

**PART 100—INTERGOVERNMENTAL REVIEW OF DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAMS AND ACTIVITIES**

Sec.

- 100.1 What is the purpose of these regulations?
- 100.2 What definitions apply to these regulations?
- 100.3 What programs and activities of the Department are subject to these regulations?
- 100.4 [Reserved]
- 100.5 What is the Secretary's obligation with respect to Federal interagency coordination?
- 100.6 What procedures apply to the selection of programs and activities under these regulations?
- 100.7 How does the Secretary communicate with state and local officials concerning the Department's programs and activities?
- 100.8 How does the Secretary provide states an opportunity to comment on proposed Federal financial assistance and direct Federal development?
- 100.9 How does the Secretary receive and respond to comments?
- 100.10 How does the Secretary make efforts to accommodate intergovernmental concerns?
- 100.11 What are the Secretary's obligations in interstate situations?
- 100.12 How may a state simplify, consolidate, or substitute federally required state plans?
- 100.13 May the Secretary waive any provision of these regulations?

**AUTHORITY:** Executive Order 12372, July 14, 1982 (47 FR 30959), as amended April 8, 1983 (48 FR 15887); sec. 401, Intergovernmental Cooperation Act of 1968, as amended (31 U.S.C. 6506); sec. 204, Demonstration Cities and Metropolitan Development Act of 1966, as amended (42 U.S.C. 3334).

**SOURCE:** 48 FR 29200, June 24, 1983, unless otherwise noted.

**§ 100.1 What is the purpose of these regulations?**

(a) The regulations in this part implement Executive Order 12372, "Intergovernmental Review of Federal Programs," issued July 14, 1982 and amended on April 8, 1983. These regulations also implement applicable provisions of section 401 of the Intergovernmental Cooperation Act of 1968 and section 204 of the Demonstration Cities and Metropolitan Development Act of 1966.

(b) These regulations are intended to foster an intergovernmental partnership and a strengthened Federalism by relying on state processes and on state, areawide, regional and local coordination for review of proposed Federal financial assistance and direct Federal development.

(c) These regulations are intended to aid the internal management of the Department, and are not intended to create any right or benefit enforceable at law by a party against the Department or its officers.

**§ 100.2 What definitions apply to these regulations?**

*Department* means the U.S. Department of Health and Human Services (HHS).

*Order* means Executive Order 12372, issued July 14, 1982, and amended April 8, 1983 and titled "Intergovernmental Review of Federal Programs."

*Secretary* means the Secretary of HHS or an official or employee of the Department acting for the Secretary under a delegation of authority.

*State* means any of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the U.S. Virgin Islands, or the Trust Territory of the Pacific Islands.

**§ 100.3 What programs and activities of the Department are subject to these regulations?**

The Secretary publishes in the FEDERAL REGISTER a list of the Department's programs and activities that are subject to these regulations and identifies which of these are subject to the requirements of section 204 of the Demonstration Cities and Metropolitan Development Act.

**§ 100.4 [Reserved]**

**§ 100.5 What is the Secretary's obligation with respect to Federal interagency coordination?**

The Secretary, to the extent practicable, consults with and seeks advice from all other substantially affected Federal departments and agencies in

**Dept. of Health and Human Services****§ 100.9**

an effort to assure full coordination between such agencies and the Department regarding programs and activities covered under these regulations.

**§ 100.6 What procedures apply to the selection of programs and activities under these regulations?**

(a) A state may select any program or activity published in the FEDERAL REGISTER in accordance with § 100.3 of this part for intergovernmental review under these regulations. Each state, before selecting programs and activities, shall consult with local elected officials.

(b) Each state that adopts a process shall notify the Secretary of the Department's programs and activities selected for that process.

(c) A state may notify the Secretary of changes in its selections at any time. For each change, the state shall submit to the Secretary an assurance that the state has consulted with local elected officials regarding the change. The Department may establish deadlines by which states are required to inform the Secretary of changes in their program selections.

(d) The Secretary uses a state's process as soon as feasible, depending on individual programs and activities, after the Secretary is notified of its selections.

**§ 100.7 How does the Secretary communicate with state and local officials concerning the Department's programs and activities?**

(a) For those programs and activities selected by a state process under § 100.6, the Secretary, to the extent permitted by law:

(1) Uses the state process to determine views of state and local elected officials; and,

(2) Communicates with state and local elected officials, through the state process, as early in a program planning cycle as is reasonably feasible to explain specific plans and actions.

(b) The Secretary provides notice to directly affected state, areawide, regional, and local entities in a state of proposed Federal financial assistance or direct Federal development if:

(1) The state has not adopted a process under the Order; or

(2) The assistance or development involves a program or activity not selected for the state process.

