State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Rutland, Township of, Tioga County	422099	March 14, 1975, Emerg; August 1, 1987, Reg; July 16, 2015, Susp.	.....do	do
Shippen, Township of, Tioga County	422100	May 23, 1975, Emerg; December 1, 1986, Reg; July 16, 2015, Susp.	.....do	do
Sullivan, Township of, Tioga County	421183	December 20, 1974, Emerg; March 1, 1987, Reg; July 16, 2015, Susp.	.....do	do
Tioga, Borough of, Tioga County	420827	February 9, 1973, Emerg; May 1, 1988, Reg; July 16, 2015, Susp.	.....do	do
Tioga, Township of, Tioga County	420828	April 17, 1973, Emerg; August 15, 1980, Reg; July 16, 2015, Susp.	.....do	do
Union, Township of, Tioga County	421184	August 7, 1975, Emerg; February 1, 1987, Reg; July 16, 2015, Susp.	.....do	do
Ward, Township of, Tioga County	422101	August 8, 1975, Emerg; July 1, 1987, Reg; July 16, 2015, Susp.	.....do	do
Wellsboro, Borough of, Tioga County	420829	December 26, 1973, Emerg; April 15, 1981, Reg; July 16, 2015, Susp.	.....do	do
Westfield, Borough of, Tioga County	422093	April 22, 1975, Emerg; March 1, 1987, Reg; July 16, 2015, Susp.	.....do	do
Westfield, Township of, Tioga County	421185	March 11, 1975, Emerg; March 1, 1987, Reg; July 16, 2015, Susp.	.....do	do
Virginia:				
Hopewell, City of, Independent City.	510080	May 27, 1975, Emerg; September 5, 1979, Reg; July 16, 2015, Susp.	.....do	do
Region IV				
Florida:				
Okeechobee, City of, Okeechobee County.	120178	July 2, 1975, Emerg; August 26, 1977, Reg; July 16, 2015, Susp.	.....do	do
Okeechobee County, Unincorporated Areas..	120177	May 1, 1975, Emerg; February 4, 1981, Reg; July 16, 2015, Susp.	.....do	do
Region IX				
California:				
Burlingame, City of, San Mateo County	065019	March 19, 1971, Emerg; September 16, 1981, Reg; July 16, 2015, Susp.	.....do	do
San Mateo, City of, San Mateo County	060328	December 26, 1974, Emerg; March 30, 1981, Reg; July 16, 2015, Susp.	.....do	do
San Mateo County, Unincorporated Areas..	060311	August 27, 1975, Emerg; July 5, 1984, Reg; July 16, 2015, Susp.	.....do	do

*.....do = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: June 25, 2015.

Roy E. Wright,

Deputy Associate Administrator, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2015–17526 Filed 7–16–15; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

45 CFR Part 101

RIN 0991–AB94

Health Resources Priority and Allocations System (HRPAS)

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

ACTION: Interim final rule.

SUMMARY: This interim final rule establishes standards and procedures by which the U.S. Department of Health and Human Services (HHS) may require that certain contracts or orders that promote the national defense be given priority over other contracts or orders. This rule also sets new standards and procedures by which HHS may allocate materials, services, and facilities to promote the national defense. This rule will implement HHS's administration of priorities and allocations actions, and establish the Health Resources Priorities and Allocation System (HRPAS). The HRPAS will cover health resources pursuant to the authority under Section 101(c) of the Defense Production Act as delegated to HHS by Executive Order 13603. Priorities authorities (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 retains the authority for allocations.

DATES: Effective July 17, 2015. Comments must be received by September 15, 2015.

ADDRESSES: You may submit comments, identified by RIN 0991–AB94 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- By email directly to *Cassandra.Freeman@hhs.gov.*
- By mail or delivery to Cassandra Freeman, Director, Division of Acquisition Policy, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 630G, Washington, DC 20201.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements or any other provisions contained in this interim final rule may

be submitted to Cassandra Freeman, Director, Division of Acquisition Policy, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 630G, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: The agency program contact is Cassandra R. Freeman, who can be contacted by phone at (202) 205–1855 or via email at *Cassandra.Freeman@hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

HHS is publishing this rule to comply with a requirement of the Defense Production Act Reauthorization of 2009 (Pub. L. 111–67) (the ''DPAR''). The Defense Production Act Reauthorization of 2009 required that HHS, and all other agencies that previously have been delegated authority to issue rated orders under Executive Order 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 non-emergency conditions. HHS's regulation, along with regulations promulgated by other agencies, will become part of the Federal Priorities and Allocations System.

