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Part II -- Area Designation Requirements

A. Purpose of this Part

The purpose of this Part is to explain how and what each State must submit in order to participate in the designation of health service areas under the National Health Policy Planning and Resources Development Act, PL____.

B. Area Designation Authority

The Congress has provided in the statute for the designation of health service areas which cover the entire country. Section 1411(b) of the Act f gives the authority for the designation of health service areas to State Governors. The Secretary of HEW, however, may intervene and designate areas, but only if

1. the criteria in Section 1411(a) of the Act are not met;

2. A Governor requests a waiver of one of the various criteria

where exceptions are expressly permitted by the Act;

3. A Governor fails to include all or part o his State in

any designated health service area.

C. Deadlines for Submission

Each Governor has been notified officially of the commencement of the area designation process. The notice includes a deadline date for the submission of area designations to HEW. In accordance with the Law, the deadline is 90 days from the date of notice. HEW is required by statute to complete the area designation process within six months of enactment, and it is imperative that the 90 day statutory deadline be adhered to strictly. Governors' designations should be postmarked on or before the deadline date specified in the initial notice,

D. Submission of Area Designations

Area designations should be submitted to HEW at one time as a complete package for the State. The designations should include all materials, information, and justifications required by the instructions in this Part.

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Submissions must include a covering letter signed by the Governor (not a delegate). The Governor's letter should specify that the material submitted constitutes his official designation of health service areas for the State pursuant to Section 1411 of PL _____. Any other prk pertinent information or comments may be included, and no special format is necessary. In order to insure that the submitted materials is complete, each separate attachment or enclosure and the number of pages in each should be identified in or on the Governor's cover letter.

Deliver or mail ______ copies of the designation material to the Regional Director in the appropriate HEW Regional Office. (See attachment ______ for addresses of Regional Offices and States covered). Mailed submissions should be sent first class Certified or Registered with a return receipt. In order to insure expeditious handling at the Regional Office, it is conspicuously suggested that submissions be/KHMASPiELIMNELY marked on the envelope or HEPREXNE wrapper as, "AREA DESIGNATION PER SECTION 1411."

E. Review and Approval

Health Service Areas are officially established through x publication in the Federal Register subsequent to HEW review of the Governor's designations. To insure consistency nationally in considering the State's submissions,

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all final area designations by the Secretary will be published simultaneously. Designation of areas throughout the United States will be completed on or before ______1975, as required by the Act. The appropriate Governor will be consulted in any case where HEW proposes, under Section 1411(b) to modify the Governor's health service area designations.

F. What to Submit

All materials which Governors are required to submit in connection with area designation is related to specific requirements of the Act. A table summarizing requirements for area designation and the related materials to be submitted is shown in Attachment 2. All materials which States are requested to submit in connection with health service area designation are either specifically required by the Act or related to determining that proposed areas meet requirements. Each Governor is required to submit 'the following materials, in order to designate health service areas:

1. Maps of Designated Areas--

A legible map or 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.

A single map may be submitted for an entire State provided that all required p boundaries can be shown distinctly. Shading and coloring or overlays can be used provided that a legend or key is shown.

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If necessary for clarity, separate maps may be provided for each H.S.A.

If an interstate health service area is being designated jointly by the Governors of adjoining states, the map(s) submitted by each State should show the entire interstate area (not just the portion in the particular State.)

If a State includes one or more Standard Metropolitan Statistical Areas, a ma map must be mi submitted showing the SMAS(s) superimposed on the designated health service areas. This map should show the entire extent of any interstate SMSA which is located partly in an adjoining State or States.

In any case, where the boundary of the health service area does not follow county lines or other political subdivisions, a description of the areas' boundary should be provided (e.g., "All of County'B' xk south of the XYZ River.")

Each health service area should be given a name and number which is to be shown on the map(s), (e.g., Michigan #2, Upper Peninsula).

The maps submitted should clearly indicate the boundaries of the designated HSAs for the entire State and their relationship to County and State boundaries, and SMSAs.

Maps of any reasonable size may be submitted provided that the required information is clearly shown.

