



## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### 44 CFR Part 333

[Docket ID FEMA-2020-0019]

RIN 1660-AB04

### Emergency Management Priorities and Allocations System (EMPAS)

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security (DHS).

**ACTION:** Final rule.

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**SUMMARY:** This final rule adopts, with minor technical edits, an interim final rule with request for comments published in the *Federal Register* on May 13, 2020, establishing standards and procedures by which the Federal Emergency Management Agency (FEMA) may require certain contracts or orders that promote the national defense be given priority over other contracts or orders and setting new standards and procedures by which FEMA may allocate materials, services, and facilities to promote the national defense under emergency and non-emergency conditions pursuant to section 101 of the Defense Production Act of 1950, as amended. These regulations are part of FEMA's response to the ongoing COVID-19 emergency.

**DATES:** *Effective Date:* This final rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**FOR FURTHER INFORMATION CONTACT:** Marc Geier, Office of Policy and Program Analysis, 202-924-0196, [FEMA-DPA@fema.dhs.gov](mailto:FEMA-DPA@fema.dhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Legal Authority

On May 13, 2020, FEMA published in the *Federal Register* an interim final rule establishing standards and procedures by which FEMA may require certain contracts or orders that promote the national defense be given priority over other contracts or orders and setting new standards and procedures by which FEMA may allocate materials, services, and facilities to promote the national defense under emergency and non-emergency conditions pursuant to section 101 of the Defense Production Act of 1950, as amended. *See* 85 FR 28500.

Section 101 of the Defense Production Act of 1950, as amended (DPA or the Act), authorizes the President to require that performance under contracts or orders (other than contracts of employment) which the President deems necessary or appropriate to promote the national defense take priority over performance under any other contract or order. For the purpose of assuring such priority, the President may require acceptance and performance of such contracts or orders in preference to other contracts or orders by any person the President finds to be capable of their performance.<sup>1</sup> Section 101 also authorizes the President to allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as the President shall deem necessary or appropriate to promote the national defense.<sup>2</sup> Executive Order 13911, “Delegating Additional Authority Under the Defense Production Act With Respect to Health and Medical Resources To Respond to the Spread of COVID–19,” 85 FR 18403 (Apr. 1, 2020), delegated the President’s authority under Section 101 to the Secretary of Homeland Security with respect to health and medical resources needed to respond to the spread of Coronavirus Disease 2019 (COVID-19) within the United States. The Secretary of Homeland Security has further delegated these authorities to the FEMA Administrator.<sup>3</sup> FEMA published its interim final rule to comply with Section 101(d),

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<sup>1</sup> 50 U.S.C. 4511(a)(1).

<sup>2</sup> 50 U.S.C. 4511(a)(2).

<sup>3</sup> DHS Delegation 09052 Rev. 00.1, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency” (Apr. 1, 2020).

which requires agencies delegated authority under Section 101 to issue final rules to establish standards and procedures by which the priorities and allocations authority is used to promote the national defense.

The interim final rule established the Emergency Management Priorities and Allocations System (EMPAS), which became part of the Federal Priorities and Allocations System (FPAS), the body of regulations that establishes standards and procedures for implementing the President's authority under Section 101(a) of the DPA. This rule finalizes the interim final rule.

## **II. Discussion Public Comments and FEMA's Responses**

The public comment period on the interim final rule closed on June 12, 2020, and four germane public comments were received. One comment was generally supportive of the regulation, pointing out that having the EMPAS rule in place allows FEMA to leverage the DPA in response to the COVID-19 pandemic over an extended period of time or eventually extend it to more general emergency preparedness activities. Given the ongoing COVID-19 pandemic, FEMA is considering use of the EMPAS regulation to combat the COVID-19 pandemic over an extended period of time. Since implementation of the regulation in May, FEMA has modified and extended an order allocating certain scarce and critical materials for domestic use to ensure the resources were not exported from the United States without specific approval by FEMA, and continues to consider options for using EMPAS to address mission needs. *See* 85 FR 48113 (Aug. 10, 2020). Finalizing the EMPAS regulation allows FEMA to respond to public comments in a timely manner and ensures FEMA's continued ability to use its authorities as appropriate in response to the COVID-19 pandemic. FEMA is also better prepared should delegations of priorities and allocations authority for other types of resources be issued in the future, as it will already have a regulatory framework in place.

