

CHAPTER 3-20  
DEPARTMENTAL PROCEDURES FOR WRITING REGULATIONS

Section 3-20-00	Purpose
10	Regulations Proposals
20	Regulations Review Panels
30	Different Procedures for Regulations of Varying Importance
40	Considerations in Developing Regulations
50	Secretarial Guidance on Issues
60	Public Participation
70	State and Local Government Participation
80	Division of Responsibilities

Exhibit X3-20-1	Regulations Proposal Format
2	Regulation Action Memorandum Format
3	Regulations Development Process

3-20-00 PURPOSE

This chapter provides policies and procedures for the development and review of regulations.

3-20-10 REGULATIONS PROPOSALS

Each principal operating component (POC) will prepare a regulations proposal for submission to its Regulation Review Panel (see **3-20-20**) covering each regulation the POC plans to draft. (If appropriate, a regulations proposal can cover more than **one** set of regulations.) The proposal will set out the following **information**:

- \* The need for the regulation;
- \* The significance of the regulation, by category ("technical," "policy significant," "major");
- \* The schedule on which the POC intends to develop the regulation;
- \* The name of the person in the POC with the responsibility (and the authority) to assign drafting responsibility, to resolve policy and procedural conflicts within the POC, and to oversee timely preparation of the regulation;
- \* A statement of which major interest groups will be affected by or interested in the regulation, and the POC's plan for involving these groups and the public in the development of the regulation;

- \* A listing of the other offices in the **Department affected** by or with special responsibility for the program being regulated.
- \* A statement whether and on what schedule an issue paper will be prepared for the Under Secretary/Secretary, with a brief description (without extended discussion) of the key policy issues involved in the regulations, and a brief statement whether contending views and alternative approaches exist, that will affect the development of the regulations.

A format for the regulations proposal is shown as Exhibit X3-20-1.

The POC will submit each such **proposal** to the Regulations Management Unit, Executive Secretariat (ES), within 45 days of any event that requires the development of new regulations (enactment of a new statute or amendments, court orders, new policy decisions, public petitions for rulemaking, etc.). In the case of new legislation, **POCs** should submit regulations proposals well in advance of this deadline -- generally even before the legislation is finally enacted.

The ES will forward the proposals to the appropriate Regulations Review Panel. Proposals submitted later than 45 days after the precipitating event must be submitted to the Under Secretary/Secretary for approval with an explanation for the delay.

No work on regulations should occur anywhere in the Department unless covered by a regulations proposal. A short one-paragraph **precis** of each regulations proposal will be published in the Federal Register, and each regulations proposal will be available to the public on request.

### 3-20-20 REGULATIONS REVIEW PANELS

Standing Regulations Review Panels are established for each of the principal operating components: ED, PHS, HCFA, SSA, and HDS. Ad hoc panels for OCR and OS will be convened as necessary. The Panels will provide a one-time, careful review of regulations proposals at the very start of the development process in order to tailor appropriately the procedures by which the regulation will be written and developed. The regulations panel for each POC will meet regularly (once a week, once every two weeks, or once a month) depending on workload. Panels will consider regulations proposals no later than 15 days after receipt by ES.

#### A. Role and Responsibilities

The purposes of the panel are procedural and are:

- \* To review the need for regulations, to secure agreement on schedules, and to review the major elements in each **POC's** plan for developing a regulation;

- \* To establish the need for continuing coordination with other **POCs** and with particular staff offices during policy discussions and drafting of the regulation;
- \* To **review** and establish the need for Secretarial policy guidance on issues involved in the proposed regulations;
- \* To permit (and indeed require) the expression of views by OS staff offices early in the process rather than the sudden surfacing of dissents after the POC has completed an arduous drafting process.

Specifically, each regulations proposal submitted to a review panel will contain recommendations from the POC on all of the major procedural decisions involved in establishing a plan to draft a regulation. The panel will discuss and evaluate the recommendations of the POC and concur or non-concur in the **POC's** recommendations. Any disagreement between the **POC** and the panel will be surfaced for decision by the Under Secretary or Secretary.

