22 *CFR* part 228, USAID only has the authority to expand the authorized geographic scope under the waiver provisions. The temporary final rule allows USAID to prioritize the purchase of EMS: From the United States only, from the cooperating/recipient country, from the geographic region to avoid diverting supplies in short supply in the United States, or from a nearby country. “Nearby country” means any bordering country or any country that is in the same geographical region as the country receiving assistance, as defined by the Department of State's regional system

(i.e., Africa; East Asia and Pacific; Europe and Eurasia; Near East; South and Central Asia; Western Hemisphere). However, if, as determined by USAID on a case-by-case basis, EMS is unavailable from the United States, the cooperating/recipient country, and a nearby country; or is unavailable in sufficient, reasonable, and available quantities, or sufficient and reasonable quality that is fit for the intended purpose, procurement from Code 935 is authorized.

### III. Temporary Changes to 22 CFR Part 228

The below changes will remain in effect until October 23, 2020 through April 30, 2021.

22 CFR 228.11 is being amended to require implementing partners to receive approval from USAID before purchasing EMS. This will allow USAID to issue a waiver for the purchase of EMS from the United States only, from the cooperating/recipient country, from specific geographic region, or from a nearby country.

22 CFR 228.30 is being amended to add subsection (e) which allows waivers to geographic areas necessary for the purchase of EMS to address the COVID-19 pandemic. For example, it authorizes purchases from the United States only, or from nearby countries that may not be included in Geographic Code 937. It also authorizes purchases from the cooperating/recipient country or from certain geographic areas when there are shortages in the United States. The Agency plans to issue a waiver to prioritize geographic areas for the purchase of EMS to address the COVID-19 pandemic.

### IV. Regulatory Considerations and Determinations

#### A. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and

materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary effects of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

This rule change narrowly applies to EMS purchased to address the COVID-19 pandemic. The estimated amount of funding potentially affected is approximately \$137 million. Buying from the United States only would positively affect the United States economy and help development of our manufacturing capacity to respond to future crises. USAID’s foreign assistance mandate is unchanged. This rule has been designated a “significant regulatory action,” but not “economically significant,” under Section 3(f) of Executive Order 12866. This rule has been reviewed by the Office of Management and Budget.

#### B. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ‘major rule’, as defined by 5 U.S.C. 804(2).

#### C. Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, USAID has considered the economic effect of the Temporary Final Rule and has certified that its provisions would not have a significant economic effect on a substantial number of small entities.

#### D. Paperwork Reduction Act

There is no reporting or documentation or other information collection requirements under the Final Rule that require analysis under the Paperwork Reduction Act. 44 U.S.C. 3501–3583.

#### List of Subjects in 22 CFR Part 228

Government procurement.

For the reasons discussed in the preamble, USAID amends 22 CFR part 228 as set forth below:

### PART 228—RULES FOR PROCUREMENT OF COMMODITIES AND SERVICES FINANCED BY USAID

■ 1. The authority citation for 22 CFR part 228 continues to read as follows:

**Authority:** Sec. 621, Pub. L. 87–195, 75 Stat. 445 (22 U.S.C. 2381), as amended, E.O. 12163, Sept. 29, 1979, 44 FR 56673; 3 CFR 1979 Comp., p. 435.

■ 2. Revise § 228.01 to read as follows:

#### § 228.01 Definitions.

Essential medical supplies means personal protective equipment, medical products and equipment, pharmaceuticals, and other medical countermeasures needed to address the COVID-19 pandemic, which are in short supply, as identified in the “Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures” issued by the Department of Health and Human Services (HHS) on March 25, 2020, as updated. USAID may designate additional materials as “emergency medical supplies” if deemed necessary and will publish notice of these additional materials in the **Federal Register**.

■ 3. Revise § 228.11 to read as follows:

#### § 228.11 Source of commodities.

The source of all commodities financed with Federal program funds appropriated under the Foreign Assistance Act of 1961, as amended, shall be Code 937 (unless Code 935 or 110 are designated in the implementing instrument), except for essential medical supplies purchased to address the COVID-19 pandemic, the source of which must be approved by USAID prior to purchase unless otherwise directed by USAID. Procurements of agricultural commodities, motor vehicles, and pharmaceuticals must also comply with the special procurement rules in § 228.19. Recipients and contractors are prohibited from engaging suppliers of commodities in an authorized country to import commodities from a country outside of the authorized principal geographic codes for the purposes of circumventing the requirements of this rule. Any violation of this prohibition will result in the disallowance by USAID of the cost of the procurement of the subject commodity.

■ 4. Revise § 228.30 to read as follows:

#### § 228.30 General.

USAID may waive the rules contained in subparts A, B, and C of this part (except for prohibited sources as defined in § 228.01, and §§ 228.21 and 228.22), in order to accomplish project

or program objectives. Except for paragraph (e) of this section, for any waivers authorized, the principal geographic code shall be Code 935, any area or country but excluding prohibited sources. All waivers must be in writing, and where applicable, are limited to the term established by the waiver. All waiver decisions will be made solely on the basis of the following criteria:

(a) Waivers to permit procurement outside of Code 937 or 110 must be based on a case by case determination that:

(1) The provision of assistance requires commodities or services of the type that are not produced in and available for purchase in Code 937 or 110;

(2) It is important to permit procurement from a country not specified in Code 937 or 110 to meet unforeseen circumstance; or

(3) To promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives.

