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DRAFT REGULATIONS
FOR DESIGNATION OF HEALTH SERVICE AREAS
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FOR DISCUSSION ONLY

BASED ON HOUSE DRAFT BILL "CLINT"

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A. ANNOUNCEMENT OF AREA DESIGNATION PROCUDRES

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1. No later than 180 days following approval of the Act, the Secretary shall establish Health Service Areas throughout the United States, and, thereafter all areas of every State shall at all times be included in a Health Service Area so established for the purposes of the Act.

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2. The Secretary shall establish Health Service Areas, or revise such areas, through publication of the boundaries (or revised boundaries) of such areas in the Federal Register. Such boundaries (or revised boundaries) shall be effective upon the date of publication in the Federal Register.

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3. Not later than 30 days following approval of the Act, the Secretary shall provide individual written notice to the to the Governor of each State announcing proceedings to designate the initial Health Service Areas. All such notices to each Governor shall be transmitted by registered mail and, in accordance with the requirements of the Act shall be deposited in the mail simultaneously.

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4. Simultaneously with the mailing of the notices required by A,3 , or immediately thereafter, the Secretary shall publish a Statement in the Federal Register that the required notices have been provided. The statement shall include the general criteria and procedures applicable to all States contained in such notices.

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5. The notice to each Governor required by 3 , shall conform to the requirements of Section 1411 (b)(1) of the Act and;

in addition, shall include or be accompanied by the following:

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- a. A copy of the Act.
- b. A specific citation of all requirements of the Act relating to the definition and designation of Health Service Areas.
- c. A list of those agencies or organizations in, or serving, the State or any portion thereof which must be consulted concerning the designation of Health Service Agencies pursuant to Section G,5
- d. The final date by which the Governors' proposals must be received by the Secretary.

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- e. The information that must be submitted to the Secretary, and, at the option of the Secretary, the format thereof.
- f. Special requirements for the designation of interstate Health Service Areas pursuant to Section H.

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- g. Where applicable, a list of interstate Standard Metropolitan Statistical Areas (SMSAs), as determined by the Office of Management and Budget, concerning which the Governors of the affected States are required to consult pursuant to Section H.

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- h. The criteria to be considered by the Secretary in determining the suitability of Health Service Areas proposed by the Governor, which shall include the criteria set forth in Sections C,1 and 2.

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- i. A copy of these Regulations
- j. The name, address and telephone number of the Federal

official who may be called upon for advice and technical assistance with respect to the designation of Health Service Areas.

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k. Specific notification that the Secretary is required to and shall designate Health Service Areas for the entire territory of each State in any case where the Governor fails to act with

respect to designation of areas for all or a portion of a State.

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B. INFORMATION AND MATERIALS TO BE SUBMITTED

1. Within 150 days of the date on which the notice described in A,3 is postmarked, the Governor of each state receiving such notice shall submit the following materials and information to the Secretary in such format as the Secretary may prescribe.

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a. A legible map or series of maps showing the boundaries of each Health Service Area proposed by the Governor to be included in whole or in part within the State. Such map or maps shall in addition show the Counties or equivalent political subdivisions included in each area and, where applicable, any Standard Metropolitan Statistical Area included in whole or in part

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b. A distinctive numerical designation and name for each proposed Health Service Area comprising a portion of any State including an agreed upon designation for any proposed interstate Health Service Areas. Such designations and names shall be indicated on the maps submitted pursuant to B,1,a.

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c. The population of the proposed Area.

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- d. A list of major Health Care Facilities in the Area.
 - e. An interstate compact or agreement with respect to the designation and boundaries of any proposed interstate area. Such agreement may take the form of a joint declaration by the Governors of the States involved, or separate concurrence with respect to the agreed upon boundaries of the interstate Health Service Area(s) in question.

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- f. Where a proposed Health Service Area includes a portion (but not all) of a Standard Metropolitan Statistical Area, appropriate justification for dividing the SMSA among different Health Service Areas.

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- g. A summary description of the procedures followed by the Governor in proposing areas and obtaining consultation thereon pursuant to Section G.