The HRPAS is part of the Federal Priorities and Allocations System. The HRPAS has two principal components: priorities and allocations. Under the priorities component, certain contracts between the government and private parties or between private parties for the production or delivery of industrial resources are required to be given priority over other contracts to facilitate expedited 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 can include critical infrastructure protection and restoration, emergency preparedness and response, and recovery from natural and man-made disasters. Priorities authorities (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 retains the authority for allocations.

On September 30, 2009, Congress amended the DPA through the Defense Production Act Reauthorization of 2009 (Pub. L. 111–67) (the ''DPAR''). The DPAR directed, all agencies to which the President has delegated priorities and allocations authority under E.O. 13603, publish final rules establishing standards and procedures by which that authority will be used to promote the national defense in both emergency and nonemergency situations. The DPAR also required all such agencies to consult as appropriate and to the extent practicable to develop a consistent and unified Federal priorities and allocations system. This rule is one of several rules to be published to implement the provisions of the DPAR. The final rules of the agencies with DPAR authorities, which are the Departments of Commerce, Energy, Transportation, Health and Human Services, Defense, and Agriculture, will comprise the Federal Priorities and Allocations System (''FPAS''). HHS is publishing this interim final rule in compliance with the provision of the DPAR noted above. HHS's HRPAS provisions are consistent with the FPAS regulations being issued by other agencies. The specific proposals in this rule are more fully described below.

Analysis of the Priorities and Allocations System

General

Section 101.1 states the purpose of the HRPAS in general terms, as providing guidance and procedures for use of the Defense Production Act (DPA) priorities and allocations authority with respect to health resources necessary or appropriate to promote the national defense.

Section 101.2 provides guidance and procedures for the use of the DPA priorities and allocation authority with respect to health resources necessary or appropriate to promote the national defense.

Section 101.3 provides an overview of the HRPAS program eligibility.

This section describes briefly aspects of the HRPAS, including the certain programs for military and health resources under the DPA.

Definitions

The ''Definitions'' section appears in § 101.20 and provides definitions for the relevant regulatory terms.

Placement of Rated Orders

Section 101.30, ''Delegation of Authority,'' describes fully the President's delegations to HHS. It also describes, in general terms, the items subject to HHS's jurisdiction. This provision facilitates public understanding of the role that each delegate agency plays in the overall priorities and allocations system.

Section 101.31, ''Priority ratings,'' describes the two possible levels of priority and program identification symbols used when rating an order.

Section 101.32, ''Elements of a rated order,'' describes in detail what each rated order must include, consisting of the appropriate priority rating, delivery date information, signatures and required language. HHS seeks comment specifically on the text of this provision.

Section 101.33, ''Acceptance and rejection of rated orders,'' details when orders placed by HHS may or must be accepted or rejected, and what the procedures are for both, including customer notification requirements and certain exceptions for emergency preparedness conditions. Specifically, persons must accept or reject rated orders for emergency response-related approved programs within fifteen (15) working days (or ten (10) working days, depending on the circumstance). HHS requires the shorter time limit in for the recipient to respond to a rated order issued in connection with an emergency response because such orders would require a shorter time frame to ensure delivery in time to provide disaster assistance, emergency response or similar activities. HHS believes that the exigent circumstances inherent in such activities justify requiring a shorter response time.

Section 101.34, ''Preferential scheduling,'' details procedures in cases where a person receives two or more conflicting rated orders. If a person is unable to resolve such a conflict, this section refers them to special priorities assistance as provided in §§ 101.40 through 101.44.

Section 101.35, ''Extension of priority ratings,'' requires a person to use rated orders with suppliers to obtain items or services needed to fill a rated order. This allows the priority rating to ''extend'' from contractor to subcontractor to supplier throughout the entire procurement chain.

Section 101.36, ''Changes or cancellations of priority ratings and rated orders,'' provides procedures for changing or cancelling a rated order, both by HHS or other persons who placed the order.

Section 101.37, ''Use of rated orders,'' lists what items must be rated. It also introduces the use of certain program identification symbols used when rated orders may be combined, and details the procedures for combining two or more rated orders, as well as rated and unrated orders.

Section 101.38, ''Limitations on placing rated orders,'' prohibits the use of rated orders in a list of specific circumstances. This section also

specifically excludes the use of rated orders for resources within the resource jurisdiction of agencies other than HHS with DPA priorities and allocations authority.

Special Priorities Assistance

Section 101.40, ''General provisions'' illustrates when and how HHS can provide special priorities assistance, and provides specific HHS points of contact and the form to be used for requesting such assistance. Special priorities assistance may generally be requested for any reason.

Section 101.41, ''Requests for priority rating authority,'' directs persons to the Department of Commerce to request rating authority for production or construction equipment. This section also identifies circumstances in which 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, and lists factors HHS will consider in deciding whether to grant this authority.

