

NIH Policy Manual

1793 - Legislative Proposals

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Transmittal Notice

1. **Explanation of Material Transmitted:** This is a revised manual issuance outlining the policy and procedures by which NIH prepares legislative proposals.
2. **Filing Instructions:**

Remove: NIH Manual 1793 dated 9/1/98.

Insert: NIH Manual Chapter 1793 dated 3/24/05.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
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A. Purpose

This chapter describes the general policy and procedures by which NIH prepares legislative proposals. These proposals are considered by HHS and may be submitted as recommendations to the Office of Management and Budget (OMB) for introduction to the Congress. For each fiscal year's submission, there also may be specific HHS requirements which supplement these general instructions, particularly in establishing submission dates. Briefly, the purpose of submitting legislative proposals is to: (1) re-authorize programs for which a formal authorization for appropriations* is due to expire, (2) correct statutory language that is incorrect or obsolete, or (3) propose new or revised statutory language to improve NIH operations or creates new programs. In general, the Department does not approve legislative proposals if regulations or administrative actions can achieve the desired result.

This chapter does not address reports to Congress, or appropriations legislation.

*Alternatively, NIH often may operate under the general authority provided in Section 301 of the PHS Act.

B. Background and References

[OMB Circular A-19](#) includes instructions on the timing and preparation of agency legislative proposals. A well-written legislative proposal expedites the review process, enabling departmental officials, the Secretary, the OMB, and congressional staff to make informed decisions. In particular, the legislative proposal must be specific, succinct, and persuasive. The proposal should: (1) describe the current practice/situation and how the current law could be improved to enhance the performance of a scientific program or administrative operation; (2) explain why an administrative remedy is not warranted or feasible; and (3) discuss the specific consequences of changing the law (e.g., what programs would benefit and any potentially negative consequences). If supporting data would provide further evidence of the need for a change in the law, it should succinctly be incorporated into the proposal or submitted as a brief attachment.

Generally, sometime early in September, each department of the Federal government must submit its package of legislative proposals to OMB in accordance with OMB Circular A-19. To meet this target date, the Office of Legislative Policy and Analysis (OLPA) oversees a process outlined in the Procedures section of this chapter that begins with a request to all the NIH Institutes and Centers (ICs) in January and ends with a submission of legislative proposals to HHS in June.

Under the routine budget and legislative review process, OMB reviews the Department's legislative proposals and gives decisions on budget-related, and sometimes non-budget-related, proposals in late November or December ("passback"). Departments may accept or appeal OMB decisions. OMB incorporates approved budget-related proposals into the President's budget and submits them to Congress in January. Once the legislative proposals have been approved, the Department may submit formal bill proposals to the Congress, provide only brief proposal descriptions, or communicate informally with Congress. The Office of the Secretary, Office of the General Counsel, Legislation Division (OS/OGC/L), drafts formal bills. In all cases, staff of the Assistant Secretary for Legislation (ASL) work to achieve congressional enactment. No draft legislative proposal should be released to anyone outside the Department until authorized by the Office of the Secretary.

C. Responsibilities

1. **Office of Legislative Policy and Analysis (OLPA):** OLPA is responsible for managing the NIH legislative proposal process. OLPA, in collaboration with the NIH Legislative Proposal Work Group, identifies and consults with IC and OD offices on needed legislative changes; advises on preparing legislative proposals; reviews recommended legislative proposals for viability and for meeting NIH program

objectives; edits proposals; and checks for consistency with the Department's required format. OLPA is the liaison between NIH and the Department on legislative proposal matters. Annually, OLPA identifies NIH authorizations of appropriations or sunset provisions that expire during the target fiscal year. OLPA also assists the ICs and OD offices in determining which legislative proposals from previous years, if any, should be resubmitted to the Department.

2. **Legislative Proposal Work Group:** In addition to advising the NIH Director on the legislative proposal process and NIH's legislative needs, the Associate Director for Legislative Policy and Analysis (ADLPA), or designee, chairs the Legislative Proposal Work Group, which reviews and comments on legislative proposals submitted by the NIH ICs and OD offices.