The panels will review each regulations proposal to consider the **POC's** recommendations on the following:

1. Whether or not the proposed regulation is necessary;
2. Classification of the regulation -- based on its importance -- into one of three categories (technical, policy significant, major) to determine
  - a. the need for early Secretarial involvement, and
  - b. the extent of clearances to be required later in the process;
3. Placement of "technical" rules into an accelerated development and approval process;
4. The schedule for developing each regulation including -- for policy significant and major regulations -- the preparation and presentation of an issue paper to the Secretary before rules are drafted;
5. The plan for intra-Departmental coordination in developing an issue paper, if needed, and in writing the regulation;
6. The plan for, and timing of, meaningful participation by affected interest groups, public interest organizations, and the public;
7. The need for other government consultations (congressional, Executive, State, local) regarding regulatory policies.

### B. Membership

The Executive Secretary (or one of his principal policy deputies) will chair each regulations review panel. The head of each WC or his or her representatives along with all other appropriate staff designated by the POC (which may vary for different regulations) will be represented on the panel. The panel will also have permanent members (at the Deputy Assistant Secretary level who can speak for the head of the staff office) from each of the following: Legislation, Planning and Evaluation, Management and **Budget, Public Affairs, and Civil Rights.** The Deputy General Counsel for Regulation Review and the appropriate Assistant General Counsel for each POC will also be members of the panel. The Head of the Regulations Management Unit in the Executive Secretariat will provide staff support to the panel and will participate in the panel's work. In addition to permanent members, selected participation in the panel meetings by the Deputy Under Secretary for Intergovernmental Affairs, the Office of the Inspector General, the Assistant Secretary for Personnel Administration, and other **POCs** will be facilitated on appropriate regulations by the Executive Secretariat.

Each Staff Assistant Secretary must, therefore, designate either a Deputy Assistant Secretary or a senior official with supervisory responsibilities as his/her representative to each of the five Regulations Review Panels. These representatives must be designated in writing and the Staff Assistant Secretary must certify that the designated individuals have the authority to commit the staff office to final positions on issues brought before the panels. If a designated representative is unable to attend a panel meeting, he/she may send a representative but the representative will have no official voice or vote in the panel's deliberations.

### 3-20-30 DIFFERENT PROCEDURES FOR REGULATIONS OF VARYING IMPORTANCE

Departmental procedures will distinguish between minor, more technical regulations and major ones that deserve more intensive careful handling. Each regulation will be classified as "major," "policy significant," or "technical." Different clearance procedures, different policy review procedures, different time schedules, and different management techniques will apply for each classification. .

The format for transmitting regulations to the Secretary is shown as Exhibit X3-20-2. A flow chart generally describing the regulation development process, without specific reference to the three types of regulations described below, is shown as Exhibit X3-20-3.

### A. Major Regulations

"**Major**" regulations (no more than 15-20 a year) will represent the regulations that are most extensive and complex and that will have the most widespread impact on the country. The classification will

depend primarily on a judgment that the Department will need to devote very substantial time and effort to developing the regulations. The regulations to implement Section 504 of the Rehabilitation Act of 1973 provide an excellent illustration of this type of regulation.

Regulations of this magnitude will require the designation of a project manager to take responsibility for moving the regulation through the drafting and clearance processes. The appropriate **POC** will nominate the project manager for the Secretary's approval. The manager will report to the Secretary on the progress in developing the regulation. But the substantive responsibility for setting policy and ultimately for producing the regulation in a timely fashion remains with the POC. Although the precise procedures for developing these regulations will largely rest within the discretion of the project manager, the following elements should be uniform:

- \* The regulation will go through both an **NOI** and NPRM stage before moving to final regulations;
- \* A thorough issues paper will be prepared by the responsible POC, with participation by all affected offices within the Department;
- \* The project manager will have the responsibility and authority to resolve all disputes of a procedural nature, to refer quickly all disputes of a substantive nature to the appropriate decision-making level, to break procedural bottlenecks, and to request resources.
- \* The project manager will be responsible for ensuring all needed coordination among affected **offices** within the Department in drafting the regulations and for expediting formal clearance throughout the Department in cooperation with ES.