Section 101.42, ''Examples of assistance,'' provides a number of examples of when special priorities assistance may be provided, although it may generally be provided for any reason.

Section 101.43 lists the criteria for granting assistance, and § 101.44 lists instances in which assistance may not be provided (*i.e.,* to secure a price advantage).

Allocation Actions

Sections 101.50 through 101.52 describe allocations and contain procedures for the use of allocation orders. Specifically, allocation orders will be used only if priorities authority will not provide a sufficient supply of material, services or facilities for national defense requirements, or when use of priorities authority will cause a severe and prolonged disruption in the supply of resources available to support normal U.S. economic activities. Allocation orders will not be used to ration materials or services at the retail level. Allocation orders will be distributed equitably among the suppliers of the resource(s) being allocated and will not require any person to relinquish a disproportionate share of the civilian market. The standards set forth in §§ 101.50 through 101.52 provide reasonable assurance that allocation orders will be used only in situations where the circumstances justify such orders.

Section 101.53 describes the three types of allocation orders that HHS might issue. The types of allocation orders are a set-aside, an allocation directive, and an allotment. A set-aside is an official action that will require a person to reserve resource capacity in anticipation of receipt of rated orders. An allocation directive is an official action that will require a person to take or refrain from taking certain actions in accordance with its provisions (an allocation directive can require a person to stop or reduce production of an item, prohibit the use of selected items, divert supply of one type of product to another, or to supply a specific quantity, size, shape, and type of an item within a specific time period). An allotment is an official action that will specify the maximum quantity of an item authorized for use in a specific program or application. HHS is requiring these three types of allocation orders because it believes that, collectively, they describe the types of actions that might be taken in any situation in which allocation is justified.

Section 101.54, ''Elements of an allocation order,'' sets forth the minimum elements of an allocation order. Those elements are:

- A detailed description of the required allocation action(s);
- Specific start and end calendar dates for each required allocation action;
- The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of the Secretary of Health and Human Services or his/her designee, which certifies that the order is authorized under this regulation and that the order is consistent with requirements of the regulation;
- A statement that reads in substance: *This is an allocation order certified for national defense use. [Insert the legal 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 101.1), which is part of the Federal Priorities and Allocations System;* and
- A current copy of the HRPAS.

HHS rquires these elements because it believes that they provide a proper balance between the need for standards to permit the public to recognize and understand an allocation order if one is issued, and the expectation that any actual allocation orders will have to be tailored to meet unforeseeable circumstances. The language of § 101.54 precludes HHS from including additional information in an allocation order if circumstances warrant doing so.

Section 101.55, ''Mandatory acceptance of allocation orders,'' requires that an allocation order must be accepted if a person is capable of fulfilling the order. If a person is unable to comply fully with the required actions specific in an allocation order, the person must notify HHS immediately, explain the extent to which compliance is possible, and give reasons why full compliance is not possible. This section also states that a person may not discriminate against an allocation order in any manner, such as by charging higher prices or imposing terms and conditions different than what the person imposed on contracts or orders for the same resource(s) that were received prior to receiving the allocation order. Section 101.55 makes it clear to the public that the limited circumstances and emergency situations that trigger issuance of an allocation order require immediate response from the public in order to address the situation in an expedient fashion.

Section 101.56, ''Changes or cancellations of an allocation order'' provides that an allocation order may be changed or cancelled by HHS.

Official Actions

Section 101.60, ''General Provisions'', provides HHS and overview regarding implementation of this subpart.

Section 101.61, ''Rating Authorizations,'' defines a rating authorization as an official action granting specific priority rating authority, and refers persons to § 101.21 to request such priority rating authority.

Section 101.62, ''Directives,'' defines a directive as an official action that requires a person to take or refrain from taking certain actions in accordance with its provisions. This section details directive compliance for the public.

Section 101.63, ''Letters and Memoranda of Understanding,'' defines a letter or memorandum of understanding as an official action that may be issued in resolving special priorities assistance cases to reflect an agreement reached by all parties, and explains its use.

Compliance

Section 101.70, ''General Provisions'' details the official actions which may be taken by HHS to enforce or administer the DPA and other applicable statutes.

Section 101.71, ''Audits and investigations,'' details the procedures for official examinations of books, records, documents, and other writings and information to ensure that the provisions of the DPA and other applicable statutes, this regulation, 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 regulation.

Section 101.72, ''Compulsory process,'' provides that if a person refuses to permit a duly authorized HHS representative to have access to necessary information, HHS may seek the institution of appropriate legal action, including ex parte application for an inspection warrant, in any forum of appropriate jurisdiction.

