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(c) The Secretary reviews each state plan that a state has simplified, consolidated, or substituted and accepts the plan only if its contents meet Federal requirements.

§ 100.13 May the Secretary waive any provision of these regulations?

In an emergency, the Secretary may waive any provision of these regulations.

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

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APPENDIX 1 TO PART 101

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

SOURCE: 89 FR 9025, Feb. 9, 2024, unless otherwise noted.

Subpart A—General

§ 101.1 Purpose.

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

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services, and facilities, including construction materials in 15 CFR part 700.

§ 101.2 Priorities and allocations authority.

(a) Section 201 of Executive Order (E.O.) 13603, delegates the President's priorities and allocations authority under section 101 of the DPA. Section 101 of the DPA provides the President with authority to require acceptance and priority performance of contracts and orders (other than contracts of employment) to promote the national defense over performance of any other contracts or orders, and to allocate materials, services, and facilities as deemed necessary or appropriate to promote the national defense to a number of agencies. Section 201 of E.O. 13603 delegates the President's authority to specific agencies as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 101.3 Program eligibility.

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

Subpart B—Definitions

§ 101.20 Definitions.

The following definitions pertain to all sections of this part:

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

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

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

Approved program means a program determined by the Secretary of Defense, the Secretary of Energy, or the Secretary of Homeland Security to be

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necessary or appropriate to promote the national defense, under the authority of the Defense Production Act and in accordance with section 202 of E.O. 13603.

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

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

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

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

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

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

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

when appropriate, the nonmilitary evacuation of the civilian population).

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

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

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

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

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

Food 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).

Food resources means all commodities and products, (simple, mixed, or compound), or complements to such commodities or products, that are capable of being ingested by other human beings or animals, irrespective of other uses to which such commodities or products may be put, at all stages of processing from the raw commodity to the products thereof in vendible form

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for human or animal consumption. “Food resources” also means potable water packaged in commercially marketable containers, all starches, sugars, vegetable and animal or marine fats and oils, seed, cotton, hemp, and flax fiber, but does not mean any such material after it loses its identity as an agricultural commodity or agriculture product.

Hazard means an emergency or disaster resulting from:

- (1) A natural disaster; or
- (2) An accidental or man-caused event.

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

Homeland Security includes efforts—

- (1) To prevent terrorist attacks within the United States;
- (2) To reduce the vulnerability of the United States to terrorism;
- (3) To minimize damage from a terrorist attack in the United States; and
- (4) To recover from a terrorist attack in the United States.

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

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

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

- (1) “*Maintenance*” is the upkeep necessary to continue any plant, facility, or equipment in working condition;
- (2) “*Repair*” is the restoration of any plant, facility, or equipment to work-

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ing condition when it has been rendered unsafe or unfit for service by wear and tear, damage, or failure of parts;

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

(4) *MRO* does not include items produced or obtained for sale to other persons or for installation upon or attachment to the property of another person, or items required for the production of such items; items needed for the replacement of any plant, facility, or equipment; or items for the improvement of any plant, facility, or equipment by replacing items which are still in working condition with items of a new or different kind, quality, or design.

Materials includes—

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

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

National defense means programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity. Such term includes emergency preparedness activities conducted pursuant to title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121, *et seq.*) and critical infrastructure protection and restoration.

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

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and Demands for Information, Inspection Authorizations, and Administrative Subpoenas.

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

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

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

Rated order means a prime contract, a subcontract, or a purchase order in support of an approved program issued in accordance with the provisions of this part.

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

Secretary means the Secretary of HHS.

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

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

(2) The construction of facilities.

(3) Other national defense programs and activities.

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

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

Water resources means all usable water, from all sources, within the jurisdiction of the United States, that can be managed, controlled, and allocated to meet emergency requirements, except “water resources” do not

include usable water that qualifies as “food resources”.

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

Subpart C—Placement of Rated Orders

§ 101.30 Delegations of authority.

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

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

§ 101.31 Priority ratings.

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

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

(3) In addition, a Directive regarding priority treatment for a given item issued by HHS for that item takes precedence over any DX rated order,

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DO rated order, or unrated order, as stipulated in the Directive. (For a full discussion of Directives, see § 101.62.)

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

§ 101.32 Elements of a rated order.

(a) Each rated order must include:

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

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

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

(4) A statement that reads in substance:

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

(c) Additional element required for certain emergency preparedness rated orders. If the rated order is placed in support of emergency preparedness requirements and expedited action is necessary and appropriate to meet these requirements, the following

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statement must be included in the order: “This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within [Insert a time limit no less than the minimum applicable time limit specified in § 101.33(e)].”

§ 101.33 Acceptance and rejection of rated orders.