The commenter suggested that EMPAS authority should be extended to include vaccine active ingredients as well as adjuvant or booster additions to vaccines; measures to permit fill and finish of large numbers of vaccine doses, including glass vials and other packaging; and provide for distribution systems and medical facilities to distribute vaccines when available at the most rapid rate. FEMA’s authority pursuant to EMPAS is clear; the President delegated FEMA<sup>4</sup> the authority to exercise section 101 of the DPA with respect to health and medical resources needed to respond to the spread of COVID-19 within the United States. The EMPAS regulation defines “health and medical resources” as “drugs, biological products, medical devices, materials, facilities, health supplies, services, and equipment required to diagnose, mitigate, prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population.” This definition mirrors the definition of “health resources” established by the Department of Health and Human Services (HHS) in their Health Resources Priority and Allocations System (HRPAS) regulation<sup>5</sup> to ensure consistency across agencies delegated authority by the President to utilize these resources to respond to the COVID-19 pandemic. Vaccines, which are defined as biological products under section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)), are considered a health and medical resource and thus would fall within the scope of the HRPAS and EMPAS regulations, including any materials associated with vaccines, including glass vials and other packaging.<sup>6</sup> Similarly, distribution systems and medical facilities for vaccine distribution also constitute health and medical resources under EMPAS.<sup>7</sup> Given the need for

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<sup>4</sup> See Executive Order 13911, 85 FR 18403 (Apr. 1, 2020), DHS Delegation 09052 Rev. 00 “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency” (Jan. 3, 2017), and DHS Delegation 09052 Rev. 00.1, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency” (Apr. 1, 2020).

<sup>5</sup> See 45 CFR 101.20.

<sup>6</sup> HHS has long held resource authority for health resources. See Executive Order 13603, 77 FR 16651 (Mar. 22, 2012) and more recently Executive Order 13909, 85 FR 16227 (Mar. 23, 2020). While Executive Order 13911 delegated the same authorities to DHS, HHS’s extensive expertise in this area would be required for any vaccine development-related efforts.

<sup>7</sup> See 44 CFR 333.8. See also 45 CFR 101.20.

consistency across agencies to ensure a unified response in combating this pandemic and avoid any confusion in implementation, FEMA is retaining the definition of “health and medical resources” from the interim final rule and believes the definition provides sufficient clarity regarding the resources covered by the rule.

The same commenter pointed out that, while FEMA already possesses subdelegated authority to use both the Department of Commerce’s Defense Priority and Allocations System (DPAS) and the Department of Agriculture’s Agriculture Priority and Allocations System (APAS) regulations, having the EMPAS regulations should enhance predictability. The commenter noted the EMPAS regulations were generally patterned after other Federal Priority and Allocations System (FPAS) regulations, with some exceptions. For example, the EMPAS regulations discuss rated orders placed by FEMA or a Delegate Agency to facilitate sales to third parties. The commenter noted this distinction could refer to contracts placed in support of hospitals or other health entities or serve as a more general reference to the overarching distributor-style role FEMA and other Federal entities have played during the COVID-19 pandemic response to date. The distinction could also set up a type of hybrid rated order/allocation action. FEMA may leverage the EMPAS regulation to facilitate sales to third parties with respect to contracts placed in support of entities seeking scarce and critical health and medical resources and to assist in the distribution of these resources as appropriate. The agency does not intend to create a hybrid rated order/allocation action.

This commenter urged FEMA to be prepared to exercise EMPAS authority and delegate authority to assure the ability to produce, manufacture, fill, and finish coronavirus vaccines, specifically requesting the regulation make clear that emergency authority includes the ability to pre-manufacture vials and syringes as necessary to provide a large number of vaccine doses. As explained above, although vaccines and associated materials are within the authority delegated by Executive Order 13911, HHS is

the agency with expertise in vaccine development and FEMA does not anticipate having a role in that process. FEMA believes the regulation provides sufficient clarity regarding the resource authority delegated by Executive Order 13911 and no changes are required in this final rule.