Sections 101.73 and 101.74 both provide procedures for notification of failure to comply with the DPA, these regulations, or HHS official actions, and describe the resulting penalties and remedies.

Section 101.75, ''Compliance Conflicts,'' requires that persons immediately contact HHS should compliance with the DPA, these regulations, or an official action prevent a person from filling a rated order or from complying with another provision of the DPA and other applicable statutes, this regulation, or an official action.

Adjustments, Exceptions, and Appeals

Section 101.80, ''Adjustments, Exceptions, and Appeals,'' reflects the procedures necessary to request an adjustment or exception to the provisions of these regulations.

Section 101.81, ''Appeals,'' provides the procedures, timing and contact information for appealing a decision made on a request for relief in the previous section.

Miscellaneous Provisions

Section 101.90, ''Protection against claims,'' provides that 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 part of this regulation or an official action.

Section 101.91, ''Records and reports,'' requires that persons are required to make and preserve for at least three years, accurate and complete records of any transaction covered by this regulation or an official action. Various requirements and procedures regarding such records are provided in this section. The confidentiality provisions of the DPA governing the submission of information pursuant to the DPA and these regulations are also set forth.

Section 101.92, ''Applicability of this regulation and official actions,'' provides the jurisdictional applicability of this regulation and official actions.

Section 101.93, ''Communications,'' provides a HHS point of contact for all communications regarding this regulation.

A. Review Under Executive Order 12866 and Executive Order 13563

HHS has examined the impacts of the interim final rule under Executive Order 12866 and Executive Order 13563. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This rule is not an economically significant regulatory action under Executive Order 12866.

A summary of the cost benefit analysis is provided below.

This rule sets criteria under which HHS (or agencies to which HHS delegates HHS's DPA authority to issue rated orders) will authorize prioritization of certain orders or contracts as well as criteria under which HHS will issue orders allocating resources or production facilities. To date, HHS has minimally exercised its prioritization authority for contracts during the response to H1N1 influenza in 2009 to order ancillary supplies in support of the Centers for Disease Control and Prevention's (CDC) Immunization Program, and not exercised its existing allocations authority.

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. A recipient of a rated order may place orders at the same priority level with suppliers and subcontractors for supplies and services necessary to fulfill the recipient's rated order and 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 rule does not require recipients to fulfill rated orders if the price or terms of sale are not consistent with the price or terms of sale of similar non-rated orders. The rule provides a defense from any liability for damages or penalties for actions taken in or inactions required for, compliance with the rule.

The impact of HRPAS on private companies receiving priority orders is expected to vary. However, in most cases, there is likely to be no economic impact in filling priority orders because it will generally just be changing the timing in which orders are completed.

HRPAS is expected to have an overall positive impact on the U.S. public and industry by maintaining and restoring the production, processing, storage, and distribution of health resources during times of both emergency and nonemergency conditions to promote national defense and to prevent civilian hardship in the food marketplace. While HHS has not yet administered HRPAS under DPA authority, the continued use of DPAS by the Department of Defense proves the utility of a priorities and allocations system.

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 interim final rule under the provisions of the Regulatory Flexibility Act and has determined that this rule, if promulgated, will not have a significant impact on a substantial number of small entities.

Number of Small Entities

Small entities include small businesses, small organizations and small governmental jurisdictions. For purposes of assessing the impacts of this interim 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 2012 Edition), has a maximum annual revenue of $33.5 million and a maximum of 1,500 employees (for some business categories, these number 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.

This rule sets criteria under which HHS (or agencies to which HHS delegates HHS's DPA authority to issue rated orders) will authorize prioritization of certain orders or contracts as well as criteria under which HHS will issue orders allocating resources or production facilities. Because the rule affects commercial transactions, HHS believes that small organizations and small governmental jurisdictions are unlikely to be affected by this rule. To date, HHS has

minimally exercised its prioritization authority for contracts during the response to 2009 H1N1 influenza to order ancillary supplies in support of HHS/CDC's Immunization Program, and not exercised its existing allocations authority. As such, HHS has no basis on which to estimate the number of small businesses that may be affected by this rule.

Impact

The interim final rule has two principle 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. A recipient of a rated order may place orders at the same priority level with suppliers and subcontractors for supplies and services necessary to fulfill the recipient's rated order and 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 rule does not require recipients to fulfill rated orders if the price or terms of sale are not consistent with the price or terms of sale of similar non-rated orders. The rule provides a defense from any liability for damages or penalties for actions taken in or inactions required for, compliance with the rule.

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 will also 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.

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:

Set-aside: an official action that requires a person to reserve resource capacity in anticipation of receipt of rated orders.