#### B. Technical Rules

At the other end of the spectrum from major regulations, "technical" rules (those reflecting no policy change, affecting small numbers of institutions/recipients or small amounts of money, or involving narrow and precise changes in a specific regulation) will follow a tightly streamlined procedure.

The POC will be given no more than 60 days to complete drafting. No NOI will be prepared, and the regulation will automatically be prepared as an NPRM, with a 30-day comment period. No OS staff clearances will be sought when the WC delivers the NPRM to ES unless requested at the Panel meeting. ES will circulate weekly to all offices a list of all "technical" rules received that week, and will provide review copies on request. Clearances with other WCs will be sought only when ES believes it appropriate if the other POC was not

present or was not invited to attend the Regulations Review Panel meeting at which the regulation was considered. One week after being placed on this list, the rule will move forward to the Under Secretary/Secretary for action.

Within 20 days following the close of the comment period, the POC will be responsible for forwarding a final rule to ES. In the absence of significant public comment, the final rule will not be circulated for clearance and will automatically be forwarded to the Secretary for signature. Substantial public comment will dictate additional procedures to be agreed upon by the POC, GC, and ES.

For this procedure to work, careful and full analysis of the regulations proposal at the Panel meeting will be required.

C. Policy Significant Rules

Between the major rules and the technical rules lies the category of "policy significant" regulations. The importance and significance of these regulations will vary substantially, and the POC's latitude to tailor the development schedule to the requirements of the regulation will be substantial.

The POCs should present regulations proposals for this category of regulations that identify in detail the extent of the development process the POC believes appropriate for the regulation in question. Choices will be available to the POC in most areas:

- \* the schedule for development;
- \* the need for an NOI;
- \* the need for coordination with other offices;
- \* the extent of public participation;
- \* the issues that need to be identified for Secretarial guidance;
- \* the length of the comment period(s).

Staff offices and other POCs will be encouraged to provide advice at the Panel meeting and to "opt out" of further clearance for regulations that do not significantly affect their work. Staff offices will be asked to justify the raising of new issues in the clearance process if the questions were not raised either at the Panel meeting or when an issues paper was developed. Staff offices and other POCs have a responsibility to raise problems directly with the POC that produced a regulation before submitting written comments to ES to ensure that a serious disagreement exists. The Executive Secretariat will not make lengthy efforts to negotiate compromise. Policy differences between offices will be **sharpened** for prompt presentation for decision to the Under Secretary/Secretary.

D. Limited Delegations of Authority

The Under Secretary may delegate authority to publish Notices of Intent, on a case-by-case basis, where the **POCs** and the Panel recommend such a delegation. For technical regulations, the Under Secretary may delegate authority, on a case-by-case basis, to publish **NPRMs**, where the **POC** and the Panel recommend such a delegation. In such cases, a preamble to the NOI or NPRM will clearly state that the notice has not been reviewed by the Under Secretary or the Secretary and is being published on the authority of the POC.

3-20-40 CONSIDERATIONS IN DEVELOPING REGULATIONS

A. Legislative

1. Does the regulation meet the intent of Congress as reflected by the formal and informal activities preceding enactment of legislation (hearings, conferences, Floor debate, etc.)?
2. What formal or informal discussion of these regulations has taken place with the Congress regarding either content or timing?
3. Which, if any, of the policies reflected in the regulation are supported or opposed by key Congressmen and/or Hill staff?
4. Will any special congressional notification be required of the Secretary/Under Secretary or any other officer of the Department if the regulation is approved or disapproved?

B. Civil Rights

1. Are the necessary prohibitions against discrimination incorporated into the regulation?
2. Do the regulations provide appropriate operational and administrative requirements to assure both equal access and non-discrimination?
3. If the regulation discusses eligibility criteria for funding and/or services, do these criteria contribute to or detract from the promotion of equal opportunity?
4. Do the program policies in the regulation encourage compliance with civil rights statutes, including incentives for the promotion of equal opportunity?

C. Intergovernmental Affairs

1. If the program being regulated relies upon State and/or local provision of services, does the regulation allow a State or local government to deliver services effectively?