2. Evidence of Consultation

As part of the area designation material, each Governor must submit evidence of compliance with Section 1411(b)(2) of the Act which requires consultation with certain local
officials and specified health agencies. Necessary materials are:
a. A brief description of the process and procedures
followed in the State in obtaining consultation
on proposed health service areas;
b. Samples of notices, letters, or other publicity
requesting consultation or comment on health
service area designation;
c. Name and addresses of all institutions, agencies,
organizations, government officials, or other

individuals formally requested to comment on the designation of Health Service Areas. (Consultation with State and areawide CHP agencies is required by Law, and must include each Federally-funded CHP and RMP serving all or a portion of the State. In addition to the mandatory consultation prescribed above, it would be highly desirable for Governors, or their representatives, to consult with other agencies, groups, and organizations in their Sx States, including : (1) Various State health and related agencies (e.g., mental health departments, vocational, rehabilitation agencies); (2) Any EHSDS sits(s) within the State; (3) Major health provider groups (e.g., State Medical Society Hospital Association);(4) PSROs; (5) Voluntary health organizations (e.g., State Heart Association, Mental Retardation Chapter); and (6) Appropriate consumer groups;

Names and addresses of all agencies or individuals making comments on area designation whether selected or not; e. Actual written comments and summaries of oral comments received from 314(a) and (b) (State and Areawide Comprehensive Health Planning Agencies), RMPs, and county or other local officials required to be consulted under Section 1411(b)(3);

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- f: Actual written comments and summaries of oral comments received from any source with respect to waivers; Summaries of other substantive comments; g.
- A resume of action taken with respect to any comments h. and the reason therefore;
- The location of files where all subcitations and comments qi. are filed and available for inspection by Federal officials; If hearings are held, their dates and a list of organizations 1. and individuals attending.

Comments received by States and action thereon should be discussed in the same format and style used in discussing comments on proposed rules in the Federal Register. Actual comments anxarapaaredxrukes inxthexRedexxixRegisterx and summaries required to be submitted (See (a)-(g) above) can be submitted in an appendex.

Required Consultation 3.

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The CHP and RMPs serving the State which must be consulted have been specifically enumerated in the initial notification to each Governor. The Act is far less specific, however, with respect to the local officials required to be consulted under Section 1411(b)(3). As a minimum, consultation with county officials and Mayors of the larger cities (particularly central cities and larger suburban jurisdictions in SMSAs) would seem to be required. The number and types of local officials contacted for comment is left to the discretion of the Governor but should include officials in each SMSAs as well as representative rural areas, and areas for which waivers are requested.

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Consultation pursuant to Section 1411(b) can take any one or combination of which is acceptable provided that files and written records are maintained.

(1) Letters from individuals or organizations;

- (2) Formal resolutions or statements adoptedby organizations or agencies;
- (3) Presentations to the Governor or other State officials;
- (4) Public hearings;
- (5) Meetings with appropriate organizations.

Where hearings or other meetings are held to obtain comments, States are requested to notify the HEW Regional Director to permit him to send staff to attend where feasible. Minutes or transcripts should be made of such meetings or hearings, but should not be sent to HEW unless requested.

States may solicit comments on area designations at any point in the 90 day period allowed for submission, but the agencies and officials whose comments are required to be solicited under Section 1411(b)(2) must be afforded an opportunity to comment on the final designations to be submitted to HEW by the Governor.

Comments required by Section 1411(b)(2) must be solicited even though the entire State is to be designated as an HSA. This gives appropriate opportunity to propose appropriate waivers or participate in interstate health service areas.

3. Required Materials on Interstate Areas

A Governor may designate, in cooperation with the other Governor(s) involved, health service areas located partly in his State and partly in an adjoining State as authorized pursuant to Section 1411(b)(1)(B) of the Act. Designation of interstate health survey areas requires submission of the following:

a) Evidence or certification that the Governors

involved or their designees have consulted and
agreed on the interstate area (exchange of letters,
identical designations, formal interstate agreements, etc.);
b) The comments received by each Governor concerning the

interstate area from respondents in the respective States. (Comments should be n solicited on the entire interstate area, but should be requested separately by each State from agencies, institutions, and individuals in its portion of the area. Comments received should be exchanged by the cooperating States included in the submissions of both;

- c) population, statistical, and other required descriptive data and information for the entire interstate area as **PXEX** jointly developed and agreed upon by the cooperating States;
- d) jointly developed justification for the entire interstate area (i.e., why an interstate area is needed);
- e) a map and other information required for all area designations.