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- h. A list of all institutions, agencies, organizations and government officials formally requested to comment on the designation of Health Service Areas.

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- i. A summary of substantive comments received by the State from any source concerning the designation of Health Service Areas or the final areas to be proposed to the Secretary, and also including a summary of any action taken with respect to such comments.

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- j. Maps or narrative descriptions showing the extent to which proposed health Service Areas submitted by the Governor are coterminous with or differ from (1) areas designated for Professional Standards Review Organizations under Section 1152 of the Social Security Act,

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- (2) existing planning areas, including those served by Comprehensive Health Planning Agencies established pursuant to P.L. 89-749, as amended and Regional Medical Programs established pursuant to P.L. 89-239, as amended.
- (3) other appropriate State planning or administrative areas.

C. APPROVAL OF HEALTH SERVICE AREAS BY THE SECRETARY

R 1. Prior to approving any Health Service Area proposed by a Governor, the Secretary shall take into consideration the following factors and determine to his satisfaction that all applicable requirements of the Act and Regulations have been met:

- a. That the the population for such areas is within the minimum and maximum specified by the Act, and that adequate justification has been provided for any proposed Health Service Area with a population of less than 500,000. A
- b. That required consultation between the Governor and State and Local officials pursuant to G,5 has taken place, and that any comments and suggestions received have been taken into consideration. F
- c. That there has been adequate consultation and agreement among the Governors concerned with respect to any proposed interstate Health Service Area.
- d. That adequate justification has been provided for the proposed division of any Standard Metropolitan Statistical Area into two or more Health Service Areas. T
- e. That all areas of the State are included within

a Health Service Area

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- f. That all proposed Health Service Areas are mutually exclusive.
 - g. That each proposed Health Service Area includes one or more major health care facilities or institutions providing general and specialized health care services available to the general public residing in such Area.
 - R** h. That each proposed Health Service Area constitutes a rational region, in accordance with the criteria in C,2, for the planning and development of health services and resources serving the residents of such Area.

2. In determining whether a proposed Health Service Area constitutes a rational region for planning pursuant to C,1,h, the Secretary shall take into consideration the following factors:

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- a. The extent of agreement within the State and the Area among affected and concerned public and professional groups and institutions and agencies, with respect to the suitability of the Area for planning.
 - F** b. The extent to which the Area includes the maximum feasible population consistent with the Act and these Regulations.
 - c. Availability for the Area of the data needed for planning.
 - T** d. Congruence with the coverage of major prepayment plans and Health Maintenance Organizations.
 - e. Congruence with areas established for Professional

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Standards Review Organizations and for existing or planned Emergency Medical Service Systems.

- f. For the initial designation of Health Service Areas under the Act, congruence with the areas served by predecessor Regional Medical Programs, Local Areawide Comprehensive Health Planning Agencies, and Experimental Health Service Delivery Systems.

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- g. Potential population growth (particularly with respect to areas are close to the maximum population for a Health Service Area, or areas containing a central city close to the minimum population for a Standard Metropolitan Statistical Area).

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- h. The extent to which Interstate Health Service Areas have been developed in connection with Standard Metropolitan Statistical Areas which cross State Boundaries.

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- i. The extent to which area boundaries will promote appropriate planning for the disadvantaged or other special population groups. (e.g. Ordinarily, it would be considered desirable to keep an indian reservation within a single Health Service Area.)

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- j. The extent to which high quality services can be enhanced through the promotion of linkages between primary and specialized care, and appropriate preventive and educational programs within the area.

- k. The capabilities of the area for supporting the

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fullest possible range of general inpatient, ambulatory, long term care and home health services, and specialized services such as those relating to mental health, drug abuse, alcoholism, developmental disabilities, and physical and vocational rehabilitation.

1. Conflict with any Health Service Areas to be designated by the Secretary pursuant to C,4 .

m. Differences among Governors of the States involved concerning the proposed boundaries of any interstate Health Service Area proposed.

n. Division of any Standard Metropolitan Statistical Area into two or more proposed Health Service Areas.

o. Other relevant factors deemed appropriate by the Secretary, either generally or in specific cases.

