		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**All Changes**
URBAN TEACHING/DSH						
	TEACHING & DSH	1,163	-0.1	-0.1	2.9	2.9
	NO TEACHING/DSH	1,181	0.4	0.4	3.9	3.8
	NO TEACHING/NO DSH	9	-2.4	-1.4	-0.7	1.3
	DSH NOT AVAILABLE2	448	4.0	1.5	8.9	8.9
TYPE OF OWNERSHIP						
	VOLUNTARY	1,991	0.0	0.2	3.3	3.2
	PROPRIETARY	1,077	1.1	0.5	4.8	4.6
	GOVERNMENT	443	-0.3	-0.1	2.7	2.8
CMHCs		32	6.6	0.0	9.9	9.1

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all final CY 2024 OPPS policies and compares those to the CY 2023 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2024 hospital inpatient wage index. The final rural SCH adjustment would continue our current policy of 7.1 percent so the budget neutrality factor is 1. The final budget neutrality adjustment for the cancer hospital adjustment is 1.0005 because the final CY 2024 target payment-to-cost ratio is less than the CY 2023 PCR target.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the final 3.1 percent OPD fee schedule update factor (3.3 percent inpatient PPS (IPPS) hospital market basket percentage increase reduced by 0.2 percentage point for the productivity adjustment).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.

These 3,611 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

44. On page 82162,

a. Second column, first full paragraph, line 24, the figure ''$778.20'' is corrected to read ''$777.39''.

b. Third column, first partial paragraph, line 2, the figure ''$40,466'' is corrected to read ''$40,424''.

c. Third column, under ''2. Estimated Effects of CY 2024 ASC

Payment System Changes'', first paragraph, line 10, the figure ''0.8881'' is corrected to read ''0.889''.

45. On page 82168, second column, first partial paragraph, line 7, the phrase ''302 hours at a cost of $6,670'' is corrected to read ''2,849 hours at a cost of $68,218''.

46. On page 82171, third column, in footnote 858 the link *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800088* is corrected to read ''*https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800083*''.

Elizabeth J. Gramling,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2024–02631 Filed 2–6–24; 4:15 pm]

BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 101

RIN 0908–AA00

Health Resources Priorities and Allocations System (HRPAS)

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing a final rule establishing standards and

procedures by which it may require acceptance and priority performance of certain contracts or orders to promote the national defense over other contracts or orders with respect to health resources. This final rule also sets new standards and procedures by which HHS may allocate materials, services, and facilities to promote the national defense. This rule finalizes the regulations as proposed in the Notice of Proposed Rule Making (NPRM) of August 16, 2023, with minor technical edits based on comments received.

DATES: This rule is effective March 11, 2024.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, telephone at (202) 260–0365 or via email at *aspr.dpa@hhs.gov.*

SUPPLEMENTARY INFORMATION: This final rule implements HHS' administration of priorities and allocations actions with respect to health resources and establishes the Health Resources Priorities and Allocations System (HRPAS). The HRPAS covers health resources pursuant to the authority under section 101(a) of the Defense Production Act (DPA) of 1950 as delegated to the Secretary of HHS (Secretary) by Executive Order (E.O.) 13603. On September 26, 2022, the Secretary delegated to the Assistant Secretary for Preparedness and Response (the ASPR) within the Administration for Strategic Preparedness and Response (ASPR), the authority under section 201 of E.O. 13603 to exercise priorities authority under section 101 of the DPA. This delegation authorized the ASPR, on behalf of the Secretary, to approve DO—[–[M1–M9] priority rating requests for health resources that promote the national defense. This delegation excludes the authority to approve all priorities provisions for health resources that require DX—[–[M1–M9] priority ratings. The Secretary retains all other authorities delegated by the President in E.O. 13603.

The HRPAS has two principal components: priorities and allocations. Under the priorities' component, the Secretary is authorized to place priority ratings on contracts or orders for health resources to support programs which have been determined by the Department of Defense, Department of Energy, or Department of Homeland Security as necessary or appropriate to promote the national defense in accordance with section 202 of E.O. 13603. Through the HRPAS rule, HHS may also respond to requests to place priority ratings on contracts or orders (requiring priority performance of contracts or orders) for health resources, as specified in the DPA, if the necessity arises. Under the priorities' component, certain contracts or orders between the government and private parties or between private parties for the production or delivery of health resources are required to be prioritized over other contracts or orders to facilitate expedited production or delivery in promotion of the U.S. national defense. The Secretary retains the authority for allocations. Under the allocations' component, materials, services, and facilities may be allocated to promote the national defense. Such requests must be determined as necessary or appropriate to promote the national defense in accordance with section 202 of E.O. 13603. For both components, the term ''national defense'' is defined in section 801(j) of E.O. 13603 as ''programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity.'' The term also includes emergency preparedness activities conducted pursuant to title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) and critical infrastructure protection and restoration. See E.O. 13603, section 801(j). Other authorities delegated to the Secretary in E.O. 13603, but not covered by this regulation may be re-delegated by the Secretary.

I. Background

HHS published an interim final rule in the **Federal Register** at 80 FR 42408 on July 17, 2015, to comply with the Part II—Priorities and Allocations, Sec 201(b) of E.O. 13603, dated March 16, 2012, and section 101(d) of the DPA, 50 U.S.C. 4511(d), and received no public comments. Based on the signficant amount of time between the publication of the interim final rule in 2015, HHS published, on August 16, 2023, a NPRM in the **Federal Register** at 88 FR 55613 to allow for comments based on HHS utilizing DPA authorities and the HRPAS to respond to COVID–19 Public Health Emergency (PHE) from 2020 to 2023 and the infant formula shortage in 2022.

II. Discussion and Analysis

HRPAS is a program established in accordance with the DPA and E.O. 13603 that supports national defense needs (for health resources), including emergency preparedness initiatives, by addressing essential civilian needs through the placing of priority ratings on contracts and orders for items and services or allocating resources, as necessary. Although a specific Presidential disaster declaration is not required, the ability to prioritize or allocate items or services requires a determination be made in accordance with section 202 of E.O. 13603, (except as provided in section 201(e) for use of the allocations authority) that the program or programs are necessary or appropriate to promote national defense, including emergency preparedness. The HRPAS outlines several conditions that must be met in order for HHS to undertake an allocation order, which include a finding, when necessary, under section 101(b) of the DPA that such a material is a scarce and critical material essential to the national defense and that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship. The President must approve the finding, in accordance with section 201(e) of E.O. 13603, before the Secretary may use the allocation authority. Under section 702(14) of the DPA (50 U.S.C. 4552(14)), the term ''national defense'' includes emergency preparedness activities conducted pursuant to the Stafford Act, and critical infrastructure protection and restoration. Authority for priorities and allocations is specified in the DPA and further defined in E.O. 13603, ''National Defense Resources Preparedness,'' dated March 16, 2012. E.O. 13603 replaced E.O. 12919 and further defined jurisdictional areas and national defense preparedness roles and responsibilities for specific agencies. E.O. 13603 did not change the intent of the DPA as it applies to HHS' functions in national defense, including emergency preparedness.

Jurisdiction

E.O. 13603 authorizes jurisdictional areas for each agency delegated title I authority under the DPA that is involved in national defense, including emergency preparedness. HHS has jurisdiction for items that fall under the category of health resources which is defined in E.O. 13603 as ''drugs, biological products, medical devices, materials, facilities, health supplies, services and equipment required to diagnose, mitigate, or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population.'' HHS cannot use its DPA authority for items or services not in its jurisdiction. Those entities in need of items or services that do not fall under the jurisdiction of HHS

should request priorities assistance from the applicable resource department. HHS will direct the requesters to the appropriate resource agency if the request comes to HHS. HHS intends to work with other resource agencies to address instances where HHS does not have jurisdiction—or where jurisdiction may be overlapping or ambiguous—for items necessary to complete the order. HHS intends to work with the other resource agencies to request prioritization of contracts or orders for other items or services necessary for use in support of programs approved for use by HHS (see next section).

HRPAS Approved Programs

On November 2, 2023, the Department of Homeland Security approved four programs to be eligible for priorities and allocations support in accordance with Section 202 of Executive Order 13603. These programs are listed in Appendix 1.

III. DPA Priorities and Allocations System Authority

The Defense Production Act Reauthorization (DPAR) of 2009 required that HHS, and all other agencies that previously have been delegated priorities and allocations authority under E.O. 13603, publish regulations providing standards and procedures for prioritization of contracts and orders and for allocation of materials, services, and facilities to promote the national defense under both emergency and nonemergency conditions. HHS' regulation, along with regulations promulgated by other agencies, are part of the Federal Priorities and Allocations System (FPAS).

On October 1, 2018, Congress amended the DPA through the John S. McCain National Defense Authorization Act (Pub. L. 115–232) which extended non-permanent provisions through September 30, 2025. Section 101(d) of the DPA, as amended, directs all agencies to which the President has delegated priorities and allocations authority under E.O. 13603 to publish final rules establishing standards and procedures by which that authority will be used to promote the national defense in both emergency and non-emergency situations. The DPAR also required all such agencies to consult with the heads of other Federal agencies as appropriate and to the extent practicable to develop a consistent and unified FPAS. This rulemaking is one of several rules published to implement section 101 of the DPA. The rules of the agencies with such authorities, which are the Departments of Commerce, Energy, Transportation, Health and Human Services, Homeland Security, Defense, and Agriculture, comprise the FPAS. HHS is publishing this NPRM rule in compliance with section 101(d) of the DPA. HHS' HRPAS provisions are consistent with the FPAS regulations issued by other agencies to the extent practicable.

The HRPAS, as part of the FPAS, has two principal components: priorities and allocations. Under the priorities component, contracts and orders between the government and private parties or between private parties for the production or delivery of health resources are required to be given priority over other contracts to facilitate expedited production and delivery in promotion of the U.S. national defense. Under the allocations component, materials, services, and facilities may be allocated to promote the national defense. For both components, the term ''national defense'' is defined broadly and includes emergency preparedness activities conducted pursuant to title VI of the Stafford Act and critical infrastructure protection and restoration priorities authorities. Priorities, allocations, and other authorities delegated to the Secretary in E.O. 13603, but not covered by this regulation may be re-delegated by the Secretary. The Secretary delegated the authority for DO priority ratings to the ASPR. The Secretary retains the authority for DX priority ratings and for allocations.