Membership: Permanent – OLPA, OGC, OB, OMA; *Rotating (Term of one Congress)* representatives from 3 ICs, appointed by OLPA.

3. **Office of the General Counsel (OGC):** The Office of the NIH Legal Advisor, which is a component of the OS/OGC, reviews the legislative proposals developed by NIH for submission to the Department, to identify legal issues related to each proposal and ensure that legal authority is correctly cited. OGC considers whether the proposed legislation is necessary to accomplish the stated purpose, whether the proposal conforms to authorizing legislation and other relevant statutes, and whether alternative administrative actions are available. OGC also may identify matters for legislative proposals.
4. **Office of Budget (OB):** OB is responsible for determining whether legislative proposals are consistent with the developed or developing budget, and provides figures for the budget-related proposals. OB works with OLPA to integrate NIH's budget with the NIH legislative proposals. Figures for costs, dollar savings and personnel should be consistent with NIH's budget submission for the target fiscal year.
5. **Office of Management Assessment (OMA):** OMA reviews the legislative proposals to determine whether alternative administrative remedies are available either through addition to, or revision of, existing regulations or changes in delegation of authorities.
6. **ICs and OD offices:** The ICs and OD offices, as requested by OLPA, annually prepare legislative proposals and participate in reviewing and commenting on draft legislative proposals. Prior to submitting legislative proposals to OLPA, the ICs and OD offices should contact OGC to determine whether legislation is needed to accomplish the desired result. The ICs and OD offices should identify any expiring statutory authorities, including authorizations of appropriations and sunsets, errors in law and obsolete provisions (e.g., references to organizations under former titles), improvements in economy or efficiency (e.g., eliminating unnecessary reports or committees), desired modifications of or exemptions from statutes, and desirable new programs that would require statutory authority.

D. Procedures

1. **January:** OLPA notifies the ICs and OD offices when legislative proposals are due. In consultation with OGC, the ICs and OD offices identify NIH authorizations of appropriations or sunset provisions that expire during the target fiscal year. OLPA assists the ICs and OD offices in determining which legislative proposals from previous years should be resubmitted to the Department.
2. **February:** ICs and OD offices have initial discussions with OGC (and/or other relevant NIH components) to evaluate whether the proposal is necessary and whether the issue can be resolved through alternative administrative remedies. Proposals should adhere to the format that appears in Appendix 1 to guide OS/GC/L in bill drafting. For complex proposals, the drafting attorney may need supplemental specifications. Legislative proposals should be limited to one or two pages, if possible. OLPA assigns a control number as specified in the sample format in Appendix 1. The DHHS Legislative Proposal Style Guide outlines specific instructions for preparing each section of the legislative proposal, as well as sample legislative proposals for reference. The “Style Guide” is updated annually, and may be obtained from OLPA.
3. **March:** ICs and OD offices submit draft legislative proposals to OLPA with documentation of OGC review finding that legislation is necessary, if any. OLPA circulates draft legislative proposals for review and comment to the Legislative Proposal Work Group. OLPA then convenes the Legislative Proposal Work Group to discuss their comments. After necessary revisions are made to the proposals, they are distributed to the ICs and OD offices for comment. Appropriate comments will be incorporated into the proposals.
4. **April:** OLPA provides comments/recommendations received to the individual sponsors of legislative proposals. After any necessary revisions are made to the proposals, the final package is submitted to the ADLPA for approval and subsequently to the NIH Director for final clearance.
5. **May:** OLPA prepares final legislative proposal package based on comments received from the NIH Director.
6. **June:** OLPA submits final NIH legislative proposal package to the HHS Office of the Assistant Secretary for Planning and Evaluation. A copy is also provided to OB. OLPA meets with appropriate NIH ICs and OD offices that have submitted legislative proposals in order to prepare for presentations before the HHS OS Legislative Team. OLPA meets with the HHS OS Legislative Team to discuss the NIH legislative proposals.
7. **July:** Department submits NIH legislative proposal package as a part of the HHS legislative proposal package to OMB for clearance.
8. **August:** OMB informs the Department of its determinations regarding the Department’s legislative proposal package.
9. **September:** Department puts package of legislative proposals in final and begins drafting legislative language, if necessary.