Another commenter offered suggested improvements to § 333.13 regarding timelines for responses to rated order requests. Specifically, the commenter recommended changes to § 333.13(d)(2) to allow for responses within 6 or 12 hours “after confirmation of receipt by vendor/contractor personnel during normal business hours.” FEMA appreciates that the proposed change would allow vendors and contractors more time to handle rated order requests consistent with their normal business practices, but rated orders are designated as such specifically because of the need to handle them differently than ordinary orders. The language in § 333.13(d)(2) mirrors the existing Department of Commerce DPAS regulations at 15 CFR 700.13(d)(2). As explained in the preamble to the interim final rule, FEMA adopted language consistent with the DPAS regulation because rated orders placed for the purpose of emergency preparedness would require a shorter timeframe to ensure delivery in time to provide disaster assistance, emergency response, or similar activities. Further, the timeframes given in § 333.13(d)(2) are the minimum allowed and only apply when “expedited action is necessary or appropriate.” As such, FEMA does not expect 6- or 12-hour response deadlines to be used frequently, and therefore does not expect the regulatory provision to impose a substantial burden on vendors and contractors. To ensure consistency across FPAS regulations, and because of the nature of FEMA’s mission, FEMA is retaining the language from the interim final rule in the final rule. Additionally, the commenter suggested the use of the term “immediately” in § 333.13(d)(3) and elsewhere could not be realistically defined. The commenter recommended alternative language, such as, “as soon as reasonably practicable” or “promptly with commercially reasonable efforts.”

Again, the language in EMPAS is consistent with the Department of Commerce's DPAS regulations, where this provision has been in use since 2014. Given the exigent circumstances under which FEMA must provide emergency preparedness, mitigation, response, and recovery services, the requirement for immediate notification is necessary to ensure the ultimate timely delivery of these services. In addition, FEMA does not believe that the alternative terms provide a significantly more definite meaning. Therefore, FEMA is retaining the language from the interim final rule to ensure consistency across FPAS regulations.

Two commenters focused their comments exclusively on vaccines, a topic not directly addressed by EMPAS. One commenter requested an ethically produced vaccine that is not developed from aborted fetal cells. The EMPAS regulation does not discuss vaccine development. As explained above, FEMA's EMPAS regulation is limited to establishing standards and procedures for priority and allocation orders for "health and medical resources" as defined in the interim final rule at § 333.8. Although vaccines fall within the scope of "health and medical resources" authority delegated to HHS and to FEMA, FEMA has not played a substantial role in the development of the vaccine given HHS's expertise in the field and long-standing resource authority in the area. Thus, FEMA is not revising the interim final rule in this regard. Finally, one commenter stated her lack of trust in vaccines and indicated she did not want vaccines to be required for school attendance. The EMPAS regulations set standards and procedures for priority and allocation orders for health and medical resources to promote the national defense in response to the COVID-19 pandemic. The regulations do not require individuals to be vaccinated.

### **III. Technical Changes**

This rule makes technical changes to the interim final rule. The authority citation for the final rule is being updated to include DHS Delegation Number 09052 Rev. 00

(Jan. 3, 2017), and to make non-substantive formatting revisions to authorities previously included. The interim final rule contained a placeholder reference to an OMB clearance number for an information collection under the Paperwork Reduction Act. *See* 44 CFR 333.20(c). OMB issued the related Paperwork Reduction Act Notice of Action on May 13, 2020, the same day the interim final rule published in the *Federal Register*. As a result of OMB’s action, FEMA now has a permanent OMB clearance number. Therefore, FEMA is removing from § 333.20(c) the placeholder reference, “1660-NW122” and adding in its place the permanent number, “1660-0149.”

#### **IV. Regulatory Analysis**

##### *A. Administrative Procedure Act (APA)*

This rule is effective immediately because the delayed effective date generally required by the APA is unnecessary. *See* 5 U.S.C. 553(d)(3). The interim final rule that this final rule makes final, with only technical changes, is already in effect.

##### *B. Executive Order 12866, Regulatory Planning and Review, Executive Order 13563, Improving Regulation and Regulatory Review, and Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs*

Executive Orders 12866 (“Regulatory Planning and Review”) and 13563 (“Improving Regulation and Regulatory Review”) direct agencies to assess the 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, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (“Reducing Regulation and Controlling Regulatory Costs”) directs agencies to reduce regulation and control regulatory costs and provides that “for every one new regulation issued, at least two prior regulations be identified for elimination, and that the

cost of planned regulations be prudently managed and controlled through a budgeting process.”

This final rule has been drafted and reviewed in accordance with Executive Order 12866. This rule has been designated a “significant regulatory action” and economically significant under Section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

This final rule adopts the interim final rule (IFR) that established standards and procedures by which FEMA may require certain contracts or orders that promote the national defense be given priority over other contracts or orders and setting new standards and procedures by which FEMA may allocate materials, services, and facilities to promote the national defense under emergency and non-emergency conditions pursuant to section 101 of the Defense Production Act of 1950, as amended.