In summary, the general rule for interstate areas is that all States involved agree upon area boundaries and required information with respect to an interstate area. Identical material is then submitted in each State's area designation package.

See the next Section of these instructions for procedures relating to interstate SMSAs.

4. SMSAs

In addition to the maps previously mentioned, showing SMSAs superimposed on designated health service areas, special information on SMSAs is not required unless the SMSA is to be divided between two or more areas. In this case, a request and justification for waiver is needed (see next Section on "Waivers").

Where an area includes an SMSA over 3-million population, no waiver request is needed, since the 3-million upper population limit can be exceeded under the provision of Section 1411(a)(3)(A). Where such an area also includes population in contiguous territory which is not part of the SMSA (as defined by OMB), full justification and explanation must be provided (i.e., the additional territory is soon expected to cross the definional line, or to be amended, and herauxexax become a part of the SMSA in question. Each standard metropolitan statistical area (SMSA) must be entirely contained within the boundaries of one health service area unless the Governor of each S tate in which a SMSA is located determines, with the approval of the Secretary, that a health service area should contain only part of the SMSA in order to meet x other requirements of the law. Any Governor proposing to divide an interstate SMSA along the State line must submit a request for a waiver. Congress has expressed clear intent that where a major metropolitan area straddles a State boundary its health service area will also cross the State boundary. While provision is made for waiving this requirement, Congress has indicated that waivers are expected to be granted rarely.

g. WAIVER REQUESTS

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In the event any areas are proposed for which waivers are being requested, additional information and justification must be supplied. Any area (1) with a current population of less than 500,000 <u>except</u> if it is one encompassing an entire State with a lesser population and/or (2) that splits or divides an SNSA, requires a waiver.

All waiver requests will be reviewed, closely scrutinized in terms of certain specific factors or conditions. In the case of proposed areas with a population less than 500,000 these include:

1. Rate of population growth in recent years.

- 2. Low population density over a large geographis area.
- 3. Major geographical barriers or natural isolation.
- Sufficiency of health facilities, manpower, resources, and services within the area to generally meet the needs of its residents.
- 5. Present hospital (or health services) utilization and referral patterns.
- 6. Whether the area is essentially a self-contained economic trade area.
- 7. Special population characteristics that have a district areal dimension (e.g., reservation Indians).
- 8. Reasonable assurance or evidence to indicate that the HSA serving the area would be able to obtain sufficient matching and/or other funds to support a minimum required professional capita staff of five(5), that the Federal grant of \$.50 per/and other

funds would equal or exceed \$200,000 annually.

Where the area proposed would split or divide an SMSA the specific* factors or conditions that would be looked at particularly include: 1. In the case of inter-State SMSAs, degree to which its population is overwhelmingly (e.g., 80% or more) in one State; or conversely, where only a small fraction of its population is in one State or another.

- 2. Also in the case of inter-State SMSAs, extent of cooperation (or non-cooperation) in other endeavors or efforts in recent years.
- 3. In the case of intra-State SMSAs, extent to which its is coterminous with existing PSRO areas.
- 4. Extent to which it is coterminous with: (a) existing health planning areas (e.g., CHP, EHSDS, RMP) and/or (b) Department of Commerce defined economic trade areas.
- 5. High degree of acceptability to local elected officials, health providers, consumer groups, and others in the area proposed.

Therefore, the basis for each waiver request should be explicit in terms of the above or other special factors or conditions. Appropriate but germane and specific information and data (as opposed to assertions or generalities) in the way of justification and explanation of each requested waiver must be submitted as part your proposed Area Designation Plan. Moreover, actual copies (as opposed to summaries) of all the relevant comments and the like received from local elected officials, legislative bodies, CHPs, RMPs, and other groups whose views were solicited, must be included with your Area Designation Plan submission. H. Population and Geographic Information

The following demographic information is required:

 1973 population for the State, a each health service area, and each SMSA;

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- Total land area for the State, each health service area, and each SMSA (in square miles);
- 3. Population projections to 1980 and population change 1970-73 for any health service area for which waivers are required.