2. HOW well do the policies reflected in the regulation correspond to any State policies or programs in the same service area?
3. What is the current or anticipated reaction of State and local governments to the policies contained in the regulation?
4. How adequate are the **POC's** plans to consult with State and local governments in drafting the regulation?
5. Are there any specific individuals and/or organizations whose advice ought to be sought in drafting or reviewing the regulatory policies before they are subject to Secretarial decision?

D. Public Affairs

1. Is the regulation written simply so that it may be understood by both recipients and beneficiaries?
2. What public affairs activity has taken place or will be required to ensure that appropriate publics are informed and that the Secretary's action in approving or disapproving the regulation is accurately conveyed?
3. What has been the media coverage or reaction to the policies proposed in the regulation and what are the **anticipated media** reactions to adopting the policies?
4. What is the anticipated "public" reaction to the policies contained in the regulation if they are approved or disapproved?
5. Is the substance of the regulation clearly explained to the public in the press release and does the press release reach the appropriate audiences?
6. If a Final regulation, have the public comments been accurately and fairly treated in the preamble to the regulation?

E. Management and Budget

1. Are current or **projected budget** changes for the program (**increases**, decreases, zero budget) taken into account in the policies contained in the regulation?
2. What is the estimated cost-benefit of the policies reflected in the regulation?
3. **Will** the procedures described by the regulation contribute to sound management of the program?
4. Are procedures described compatible with other Federal administrative requirements?



5. What reaction, if any, will the appropriations committees in Congress have to the approval or disapproval of the regulation?
6. What plans does the Department have for managing the implementation of the requirements set forth in the regulation?
7. Are these plans compatible with the Department's management and personnel policies?
8. What is the present or anticipated reaction of OMB to the policies contained in the regulation?

F. Planning and Evaluation

1. Are the policies reflected in the regulations consistent with Administration policies or initiatives?
2. In what way do the policies and procedures required by the regulation allow for coordination with other Federal, State, local, or private sector programs servicing similar populations or will they impede Federal program coordination?
3. How do the regulations contribute to, or detract from, achievements of the Department's long-range plans and objectives?
4. Are the policies or procedures in the regulation based on the results of research or studies conducted either inside or outside the Department?
5. If the regulation amends existing program requirements, do the proposed amendments reflect the results of prior program evaluation?
6. Is the Department prepared to evaluate the impact of the regulation once implemented?
7. Do the regulations contain unnecessary planning requirements for State or local governments? Are necessary planning requirements properly related to similar requirements in related programs?
8. 'Has the analysis of economic impact (formerly inflation impact) been properly performed, pursuant to Executive Orders 11829 and **11921**?
9. Do the regulations require some form of evaluation, monitoring or reporting? Are these requirements 'adequate and necessary?

G. Legal

1. Does the regulation meet the President's requirements of clarity, timeliness, and identification of those responsible for its preparation?

2. What litigation, if any, affects the policies or procedures contained in the regulation? Has the probable impact of approval or disapproval of the regulation on pending litigation been considered?
3. Are there any outstanding issues or questions about whether the regulation as drafted is legally sufficient?
4. Are there any policy and legal issues that have not been resolved? What legal and policy alternatives are available to the Department in the resolution of them? Does their resolution require major study or documentation?
5. What major and minor risks are being assumed by the Department as a result of the form and/or content of the regulation?
6. How does the regulation contribute to the Department's regulations recodification initiative?
7. If a Final regulation, have the public comments been accurately and fairly treated in the preamble of the regulation?

#### 3-20-50 SECRETARIAL GUIDANCE ON ISSUES

For major and policy significant regulations, issues identified early -- either in the proposal to regulate or, more frequently, in a separate issues paper -- will be forwarded to the Executive Secretariat for presentation to the Under Secretary/Secretary. The development process will not stop while awaiting policy guidance, however. If guidance is to be provided, ES will either transmit the guidance in writing based on the issue paper, schedule a meeting, or request additional written materials.