IV. Summary of Significant Changes From the 2015 Interim Final Rule to the 2023 NPRM

a. HHS' interim final rule had a 60-day comment period that ended on September 15, 2015. HHS received no comments on the interim Final Rule. HHS has made minor revisions to its interim final rule based on the use of these authorities to response to the COVID–19 PHE, the infant formula shortage, and deliberations with interagency partners. These changes were reflected in the NPRM (88 FR 55613: 08/16/2023).

(1) Section 101.1, Purpose, was revised to add livestock resources, veterinary resources, and plant health resources.

(2) Section 101.20, Definitions, was revised to include a new definition of priority rating and program identification symbol and add a definition of ''working day.''

(3) Section 101.30, Delegation of Authority, was revised to include the delegation of DO priority rating authority of the DPA, and section 201 of E.O. 13603, from the Secretary of HHS to the Assistant Secretary for Preparedness and Response (the ASPR).

(4) Section 101.63, Letters and Memoranda of Understanding was revised to delete references to Memoranda.

b. Analysis of Other Technical Edits: Several editorial changes were made to the rule and are summarized below.

(1) Placement of Rated Orders

(a) Section 101.33. The acceptance and rejection times for rated orders are revised. The preamble section of the interim final rule was inconsistent with the provisions in §§ 101.32 and 101.33 with respect to the time limits for acceptance and rejection of rated orders. Most rated orders will continue to require acceptance or rejection within 10 or 15 working days depending on the type of rating. Rated orders placed in support of emergency preparedness requirements may require acceptance or rejection within a shorter timeframe that is specified in the rated order. The minimum times for acceptance or rejection that such orders may specify are six business (6) hours for emergencies that have occurred, or 12 business hours if needed to prepare for an imminent hazard. Also, ''time limit in'' has been changed to ''minimum times,'' which is the correct terminology.

(b) Section 101.33(d)(2). Customer notification requirements require persons who have accepted a rated order to give notice if performance will be delayed. The time limit to provide written confirmation of a verbal notice is five (working) days; the time limit is revised to one (1) working day to provide written confirmation of a verbal notice. HHS believes that the nature of rated orders supporting national defense requirements justifies expeditious communications and that once a verbal notice of delayed performance has been given, putting that notice into writing should not take more than one working day.

(2) Allocation Actions

Sections 101.51 and 101.51(a) are revised to conform with language in the other FPAS regulations and comply with the requirement in section 101(d)(2) of the DPA for the regulations to be consistent and unified.

Section 101.53 is revised 101.53 to change ''is requiring'' to ''as established.'' The rationale for this change is that ''is requiring'' implies that the allocations process is a constant obligation.

(3) Elements of an Allocation Order

(a). Section 101.54(c) is revised to include a new element to be included in an allocation order that gives constructive notice through publication in the **Federal Register**.

(4) Official Actions

(a) Section 101.63. ''Memorandums of Understanding'' (MOUs) are universally known in the Federal Government as an agreement between agencies/parties, sometimes completed under the Economy Act, and the use of MOUs in implementing priorities authorities could cause confusion. Therefore, the terms ''Memorandum of Understanding'' or ''Memoranda of Understanding'' in § 101.63 and other sections in the interim rule are deleted.

(b) Section 101.1 Purpose

Section 101.1 revises the sentence regarding guidance and procedures for use of DPA authorities to include livestock, veterinary resources, plant health resources, and all forms of energy. In addition, HHS deleted reference to 32 CFR part 555, referring to priorities and allocations for water resources.

(c) Section 101.3 Program Eligibility

Section 101.3 is revised to delete ''deployment and sustainment of military forces,'' to track with section 702(14) of the DPA.

(d) Section 101.20 Definitions

(1) Revise definition of ''National defense'' to delete ''health'' and add ''energy'' to track definition of ''national defense'' in section 702(14) of the DPA.

(2) Delete sentence stating, ''Natural resources such as oil and gas,'' from the definition of ''Materials.''

(3) Revise the definition of ''person.''

(4) Revise the definition of ''priority rating.''

(5) Add a definition for ''Working day.''

e. Section 101.30 Delegations of Authority

Revised to change ''priority rating activities'' to ''priorities authorities'' to track E.O. 13603.

f. Section 101.31 Priority Ratings

(1) Paragraph (a)(1), Levels of priority is revised to change ''Federal'' to ''Health Resources'' because agency regulations establish priority levels.

g. Section 101.32 Elements of a Rated Order

(2) Paragraph (d)(2)(i). The preamble discussion of § 101.33 is revised to correct the 2-day time frame for acceptance or rejection of rated orders for emergency preparedness to be consistent with §§ 101.32 and 101.33.

h. Section 101.33 Acceptance and Rejection of Rated Orders

Paragraph (e). The discussion of § 101.33 of the preamble of the interim final rule is inconsistent with the 2-working daytime frame for acceptance or rejection of rated orders in § 101.33. The preamble is revised to correct this inconsistency.

i. Section 101.37 Use of Rated Orders

(1) Paragraph (a)(4) ''Facilities needed to produce rated orders, and'' is deleted because ''facilities'' are considered an industrial resource and not eligible for priorities and allocations under the HHS-administered HRPAS regulation.

j. Section 101.38 Limitations on Placing Rated Orders

(1) Paragraph (b)(1). Revising paragraph (b)(1) to insert ''livestock resources, veterinary resources, and plant health resources,'' to track E.O. 13603.

(2) Paragraph (b)(2). Revising paragraph (b)(2) to add ''All forms of energy'' in lieu of ''Energy supplies,'' to track E.O. 13603.

(3) Paragraph (b)(5). (3) Paragraph (b)(5). Adding a paragraph clarifying Department of Commerce's resource jurisdiction over ''industrial resources.''

(4) Paragraph (b)(6). Changing former paragraph (b)(5) (now paragraph (b)(6)) to clarify that HRPAS priorities and allocations authority may not be applied to communication services as the ''resource judication.''

k. Section 101.40 General Provisions

Paragraph (a). Revised the introductory sentence of paragraph (a). The rationale for this change is once a rating is authorized, in most instances, no further action is required by HHS.

l. Section 101.60 General Provisions

Paragraph (b). Revising paragraph (b) to replace ''Memoranda'' of Understanding with ''Letters.''

m. Section 101.62 Directives

Paragraph (d). Deleting paragraph (d) relating to an Allocation Directive, as it was deleted in the Department of Commerce's final rule.

n. Section 101.63 Letters and Memoranda of Understanding

Revising § 101.63 to delete ''and Memoranda'' in paragraphs (a) and (b).

o. Section 101.74 Violations, Penalties, and Remedies

Paragraph (a). Deleted language specific to the Selective Service Act and related statutes because HHS has not been delegated authority under the Selective Service Act, and the sentence, as well as the reference to the Selective Service Act earlier in this paragraph, have been deleted.

p. Appendix 1 includes four approved programs that are eligible for priorities and allocations support in accordance with Section 202 of Executive Order 13603. These programs are listed in Appendix 1.

V. Summary of Public Comments to the HRPAS NPRM

Based on the signficant amount of time since the publication of the interim final rule in 2015, HHS published, on August 16, 2023, a NPRM in the **Federal Register** (88 FR 55613) to allow for comments based on HHS utilizing DPA and HRPAS authorities in response to COVID–19 and the infant formula shortage in 2022. The comment period for the NPRM closed on September 15, 2023. During the 30-day comment period, HHS received two comments on the HRPAS NPRM. One comment, from a private citizen, was generally supportive of the regulation and primarily requested clarification and identified minor technical errors that have been addressed in this final rule. The second comment was from a coalition advocating on behalf of their stakeholders. This second comment was not specific to the HRPAS or DPA authorities and no edits were required to the HRPAS final rule.

HHS considered all comments received on the NPRM and, based on the comments received, HHS has made minor technical changes from the NPRM (88 FR 55613) to include the following revisions in this final rule:

- In IV of the Preamble, § 101.54(e) is revised to reference § 101.54(c)
- In IV of the Preamble, ''State, local, or Tribal governments'' is revised to reference ''State, Local, Tribal, or Territorial governments.''
- In IV of the Preamble, ''commodities of products'' is revised to read ''commodities or products'' and § 101.20 was revised, consistent with this change.
- Section 101.32(a)(4) is revised to reference § 101.32(a)(4)(a) and (b).
- Section 101.33(c) is revised to reference § 101.32(a)(4)(b).
- Section 101.37(d)(1)(ii) is revised to reference § 101.32(a)(4).

• Section 101.43 is revised to delete reference to ''the Department of Commerce for industrial resources.''

VI. Regulatory Analysis

A. Review Under E.O. 12866, E.O. 13563, and E.O. 14094

(1) Executive Orders 12866 (''Regulatory Planning and Review''), 13563 (''Improving Regulation and Regulatory Review''), and 14094 (''Modernizing 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). Under E.O. 12866, ''significant'' regulatory actions are subject to review by OMB. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. E.O. 14094 amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). This final rule has been drafted and reviewed in accordance with these Executive Orders. This rule has been designated a ''significant regulatory action'' by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs, under section 3(f) of E.O. 12866.

(2) This final rule adopts the interim final rule (IFR) that established standards and procedures by which HHS 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 HHS may allocate materials, services, and facilities to promote the national defense under emergency and non-emergency conditions pursuant to section 101 of the DPA of 1950, as amended. Accordingly, relative to a post-IFR baseline, this final rule has limited economic impact.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. HHS reviewed this final rule under the provisions of the Regulatory Flexibility Act and has determined that this rulemaking, if promulgated, will not have a significant impact on a substantial number of small entities.