Population figures are to be based on the U.S. Bureau of the Census's current population estimates for 1973. These are the most recent figures available nationally by county.

I. Coordination of HSA Boundaries with Other Types of Areas

In accordance with Section 1411(a)(4), to the maximum extent feasible, the boundaries of the health service must be coordinated with the boundaries of Professional Standards Review Organizations, existing regional planning areas, and State planning and administrative areas. Since it is recognized that the boundaries of areas defined for different purposes cannot all be identical, the criteria for designation of health service areas do not require that their boundaries be identical with those for PSRO areas, regional planning areas, or State planning and administrative areas. In order to comply with the above requirement, however, where a health service area contains more than a single PSRO, an effort should be made to include two or more whole PSROs. If a health service area is not to have identical boundaries with those of substate planning areas, it would be preferable that the area include the areas of two or more whole EME substate planning areas. Finally, if any such areas are to be divided among health service areas, the division should generally follow existing geopolitical boundaries.

In order to demonstrate compliance with Section 1411(a)(4), the following materials are required:

 Astatement or certification signed by an appropriate State official to the effect that the requirements of Section 1411(a)(4) have been a considered in the process of developing health service area designations;

- 2. Statements or map, or diagrams showing how the designated areas match the boundaries for:
 - (a) Professional Standard Review Organization;
 - (b) Sub-State Planning and Development Districts;
 - (c) Comprehensive 1 Health Program;
 - (d) Regional Medical Programs;
 - (e) Local political boundaries, i.e., counties and equivalents, major municipalities, and appropriate and special districts;
 - (f) Councils of Governments;
 - (g) Multiple Planning Districts.

Keep the submissions on coordination as simple as possible. A statement such as, "The State, PSRO, and health service area are identical " will suffice where appropriate.

Centers for Highly Specilized Services

Section 1411(a)(2) requires that XMM to the extent practicable, a health service area must include at least one center for the provision of highly specialized services. The requirement for the inclusion of such a center reflects Congressional desire that the health service areas provide a self-contained, comprehensive and complete range of health services such that an individual residing in the area would rarely if ever have to leave it in order to obtain needed medical care.

In order to comply with the above requirement, the names and locations of medical schools, academic health centers or major hospitals in each designated health **sx** service area should be provided. Since the legislation only requires a center for highly specialized services where feasible, failure of an area to have such a center does not require a request for a waiver. Where a center is absent in any area, however, the designation materials should include an explanation of how the people residing within this area will receive such specialized services, i.e., affiliated agreements with existing facilities or proposed approved construction plans.

K. Descriptive Area Information and Statistics

Section 1411(a)(1) of the Act requires that each health XEXIXE service area must be a rational geographic region containing a comprehensive range of health services and of a character suitable for the effective planning and development of health services. Suitable narrative and statistical information must be submitted for each designated health service area to insure compliance with this requirement. Any narrative xkmxdt should be

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be as brief as possible and kith hit the highlights. Lengthy descriptions will simply hinder Federal review which must be completed within two months of the State's submission. Relevant data which should be included is listed below:

1. Facilities Description

For each proposed health service area a list of hospitals by name and number of beds. If possible, the number of long term care facilities and beds should be included for each proposed health service area. Also show mental km health and rehabilitation facilities, where these exist;

2. Manpower Resources Description

Description of manpower resources within the proposed health service area.

- a) Number of M.D.'s by specialty;
- b) Number of nurses by RN's and LPN;
- c) Availability of Allied Health Manpower;

3. Other Relevant Data and Information

- a) Coverage of major prepayment plans;
- b) VA, PHS, and military facilities in the area, and population covered;
- c) Special characteristics of the area such as
 - major vacation populations, flood, or earthquake hazards, etc.

List of Attachment.

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1.	Addresses of HEW Regional Offices and States covered.
2.	Table showing materials required for area designation
	in relation to requirements of the Act.
3.	Illustrative maps.
4.	Illustrative format for submission.
5.	Check list of items to be ksubmitted.
6.	Copy of Section 1411 of the Act.