#### 3-20-60 PUBLIC PARTICIPATION

The **POCs** must make new efforts to strengthen the Department's communication with the public in the development of regulations. Without the continued involvement of the providers and consumers of HEW-funded services, State and local governments, industry, academia, public interest organizations, and others in the evolution of HEW policies, those policies will neither be responsive to **ongressional** intent nor to national needs.

The new regulations procedures seek faster development of regulations. More rapid preparation of regulations must not be at the expense of more extensive and more effective consultation with the public and affected interest groups. And the Department must not rely solely on publication of **NOIs** and **NPRMs** in the Federal Register to generate public comment.

The General Counsel and the Office of the Assistant Secretary for Public Affairs, through membership on each agency regulations panel, will have the specific responsibility to review whether the regulations proposal provides appropriate and meaningful public participation in the development of each regulation.

A short summary of each regulations proposal will be published in the Federal Register immediately after it has been reviewed by a Regulations Review Panel to inform the public that the Department will be preparing particular sets of regulations. The full proposal will be available to the public on request. In addition, the Department will attempt every six months to publish a list of the major regulations it projects will be undertaken in the ensuing six months.

**In** short, the methods for achieving public participation in the development of major regulations and many policy significant regulations will be expanded not only to include use of Federal Register Notices of Intent and Notices of Proposed Rulemaking, but also specially designed activity to reach appropriate audiences with appropriate information.

This Department will utilize not only general public hearings during the **NOI** and NPRM comment period as a means of achieving public participation, but it will also take the initiative to contact individuals and organizations (both providers and recipients) who are most affected by our policies.

#### 3-20-70 STATE AND **LOCAL** GOVERNMENT PARTICIPATION

A special effort will be made to strengthen the Department's consultation with state and local governments in the development of regulations that govern their actions.

#### 3-20-80 DIVISION OF RESPONSIBILITIES

##### A. Principal Operating Components

Agency heads will continue to be responsible for deciding on the need for regulations, for recommending the appropriate process for drafting of each regulation, and for the actual drafting. WCS will be responsible for coordinating the development of issue papers for Secretarial review, but will be required to **reflect the** views (as dissenting or concurring) in that paper of other line and staff offices that either the POC or the Review Panel identifies as an interested party,

##### B. Staff Assistant Secretaries

The role of staff Assistant Secretaries has been modified from one of clearance at the end of the process, to that of participation in early phases of regulations development. The opportunity for staff from these offices to participate in issue identification and regulations drafting has been increased,,. thereby expanding the over-all pool of available talent focusing on regulations development.

The Executive Secretariat has, in consultation with the staff offices, identified specific issues relevant to the special expertise and responsibility of each staff office. (See Section 3-20-40.) The Secretary has reviewed and approved these areas of responsibility.

Staff **offices** will focus on these issues in their participation on regulations panels, and each office will provide written responses to these **questions** for each regulation circulated by ES for clearance.

C. Office of the General Counsel

The Office of the General Counsel will:

1. Review thoroughly and skeptically the need for regulations.
2. Participate in the writing of regulations. The extent of GC participation in writing may vary from agency to agency. GC may review program drafts of regulations and make changes in them, or draft regulations from program specification, or draft regulations without program specifications, or serve on drafting teams. The ideal is to have a single drafting process to avoid extensive passing of drafts back and forth between GC and the program.
3. Identify the extent of the legal need to write regulations.
4. Raise and comment on policy issues and assure that the policy and legal alternatives are fully presented.
5. Examine regulations for **legal** sufficiency, simplicity, clarity and brevity; assure adequate public participation and **openness** of the process.

D. Executive Secretariat

The Executive Secretariat is responsible for implementing the revised procedures for rule development and assisting the **POCs** to see that the system achieves the objectives of timeliness, coordination, and early Secretarial involvement.

The Executive Secretariat will oversee the scheduling of regulations development, monitor compliance with these schedules, chair the regulations panels, and clear regulatory documents with appropriate line and staff offices. The Secretariat will continue to perform quality control to ensure the completeness of staff work submitted to the Secretary. The Regulations Management Unit within the Secretariat will **serve as** the principal staff for each regulations panel.