3. Except as provided in C,4 within 150 days of the date on which the the notice required pursuant to A,3 was deposited in the mails, the Secretary shall publish in the Federal Register the Health Service Area Boundary designations submitted by the Governors which upon their publication shall constitute the boundaries for such Health Service Areas

4. If the Secretary determines that a boundary submitted to him for a Health Service Area does not meet the requirements of Section 1411 (a) of the Act, of Sections C,1 and C,2 of these Regulations, he shall make such revision in the boundaries for such area (and as necessary, in the boundaries for adjoining Health Service Areas) as may be necessary to meet such requirements; and the revised boundary (or boundaries) shall,

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upon publication in the Federal Register, constitute the boundary (or boundaries) for such Health Service Area (or Areas).

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5. The Secretary shall notify the Governor of each State of the boundaries established for the Health Service Areas for such State (including interstate areas lying partly within a State). Such notice may take the form of a copy or citation of the notice(s) published in the Federal Register pursuant to Sections C,3 and C,4. In the case of any Health Service Area Designated by the Secretary, pursuant to Section C,4, the notification required by this Section shall include a full explanation of the reasons for the Secretary's action, citing the specific provisions of the Act and/or these Regulations.

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6. In designating any Health Service Area pursuant to Section C,4, the Secretary may rely on information from any appropriate source including (a) information and materials submitted by the Governor pursuant to Section B,1, (b) information in the records of the Department of Health, Education and Welfare, (c) The Department's staff, including the staff of the HEW Regional Offices, and (d) other reliable sources.

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D. BASIS FOR DETERMINING POPULATION

1. For the purpose of defining Health Service Areas and allocating funds pursuant to the Act, the population of (a) each State, (b) each Standard Metropolitan Statistical Area, and (c) each County or equivalent political subdivision within a State, shall be the most recent Current Population Estimate prepared by the Bureau of the Census which is available for all States.

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D necessary for the purposes of the Act, the population of any area within a State smaller than a County shall be determined by the State in accordance with accepted statistical practice, and shall be consistent with the Census Bureau's Current Population Estimates for the State and related Counties and Standard Metropolitan Statistical Areas therein. The appropriate Census figures shall be transmitted annually to each State by the Health Resources Administration.

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E. POPULATION REQUIREMENTS FOR HEALTH SERVICE AREAS

1. At the time of its initial establishment, no Health Service area shall have a population of more than three million, unless such Area contains a Standard Metropolitan Statistical Area with a population of more than three million. To the extent practical, areas of three million population, or close to that figure, that are likely to substantially exceed three million population due to short term growth ordinarily should not be established.

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2. After initial establishment, if the population of a Health Service Area increases substantially beyond three million population, the Secretary shall notify the Governor(s) of the State(s) involved of the need to consider revision of the Area.

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3. No Health Service Area may have a population of less than five hundred thousand unless (a) such Area comprises the entire population of a State which has a population of less than five hundred thousand, or (b) has a population of at least two

D hundred thousand and is deemed by the Governor(s) of the State(s) in which such Area is located (with the approval of the Secretary) to comply with all other requirements of Section 1411 (a) of the Act. Publication of the boundaries of such Area by the Secretary in the Federal Register constitutes the Secretary's approval for the lower population limit for the Area.

R 4. In order to promote economies of scale in planning for health services and resources, Governors are encouraged to propose Health Service Areas with the largest practical population subject to the requirements of the Act and Regulations. Where the population of a State exceeds five hundred thousand, the designation of smaller Health service Areas ordinarily will not be approved by the Secretary. Accordingly, Health Service Areas of less than five hundred thousand population will be approved only on request by the governor(s) involved and only on the basis of (a) rapid potential population growth to five hundred thousand or more, or (b) **A** other substantial need fully documented and justified in such form as the Secretary may prescribe. **F**

5. Once established, Health Service Areas may be subdivided into areas of smaller population for the administrative convenience of the Health Systems Agency serving such Area(s). **T** All such subdivisions of a Health Service Area established for any purpose shall be reflected in the Health Systems plan required pursuant to Section 1413 (b) of the Act. Approval by the Sec-

retary is not required for such sub-areas.