(1) Number of Small Entities

(a) Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this final rule on small entities, a small business, as described in the Small Business Administration's Table of Small Business Size Standards Matched to North American Industry Classification System Codes (January 2022 Edition), has a maximum annual revenue of $33.5 million and a maximum of 1,500 employees (for some business categories, these numbers are lower). A small governmental jurisdiction is a government of a city, town, school district or special district with a population of less than 50,000. A small organization is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

(b) This rulemaking sets criteria under which HHS (or agencies to which HHS delegates HHS' DPA authority to issue rated orders) will authorize prioritization of certain contracts or orders for health resources as well as criteria under which HHS will issue orders allocating materials, services, and facilities. Because the rulemaking affects specific commercial transactions, HHS believes that small non-profit organizations and small governmental jurisdictions are unlikely to be directly affected by this rulemaking.

(c) Prior to the COVID–19 PHE, HHS had minimally exercised its prioritization authority for contracts and orders and had not exercised its allocation authorities. To date, HHS has exercised title I priorities authorities approximately 70 times in responding to the COVID–19 PHE to prioritize contracts thus ensuring rapid industrial mobilization for critical health resources (*e.g.,* N95 facemasks, vaccines, therapeutics, and diagnostics) to meet urgent emergency preparedness and response requirements. In response to the initial wave of the COVID–19 pandemic, HHS leveraged its allocations authority, in conjunction with a DX rated order, to re-distribute N–95 facemasks that were seized by the U.S. Customs and Border Protection. Several health resource materials have been identified as essential in responding to the COVID–19 pandemic and these items, such as personal protective equipment (PPE), ventilators, medical countermeasures, and ancillary supplies are in high demand. Therefore, a priority rating was necessary to provide the quantities of these health resources within a specified timeframe to respond to the COVID–19 pandemic. Additionally, in response to the infant formula shortage, HHS issued three priority rated orders to help ensure timely delivery of key ingredients to infant formula manufacturers.

(2) Impact

(a) The final rule has two principal components: prioritization and allocation. Under prioritization, HHS, or its Delegate Agency, designates 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 as necessary to meet the delivery requirement of the rated order. A recipient of a rated order must place orders at the same priority level with suppliers and subcontractors for supplies and services necessary to fulfill the recipient's rated order. The suppliers and subcontractors must treat the request from the rated order recipient as a rated order with the same priority level as the original rated order. The rulemaking 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 rulemaking provides protection against claims for actions taken in, or inactions required for, compliance with the rulemaking.

(b) Although rated orders could require a firm to fill one order prior to filling another, they will not necessarily require a reduction in the total volume of orders. The regulations also do not require the recipient of a rated order to reduce prices or provide rated orders with more favorable terms than a similar non-rated order. Under these circumstances, the economic effects on the rated order recipient of substituting one order for another are likely to be mutually offsetting, resulting in no net economic impact.

(c) Allocations could be used to control the general distribution of materials or services in the civilian market. Specific allocation actions that HHS might take are as follows:

1. *Set-aside:* an official action that requires a person to reserve materials, services, or facilities capacity in anticipation of receipt of rated orders.

2. *Directive:* an official action that requires a person to take or refrain from taking certain actions in accordance with its provisions. A directive can require a person to stop or reduce production of an item; prohibit the use of selected materials, services, or

facilities; or divert the use of materials, services, or facilities from one purpose to another.

3. *Allotment:* an official action that specifies the maximum quantity of a material, service, or facility authorized for a specific use to promote the national defense.

(d) In response to the COVID–19 PHE, HHS leveraged its allocations authority, in conjunction with a DX rated order to re-distribute N–95 facemasks that were seized by the U.S. Customs and Border Protection. As required by section 101(a)(2) of the DPA and by section 201(a)(3) of E.O. 13603, HHS may implement allocations only if the materials, services, and facilities are deemed necessary or appropriate to promote the national defense. ''National defense'' covers programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any related activity. Such terms include emergency preparedness activities conducted pursuant to title VI of the Stafford Act and critical infrastructure protection and restoration.

(e) Any allocation actions taken by HHS must assure that small business concerns shall be accorded, to the extent practicable, a fair share of the materials or services covered by the allocation action, in proportion to the share received by small business concerns under normal conditions, giving such special consideration as may be possible to emerging business concerns. 50 U.S.C. 4551(e).

Conclusion

(f) Although HHS cannot precisely determine the number of small entities that will be affected by this rulemaking, HHS believes that the overall impact on such entities will not be significant. In most instances, rated contracts or orders will be fulfilled in addition to other (unrated) contracts or orders and, in some instances might actually increase the total amount of business of the firm that receives a rated contract or order.

(g) Because allocations can be imposed only after a finding required under section 101(b) of the DPA, and approved by the President in accordance with section 201(e) of E.O. 13603, that such material is a scarce and critical material essential to the national defense and that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship, and because HHS has only used its allocations authority one time in response to the initial wave of COVID–19, one can expect allocations will be ordered only in rare and unique circumstances. Any allocation actions would also have to comply with section 701(e) of DPA (50 U.S.C. 4551(e)), which provides that small business concerns be accorded, to the extent practicable, a fair share of the material, including services, in proportion to the share received by such business concerns under normal conditions, giving such special consideration as may be possible to emerging business concerns.

Therefore, HHS believes that the requirement for a finding under section 101(b) of the DPA, and approved by the President in accordance with section 201(e) of E.O. 13603, that such a material is a scarce and critical material essential to the national defense and that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship and the provisions of section 701 of the DPA indicate that any impact on small business will not be significant.

(h) For the reasons set forth above, the Secretary of HHS certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

C. Review Under the Paperwork Reduction Act

The purposes of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* include minimizing the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing for public comment a summary of the collection of information and a brief description of the need for and proposed use of the information.

A Federal agency may not conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and it displays a currently valid OMB control number. The public is also not required to respond to a collection of information unless it displays a currently valid OMB control number. In addition, notwithstanding any other provisions of law, no person will be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512).

In accordance with the PRA, the Department has submitted one new Information Collection Request (ICR) to OMB in concert with the publishing of this final rule.

D. Review Under E.O. 13132

HHS reviewed this proposed rule pursuant to E.O. 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999), which imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. HHS determined that the rulemaking will 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.

E. Review Under Unfunded Mandates Reform Act

Title II of the Unfunded Mandate Reform Act of 1995 (UMRA, Pub. L. 104–4) requires Federal agencies to assess the effects of their regulatory actions on State, Local, Tribal, or Territorial governments or the private sector. Agencies generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures of $100 million or more in any one year for State, Local, Tribal, or Territorial governments, in the aggregate, or to the private sector. This rule contains no Federal mandates as defined by title II of UMRA for State, Local, Tribal, or Territorial governments or for the private sector; therefore, this rule is not subject to the requirements of sections 202 and 205 of Unfunded Mandate Reform Act.

F. Approval of the Office of the Secretary

The Secretary of Health and Human Services has approved publication of this final rule.

List of Subjects in 45 CFR Part 101

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, HHS is revising part 101 of title 45 of the Code of Federal Regulations as follows:

PART 101—HEALTH RESOURCES PRIORITIES AND ALLOCATIONS SYSTEM (HRPAS)

Sec.

Authority: Defense Production Act of 1950, as amended (50 U.S.C. 4501, *et seq.*), and Executive Order 13603 (77 FR 16651, 3 CFR, March 16, 2012).

Subpart A—General

§ 101.1 Purpose.

This part provides guidance and procedures for use of Defense Production Act (DPA) of 1950 section 101 priorities and allocations authority with respect to health resources necessary or appropriate to promote the national defense. The guidance and procedures in this part are consistent with the guidance and procedures provided in other regulations that form the Federal Priorities and Allocations System (FPAS). Guidance and procedures for use of the DPA priorities and allocations authority with respect to other types of resources are provided for: food resources, food resource facilities, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer in 7 CFR part 789; all forms of energy in 10 CFR part 217; all forms of civil transportation in 49 CFR part 33; and all other materials, services, and facilities, including construction materials in 15 CFR part 700.

§ 101.2 Priorities and allocations authority.

(a) Section 201 of Executive Order (E.O.) 13603, delegates the President's priorities and allocations authority under section 101 of the DPA. Section 101 of the DPA provides the President with authority to require acceptance and priority performance of contracts and 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 to a number of agencies. Section 201 of E.O. 13603 delegates the President's authority to specific agencies as follows:

(1) The Secretary of Agriculture with respect to food resources, food resource facilities, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer;

(2) The Secretary of Energy with respect to all forms of energy;

(3) The Secretary of Health and Human Services with respect to health resources;

(4) The Secretary of Transportation with respect to all forms of civil transportation;

(5) The Secretary of Defense with respect to water resources; and

(6) The Secretary of Commerce for all other materials, services, and facilities, including construction materials.

(b) Section 202 of E.O. 13603 states that the authority delegated in section 201, except as provided in section 201(e) of E.O. 13603, may be used only to support programs that have been determined in writing as necessary or appropriate to promote the national defense:

(1) By the Secretary of Defense with respect to military production and construction, military assistance to foreign nations, military use of civil transportation, stockpiles managed by the Department of Defense, space, and directly related activities.

(2) By the Secretary of Energy with respect to energy production and construction, distribution, and use, and directly related activities; and

(3) By the Secretary of Homeland Security with respect to all other national defense programs, including civil defense and continuity of Government.

(c) Section 201(e) of E.O. 13603 provides that each department that is delegated allocations authority under section 201(a) of E.O. 13603 may use this authority with respect to control of the general distribution of any material (including applicable services) in the civilian market only after:

(1) Making the finding required under section 101(b) of the DPA; and

(2) The finding has been approved by the President.

§ 101.3 Program eligibility.

Certain programs to promote the national defense are approved for priorities and allocations support. These include programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity. Other eligible programs include emergency preparedness activities conducted pursuant to title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), and critical infrastructure protection and restoration.

Subpart B—Definitions

§ 101.20 Definitions.

The following definitions pertain to all sections of this part:

Allocation means the control of the distribution of materials, services, or facilities for a purpose deemed necessary or appropriate to promote the national defense.

Allocation order means an official action to control the distribution of materials, services, or facilities for a purpose deemed necessary or

appropriate to promote the national defense.

Allotment means an official action that specifies the maximum quantity or use of a material, service, or facility authorized for a specific use to promote the national defense.