Allocations directive: an official action that requires a person to take or refrain from taking certain actions in accordance with its provisions. An allocation directive can require a person to stop or reduce production of an item, prohibit the use of selected items, or divert supply of one type of product to another, or to supply a specific quantity, size, shape, and type of an item within a specific time period.

Allotment: an official action that specifies the maximum quantity of an item authorized for use in a specific program or application.

HHS has not yet taken any actions under its existing allocations authority, and any future allocations actions would be used only in extraordinary circumstances. As required by section 101(b) of the Defense Production Act of 1950, as amended, (50 U.S.C. App. Sec. 2071), hereinafter ''DPA,'' and by Section 201(a) (3) of Executive Order 13603, HHS may implement allocations only if the Secretary of Health and Human Services makes, and the President approves, and determines that there is a scarcity of critical materials and services essential to the national defense, and that the requirements of the national defense cannot otherwise be met without a significant interruption of normal distribution of these essential materials or services in the civilian marketplace that would cause considerable hardship. ''National defense'' covers programs for military and health resources production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any related activity. Such term includes emergency preparedness activities conducted pursuant to title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5195 *et seq.*) and critical infrastructure protection and restoration.

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. App. Sec. 2151(e).

Conclusion

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

Because allocations can be imposed only after an agency determination confirmed by the President, and because HHS has not yet used its allocations authority that has existed since passage of the Defense Production Act in 1950, one can expect allocations will be ordered only in particular circumstances. Any allocation actions would also have to comply with Section 701(e) of DPA (50 U.S.C. app. 2151(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 Presidential determination and the provisions of section 701 of the DPA indicate that any impact on small business will not be significant.

Therefore, for the reasons set forth above, the Secretary of the Department of Health and Human Services certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities.

C. Review Under the Paperwork Reduction Act

This interim final rule contains a collection-of-information requirement for Request for Special Priorities Assistance, which is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval. Data required will include: name, location, contact information, items for which the applicant is requesting assistance on, quantity, and delivery date. Public reporting burden for submission of a request for special priorities assistance or priority rating authority is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information

to (see *Cassandra.Freeman@hhs.gov,* Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 630G, Washington, DC 20201).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

Title: Request for Special Priorities Assistance for HRPAS.

OMB Control Number: To be provided by OMB.

Type of Request: New Collection.

Abstract: HRPAS will efficiently place priority ratings on contracts or orders of health resources within its authority as specified in the Defense Production Act (DPA) of 1950, as amended, when necessary. Applicants (Government agencies or private individuals with a role in emergency preparedness, response, and recovery functions) will request authorization from HHS to place a rating on a contract for items to support national defense activities. Applicants must supply, at time of request, their name, location, contact information, items for which the applicant is requesting assistance on, quantity, and delivery date. Applicants can submit the request by mail or fax.

Estimate of Burden: Public reporting for this collection of information is estimated to average 30 minutes per response.

Type of Respondents: Individuals, businesses, and Agencies with responsibilities for emergency preparedness and response.

Estimated Number of Respondents: 100.

Estimated Number of Responses per Respondents: 0.95.

Estimated Total Number of Respondents: 95.

Estimate Total Annual Burden Hours on Respondents: 50 hours.

We are requesting comments on all aspects of this information collection to help us: (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of HHS, including whether the information will have practical utility; (2) Evaluate the accuracy of HHS's estimate of burden including the validity of the methodology and assumptions used; (3) Enhance the quality, utility and clarity of the information to be collected; (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. All comments received in response to this document, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

D. Review Under Executive Order 13132

HHS reviewed this rule pursuant to Executive Order 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 rule 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, or Tribal 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, or Tribal 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, or Tribal governments or for the private sector; therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

F. Approval of the Office of the Secretary

The Secretary of Health and Human Services has approved publication of this interim 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 adds part 101 to subchapter A of title 45 of the Code of Federal Regulations to read as follows:

PART 101—DESCRIBING AGENCY NEEDS

Subpart A—Health Resources Priorities and Allocations System

General

Sec.
101.1 Purpose.
101.2 Priorities and allocations authority.
101.3 Program eligibility.

Subpart B—Definitions

101.20 Definitions.

Subpart C—Placement of Rated Orders

101.30 Delegations of authority.
101.31 Priority ratings.
101.32 Elements of a rated order.
101.33 Acceptance and rejection of rated orders.
101.34 Preferential scheduling.
101.35 Extension of priority ratings.
101.36 Changes or cancellations of priority ratings and rated orders.
101.37 Use of rated orders.
101.38 Limitations on placing rated orders.