(b) Case by case waivers under paragraph (a) of this section may be made on the basis of a commodity or service type or category, rather than processing repeat, individual waivers for an identical or substantially similar commodity or service. Such waivers may be approved on a regional, country, or program basis. For purposes of paragraph (a)(1) of this section, “produced in and available for purchase in” shall have the same meaning as the definition of “available for purchase” in § 228.01. A waiver under paragraph (a)(1) of this section may also be based on the fact that a commodity is not available for purchase in Code 937 or 110 in sufficient, reasonable, and available quantities or sufficient and reasonable quality that is fit for the intended purpose.

(c) A waiver to authorize procurement from outside the United States of agricultural commodities, motor vehicles, and pharmaceuticals must meet the requirements of § 228.19.

(d) Any individual transaction not exceeding \$25,000 (excluding essential medical supplies purchased to address the COVID-19 pandemic), excluding those covered by special procurement rules in § 228.19, and excluding procurements from prohibited sources) does not require a waiver and is hereby authorized.

(e) For purchases of essential medical supplies to address the COVID-19 pandemic, waivers shall be authorized to the United States only, to the cooperating/recipient country, and/or to a nearby country. Nearby country means

any bordering country or any country that is in the same geographical region as the country receiving assistance, as defined by the Department of State’s regional system. If, as determined by USAID on a case by case basis, essential medical supplies are unavailable from the United States, the cooperating/recipient country, and a nearby country, or are unavailable in sufficient, reasonable, and available quantities or sufficient and reasonable quality that is fit for the intended purpose, procurement from Code 935 is authorized.

**Suk J. Jin,**

*Deputy General Counsel, U.S. Agency for International Development.*

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**BILLING CODE 6116-02-P**

## DEPARTMENT OF JUSTICE

### Office of the Attorney General

#### 28 CFR Part 0

#### AG Order No. 4877-2020

**AGENCY:** Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This final rule authorizes the Assistant Attorney General in charge of the Criminal Division to perform the functions of the “Designated Authority” under executive agreements on access to data by foreign governments that either designate the Attorney General or the Department of Justice (the “Department”) as such authority or authorize the Attorney General to specify a Designated Authority, and for which the Attorney General has designated the Criminal Division as such authority. It also authorizes the Assistant Attorney General to further delegate that authority to officials in the Criminal Division, including officials in the Office of International Affairs (“OIA”).

**DATES:** *Effective:* October 23, 2020.

**FOR FURTHER INFORMATION CONTACT:**

Vaughn Ary, Director, Office of International Affairs, Criminal Division, U.S. Department of Justice, Washington, DC 20005; Telephone (202) 514-0000.

**SUPPLEMENTARY INFORMATION:** Congress authorized the United States to enter into executive agreements with foreign governments under which the parties afford each other reciprocal rights of access to data covered by such agreements in response to qualifying, lawful orders. *See* Clarifying Lawful Overseas Use of Data Act, Public Law 115-141, Div. V, Section 105(a) (March

23, 2018), 18 U.S.C. 2523 (“CLOUD Act”). The first such executive agreement was concluded between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland. *See* Agreement between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland on Access to Electronic Data for the Purpose of Countering Serious Crime (October 3, 2019), available at <https://www.justice.gov/dag/cloudact> (the “U.S.–U.K. Agreement”). The U.S.–U.K. Agreement provides that a “Designated Authority” for each country shall perform certain, specified functions necessary to implement the agreement. As applied to the United States, “Designated Authority” is defined under the agreement as “the governmental entity designated . . . by the Attorney General. *Id.* at Article 1.8. To address the requirements of this executive agreement, the Attorney General has designated the Criminal Division as the “Designated Authority” in a **Federal Register** notice published concurrently with this rule. The final rule authorizes the Assistant Attorney General in charge of the Criminal Division to exercise the responsibilities of the Designated Authority and provides that the Assistant Attorney General may further delegate those responsibilities to officials within the Criminal Division, including officials in OIA. OIA serves as the Central Authority for the United States with respect to requests for information, evidence and other assistance received from and made to foreign authorities under mutual legal assistance treaties, multilateral conventions, and executive agreements regarding legal assistance in criminal matters. *See* 28 CFR 0.64–1 (authorizing the Assistant Attorney General in charge of the Criminal Division to re-delegate the duties of the “Central Authority” to certain officials in OIA). Thus, OIA already carries out responsibilities similar to those of a Designated Authority under executive agreements negotiated pursuant to 18 U.S.C. 2523.

To address future agreements of this nature, this final rule applies to any executive agreement under 18 U.S.C. 2523 that either designates the Attorney General or the Department of Justice as the Designated Authority or authorizes the Attorney General to designate a Designated Authority, and for which the Attorney General has designated the Criminal Division as such authority.