Approved program means a program determined by the Secretary of Defense, the Secretary of Energy, or the Secretary of Homeland Security to be necessary or appropriate to promote the national defense, under the authority of the Defense Production Act and in accordance with section 202 of E.O. 13603.

Construction means the erection, addition, extension, or alteration of any building, structure, or project, using materials or products which are to be an integral and permanent part of the building, structure, or project. Construction does not include maintenance and repair.

Critical infrastructure means any systems and assets, whether physical or cyber-based, so vital to the United States that the degradation or destruction of such systems and assets would have a debilitating impact on national security, including, but not limited to, national economic security and national public health or safety.

Defense Production Act or *DPA* means the Defense Production Act of 1950, as amended (50 U.S.C. 4501 *et seq.*).

Delegate agency means a Federal Government agency authorized by delegation from the Department of Health and Human Services (HHS) to place priority ratings on contracts or orders needed to support approved programs.

Directive means an official action that requires a person to take or refrain from taking certain actions in accordance with its provisions.

Emergency preparedness means all those activities and measures designed or undertaken to prepare for or minimize the effects of a hazard upon the civilian population, to deal with the immediate emergency conditions which would be created by the hazard, and to effectuate emergency repairs to, or the emergency restoration of, vital utilities and facilities destroyed or damaged by the hazard. ''Emergency Preparedness'' includes the following:

(1) Measures to be undertaken in preparation for anticipated hazards (including the establishment of appropriate organizations, operational plans, and supporting agreements, the recruitment and training of personnel, the conduct of research, the procurement and stockpiling of necessary materials and supplies, the provision of suitable warning systems, the construction or preparation of shelters, shelter areas, and control centers, and, when appropriate, the nonmilitary evacuation of the civilian population).

(2) Measures to be undertaken during a hazard (including the enforcement of passive defense regulations prescribed by duly established military or civil authorities, the evacuation of personnel to shelter areas, the control of traffic and panic, and the control and use of lighting and civil communications).

(3) Measures to be undertaken following a hazard (including activities for firefighting; rescue; emergency medical, health and sanitation services; monitoring for specific dangers of special weapons; unexploded bomb reconnaissance; essential debris clearance; emergency welfare measures; and immediately essential emergency repair or restoration of damaged vital facilities).

Facilities includes all types of buildings, structures, or other improvements to real property (but excluding farms, churches or other places of worship, and private dwelling houses), and services relating to the use of any such building, structure, or other improvement.

Farm equipment means equipment, machinery, and repair parts manufactured for use on farms in connection with the production or preparation for market use of food resources.

Fertilizer means any product or combination of products that contain one or more of the elements nitrogen, phosphorous, and potassium for use as a plant nutrient.

Food resources means all commodities and products, (simple, mixed, or compound), or complements to such commodities or products, that are capable of being ingested by other human beings or animals, irrespective of other uses to which such commodities or products may be put, at all stages of processing from the raw commodity to the products thereof in vendible form for human or animal consumption. ''Food resources'' also means potable water packaged in commercially marketable containers, all starches, sugars, vegetable and animal or marine fats and oils, seed, cotton, hemp, and flax fiber, but does not mean any such material after it loses its identity as an agricultural commodity or agriculture product.

Food resource facilities means plants, machinery, vehicles (including on farm), and other facilities required for the production, processing, distribution, and storage (including cold storage) of food resources, and for the domestic distribution of farm equipment and fertilizer (excluding transportation thereof).

Hazard means an emergency or disaster resulting from:

(1) A natural disaster; or

(2) An accidental or man-caused event.

Health resources means drugs, biological products, medical devices, materials, facilities, health supplies, services and equipment required to diagnose, mitigate, or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population.

Homeland Security includes efforts—

(1) To prevent terrorist attacks within the United States;

(2) To reduce the vulnerability of the United States to terrorism;

(3) To minimize damage from a terrorist attack in the United States; and

(4) To recover from a terrorist attack in the United States.

Industrial resource means all materials, services, and facilities, including construction materials, the authority for which has not been delegated to other agencies under E.O. 13603. The term ''Industrial resource'' does not include food resources, food resource facilities, livestock resources, veterinary resources, and the domestic distribution of farm equipment and commercial fertilizer; all forms of energy; health resources; all forms of civil transportation; and water resources.

Item means any raw, in process, or manufactured material, article, commodity, supply, equipment, component, accessory, part, assembly, or product of any kind, technical information, process, or service.

Maintenance and Repair and/or Operating Supplies (*MRO*) includes the following—

(1) ''*Maintenance*'' is the upkeep necessary to continue any plant, facility, or equipment in working condition;

(2) ''*Repair*'' is the restoration of any plant, facility, or equipment to working condition when it has been rendered unsafe or unfit for service by wear and tear, damage, or failure of parts;

(3) ''*Operating Supplies*'' are any resources carried as operating supplies according to a person's established accounting practice. ''Operating Supplies'' may include hand tools and expendable tools, jigs, dies, fixtures used on production equipment, lubricants, cleaners, chemicals, and other expendable items; and

(4) *MRO* does not include items produced or obtained for sale to other persons or for installation upon or attachment to the property of another

person, or items required for the production of such items; items needed for the replacement of any plant, facility, or equipment; or items for the improvement of any plant, facility, or equipment by replacing items which are still in working condition with items of a new or different kind, quality, or design.

Materials includes—

(1) Any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and

(2) Any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items.

National defense means programs for military and energy 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. 5121, *et seq.*) and critical infrastructure protection and restoration.

Official action means an action taken by HHS under the authority of the DPA, E.O. 13603, and this part or another regulation under the FPAS. Such actions include the issuance of Rating Authorizations, Directives, Set Asides, Allotments, Letters of Understanding, and Demands for Information, Inspection Authorizations, and Administrative Subpoenas.

Person includes any individual, corporation, partnership, association, or any other organized group of persons, or legal successor or representative thereof; or any State or local government or agency thereof; and for purposes of administration of this part, includes the Federal Government and any authorized foreign government or international organization or agency thereof, delegated authority as provided in this part.

Priority rating is an identifying code assigned by HHS, a Delegate Agency or authorized person placed on all rated orders for health resources and consisting of the rating symbol and program identification symbol.

Program Identification Symbols is an abbreviation used to indicate which approved program is supported by a rated order.

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.

Resource department means any agency delegated priorities and allocations authority as specified in § 101.2.

Secretary means the Secretary of HHS.

Services includes any effort that is needed for or incidental to—

(1) The development, production, processing, distribution, delivery, or use of a health resource.

(2) The construction of facilities.

(3) Other national defense programs and activities.

Set-aside means an official action that requires a person to reserve materials, services, or facilities capacity in anticipation of the receipt of rated orders.

Stafford Act means title VI (Emergency Preparedness) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (42 U.S.C. 5121 *et seq.*).

Water resources means all usable water, from all sources, within the jurisdiction of the United States, that can be managed, controlled, and allocated to meet emergency requirements, except ''water resources'' do not include usable water that qualifies as ''food resources''.

Working day means any day that the recipient of an order is open for business.

Subpart C—Placement of Rated Orders

§ 101.30 Delegations of authority.

(a) The priorities and allocations authorities of the President under section 101 of the DPA with respect to health resources have been delegated to the Secretary under E.O. 13603. The Secretary may re-delegate the Secretary's priorities authorities under the DPA to authorize a Delegate Agency to assign priority ratings to orders for health resources needed for use in approved programs.

(b) Pursuant to 87 FR 58363 published in the **Federal Register** on September 26, 2022, the Secretary delegated to the Assistant Secretary for Preparedness and Response (the ASPR) within the Administration for Strategic Preparedness and Response (ASPR), the authority under section 201 of E.O. 13603 to exercise priorities authority under section 101 of the DPA. This delegation authorized the ASPR, on behalf of the Secretary, to approve DO—[–[M1–M9] priority rating requests for health resources that promote the national defense, though this delegation excludes the authority to approve all priorities provisions for health resources that require DX—[–[M1–M9] priority ratings.

§ 101.31 Priority ratings.

(a) *Levels of priority.* (1) There are two levels of priority established by the HRPAS, identified by the rating symbols ''DO'' and ''DX''.

(2) All DO rated orders have equal priority with each other and take precedence over unrated orders. All DX rated orders have equal priority with each other and take precedence over DO rated orders and unrated orders. (For resolution of conflicts among rated orders of equal priority, see § 101.34(c).

(3) In addition, a Directive regarding priority treatment for a given item issued by HHS for that item takes precedence over any DX rated order, DO rated order, or unrated order, as stipulated in the Directive. (For a full discussion of Directives, see § 101.62.)

(b) *Priority ratings.* A priority rating is an identifying code assigned by a Delegate Agency or authorized person placed on all rated orders for health resources. It consists of the rating symbol and the program identification symbol.

§ 101.32 Elements of a rated order.

(a) Each rated order must include:

(1) The appropriate priority rating (*e.g.,* DO–[M1–M9 or DX—[–[M1–M9];

(2) A required delivery date or dates. The words ''immediately'' or ''as soon as possible'' do not constitute a delivery date. A ''requirements contract,'' ''basic ordering agreement,'' ''prime vendor contract,'' or similar procurement document bearing a priority rating may contain no specific delivery date or dates and may provide for the furnishing of items or service from time-to-time or within a stated period against specific purchase orders, such as ''calls,'' ''requisitions,'' and ''delivery orders.'' These purchase orders must specify a required delivery date or dates and are to be considered as rated as of the date of their receipt by the supplier and not as of the date of the original procurement document;

(3) The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order. The signature or use of the name certifies that the rated order is authorized under this part and that the requirements of this part are being followed; and

(4) A statement that reads in substance:

(b) This is a rated order certified for national defense use, and you are required to follow all the provisions of the Health Resources Priorities and Allocations System regulation at 45 CFR part 101.

(c) Additional element required for certain emergency preparedness rated orders. If the rated order is placed in support of emergency preparedness requirements and expedited action is necessary and appropriate to meet these requirements, the following statement must be included in the order: ''This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within [Insert a time limit no less than the minimum applicable time limit specified in § 101.33(e)].''