Subpart D—Special Priorities Assistance

101.40 General provisions.
101.41 Requests for priority rating authority.
101.42 Examples of assistance.
101.43 Criteria for assistance.
101.44 Instances where assistance may not be provided.

Subpart E—Allocation Actions

101.50 Policy.
101.51 General procedures.
101.52 Controlling the general distribution of a material in the civilian market.
101.53 Types of allocation orders.
101.54 Elements of an allocation order.
101.55 Mandatory acceptance of an allocation order.
101.56 Changes or cancellations of an allocation order.

Subpart F—Official Actions

101.60 General provisions.
101.61 Rating Authorizations.
101.62 Directives.
101.63 Letters and Memoranda of Understanding.

Subpart G—Compliance

101.70 General provisions.
101.71 Audits and investigations.
101.72 Compulsory process.
101.73 Notification of failure to comply.
101.74 Violations, penalties, and remedies.
101.75 Compliance conflicts.

Subpart H—Adjustments, Exceptions, and Appeals

101.80 Adjustments or exceptions.
101.81 Appeals.

Subpart I—Miscellaneous Provisions

101.90 Protection against claims.
101.91 Records and reports.
101.92 Applicability of this part and official actions.
101.93 Communications.

Authority: 50 U.S.C. App. 2061–2171;

Subpart A—Health Resources Priorities and Allocations System

General

§ 101.1 Purpose.

This section provides guidance and procedures for use of Defense Production Act (DPA) of 1950 Section 101(a) priorities and allocations authority with respect to all forms of 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, as a whole, form the Federal Priorities and Allocations System. 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, and the domestic distribution of farm equipment and commercial fertilizer in7 CFR part 700; energy supplies in 10 CFR part 217; all forms of civil transportation in 49 CFR part 33; water resources in 32 CFR part 555; and all other materials, services, and facilities, including construction materials in the Defense Priorities and Allocations System (DPAS) regulation (15 CFR part 700).

§ 101.2 Priorities and allocations authority.

(a) Section 201 of E.O. 13603, delegates the President's authority under Section 101 of the DPA. DPA Section 101 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(a) of E.O. 13603 states that the priorities and allocations authority delegated in Section 201 of that Executive Order 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 priorities and 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.

(d) Priorities authorities (and other authorities delegated to the Secretary in E.O. 13603 but not covered by this regulation) have been re-delegated by the Secretary to the Assistant Secretary for Preparedness and Response (the ''ASPR''). The Secretary retains the authority for allocations.

§ 101.3 Program eligibility.

Certain programs to promote the national defense are eligible for priorities and allocations support. These include programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, deployment and sustainment of military forces, 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. 5195 *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, 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. App. 2061 *et seq.*).

Delegate agency means a Federal government agency authorized by delegation from 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, phosphorus, 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 either 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 agricultural 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 human-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, but not including: Food resources, food resource facilities, and the domestic distribution of farm equipment and commercial fertilizer; all forms of 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 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.

(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;

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

(3) Natural resources such as oil and gas.

National defense means programs for military and health resources production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity. Such term includes emergency preparedness activities conducted pursuant to title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5195, *et seq.*) and critical infrastructure protection and restoration.

Official action means an action taken by the Department of Health and Human Services or another resource agency under the authority of the Defense Production Act, E.O.13603, and this part or another regulation under the Federal Priorities and Allocations System. Such actions include the issuance of Rating Authorizations, Directives, Set Asides, Allotments, Letters of Understanding, Memoranda of Understanding, and Demands for Information, Inspection Authorizations, and Administrative Subpoenas.

Person includes an 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.

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

Secretary means the Secretary of Health and Human Services.

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

(1) The development, production, processing, distribution, delivery, or use of an industrial resource or a critical technology item;

(2) The construction of facilities;

(3) The movement of individuals and property by all modes of civil transportation; or

(4) 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. 5195–5197h).

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 does not include usable water that qualifies as ''food resources''.

Subpart C—Placement of Rated Orders

§ 101.30 Delegations of authority.

The priorities and allocations authorities of the President under Title I of the DPA with respect to all forms of health resources have been delegated to the Secretary under E.O. 13603. The Secretary may re-delegate the Secretary's priority rating activities under the DPA though the allocations authority provided to the Secretary is not subject to delegation per Section 201(e) of E.O. 13603.

§ 101.31 Priority ratings.

(a) *Levels of priority.* (1) There are two levels of priority established by Federal Priorities and Allocations System regulations, 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 the Department of Health and Human Services 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) *Program identification symbols.* Program identification symbols, such as ''DO–HR'', or ''DX–HR'', indicate which approved program is being supported by a rated order. Programs may be approved under the procedures of E.O. 13603 Section 202 at any time. Program identification symbols do not connote any priority.