F. SPECIAL REQUIREMENTS FOR STANDARD METROPOLITAN STATISTICAL AREAS AND INTERSTATE AREAS

1. In accordance with Section 1411 (a)(4) of the Act, no Health Service Area boundaries shall cross the boundaries of a Standard Metropolitan Statistical Area which Standard Metropolitan Statistical Area is located entirely within a single State, unless the Governor of such State submits a request for an exception and the reasons therefor including patient origin data and other factual studies supporting the division of the Standard Metropolitan Statistical Area among two or more Health Service Areas. The Secretary shall approve such request only if, in his opinion, the division of the Standard Metropolitan Statistical Area is justified on the basis of actual patterns of care as reflected in the supporting data or other available information.

2. A Health Service Area encompassing all, or part of a Standard Metropolitan Statistical Area may also include contiguous territory not defined as part of the Standard Metropolitan Statistical Area by the Office of Management and Budget. Contiguous areas which appear likely to be included as part of a Standard Metropolitan Statistical Area (in accordance with the Office of Management and Budget's definition of such areas) in the foreseeable future should receive consideration for inclusion in the same Health Service Area as the Standard Metropolitan Statistical Area in question.

3. Governors of adjoining States may agree (as specified in

Section B,1,c) on the designation of interstate Health Service Area. In the case of interstate Standard Metropolitan Statistical Areas, the Governors of the States concerned are required to consult in order to gain agreement on inclusion of the interstate Standard Metropolitan Statistical Area in a single Health Service Area in accordance with Section 1411 (a)(4) of the Act and Section F,1 of these Regulations. Such agreement, or lack thereof, with respect to including any interstate Standard Metropolitan Statistical Area in a single Health Service Area shall be reported to the Secretary in accordance with Sections B,1,c and d. Failure of the Governors concerned to agree on a single Health Service Area for any interstate Standard Metropolitan Statistical Area shall be considered by the Secretary who, in accordance with Section C,4, shall establish appropriate Health Service Area boundaries.

G. CONSULTATION BY GOVERNORS IN CONNECTION WITH THE DESIGNATION OF HEALTH SERVICE AREAS

1. In considering Health Service Area boundaries to be proposed to the Secretary, either for initial establishment or for subsequent revision, the Governor of each State is required to consult with government and private agencies and organizations, elected officials and consumers for the purpose of either (a) soliciting initial suggestions concerning such Health Service Area boundaries, and (b) affording an opportunity to comment on such Areas when tentatively selected by the Governor.
2. The method of consultation required by G,1 may be specified by the Governor and may include, among other things, (a) public

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hearings, (b) written or oral positions or statements by organizations, (c) expressions of the views of concerned individuals or appropriate experts, (d) formal resolutions by legislative bodies or actions by elected officials, or (e) a combination of these.

3. Consultation required by Section G,5 must be requested from the appropriate individuals and/or organizations in writing.

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4. All comments received pursuant and records of hearings or other formal State proceedings concerning the designation of Health Service Areas pursuant to the Act and these Regulations shall be filed in a single place and shall be available for inspection and copying by the general public or HEW officials. Copies of such materials shall be furnished to the Secretary on request and summaries thereof shall be provided to the Secretary pursuant to Section B,1,g

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5. In carrying out the requirements of Section G, the Governor shall consult with the following, where these exist.

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- a. State Agencies including,
 - (1) The State Health Planning Agency established pursuant to Section 314 (a) of the Public Health Service Act.
 - (2) State Health Facilities Construction Agencies (citation)
 - (3) State Mental Health Agencies (citation)
 - (4) State Mental Retardation Agencies (citation)

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- (5) State Vocational Rehabilitation Agencies
- (6) State Alcoholism Agencies
- (7) State Drug Abuse Agencies

b. Voluntary Agencies including,

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- (1) Agency that carries out areawide comprehensive regional, metropolitan, or other local area planning pursuant to Section 314 (b) of the Public Health Service Act.