§ 101.33 Acceptance and rejection of rated orders.

(a) *Mandatory acceptance.* (1) Except as otherwise specified in this section, a person shall accept every rated order received and must fill such orders regardless of any other rated or unrated orders that have been accepted.

(2) A person shall not discriminate against rated orders in any manner such as by charging higher prices or by imposing different terms and conditions than for comparable unrated orders.

(b) *Mandatory rejection.* Unless otherwise directed by HHS for a rated order involving health resources:

(1) A person shall not accept a rated order for delivery on a specific date if unable to fill the order by that date. However, the person must inform the customer of the earliest date on which delivery can be made and offer to accept the order on the basis of that date. Scheduling conflicts with previously accepted lower rated or unrated orders are not sufficient reason for rejection under this section.

(2) A person shall not accept a DO rated order for delivery on a date which would interfere with delivery of any previously accepted DO or DX rated orders. However, the person must offer to accept the order based on the earliest delivery date otherwise possible.

(3) A person shall not accept a DX rated order for delivery on a date which would interfere with delivery of any previously accepted DX rated orders but must offer to accept the order based on the earliest delivery date otherwise possible.

(4) If a person is unable to fill all of the rated orders of equal priority status received on the same day, the person must accept, based upon the earliest delivery dates, only those orders which can be filled, and reject the other orders. For example, a person must accept order A requiring delivery on December 15 before accepting order B requiring delivery on December 31. However, the person must offer to accept the rejected orders based on the earliest delivery dates otherwise possible.

(c) *Optional rejection.* Unless otherwise directed by HHS for a rated order involving health resources, rated orders may be rejected in any of the following cases as long as a supplier does not discriminate among customers:

(1) If the person placing the order is unwilling or unable to meet regularly established terms of sale or payment;

(2) If the order is for an item not supplied or for a service not capable of being performed;

(3) If the order is for an item or service produced, acquired, or provided only for the supplier's own use for which no orders have been filled for two years prior to the date of receipt of the rated order. If, however, a supplier has sold some of these items or provided similar services, the supplier is obligated to accept rated orders up to that quantity or portion of production or service, whichever is greater, sold or provided within the past two years;

(4) If the person placing the rated order, other than the U.S. Government, makes the item or performs the service being ordered;

(5) If acceptance of a rated order or performance against a rated order would violate any other regulation, official action, or order of the HHS issued under the authority of the DPA or another relevant statute.

(d) *Customer notification requirements.* (1) Except as provided in paragraph (e) of this section, a person must accept or reject a rated order in writing or electronically within fifteen (15) working days after receipt of a DO-rated order and within ten (10) working days after receipt of a DX-rated order. If the order is rejected, the person must give reasons in writing or electronically for the rejection.

(2) If a person has accepted a rated order and subsequently finds that shipment or performance will be delayed, the person must notify the customer immediately, give the reasons for the delay, and advise of a new shipment or performance date. If notification is given verbally, written (hard copy) or electronic confirmation must be provided within one (1) working day of the verbal notice.

(e) *Exception for emergency response conditions.* If the rated order is placed for the purpose of emergency preparedness, and expedited action is necessary or appropriate to meet these requirements and the order includes the statement as set forth in § 101.32(a)(4)(b), a person must accept or reject a rated order and transmit the acceptance or rejection in writing or in an electronic format within the time frame specified in the rated order (usually within two working days after receipt of the order). The minimum times for acceptance or rejection that such orders may specify are six (6) hours after receipt if the order is issued by an authorized person in response to a hazard that has occurred; or twelve (12) hours after receipt if the order is issued by an authorized person to prepare for an imminent hazard.

§ 101.34 Preferential scheduling.

(a) A person must schedule operations, including the acquisition of all needed production items or services, in a timely manner to satisfy the delivery requirements of each rated order. Modifying production or delivery schedules is necessary only when required delivery dates for rated orders cannot otherwise be met.

(b) DO rated orders must be given production preference over unrated orders, if necessary, to meet required delivery dates, even if this requires the diversion of items being processed or ready for delivery or services being performed against unrated orders. Similarly, DX rated orders must be given preference over DO rated orders and unrated orders. (Examples: If a person receives a DO rated order with a delivery date of June 3 and if meeting that date would mean delaying production or delivery of an item for an unrated order, the unrated order must be delayed. If a DX rated order is received calling for delivery on July 15 and a person has a DO rated order requiring delivery on June 2 and operations can be scheduled to meet both deliveries, there is no need to alter production schedules to give any additional preference to the DX rated order. However, if business operations cannot be altered to meet both the June 2 and July 15 delivery dates, then the DX rated order must be given priority over the DO rated order.)

(c)(1) If a person finds that delivery or performance against any accepted rated orders conflicts with the delivery or performance against other accepted rated orders of equal priority status, the person shall give precedence to the conflicting orders in the sequence in which they are to be delivered or performed (not to the receipt dates). If the conflicting orders are scheduled to be delivered or performed on the same day, the person shall give precedence to those orders that have the earliest receipt dates.

(2) If a person is unable to resolve rated order delivery or performance conflicts under this section, the person should promptly seek special priorities assistance as provided in §§ 101.40 through 101.44. If the person's customer objects to the rescheduling of delivery

or performance of a rated order, the customer should promptly seek special priorities assistance as provided in §§ 101.40 through 101.44. For any rated order against which delivery or performance will be delayed, the person must notify the customer as provided in § 101.33(d)(2).

(d) If a person is unable to purchase needed production items in time to fill a rated order by its required delivery date, the person must fill the rated order by using inventoried production items. A person who uses inventoried items to fill a rated order may replace those items with the use of a rated order as provided in § 101.37(b).

§ 101.35 Extension of priority ratings.

(a) A person must use rated orders with suppliers to obtain items or services needed to fill a rated order. The person must use the priority rating indicated on the customer's rated order, except as otherwise provided in this part or as directed by HHS.

(b) The priority rating must be included on each successive order placed to obtain items or services needed to fill a customer's rated order. This continues from contractor to subcontractor to supplier throughout the entire procurement chain.

§ 101.36 Changes or cancellations of priority ratings and rated orders.

(a) The priority rating on a rated order may be changed or canceled by:

(1) An official action of HHS; or

(2) Written notification from the person who placed the rated order (including a Delegate Agency).

(b) If an unrated order is amended to make it a rated order, or a DO rating is changed to a DX rating, the supplier must give the appropriate preferential treatment to the order as of the date the change is received by the supplier.

(c) An amendment to a rated order that significantly alters a supplier's original production or delivery schedule shall constitute a new rated order as of the date of its receipt. The supplier must accept or reject the amended order according to the provisions of § 101.33.

(d) The following amendments do not constitute a new rated order: a change in shipping destination; a reduction in the total amount of the order; an increase in the total amount of the order which has negligible impact upon deliveries; a minor variation in size or design (prior to the start of production); or a change which is agreed upon between the supplier and the customer.

(e) If a person no longer needs items or services to fill a rated order, any rated orders placed with suppliers for the items or services, or the priority rating on those orders, must be canceled.

(f) When a priority rating is added to an unrated order, or is changed or canceled, all suppliers must be promptly notified in writing.

§ 101.37 Use of rated orders.

(a) A person must use rated orders to obtain:

(1) Items which will be physically incorporated into other items to fill rated orders, including that portion of such items normally consumed or converted into scrap or by-products in the course of processing;

(2) Containers or other packaging materials required to make delivery of the finished items against rated orders;

(3) Services, other than contracts of employment, needed to fill rated orders;

(4) MRO needed to produce the finished items to fill rated orders.

(b) A person may use a rated order to replace inventoried items (including finished items) if such items were used to fill rated orders, as follows:

(1) The order must be placed within 90 days of the date of use of the inventory.

(2) A DO rating symbol and the program identification symbol indicated on the customer's rated order must be used on the order. A DX rating may not be used even if the inventory was used to fill a DX rated order.

(3) If the priority ratings on rated orders from one customer or several customers contain different program identification symbols, the rated orders may be combined.

(c) A person may combine DX and DO rated orders from one customer or several customers if the items or services covered by each level of priority are identified separately and clearly.

(d) Combining rated and unrated orders.

(1) A person may combine rated and unrated order quantities on one purchase order provided that:

(i) The rated quantities are separately and clearly identified; and

(ii) The four elements of a rated order, as required by § 101.32, are included on the order with the statement required in § 101.32(a)(4) modified to read in substance: ''This purchase order contains rated order quantities certified for national defense use, and you are required to follow all applicable provisions of the Health Resources Priorities and Allocations System regulations at 45 CFR part 101 only as it pertains to the rated quantities''.

(2) A supplier must accept or reject the rated portion of the purchase order as provided in § 101.33 and give preferential treatment only to the rated quantities as required by this part. This part may not be used to require preferential treatment for the unrated portion of the order.

(3) Any supplier who believes that rated and unrated orders are being combined in a manner contrary to the intent of this part or in a fashion that causes undue or exceptional hardship may submit a request for adjustment or exception under § 101.80.

(e) A person may place a rated order for the minimum commercially procurable quantity even if the quantity needed to fill a rated order is less than that minimum. However, a person must combine rated orders as provided in paragraph (c) of this section, if possible, to obtain minimum procurable quantities.

(f) A person is not required to place a priority rating on an order for less than one-half of the Simplified Acquisition Threshold (as established in the Federal Acquisition Regulation (FAR) (see 48 CFR 2.101) or in other authorized acquisition regulatory or management systems) whichever amount is greater, provided that delivery can be obtained in a timely fashion without the use of the priority rating.

§ 101.38 Limitations on placing rated orders.

(a) *General limitations.* (1) A person may not place a DO or DX rated order pursuant to this part unless the person in receipt of the rated order has been explicitly authorized to do so by HHS or a Delegate Agency or is otherwise permitted to do so by this part.