This notice may be made by publication in the FEDERAL REGISTER or other appropriate means, which the Department in its discretion deems appropriate.

**§ 100.8 How does the Secretary provide states an opportunity to comment on proposed Federal financial assistance and direct Federal development?**

(a) Except in unusual circumstances, the Secretary gives state processes or directly affected state, areawide, regional and local officials and entities:

(1) At least 30 days from the date established by the Secretary to comment on proposed direct Federal development or Federal financial assistance in the form of noncompeting continuation awards; and

(2) At least 60 days from the date established by the Secretary to comment on proposed direct Federal development or Federal financial assistance other than noncompeting continuation awards.

(b) This section also applies to comments in cases in which the review, coordination, and communication with the Department have been delegated.

(c) Applicants for programs and activities subject to section 204 of the Demonstration Cities and Metropolitan Act shall allow areawide agencies a 60-day opportunity for review and comment.

**§ 100.9 How does the Secretary receive and respond to comments?**

(a) The Secretary follows the procedures in § 100.10 if:

(1) A state office or official is designated to act as a single point of contact between a state process and all Federal agencies, and

(2) That office or official transmits a state process recommendation for a program selected under § 100.6.

(b) The single point of contact is not obligated to transmit comments from state, areawide, regional or local officials and entities where there is no state process recommendation.

## § 100.10

(2) If a state process recommendation is transmitted by a single point of contact, all comments from state, areawide, regional, and local officials and entities that differ from it must also be transmitted.

(c) If a state has not established a process, or is unable to submit a state process recommendation, state, areawide, regional and local officials and entities may submit comments either to the applicant or to the Department.

(d) If a program or activity is not selected for review under a state process, state, areawide, regional and local officials and entities may submit comments either to the applicant or to the Department. In addition, if a state process recommendation for a non-selected program or activity is transmitted to the Department by the single point of contact, the Secretary follows the procedures of § 100.10 of this part.

(e) The Secretary considers comments which do not constitute a state process recommendation submitted under these regulations and for which the Secretary is not required to apply the procedures of § 100.10 of this part, when such comments are provided by a single point of contact, by the applicant, or directly to the Department by a commenting party.

(f) If an applicant receives comments under § 100.9(a)(2), (c) or (d) of this part, it must forward such comments to the Department with its application materials.

### § 100.10 How does the Secretary make efforts to accommodate intergovernmental concerns?

(a) If a state process provides a state process recommendation to the Department through its single point of contact, the Secretary either:

- (1) Accepts the recommendation;
- (2) Reaches a mutually agreeable solution with the state process; or
- (3) Provides the single point of contact with such written explanation of the decision as the Secretary in this or her discretion deems appropriate. The Secretary may also supplement the written explanation by providing the explanation to the single point of contact by telephone, other telecommunication, or other means.

## 45 CFR Subtitle A (10-1-24 Edition)

(b) In any explanation under paragraph (a)(3) of this section, the Secretary informs the single point of contact that:

(1) The Department will not implement its decision for at least ten days after the single point of contact receives the explanation; or

(2) The Secretary has reviewed the decision and determined that, because of unusual circumstances, the waiting period of at least ten days is not feasible.

(c) For purposes of computing the waiting period under paragraph (b)(1) of this section, a single point of contact is presumed to have received written explanation 5 days after the date such notification is dated.

### § 100.11 What are the Secretary's obligations in interstate situations?

(a) The Secretary is responsible for:

(1) Identifying proposed Federal financial assistance and direct Federal development that have an impact on interstate areas;

(2) Notifying appropriate officials and entities in states which have adopted a process and which select the Department's program or activity.

(3) Making efforts to identify and notify the affected state, areawide, regional, and local officials and entities in those states that have not adopted a process under the Order or do not select the Department's program or activity;

(4) Responding pursuant to § 100.10 of this part if the Secretary receives a recommendation from a designated areawide agency transmitted by a single point of contact, in cases in which the review, coordination, and communication with the Department have been delegated.

(b) The Secretary uses the procedures in § 100.10 if a state process provides a state process recommendation to the Department through a single point of contact.

### § 100.12 How may a state simplify, consolidate, or substitute federally required state plans?

(a) As used in this section:

(1) *Simplify* means that a state may develop its own format, choose its own

**Dept. of Health and Human Services****§ 101.1**

submission date, and select the planning period for a state plan.

(2) *Consolidate* means that a state may meet statutory and regulatory requirements by combining two or more plans into one document and that the state can select the format, submission date, and planning period for the consolidated plan.

(3) *Substitute* means that a state may use a plan or other document that it has developed for its own purposes to meet Federal requirements.

(b) If not inconsistent with law, a state may decide to try to simplify, consolidate, or substitute federally required state plans without prior approval by the Secretary.

(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)****Subpart A—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 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.

**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