Accordingly, relative to a post-IFR baseline, this final rule has no economic impact.

Below, FEMA also examines the rule’s impacts relative to a pre-IFR baseline.

This rule sets criteria and procedures under which FEMA will authorize prioritization of certain orders or contracts as well as criteria under which FEMA will issue orders allocating materials, services, and facilities. Under prioritization, FEMA will designate certain orders as one of two possible priority levels. Once so designated, such orders are referred to as “rated orders.” The recipient of a rated order must give it priority over an unrated order or an order with a lower priority rating. A recipient of a rated order may place orders of the same priority level with their suppliers and subcontractors for supplies and services necessary to fulfill FEMA’s rated order. The suppliers and subcontractors must treat the request from the recipient as a rated order with the same priority level as the original rated order. The rule does not require recipients to fulfill rated orders if the price or terms of sale are not consistent with the price or terms of sale of similar non-rated orders. The rule provides a defense from any

liability for damages or penalties for any action or inaction required to maintain compliance with the rule.

The impact of EMPAS on private companies receiving priority orders is expected to vary. FEMA's issuance of a priority-rated order will generally only modify the timing in which other orders are completed. Deferred orders may face delays, which impose a burden on potential recipients of these orders. FEMA's exercise of its priorities and allocations authorities under section 101 of the DPA and EMPAS is expected to have an overall positive impact on the U.S. public and industry by creating a framework by which FEMA exercises its delegated authorities, as discussed above.

Since implementation of the regulation in May, FEMA has modified and extended an allocation order allocating certain scarce and critical materials for domestic use to ensure those resources were not exported from the United States without specific approval by FEMA, and FEMA continues to consider options for using EMPAS to address mission needs. *See* 85 FR 48113 (Aug. 10, 2020). Finalizing the EMPAS regulation allows FEMA to respond to public comments in a timely manner and ensures FEMA's continued ability to use its authorities as appropriate in response to the COVID-19 pandemic. FEMA is also better prepared should delegations of priorities and allocations authority for other types of resources be issued in the future.

### *C. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires an agency to consider the impacts of certain rules on small entities. The RFA's regulatory flexibility analysis requirements apply to only those rules for which an agency was required to publish a general notice of proposed rulemaking pursuant to 5 U.S.C. 553(b) or any other law. *See* 5 U.S.C. 604(a). As discussed previously, FEMA did not issue a notice of proposed rulemaking for this action, and was not required to do so under any law. Thus, the RFA's requirements relating to a final regulatory flexibility analysis do not apply.

*D. Unfunded Mandates Reform Act of 1995*

As noted above, no notice of proposed rulemaking was published in advance of this action. Therefore, the written statement provisions of the Unfunded Mandates Reform Act of 1995, as amended, do not apply to this regulatory action. *See* 2 U.S.C. 1532.

*E. Paperwork Reduction Act of 1995*

This rule contains information collections necessary to support FEMA's implementation of the President's priorities and allocations authority under Title I of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. 4501, *et seq.*). The purpose of this authority is to ensure the timely delivery of products, materials, and services necessary or appropriate to promote the national defense.

The Requests for Special Priorities Assistance collection, 1660-0149, was submitted under OMB's emergency clearance procedures. Currently, FEMA is seeking public comment on collection 1660-0149 through the normal clearance process (see 85 FR 65066, Oct. 14, 2020<sup>8</sup>).

The new Rated Orders, Adjustments, Exceptions, or Appeals Under the Emergency Management Priorities and Allocations System (EMPAS) collection, 1660-0150, cleared OMB's emergency clearance procedures and has an expiration date of 4/30/21. Additionally, FEMA will seek public comments on the collection through the normal clearance process.

*F. Privacy Act*

Under the Privacy Act of 1974, 5 U.S.C. 552a, an agency must determine whether implementation of a proposed regulation will result in a system of records. A "record" is any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his/her education, financial transactions, medical

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<sup>8</sup> Collection 1660-0149's 30-day comment period ended on November 13, 2020.

history, and criminal or employment history and that contains his/her name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. See 5 U.S.C. 552a(a)(4). A “system of records” is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. An agency cannot disclose any record which is contained in a system of records except by following specific procedures.