(c) *Priority ratings.* A priority rating consists of the rating symbol—DO or DX—and the program identification symbol, such as DO–HR or DX–HR.

§ 101.32 Elements of a rated order.

Each rated order must include:

(a) The appropriate priority rating (*e.g.* DO–HR or DX–HR);

(b) 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;

(c) 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

(d)(1) A statement that reads in substance:

> 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.

(2) 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 sentences should be added following the statement set forth in paragraph (d)(1) of this section:

(i) This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within two (2) days after receipt of the order if:

(A) The order is issued in response to a hazard that has occurred; or

(B) If the order is issued to prepare for an imminent hazard, as specified in HRPAS § 101.33(e).

(ii) [Reserved]

§ 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 all forms of 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 all forms of 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 or electronic confirmation must be provided within five (5) working days.

(e) *Exception for emergency response conditions.* If the rated order is placed for the purpose of emergency preparedness, a person must accept or reject a rated order and transmit the acceptance or rejection in writing or in an electronic format within two (2) days after receipt of the order if:

(1) The order is issued in response to a hazard that has occurred; or

(2) The order is issued 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.)

(c) *Conflicting rated orders.* (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 the Department of Health and Human Services.

(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 originating agency that placed the rated order.

(b) If an unrated order is amended so as 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; 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; and

(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 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. In this case, the program identification symbol ''H1'' must be used (*i.e.,* DO–H1).

(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. If different program identification symbols are indicated on those rated orders of equal priority, the person must use the program identification symbol ''H1'' (*i.e.,* DO–H1 or DX–H1).

(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(d) 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, subpart A, 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 unless entitled to do so under 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; and

(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.]

(vi) 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 cause a public health emergency 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, and the domestic distribution of farm equipment and commercial fertilizer (Resource agency with jurisdiction—Department of Agriculture);

(2) Energy supplies (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); and

(5) Communications services (Resource agency with jurisdiction—National Communications System under E.O. 12472 of April 3, 1984).

Subpart D—Special Priorities Assistance

§ 101.40 General provisions.

(a) The six regulations that comprise the Federal Priorities and Allocations System are designed to be largely self-executing. 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 the Secretary for guidance, as specified in § 101.93. If the HHS is unable to resolve the problem or to authorize the use of a priority rating and believes additional assistance is warranted, HHS may forward the request to another agency with resource jurisdiction, or 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.

(c) A request for special priorities assistance or priority rating authority must be submitted to the Secretary, as specified in § 101.93.

§ 101.41 Requests for priority rating authority.

(a) 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, the Department of Health and Human Services, in order to promote the national defense, 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 the Department of Health and Human Services 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 and our use of that priority rating with our suppliers in no way commits the Department of Health and Human Services 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) The 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 agencies to which HHS has delegated its authority to issue rated orders (the ''Delegate Agency''), or the Department of Commerce for industrial resources to effect 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) It is the policy of the Federal Government that the allocations authority under title I of the Defense Production Act may:

(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.

When HHS plans to execute its allocations authority to address a supply problem within its resource jurisdiction, the Department shall develop a plan that includes the following information:

(a) A copy of the Secretary's finding for Presidential approval made, in accordance with Section 201(e) of E.O. 13603, that the material or materials at issue are scarce and critical materials essential to the national defense and that the requirements for national defense for such material(s) cannot otherwise be met without creating a significant dislocation of the normal distribution of such material(s) in to such a degree as to create appreciable hardship.

(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.

(a) 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:

(1) Made a written finding that:

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

(ii) 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;

(2) Submitted the finding for the President's approval through the Assistant to the President for National Security Affairs; and

(3) The President has approved the finding.

(b) The requirements of this section may not delegated by the Secretary (See E.O. 13603, Section 201(e)).

§ 101.53 Types of allocation orders.

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

(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.

§ 101.54 Elements of an allocation order.

Each allocation order must include:

(a) A detailed description of the required allocation action(s);

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

(c) The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of the Secretary of Health and Human Services. The signature or use of the name certifies that the order is authorized under this part and that the requirements of this part are being followed;

(d) A statement that reads in substance:

This is an allocation order certified for national defense use. [Insert the legal 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, subpart A), which is part of the Federal Priorities and Allocations System; and

(e) A current copy of the Health Resources Priorities and Allocations System regulation (subpart A of this part).

§ 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 Secretary, 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, written or electronic confirmation must be provided within five (5) working days. Such notification does not release the person from complying with the order to the fullest extent possible, until the person is notified by the Department of Health and Human Services 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 the Department of Health and Human Services.

Subpart F—Official Actions

§ 101.60 General provisions.