(2) Rated orders may not be used to obtain:

(i) Delivery on a date earlier than needed;

(ii) A greater quantity of the item or services than needed, except to obtain a minimum procurable quantity. Separate rated orders may not be placed solely for the purpose of obtaining minimum procurable quantities on each order;

(iii) Items or services in advance of the receipt of a rated order, except as specifically authorized by HHS (see § 101.41(c) for information on obtaining authorization for a priority rating in advance of a rated order);

(iv) Items that are not needed to fill a rated order, except as specifically authorized by HHS, or as otherwise permitted by this part; or

(v) Any of the following items unless specific priority rating authority has been obtained from HHS, a Delegate Agency, or the Department of Commerce, as appropriate:

(A) Items for plant improvement, expansion, or construction, unless they will be physically incorporated into a

construction project covered by a rated order; or

(B) Production or construction equipment or items to be used for the manufacture of production equipment. [For information on requesting priority rating authority, see § 101.41.]

(C) Any items related to the development of chemical or biological warfare capabilities or the production of chemical or biological weapons unless such development or production has been authorized by the President or the Secretary of Defense. This provision does not however prohibit the use of the priority and allocations authority to acquire or produce qualified countermeasures that are necessary to treat, identify, or prevent harm from any biological or chemical agent that may pose a public health threat affecting national security.

(b) *Jurisdictional limitations.* Unless authorized by the resource agency with jurisdiction, the provisions of this part are not applicable to the following resources:

(1) Food resources, food resource facilities, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer (Resource agency with jurisdiction—Department of Agriculture);

(2) All forms of energy (Resource agency with jurisdiction—Department of Energy);

(3) All forms of civil transportation (Resource agency with jurisdiction—Department of Transportation);

(4) Water resources (Resource agency with jurisdiction—Department of Defense/U.S. Army Corps of Engineers);

(5) All materials, services, and facilities, including construction materials (industrial resources) for which the authority has not been delegated to other agencies under E.O. 13603 (Resource agency with jurisdiction—Department of Commerce);

(6) The priorities and allocations authority of this part may not be applied to communications services (Resource agency with jurisdiction—National Communications System under E.O. 13618 of July 6, 2012).

Subpart D—Special Priorities Assistance

§ 101.40 General provisions.

(a) Once a priority rating has been authorized pursuant to this part, further action by HHS is generally not needed. However, from time-to-time, production or delivery problems will arise in connection with rated orders for health resources as covered under this part. In this event, a person should immediately contact ASPR for guidance, as specified in § 101.93. ASPR serves as the lead policy office for emergency preparedness and response operations on behalf of HHS and manages the Department's delegated DPA authorities. If ASPR is unable to resolve the problem or to authorize the use of a priority rating and believes additional assistance is warranted, ASPR may forward the request to another agency with resource jurisdiction, such as the Department of Commerce, as appropriate, for action. Special priorities assistance is provided to alleviate problems that do arise.

(b) Special priorities assistance is available for any reason consistent with this part. Generally, special priorities assistance is provided to expedite deliveries, resolve delivery conflicts, place rated orders, locate suppliers, or to verify information supplied by customers and vendors. Special priorities assistance may also be used to request rating authority for items that are not normally eligible for priority treatment.

§ 101.41 Requests for priority rating authority.

(a) *Rating authority for items or services not normally rated.* If a rated order is likely to be delayed because a person is unable to obtain items or services not normally rated under this part, the person may request the authority to use a priority rating in ordering the needed items or services.

(b) *Rating authority for production or construction equipment.* (1) A request for priority rating authority for production or construction equipment must be submitted to the U.S. Department of Commerce on Form BIS–999.

(2) When the use of a priority rating is authorized for the procurement of production or construction equipment, a rated order may be used either to purchase or to lease such equipment. However, in the latter case, the equipment may be leased only from a person engaged in the business of leasing such equipment or from a person willing to lease rather than sell.

(c) *Rating authority in advance of a rated prime contract.* (1) In certain cases, and upon specific request HHS may authorize a person to place a priority rating on an order to a supplier in advance of the issuance of a rated prime contract. In these instances, the person requesting advance-rating authority must obtain sponsorship of the request from HHS or the appropriate Delegate Agency. The person shall also assume any business risk associated with the placing of rated orders in the event the rated prime contract is not issued.

(2) The person must state the following in the request: It is understood that the authorization of a priority rating in advance of our receiving a rated prime contract from the Department of Health and Human Services (HHS) and our use of that priority rating with our suppliers in no way commits HHS or any other government agency to enter into a contract or order or to expend funds. Further, we understand that the Federal Government shall not be liable for any cancellation charges, termination costs, or other damages that may accrue if a rated prime contract is not eventually placed and, as a result, we must subsequently cancel orders placed with the use of the priority rating authorized as a result of this request.

(3) In reviewing requests for rating authority in advance of a rated prime contract, HHS will consider, among other things, the following criteria:

(i) The probability that the prime contract will be awarded;

(ii) The impact of the resulting rated orders on suppliers and on other authorized programs;

(iii) Whether the contractor is the sole source;

(iv) Whether the item being produced has a long lead time;

(v) The time period for which the rating is being requested;

(4) HHS may require periodic reports on the use of the rating authority granted under paragraph (c) of this section.

(5) If a rated prime contract is not issued, the person shall promptly notify all suppliers who have received rated orders pursuant to the advanced rating authority that the priority rating on those orders is cancelled.

§ 101.42 Examples of assistance.

(a) While special priorities assistance may be provided for any reason in support of this part, it is usually provided in situations where:

(1) A person is experiencing difficulty in obtaining delivery against a rated order by the required delivery date; or

(2) A person cannot locate a supplier for an item or service needed to fill a rated order.

(b) Other examples of special priorities assistance include:

(1) Ensuring that rated orders receive preferential treatment by suppliers;

(2) Resolving production or delivery conflicts between various rated orders;

(3) Assisting in placing rated orders with suppliers;

(4) Verifying the urgency of rated orders; and

(5) Determining the validity of rated orders.

§ 101.43 Criteria for assistance.

Requests for special priorities assistance should be timely, *i.e.,* the request has been submitted promptly and enough time exists for HHS, or the Delegate Agency to affect a meaningful resolution to the problem, and must establish that:

(a) There is an urgent need for the item; and

(b) The applicant has made a reasonable effort to resolve the problem.

§ 101.44 Instances where assistance may not be provided.

Special priorities assistance is provided at the discretion of HHS or the Delegate Agency when it is determined that such assistance is warranted to meet the objectives of this part. Examples where assistance may not be provided include situations when a person is attempting to:

(a) Secure a price advantage;

(b) Obtain delivery prior to the time required to fill a rated order;

(c) Gain competitive advantage;

(d) Disrupt an industry apportionment program in a manner designed to provide a person with an unwarranted share of scarce items; or

(e) Overcome a supplier's regularly established terms of sale or conditions of doing business.

Subpart E—Allocation Actions

§ 101.50 Policy.

(a) Allocation orders will:

(1) Only be used when there is insufficient supply of a material, service, or facility to satisfy national defense supply requirements through the use of the priorities authority or when the use of the priorities authority would cause a severe and prolonged disruption in the supply of materials, services, or facilities available to support normal U.S. economic activities; and

(2) Not be used to ration materials or services at the retail level.

(b) Allocation orders, when used, will be distributed equitably among the suppliers of the materials, services, or facilities being allocated and not require any person to relinquish a disproportionate share of the civilian market.

§ 101.51 General procedures.

Before the Department of Health and Human Services uses its allocations authority to address a supply problem within its resource jurisdiction, it will develop a plan that includes:

(a) A copy of the written determination made in accordance with section 202 of Executive Order 13603, that the program or programs that would be supported by the allocation action are necessary or appropriate to promote the national defense.

(b) A detailed description of the situation to include any unusual events or circumstances that have created the requirement for an allocation action;

(c) A statement of the specific objective(s) of the allocation action;

(d) A list of the materials, services, or facilities to be allocated;

(e) A list of the sources of the materials, services, or facilities that will be subject to the allocation action;

(f) A detailed description of the provisions that will be included in the allocation orders, including the type(s) of allocation orders, the percentages or quantity of capacity or output to be allocated for each purpose, and the duration of the allocation action (*i.e.,* anticipated start and end dates);

(g) An evaluation of the impact of the proposed allocation action on the civilian market; and

(h) Proposed actions, if any, to mitigate disruptions to civilian market operations.

§ 101.52 Controlling the general distribution of a material in the civilian market.

No allocation action taken by HHS may be used to control the general distribution of a material in the civilian market, unless the Secretary has:

(a) Made a written finding that:

(1) Such material is a scarce and critical material essential to the national defense, and

(2) The requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship;

(b) Submitted the finding for the President's approval through the Assistant to the President and National Security Advisor and the Assistant to the President for Homeland Security and Counterterrorism; and

(c) The President has approved the finding.

§ 101.53 Types of allocation orders.

There are three types of allocation orders available for communicating allocation actions.

(a) *Set-aside.* An official action that requires a person to reserve materials, services, or facilities capacity in anticipation of the receipt of rated orders.

(b) *Directive.* An official action that requires a person to take or refrain from taking certain actions in accordance with its provisions. A directive can require a person to: Stop or reduce production of an item; prohibit the use of selected materials, services, or facilities; or divert the use of materials, services, or facilities from one purpose to another; and

(c) *Allotment.* An official action that specifies the maximum quantity of a material, service, or facility authorized for a specific use to promote the national defense.

§ 101.54 Elements of an allocation order.

Allocation orders may be issued directly to the affected persons or by constructive notice through publication in the **Federal Register**. This section describes the elements that each order must include.

(a) Each allocation order must include:

(1) A detailed description of the required allocation action(s), including its relationship to any received DX rated orders, DO rated orders, and unrated orders;

(2) Specific start and end calendar dates for each required allocation action;

(3) The written signature on a manually placed order or the digital signature on an electronically placed order of the Secretary of HHS.

(b)(1) Elements to be included in orders issued directly to affected persons:

(2) A statement that reads in substance: ''This is an allocation order certified for national defense use. [Insert the name of the person receiving the order] is required to comply with this order, in accordance with the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR part 101);

(c)(1) Elements to be included in an allocation order that gives constructive notice through publication in the **Federal Register***:*

(2) A statement that reads in substance: ''This is an allocation order certified for national defense use. [Insert the name(s) of the person(s) to whom the order applies or a description of the class of persons to whom the order applies] is (are) required to comply with this order, in accordance with the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR part 101).