In accordance with DHS policy, FEMA has completed two Privacy Threshold Analyses (PTAs). DHS has determined that this rulemaking does not affect the 1660-1660-0149 and the 1660-0150 OMB Control Numbers’ compliance with the E-Government Act of 2002 or the Privacy Act of 1974, as amended. Specifically, DHS has concluded that the 1660-0149 and 1660-0150 OMB Control Numbers are covered by the DHS/ALL/PIA-065 Electronic Contract Filing System (ECFS) Privacy Impact Assessment (PIA). Additionally, DHS has decided that the 1660-0149 and the 1660-0150 OMB Control Numbers are covered by the DHS/ALL-021 Department of Homeland Security Contractors and Consultants, 73 FR 63179 (Oct. 23, 2008) System of Records Notice (SORN).

*G. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments*

Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments,” 65 FR 67249, November 9, 2000, applies to agency regulations that have Tribal implications, that is, regulations that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Under this Executive order, to the extent practicable and permitted by law, no agency shall promulgate any regulation that has Tribal implications, that imposes

substantial direct compliance costs on Indian Tribal governments, and that is not required by statute, unless funds necessary to pay the direct costs incurred by the Indian Tribal government or the Tribe in complying with the regulation are provided by the Federal Government, or the agency consults with Tribal officials.

FEMA has reviewed this final rule under Executive Order 13175 and has determined that this final rule does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

#### *H. Executive Order 13132, Federalism*

Executive Order 13132, “Federalism,” 64 FR 43255, August 10, 1999, sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have “substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.” Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action.

FEMA has determined that this rulemaking does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore does not have federalism implications as defined by the Executive order.

#### *I. National Environmental Policy Act of 1969 (NEPA)*

Under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321 *et seq.*, an agency must prepare an environmental assessment or environmental impact statement for any rulemaking that significantly affects the quality of the human environment. FEMA has determined that this rulemaking does not significantly affect the quality of the human environment and consequently has not prepared an environmental assessment or environmental impact statement.

Rulemaking is a major Federal action subject to NEPA. Categorical exclusion A3 included in the list of exclusion categories at Department of Homeland Security Instruction Manual 023-01-001-01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A, issued November 6, 2014, covers the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, and advisory circulars if they meet certain criteria provided in A3(a-f). This interim final rule meets Categorical Exclusion A3(a), “[t]hose of a strictly administrative or procedural nature,” and A3(b), “[t]hose that implement, without substantive change, statutory or regulatory requirements.”

#### *J. Congressional Review of Agency Rulemaking*

Under the Congressional Review of Agency Rulemaking Act (CRA), 5 U.S.C. 801-808, before a rule can take effect, the Federal agency promulgating the rule must: submit to Congress and to the Government Accountability Office (GAO) a copy of the rule; a concise general statement relating to the rule, including whether it is a major rule; the proposed effective date of the rule; a copy of any cost-benefit analysis; descriptions of the agency’s actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act; and any other information or statements required by relevant Executive orders.

FEMA has submitted this final rule to the Congress and to GAO pursuant to the CRA. The Office of Management and Budget has determined that this rule is a “major rule” within the meaning of the CRA. As this rule contains FEMA’s finding for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, there is not a required delay in the effective date. *See* 5 U.S.C. 808(2).

### **List of Subjects in 44 CFR Part 333**

Administrative practice and procedure, Business and industry, Government contracts, National defense, Reporting and recordkeeping requirements, Strategic and critical materials.

For the reasons stated in the preamble, the interim rule adding 44 CFR part 333, which was published at 85 FR 28500 on May 13, 2020, is adopted as final with the following changes:

### **PART 333—EMERGENCY MANAGEMENT PRIORITIES AND ALLOCATIONS SYSTEM**

1. The authority citation for part 333 is revised to read as follows:

**Authority:** 6 U.S.C. 313, 314; 50 U.S.C. 4511, *et seq.*; E.O. 13603, 77 FR 16651; E.O. 13909, 85 FR 16227; E.O. 13911, 85 FR 18403; DHS Delegation 09052, Rev. 00 (Jan. 3, 2017); DHS Delegation 09052 Rev 00.1 (Apr. 1, 2020).

#### **§ 333.20 [Amended]**

2. In § 333.20, amend paragraph (c) by removing “1660-NW122” and adding in its place “1660-0149.”

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**Pete Gaynor,**

*Administrator,*

*Federal Emergency Management Agency.*