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

(b) These official actions include, but are limited to, Rating Authorizations, Directives, and Memoranda 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 Priorities 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.

(d) An Allocations Directive takes precedence over all Priorities Directives, DX-rated orders, DO-rated orders, and unrated orders previously or subsequently received, unless a contrary instruction appears in the Directive.

§ 101.63 Letters and Memoranda of Understanding.

(a) A Letter or Memorandum 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 or Memorandum 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 or Memoranda 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 Defense Production Act and other applicable statutes, this part, or an official action of the Department of Health and Human Services is a criminal act, punishable as provided in the Defense Production Act 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 Defense Production Act 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 Defense Production Act 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 Defense Production Act 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 Defense Production Act 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 the Department of Health and Human Services to have access to any premises or to the source of information necessary to the administration or the enforcement of the Defense Production Act 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's 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 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, the priorities provisions of the Selective Service Act 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. The maximum penalties provided by the Selective Service Act and related statutes are a $50,000 fine, or three years 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 the Secretary, 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 the Secretary 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 Section. 94a.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 days after receipt of a written notice of denial. After this 45 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 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 particular 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 and its schedules 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 Secretary, U.S. Department of Health and Human Services, and Washington, DC.

Dated: March 3, 2015.

Sylvia M. Burwell,

Secretary.

Editorial note: This document was received by the Office of the Federal Register on July 8, 2015.

[FR Doc. 2015–17047 Filed 7–16–15; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 140214145–5582–02]

RIN 0648–BD81

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coral, Coral Reefs, and Live/Hard Bottom Habitats of the South Atlantic Region; Amendment 8

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Amendment 8 to the Fishery Management Plan for Coral, Coral Reefs, and Live/Hard Bottom Habitats of the South Atlantic Region (FMP) (Amendment 8), as prepared by the South Atlantic Fishery Management Council (Council). This final rule expands portions of the northern and western boundaries of the Oculina Bank Habitat Area of Particular Concern (HAPC) (Oculina Bank HAPC) and allows transit through the Oculina Bank HAPC by fishing vessels with rock shrimp onboard; modifies vessel monitoring system (VMS) requirements for rock shrimp fishermen transiting through the Oculina Bank HAPC with rock shrimp on aboard; expands a portion of the western boundary of the Stetson Reefs, Savannah and East Florida Lithoherms, and Miami Terrace Deepwater Coral HAPC (CHAPC) (Stetson-Miami Terrace CHAPC), including modifications to the shrimp access area A, which is renamed ''shrimp access area 1''; and expands a portion of the northern boundary of the Cape Lookout Lophelia Banks Deepwater CHAPC (Cape Lookout CHAPC). In addition, this rule makes a minor administrative change to the names of the shrimp fishery access areas. The purpose of this rule is to increase protections for deepwater coral based on new information for deepwater coral resources in the South Atlantic.

DATES: This rule is effective August 17, 2015.

ADDRESSES: Electronic copies of Amendment 8, which includes an environmental assessment and a regulatory impact review, may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/s_atl/coral/index.html.*

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted in writing to Anik Clemens, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701; and OMB, by email at *OIRA Submission@omb.eop.gov,* or by fax to 202–395–7285.

FOR FURTHER INFORMATION CONTACT: Karla Gore, Southeast Regional Office, telephone: 727–824–5305.

SUPPLEMENTARY INFORMATION: South Atlantic coral is managed under the FMP. The FMP is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

On May 20, 2014, NMFS published a notice of availability for Amendment 8 and requested public comment (79 FR 28880). On July 3, 2014, NMFS published a proposed rule for Amendment 8 and requested public comment (79 FR 31907). Subsequently, NMFS published a correction to the notice of availability (79 FR 37269, July 1, 2014) and the proposed rule (79 FR 37270, July 1, 2014) to correct an error in the size of the Oculina Bank HAPC. The proposed rule and NOA stated that the size of the Oculina Bank HAPC would expand ''by 405.42 square miles (1,050 square km), for a total area of 694.42 square miles (1,798.5 square km) . . .'' However, this was incorrect. The published corrections explained that the increase in size of the Oculina Bank HAPC would be 343.42 square miles (889.5 square km), for a total area of 632.42 square miles (1,638 square km). The Secretary approved the amendment on August 18, 2014. The proposed rule and Amendment 8 set forth the rationale for the actions contained in this final rule. A summary of the actions implemented by this final rule is provided below.

Management Measures Contained in This Final Rule

This final rule expands the boundaries of the Oculina Bank HAPC and allows transit through the Oculina Bank HAPC by fishing vessels with rock shrimp onboard; modifies the VMS