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

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

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

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

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

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

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

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on December 15 before accepting order B requiring delivery on December 31. However, the person must offer to accept the rejected orders based on the earliest delivery dates otherwise possible.

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

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

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

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

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

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

(d) *Customer notification requirements.*

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

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

electronic confirmation must be provided within one (1) working day of the verbal notice.

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

§ 101.34 Preferential scheduling.

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

(b) DO rated orders must be given production preference over unrated orders, if necessary, to meet required delivery dates, even if this requires the diversion of items being processed or ready for delivery or services being performed against unrated orders. Similarly, DX rated orders must be given preference over DO rated orders and unrated orders. (Examples: If a person receives a DO rated order with a delivery date of June 3 and if meeting that date would mean delaying production or delivery of an item for an unrated order, the unrated order must be delayed. If a DX rated order is received calling for delivery on July 15 and a person has a DO rated order requiring delivery on June 2 and operations can be scheduled to meet both deliveries, there is no need to alter production schedules to give any additional preference to the DX rated

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order. However, if business operations cannot be altered to meet both the June 2 and July 15 delivery dates, then the DX rated order must be given priority over the DO rated order.)

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

(2) If a person is unable to resolve rated order delivery or performance conflicts under this section, the person should promptly seek special priorities assistance as provided in §§101.40 through 101.44. If the person's customer objects to the rescheduling of delivery or performance of a rated order, the customer should promptly seek special priorities assistance as provided in §§101.40 through 101.44. For any rated order against which delivery or performance will be delayed, the person must notify the customer as provided in §101.33(d)(2).

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

§ 101.35 Extension of priority ratings.

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

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

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

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

(1) An official action of HHS; or

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

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

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

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

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

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

§ 101.37 Use of rated orders.

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

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

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

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

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

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

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

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

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

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

(d) Combining rated and unrated orders.

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

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

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

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

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

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

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

§ 101.38 Limitations on placing rated orders.

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

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

(i) Delivery on a date earlier than needed;

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

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

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

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

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

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construction project covered by a rated order; or

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

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

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

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

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

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

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

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

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

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Subpart D—Special Priorities Assistance

§ 101.40 General provisions.

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

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

§ 101.41 Requests for priority rating authority.

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

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

(2) When the use of a priority rating is authorized for the procurement of

production or construction equipment, a rated order may be used either to purchase or to lease such equipment. However, in the latter case, the equipment may be leased only from a person engaged in the business of leasing such equipment or from a person willing to lease rather than sell.

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

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

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

- (i) The probability that the prime contract will be awarded;
 - (ii) The impact of the resulting rated orders on suppliers and on other authorized programs;
 - (iii) Whether the contractor is the sole source;
 - (iv) Whether the item being produced has a long lead time;
 - (v) The time period for which the rating is being requested;
- (4) HHS may require periodic reports on the use of the rating authority

granted under paragraph (c) of this section.

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

§ 101.42 Examples of assistance.

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

- (1) A person is experiencing difficulty in obtaining delivery against a rated order by the required delivery date; or
- (2) A person cannot locate a supplier for an item or service needed to fill a rated order.

(b) Other examples of special priorities assistance include:

- (1) Ensuring that rated orders receive preferential treatment by suppliers;
- (2) Resolving production or delivery conflicts between various rated orders;
- (3) Assisting in placing rated orders with suppliers;
- (4) Verifying the urgency of rated orders; and
- (5) Determining the validity of rated orders.

§ 101.43 Criteria for assistance.

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

- (a) There is an urgent need for the item; and
- (b) The applicant has made a reasonable effort to resolve the problem.

§ 101.44 Instances where assistance may not be provided.

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

- (a) Secure a price advantage;
- (b) Obtain delivery prior to the time required to fill a rated order;

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- (c) Gain competitive advantage;
- (d) Disrupt an industry apportionment program in a manner designed to provide a person with an unwarranted share of scarce items; or
- (e) Overcome a supplier's regularly established terms of sale or conditions of doing business.

Subpart E—Allocation Actions

§ 101.50 Policy.

- (a) Allocation orders will:
 - (1) Only be used when there is insufficient supply of a material, service, or facility to satisfy national defense supply requirements through the use of the priorities authority or when the use of the priorities authority would cause a severe and prolonged disruption in the supply of materials, services, or facilities available to support normal U.S. economic activities; and
 - (2) Not be used to ration materials or services at the retail level.
- (b) Allocation orders, when used, will be distributed equitably among the suppliers of the materials, services, or facilities being allocated and not require any person to relinquish a disproportionate share of the civilian market.

§ 101.51 General procedures.