- (2) Regional Medical Programs established in accordance with Title IX of the Public Health Service Act.

- (3) Experimental Health Service Delivery Systems

- (4) Professional Standards Review Organizations designated under Section 1152 of the Social Security Act.

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- (5) Appropriate professional and consumer groups deemed by the Governor to have a significant interest in, or to be likely to be affected by decisions concerning the designation of Health Service Areas

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c. Elected Officials of Bodies, including,

- (1) Mayors of incorporated cities of fifty thousand or more population

- (2) Chief Executive Officers of Counties (or equivalent political subdivisions) of fifty thousand or more populations

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- (3) Elected officials of representative (as determined

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by the Governor) of incorporated places and Counties of less than five hundred thousand population within the State

d. Other appropriate groups or individuals, at the discretion of the Governor

6. Organizations enumerated in Section G,5, (1) through (4) which serve any portion of a State must be consulted by the Governor ^{ACCORDING} to such section irrespective of whether the principal office of such organization is, or is not, located in the State in question.

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7. With respect to the designation of interstate Health Service Areas, the consultation required with the organizations agencies and officials enumerated in G,5 shall be required of each governor concerned, only with respect to those organizations and agencies serving that governor's particular State and officials of the political subdivisions of such State. Governors are urged to exchange comments received for their respective portions of proposed interstate Health Service Areas prior to reaching a decision on whether to recommend such Areas to the Secretary.

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H. CONSULTATION BY GOVERNORS ON DESIGNATION OF INTERSTATE HEALTH SERVICE AREAS

Consultation among Governors regarding designation of Health Service Areas for Interstate Standard Metropolitan Statistical Areas, or any other proposed interstate Health Service Area, may take place in any manner agreeable to the respective Governors

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concerned. Such consultation may be carried out through negotiation between representatives as authorized by Section J, and through written or oral communication. The latter may be either in person or by phone. All consultation among Governors their delegates, representatives, or staff concerning the designation of interstate Health Service Areas, shall be evidenced by a written record maintained by each State and showing all communication between the respective States concerning such matters.

I. REVISION OF HEALTH SERVICE AREA BOUNDARIES

1. The Governor of a State may at any time after consultation with the entities specified in Section G,5, and in the case of interstate Health Service Areas, the Governor(s) of the adjoining State(s) concerned pursuant to Section H, submit to the Secretary revised boundaries for one or more Health Service Areas (previously established in accordance with the Act and Regulations) within a State or States

2. The Governor of a State shall seek the consultation required by Section G, and in the case of an interstate Health Service Area, Section H, and shall propose necessary revisions in the Boundaries of established Health Service Areas in the following cases:

- a. Establishment of a new Standard Metropolitan Statistical Area by the Office of Management and Budget
- b. Addition of a County or Counties to an established

Standard Metropolitan Statistical Area.

- c. Population growth of a Health Service Area substantially above three million (unless the Area contains a Standard Metropolitan Statistical Area of more than three million population).
- d. Population loss below five hundred thousand for any Health Service Area not previously approved by the Secretary for such lesser population pursuant to Section E, 3.

- e. Population loss of any Health Service Area to less than two hundred thousand.

3. If any of the circumstances described in 1,2, a through d occur, the Secretary shall notify the Governor(s) of the State(s) involved as soon thereafter as possible by registered mail, and the Governor (s) in question shall submit proposed revisions within 90 days of such notice.

4. If the Governor(s) fail to submit proposed Health Service Area revisions in accordance with 1,3, the Secretary shall make appropriate revisions in such boundaries within 150 days of the notice described in Section 1,3 and shall publish such Boundaries in the Federal Register as the boundaries for such Health Service Area(s).

J. DELEGATION OF THE GOVERNOR'S RESPONSIBILITIES

1. The term Governor shall mean the Governor or Chief Executive Officer of any State as defined in the Act.

2. The duties and responsibilities of the Governor under the

D Act and Regulations may be performed by any State employee formally designated to carry out such responsibilities through the operation of State Law, or formal delegation or other written executive action by the Governor.

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