E. Records Retention and Disposal

For this chapter, records pertaining to *Legislative Proposals* are retained and disposed of under the authority of [NIH Manual 1743](#), “Keeping and Destroying Records,” Item 1100-A-2, which states:

1100-A-2 *Legislative proposals* which have not yet been enacted into law. Included are supporting documents such as testimony before congressional committees and studies assessing existing authorities to meet present and future program objectives.

Disposition: Review for disposal at least every 5 years and destroy what is not needed for administrative reference. Earlier disposal is authorized.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages.

E-mail messages must also be provided to members of Congress or Congressional committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are sometimes retained for significant periods of time, e-mail messages and attachments may be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

F. Internal Controls

The purpose of this manual issuance is to establish the policy and procedures by which NIH prepares legislative proposals.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter (Issuing Office):** OLPA
2. **Frequency of Review (in years):** Biennial
3. **Method of Review:** Other Review (describe): Annual Compliance Assessment conducted by Legislative Proposal Work Group. This assessment will ensure targeted offices are complying with this policy and the requirements associated with legislative and legislative proposals. A report will be developed for the Director, OLPA that describes how the policies and procedures were tested and any problems and/or issues

identified for correction.

4. **Review Report to be sent to:** Deputy Director for Management

Appendix 1 – Legislative Proposal Format

FORMAT

(Proposal Number assigned by OLPA)

(Date)

Fiscal Year 2003 DHHS LEGISLATIVE PROPOSAL

(AGENCY)

(Brief Title)

Brief statement of what the proposal would accomplish.

Current Law (or Problem): Describe simply, provisions of law that the proposal would amend and that make the proposal necessary; or explain that no law exists and the problem this causes.

Proposal: State proposal in descriptive detail, beginning with ANY other verb than “Amend.”

Rationale: Provide a strong justification for the proposal; include the following, as applicable:

- Describe the problems the proposal would solve and how it would solve them.
- Cite any supporting research or reports.
- Describe whether the proposal would result in an unfunded mandate* being imposed upon the States, local governments, tribal governments, or private sector.

Impact: Explain who would be affected by the proposal and the extent of this effect. Include the sentence: The proposal complies with the Federalism principles in [Executive Order 13132](#) . If the latter is not true, do not submit the proposal.

Cost: Label this section “Cost,” “Revenue,” or “Authorization Level,” as appropriate.

- Provide a table showing estimated costs, savings, revenues, or reauthorization level, in millions of dollars.
- Give estimates for five years. For reauthorization requests, first year must contain the same number reflected in the budget submission followed by "Such Sums As Necessary" for outyears.
- If no costs, savings, or revenues, say “None.”
- Explain and justify how you calculated estimates.
- Indicate whether and by how much the proposal would increase/reduce costs on other groups or entities.

Personnel Requirements: Optional; include only if significant and/or reflected in the budget; show estimated personnel impact in full-time equivalents (FTEs).

Effective Date: Indicate either "Upon enactment" or a specific date.

Other Data: Optional; provide information here that doesn't fit under other headings, including any draft bill language.

***Unfunded Mandates:** In Public Law 104-4, the Unfunded Mandates Reform Act of 1995, Congress required of itself that it assess and consider all costs created in its laws which would constitute unfunded Federal mandates on States, local governments, tribal governments, and the private sector. Reductions in appropriation authorizations without commensurate reductions in program requirements also constitute unfunded mandates. The law also requires agencies to be more accountable for mandates that would be established through regulations.

If the legislative proposal would likely lead to the imposition of an unfunded mandate, explain the likely source of the mandate under this Impact section; under the Rationale section, provide a strong argument for and explanation why the mandate is justified. Include under the Cost section an estimate of costs expected to be incurred by the States, local governments, tribal governments, or private sector as a result of the additional mandated work effort or benefits payments. Indicate in the proposal other proposals which will address how we recommend paying for the mandate.