§ 101.55 Mandatory acceptance of an allocation order.

(a) Except as otherwise specified in this section (see paragraph (c) of this section), a person shall accept and comply with every allocation order received.

(b) A person shall not discriminate against an allocation order in any manner such as by charging higher prices for materials, services, or facilities covered by the order or by imposing terms and conditions for contracts and orders involving allocated materials, services, or facilities that differ from the person's terms and conditions for contracts and orders for the materials, services, or facilities prior to receiving the allocation order.

(c) If a person is unable to comply fully with the required action(s) specified in an allocation order, the person must notify the ASPR, as specified in § 101.93, immediately, explain the extent to which compliance is possible, and give the reasons why full compliance is not possible. If notification is given verbally, then written or electronic confirmation must be provided within one (1) working day. Such notification does not release the person from complying with the order to the fullest extent possible, until the person is notified by HHS that the order has been changed or cancelled.

§ 101.56 Changes or cancellations of an allocation order.

An allocation order may be changed or canceled by an official action of HHS. Notice of such changes or cancellations may be provided directly to persons to whom the order being cancelled or modified applies or constructive notice may be provided by publication in the **Federal Register**.

Subpart F—Official Actions

§ 101.60 General provisions.

(a) HHS may take specific official actions to implement the provisions of this part.

(b) These official actions include, but are not limited to, Rating Authorizations, Directives, and Letters of Understanding (See § 101.20.)

§ 101.61 Rating Authorizations.

(a) A Rating Authorization is an official action granting specific priority rating authority that:

(1) Permits a person to place a priority rating on an order for an item or service not normally ratable under this part; or

(2) Authorizes a person to modify a priority rating on a specific order or series of contracts or orders.

(b) To request priority rating authority, see § 101.41.

§ 101.62 Directives.

(a) A Directive is an official action that requires a person to take or refrain from taking certain actions in accordance with its provisions.

(b) A person must comply with each Directive issued. However, a person may not use or extend a Directive to obtain any items from a supplier, unless expressly authorized to do so in the Directive.

(c) A Directive takes precedence over all DX rated orders, DO rated orders, and unrated orders previously or subsequently received, unless a contrary instruction appears in the Directive.

§ 101.63 Letters of Understanding.

(a) A Letter of Understanding is an official action that may be issued in resolving special priorities assistance cases to reflect an agreement reached by all parties including HHS, the Department of Commerce (if applicable), a Delegate Agency (if applicable), the supplier, and the customer.

(b) A Letter of Understanding is not used to alter scheduling between rated orders, to authorize the use of priority ratings, to impose restrictions under this part. Rather, Letters of Understanding are used to confirm production or shipping schedules that do not require modifications to other rated orders.

Subpart G—Compliance

§ 101.70 General provisions.

(a) HHS may take specific official actions for any reason necessary or appropriate to the enforcement or the administration of the Defense Production Act and other applicable statutes, this part, or an official action. Such actions include Administrative Subpoenas, Demands for Information, and Inspection Authorizations.

(b) Any person who places or receives a rated order or an allocation order must comply with the provisions of this part.

(c) Willful violation of the provisions of title I or section 705 of the DPA and other applicable statutes, this part, or an official action of HHS is a criminal act, punishable as provided in the DPA and other applicable statutes, and as set forth in § 101.74.

§ 101.71 Audits and investigations.

(a) Audits and investigations are official examinations of books, records, documents, other writings, and information to ensure that the provisions of the DPA and other applicable statutes, this part, and official actions have been properly followed. An audit or investigation may also include interviews and a systems evaluation to detect problems or failures in the implementation of this part.

(b) When undertaking an audit or investigation, HHS shall:

(1) Define the scope and purpose in the official action given to the person under investigation; and

(2) Have ascertained that the information sought, or other adequate and authoritative data are not available from any Federal or other responsible agency.

(c) In administering this part, HHS may issue the following documents that constitute official actions:

(1) *Administrative Subpoenas.* An Administrative Subpoena requires a person to appear as a witness before an official designated by HHS to testify under oath on matters of which that person has knowledge relating to the enforcement or the administration of the DPA and other applicable statutes, this part, or official actions. An Administrative Subpoena may also require the production of books, papers, records, documents and physical objects or property.

(2) *Demands for Information.* A Demand for Information requires a person to furnish to a duly authorized representative of HHS any information necessary or appropriate to the enforcement or the administration of the DPA and other applicable statutes, this part, or official actions.

(3) *Inspection Authorizations.* An Inspection Authorization requires a person to permit a duly authorized representative of HHS to interview the person's employees or agents, to inspect books, records, documents, other writings, and information, including electronically-stored information, in the person's possession or control at the place where that person usually keeps them or otherwise, and to inspect a person's property when such interviews and inspections are necessary or appropriate to the enforcement or the administration of the DPA and related statutes, this part, or official actions.

(d) The production of books, records, documents, other writings, and information will not be required at any place other than where they are usually kept, if, prior to the return date specified in the Administrative Subpoena or Demand for Information, a duly authorized official of HHS is furnished with copies of such material that are certified under oath to be true copies. As an alternative, a duly authorized representative of HHS may enter into a stipulation with a person as to the content of the material.

(e) An Administrative Subpoena, Demand for Information, or Inspection Authorization shall include the name, title, or official position of the person to be served, the evidence sought to be adduced, and its general relevance to the scope and purpose of the audit, investigation, or other inquiry. If employees or agents are to be interviewed; if books, records,

documents, other writings, or information are to be produced; or if property is to be inspected; the Administrative Subpoena, Demand for Information, or Inspection Authorization will describe them with particularity.

(f) Service of documents shall be made in the following manner:

(1) Service of a Demand for Information or Inspection Authorization shall be made personally, or by Certified Mail-Return Receipt Requested at the person's last known address. Service of an Administrative Subpoena shall be made personally. Personal service may also be made by leaving a copy of the document with someone at least 18 years old at the person's last known dwelling or place of business.

(2) Service upon other than an individual may be made by serving a partner, corporate officer, or a managing or general agent authorized by appointment or by law to accept service of process. If an agent is served, a copy of the document shall be mailed to the person named in the document.

(3) Any individual 18 years of age or over may serve an Administrative Subpoena, Demand for Information, or Inspection Authorization. When personal service is made, the individual making the service shall prepare an affidavit as to the manner in which service was made and the identity of the person served, and return the affidavit, and in the case of subpoenas, the original document, to the issuing officer. In case of failure to make service, the reasons for the failure shall be stated on the original document.

§ 101.72 Compulsory process.

(a) If a person refuses to permit a duly authorized representative of HHS to have access to any premises or to the source of information necessary to the administration or the enforcement of the DPA and other applicable statutes, this part, or official actions, HHS, through its authorized representative may seek compulsory process. Compulsory process means the institution of appropriate legal action, including ex parte application for an inspection warrant or its equivalent, in any forum of appropriate jurisdiction.

(b) Compulsory process may be sought in advance of an audit, investigation, or other inquiry, if, in the judgment of the Secretary there is reason to believe that a person will refuse to permit an audit, investigation, or other inquiry, or that other circumstances exist which make such process desirable or necessary.

§ 101.73 Notification of failure to comply.

(a) At the conclusion of an audit, investigation, or other inquiry, or at any other time, HHS may inform the person in writing of HHS' position regarding that person's non-compliance with the requirements of the DPA and other applicable statutes, this part, or an official action.

(b) In cases where HHS determines that failure to comply with the provisions of the DPA and other applicable statutes, this part, or an official action was inadvertent, the person may be informed in writing of the particulars involved and the corrective action to be taken. Failure to take corrective action may then be construed as a willful violation of the DPA and other applicable statutes, this part, or an official action.

§ 101.74 Violations, penalties, and remedies.

(a) Willful violation of the provisions of the DPA, and related statutes (when applicable), this part, or an official action, is a crime and upon conviction, a person may be punished by fine or imprisonment, or both. The maximum penalties provided by the DPA are a $10,000 fine, or one year in prison, or both.

(b) The Government may also seek an injunction from a court of appropriate jurisdiction to prohibit the continuance of any violation of, or to enforce compliance with, the DPA, this part, or an official action.

(c) In order to secure the effective enforcement of the DPA and other applicable statutes, this part, and official actions, the following are prohibited:

(1) No person may solicit, influence, or permit another person to perform any act prohibited by, or to omit any act required by, the DPA and other applicable statutes, this part, or an official action.

(2) No person may conspire or act in concert with any other person to perform any act prohibited by, or to omit any act required by, the DPA and other applicable statutes, this part, or an official action.

(3) No person shall deliver any item if the person knows or has reason to believe that the item will be accepted, redelivered, held, or used in violation of the DPA and other applicable statutes, this part, or an official action. In such instances, the person must immediately notify HHS that, in accordance with this provision, delivery has not been made.

§ 101.75 Compliance conflicts.

If compliance with any provision of the DPA and other applicable statutes, this part, or an official action would prevent a person from filling a rated order or from complying with another provision of the DPA and other applicable statutes, this part, or an official action, the person must immediately notify HHS, as specified in § 101.93, for resolution of the conflict.

Subpart H—Adjustments, Exceptions, and Appeals

§ 101.80 Adjustments or exceptions.

(a) A person may submit a request to HHS for an adjustment or exception on the ground that:

(1) A provision of this part or an official action results in an undue or exceptional hardship on that person not suffered generally by others in similar situations and circumstances; or

(2) The consequences of following a provision of this part or an official action are contrary to the intent of the DPA and other applicable statutes, or this part.

(b) Each request for adjustment or exception must be in writing and contain a complete statement of all the facts and circumstances related to the provision of this part or official action from which adjustment is sought and a full and precise statement of the reasons why relief should be provided.

(c) The submission of a request for adjustment or exception shall not relieve any person from the obligation of complying with the provision of this part or official action in question while the request is being considered unless such interim relief is granted in writing by the Secretary or the Secretary's designated representative.