REGULATIONS PROPOSAL  
FORMAT

3. Summary

Short (100 words) **summary** of **regulations** proposal -- Program involved, substance of proposed regulation, **etc.** with **name**, address, telephone number of individual the Public can contact for information. (This information **will appear** in the Federal Register. This summary should **appear** on a separate page and be signed by the **POC** Head and dated.)

2. General Program Description

**summarize** briefly the **general program** to be affected by the proposed regulation:

- \* Overall program purpose
- \* Statutory Base
- \* Fiscal History (a **chronology** of authorization and appropriations for the past three **fiscal** Years)

3. Basis of Regulation

**Why** must a regulation be developed? What prompted the **development** of this proposal to regulate (new or amended statute, court order, policy decision, POC **decision**, public petition, etc.)?

4. Regulatory Provisions

Briefly describe what the **regulation** will do.

5. Major Issues

What, if any, are the **anticipated** issues that **will have** to be resolved before the regulation is finalized?

6. External Expectations and Views

**summarize** the known views or expectations Of major constituencies -- providers, **recipients**, **state/local** governments, Congress. and/or other executive agencies **on** the issues described above. Indicate the anticipated level Of controversy in resolving issues.

7. Cost Implications

Briefly describe the anticipated. costs of implementing the proposed regulation on the Federal government, **State/** local **governments**, and/or the private **sector**.

REGULATIONS PROPOSAL FORMAT (Continued)

3. Classification

Based upon 6 and 7 above, how would the POC classify this regulation?

Major \_\_\_\_\_ Policy Significant \_\_\_\_\_ Technical \_\_\_\_\_

9. Schedule

Based upon its classification, indicate which steps the POC proposes to complete for the development of the regulation and the anticipated dates for completion of each step:

Issue Paper to the Secretary Date to OS:  
(Required for "major," optional  
for "policy significant")

Notice of Intent Date to OS:  
(Required for "major," optional  
for "policy significant")

Notice of Proposed Rulemaking Date to OS:

Final Regulation Date to OS:

10. Coordination

Describe the POC's plan to coordinate preparation of issue papers and/or regulation documents with other offices in the Department. List all offices to be included for each step of the process.

11. Public Participation

Describe the POC's plans to seek public involvement in the development of the regulation, including anticipated mailings, public hearings, publications, special meetings. Identify what particular individuals or groups the POC will attempt to involve through its outreach activities and how those activities will be conducted.

12. POC Designee

Provide the name, title, address and phone number of the individual designated by the POC head with the responsibility for developing the regulation and authority to speak for the POC head.

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

Exhibit X3-20-2

GENERAL ADMINISTRATION

HEW TN-78.1 (2/1/78)

DATE:

TO : The Secretary

FROM : Submitting Agency

SUBJECT: Regulation Action Memorandum **Format**

## 1. Program Description

Summarize the program to be affected by the proposed regulation:

- ° Program Purpose
- ° Statutory Basis
- ° Fiscal History
- ° Administrative Experience

## 2. Provisions of the Regulation

What **does** this regulation propose to do and how will it contribute to meeting the specific goals and objectives of the program in terms of:

- ° Services provided beneficiaries
- ° The achievement of program goals and objectives **in** a more cost/beneficial way
- ° The improvement of service delivery **systems** (Federal, State, and local administration)

## 3. cost Implications

Briefly describe the anticipated costs of implementing the proposed regulation on the Federal government, State/local governments, and/or the private sector.

## 4. Public Participation

Describe the nature and scope of Department activities to involve both the general and specialized publics in the **development** of this regulation.

## 5. Non-Selected Options

For major issues contained in the regulation, what other approaches were considered but not selected? Why were the approaches considered less effective than those written into the regulation?

Regulation Action Memorandum Format (Continued)

6. Consequences of Disapproval

What would happen if the regulation was not approved?

7. Expectations

Summarize the views and expectations of Congress, other executive agencies and interest groups concerning the proposed regulation.

8. Urgency

Describe any internal or external factors that would require some action to be taken on the proposed regulation within a specific time period (statutory deadline, court order, funding cycle).



REGULATIONS DEVELOPMENT PROCESS