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

- (a) A copy of the written determination made in accordance with section 202 of Executive Order 13603, that the program or programs that would be supported by the allocation action are necessary or appropriate to promote the national defense.
- (b) A detailed description of the situation to include any unusual events or circumstances that have created the requirement for an allocation action;
- (c) A statement of the specific objective(s) of the allocation action;
- (d) A list of the materials, services, or facilities to be allocated;
- (e) A list of the sources of the materials, services, or facilities that will be subject to the allocation action;
- (f) A detailed description of the provisions that will be included in the al-

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location orders, including the type(s) of allocation orders, the percentages or quantity of capacity or output to be allocated for each purpose, and the duration of the allocation action (*i.e.*, anticipated start and end dates);

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

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

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

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

- (a) Made a written finding that:
 - (1) Such material is a scarce and critical material essential to the national defense, and
 - (2) The requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship;
- (b) Submitted the finding for the President's approval through the Assistant to the President and National Security Advisor and the Assistant to the President for Homeland Security and Counterterrorism; and
- (c) The President has approved the finding.

§ 101.53 Types of allocation orders.

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

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

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

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

§ 101.54 Elements of an allocation order.

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

(a) Each allocation order must include:

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

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

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

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

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

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

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

§ 101.55 Mandatory acceptance of an allocation order.

(a) Except as otherwise specified in this section (see paragraph (c) of this

section), a person shall accept and comply with every allocation order received.

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

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

§ 101.56 Changes or cancellations of an allocation order.

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

Subpart F—Official Actions

§ 101.60 General provisions.

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

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

§ 101.61 Rating Authorizations.

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

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

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

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

§ 101.62 Directives.

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

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

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

§ 101.63 Letters of Understanding.

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

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

Subpart G—Compliance

§ 101.70 General provisions.

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

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

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

§ 101.71 Audits and investigations.

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

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

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

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

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

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

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

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

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

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

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

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

years old at the person's last known dwelling or place of business.

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

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

§ 101.72 Compulsory process.

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

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

§ 101.73 Notification of failure to comply.

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

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applicable statutes, this part, or an official action.

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

§ 101.74 Violations, penalties, and remedies.

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

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

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

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

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

(3) No person shall deliver any item if the person knows or has reason to believe that the item will be accepted, re-delivered, 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.

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§ 101.75 Compliance conflicts.

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

Subpart H—Adjustments, Exceptions, and Appeals

§ 101.80 Adjustments or exceptions.

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

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

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

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

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

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

§ 101.81 Appeals.

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

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through the Secretary's designated representative, shall review and reconsider the denial.

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

(2) For requests for adjustment or exception involving rated orders placed for the purpose of emergency preparedness (see §101.33(e)), an appeal must be received by the Secretary, no later than 15 business days after receipt of a written notice of denial. Contract performance under the order shall not be stayed pending resolution of the appeal.

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

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

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

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

(g) The submission of an appeal under this section shall not relieve any person from the obligation of complying with the provision of this part or offi-

cial action in question while the appeal is being considered unless such relief is granted in writing by the Secretary.

Subpart I—Miscellaneous Provisions

§ 101.90 Protection against claims.

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

§ 101.91 Records and reports.

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

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

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

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

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

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an official action, is deemed to be confidential under DPA section 705(d) and shall be handled in accordance with applicable Federal law.

§ 101.92 Applicability of this part and official actions.

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

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

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

§ 101.93 Communications.

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

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

PART 102—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

Sec.

102.1 Applicability.

102.2 Applicability date.

102.3 Penalty adjustment and table.

AUTHORITY: Pub. L. 101–410, Sec. 701 of Pub. L. 114–74, 31 U.S.C. 3801–3812.

SOURCE: 81 FR 61565, Sept. 6, 2016, unless otherwise noted.

§ 102.1 Applicability.

This part applies to each statutory provision under the laws administered by the Department of Health and Human Services concerning the civil monetary penalties which may be assessed or enforced by an agency pursuant to Federal law or is assessed or enforced pursuant to civil judicial actions in the Federal courts or administrative proceedings. The regulations cited in this part supersede existing HHS regulations setting forth civil monetary penalty amounts. If applicable, the HHS agencies responsible for specific civil monetary penalties will amend their regulations to reflect the adjusted amounts and/or a cross-reference to 45 CFR part 102 in separate actions as soon as practicable.

§ 102.2 Applicability date.

The increased penalty amounts set forth in the right-most column of the table in Section 102.3, “Maximum Adjusted Penalty (\$)”, apply to all civil monetary penalties which are assessed after August 1, 2016, including those penalties whose associated violations occurred after November 2, 2015.

APPENDIX 1 TO PART 101

Program identification symbol	Approved program	Agency
M1	Emergency Support Function 8 Public Health and Medical Services.	Department of Health and Human Services.