(d) A decision of the Secretary or the Secretary's designated representative under this section may be appealed to the Secretary. (For information on the appeal procedure, see § 101.81.)

§ 101.81 Appeals.

(a) Any person whose request for adjustment or exception was denied by the Secretary or the Secretary's designated representative under § 101.80, may appeal to the Secretary who, through the Secretary's designated representative, shall review and reconsider the denial.

(b)(1) Except as provided in paragraph (b)(2) of this section, an appeal must be received by the Secretary no later than 45 business days after receipt of a written notice of denial. After this 45-business day period, an appeal may be accepted at the discretion of the Secretary.

(2) For requests for adjustment or exception involving rated orders placed for the purpose of emergency

preparedness (see § 101.33(e)), an appeal must be received by the Secretary, no later than 15 business days after receipt of a written notice of denial. Contract performance under the order shall not be stayed pending resolution of the appeal.

(c) Each appeal must be in writing and contain a complete statement of all the facts and circumstances related to the action appealed from and a full and precise statement of the reasons the decision should be modified or reversed.

(d) In addition to the written materials submitted in support of an appeal, an appellant may request, in writing, an opportunity for an informal hearing. This request may be granted or denied at the discretion of the Secretary or the Secretary's designated representative.

(e) When a hearing is granted, the Secretary may designate an HHS employee to act as the Secretary's representative and hearing officer to conduct the hearing and to prepare a report. The hearing officer shall determine all procedural questions and impose such time or other limitations deemed reasonable. In the event that the hearing officer decides that a printed transcript is necessary, all expenses shall be borne by the appellant.

(f) When determining an appeal, the Secretary may consider all information submitted during the appeal as well as any recommendations, reports, or other relevant information and documents available to HHS or consult with any other persons or groups.

(g) The submission of an appeal under this section shall not relieve any person from the obligation of complying with the provision of this part or official action in question while the appeal is being considered unless such relief is granted in writing by the Secretary.

Subpart I—Miscellaneous Provisions

§ 101.90 Protection against claims.

A person shall not be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with any provision of this part, or an official action, notwithstanding that such provision or action shall subsequently be declared invalid by judicial or other competent authority.

§ 101.91 Records and reports.

(a) Persons are required to make and preserve for at least three years, accurate and complete records of any transaction covered by this part or an official action.

(b) Records must be maintained in sufficient detail to permit the determination, upon examination, of whether each transaction complies with the provisions of this part or any official action. However, this part does not specify any method or system to be used.

(c) Records required to be maintained by this part must be made available for examination on demand by duly authorized representatives of HHS as provided in § 101.71.

(d) In addition, persons must develop, maintain, and submit any other records and reports to HHS that may be required for the administration of the DPA and other applicable statutes, and this part.

(e) DPA section 705(d), as implemented by E.O. 13603, provides that information obtained under this section which the Secretary deems confidential, or with reference to which a request for confidential treatment is made by the person furnishing such information, shall not be published or disclosed unless the Secretary determines that the withholding of this information is contrary to the interest of the national defense. Information required to be submitted to HHS in connection with the enforcement or administration of the DPA, this part, or an official action, is deemed to be confidential under DPA section 705(d) and shall be handled in accordance with applicable Federal law.

§ 101.92 Applicability of this part and official actions.

(a) This part and all official actions, unless specifically stated otherwise, apply to transactions in any state, territory, or possession of the United States and the District of Columbia.

(b) This part and all official actions apply not only to deliveries to other persons but also include deliveries to affiliates and subsidiaries of a person and deliveries from one branch, division, or section of a single entity to another branch, division, or section under common ownership or control.

(c) This part shall not be construed to affect any administrative actions taken by HHS, or any outstanding contracts or orders placed pursuant to any of the regulations, orders, schedules, or delegations of authority previously issued by HHS pursuant to authority granted to HHS, by the President under the DPA and E.O. 13603. Such actions, contracts, or orders shall continue in full force and effect under this part unless modified or terminated by proper authority.

§ 101.93 Communications.

All communications concerning this part, including requests for copies of the part and explanatory information, requests for guidance or clarification, and requests for adjustment or exception shall be addressed to the Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services, Washington, DC 20201. Ref: HRPAS, or email *aspr.dpa@hhs.gov*.

Appendix 1 to Part 101

Program identification symbol	Approved program	Agency
M1	Emergency Support Function 8 Public Health and Medical Services.	Department of Health and Human Services.
M2	Strategic National Stockpile	Department of Health and Human Services.
M3	Biodefense and Related Medical Countermeasures	Department of Health and Human Services.
M4	ASPR Critical Infrastructure Protection Program	Department of Health and Human Services.

Dated: January 26, 2024.

Xavier Becerra,

Secretary, U.S. Department of Health, and Human Services.

[FR Doc. 2024–01947 Filed 2–8–24; 8:45 am]

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NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

45 CFR Parts 1149 and 1158

RIN 3135–AA33

Civil Penalties Adjustment for 2024

AGENCY: National Endowment for the Arts, National Foundation on the Arts and the Humanities.

ACTION: Final rule.

SUMMARY: The National Endowment for the Arts (NEA) is adjusting the maximum civil monetary penalties (CMPs) that may be imposed for violations of the Program Fraud Civil Remedies Act (PFCRA) and the NEA's Restrictions on Lobbying to reflect the requirements of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act). The 2015 Act further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. This final rule provides the 2024 annual inflation adjustments to the initial ''catch-up'' adjustments made on June 15, 2017, and reflects all other inflation adjustments made in the interim.

DATES: This rule is effective February 9, 2024.

FOR FURTHER INFORMATION CONTACT: Daniel Fishman, Assistant General Counsel, National Endowment for the Arts, 400 7th St. SW, Washington, DC 20506, Telephone: 202–682–5418.

SUPPLEMENTARY INFORMATION:

1. Background

On December 12, 2017 the NEA issued a final rule entitled ''Federal Civil Penalties Adjustments'' [1] which finalized the NEA's June 15, 2017 interim final rule entitled ''Implementing the Federal Civil Penalties Adjustment Act Improvements Act'',[2] implementing the 2015 Act (section 701 of Pub. L. 114–74), which amended the Inflation Adjustment Act (28 U.S.C. 2461 note) requiring catch-up and annual adjustments to the NEA's CMPs. The 2015 Act requires agencies make annual adjustments to its CMPs for inflation.

A CMP is defined in the Inflation Adjustment Act as any penalty, fine, or other sanction that is (1) for a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; (2) assessed or enforced by an agency pursuant to Federal law; and (3) assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

These annual inflation adjustments are based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October preceding the date of the adjustment, relative to the October CPI–U in the year of the previous adjustment. The formula for the amount of a CMP inflation adjustment is prescribed by law, as explained in OMB Memorandum M–16–06 (February 24, 2016), and therefore the amount of the adjustment is not subject to the exercise of discretion by the Chairman of the National Endowment for the Arts (Chairman).

The Office of Management and Budget has issued guidance on implementing and calculating the 2024 adjustment under the 2015 Act.[3] Per this guidance, the CPI–U adjustment multiplier for this annual adjustment is 1.03241. In its prior rules, the NEA identified two CMPs, which require adjustment: the penalty for false statements under the PFCRA and the penalty for violations of the NEA's Restrictions on Lobbying. With this rule, the NEA is adjusting the amount of those CMPs accordingly.

2. Dates of Applicability

The inflation adjustments contained in this rule shall apply to any violations assessed after January 15, 2024.

3. Adjustments

Two CMPs in NEA regulations require adjustment in accordance with the 2015 Act: (1) the penalty associated with the Program Fraud Civil Remedies Act (45 CFR 1149.9) and (2) the penalty associated with Restrictions on Lobbying (45 CFR 1158.400; 45 CFR part 1158, app. A).

A. Adjustments to Penalties Under the NEA's Program Fraud Civil Remedies Act Regulations

The current maximum penalty under the PFCRA for false claims and statements is currently set at $13,507. The post-adjustment penalty or range is obtained by multiplying the pre-adjustment penalty or range by the percent change in the CPI–U over the relevant time period and rounding to the nearest dollar. Between October 2022 and October 2023, the CPI–U increased by a multiplier of 103.241%. Therefore, the new post-adjustment maximum penalty under the PFCRA for false statements is $13,507 × 1.03241 = $13,944.76 which rounds to $13,945. Therefore, the maximum penalty under the PFCRA for false claims and statements will be $13,945.

B. Adjustments to Penalties Under the NEA's Restrictions on Lobbying Regulations

The penalty for violations of the Restrictions on Lobbying is currently set at a range of a minimum of $23,714 and a maximum of $237,268. The post-adjustment penalty or range is obtained by multiplying the pre-adjustment penalty or range by the percent change in the CPI–U over the relevant time period and rounding to the nearest dollar. Between October 2022 and October 2023, the CPI–U increased by a multiplier of 103.241%. Therefore, the new post-adjustment minimum penalty under the Restrictions on Lobbying is $23,714 × 1.03241 = $24,482.57074, which rounds to $24,483 and the maximum penalty under the Restrictions on Lobbying is $237,268 × 1.03241 = $244,957.86, which rounds to $244,958. Therefore, the range of penalties under the law on the Restrictions on Lobbying shall be between $24,483 and $244,958.

Administrative Procedure Act

Section 553 of the Administrative Procedure Act requires agencies to provide an opportunity for notice and comment on rulemaking and also requires agencies to delay a rule's effective date for 30 days following the date of publication in the **Federal Register** unless an agency finds good cause to forgo these requirements. However, section 4(b)(2) of the 2015 Act requires agencies to adjust civil monetary penalties notwithstanding section 553 of the Administrative Procedure Act (APA) and publish annual inflation adjustments in the **Federal Register**. ''This means that the public procedure the APA generally requires . . . is not required for agencies to issue regulations implementing the annual adjustment.'' OMB Memorandum M–18–03.

Even if the 2015 Act did not except this final rule from section 553 of the APA, the NEA has good cause to dispense with notice and comment. Section 553(b)(B), authorizes agencies to

[1] 82 FR 58348.

[2] 82 FR 27431.

[3] OMB Memorandum M–24–07 (December 19, 2023).