

NIH POLICY MANUAL

1792 - LEGISLATIVE IMPLEMENTATION

Issuing Office: OD/OLPA 496-3471

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NOTE TO RECIPIENTS:

NIH has begun a new process to ensure the proper review and implementation of new requirements and responsibilities for recently-enacted legislation. The purpose of this legislative implementation process is to coordinate and guide the development of a Legislative Implementation Action Plan (LIAP) for a legal, thoughtful and timely response to newly enacted Congressional legislation that affects NIH, including appropriations legislative language, such as restrictions on the use of appropriated funds (e.g., anti-lobbying); earmarks for particular programs or projects; and changes in the availability of funds (e.g., earmarks available until expended). As part of this new process, a standing committee, the Legislative Implementation Work Group, has been established.

The Work Group is chaired by the Office of Legislative Policy and Analysis (OLPA); permanent members include the Office of General Counsel (OGC), the Office of Management Assessment (OMA), and the Office of Financial Management (OFM). Rotating members include two legislative contacts from an ICD with experience in legislative implementation and one legislative contact from an ICD with little or no experience. As part of this ongoing process, the Work Group meets within approximately 30 days after enactment of applicable legislation and at least twice a year (or as needed) to coordinate and guide the development of LIAPs for new laws that affect NIH, and to review the status of NIH's role in implementing such new laws. The Work Group: assists in the interpretation of legislative language; identifies the lead ICD and Offices responsible for implementation; ensures appropriate coordination of required activities; and prioritizes and tracks progress.

This new process formalizes legislative implementation for appropriations law with the establishment of a subgroup, chaired by OLPA, with representation from OFM.

The attached chapter:

1. Describes policies and procedures for the preparation and implementation of LIAPs;
2. Describes the involvement and responsibilities of the Work Group and NIH

ICDs and Offices;

3. Provides the criteria for the development of an LIAP; and
4. Provides the format for preparing and submitting an LIAP.

If you have any questions regarding this note, please contact OLPA at (301) 496-3471.

INTRODUCTION

This chapter announces the establishment of a new legislative implementation process designed to ensure a legal, thoughtful, and timely response to newly enacted Congressional legislation that affects NIH, including appropriations legislative language. Under this new process, a standing committee composed of OD and ICD members has been charged with determining implementation requirements and responsibilities, reviewing proposed plans, and tracking associated progress, in addition to overseeing coordination and collaboration with the Office of the Secretary, other DHHS operating divisions, and other Federal agencies, as appropriate.

Features of the New Legislative Implementation Process:

- Management, oversight, and direction are provided by the Office of Legislative Policy and Analysis (OLPA).
- A standing committee, chaired by OLPA, has been established to develop the best strategy for legislative implementation and to identify a lead ICD or Office responsible for implementation. The standing committee meets approximately 30 days after enactment of applicable legislation and at least twice a year (or as needed) to coordinate and guide the development of implementation action plans and to review the status of NIH's role in implementing such new laws. The permanent members of the committee are representatives from the Office of General Counsel, the Office of Management Assessment (OMA), and the Office of Financial Management (OFM); the committee also has rotating ICD representatives.

The lead ICD or Office is responsible for:

1. Developing a legislative implementation action plan and submitting it to the standing committee for review. With few exceptions, development and approval of legislative implementation action plans should not exceed a period of 120 calendar days from the time of assignment to a lead ICD or Office.
2. Consulting with the standing committee for assistance and guidance, coordinating with other entities as necessary, implementing the legislation, and providing a final report to the standing committee informing it that the law has been implemented.
 - This new process formalizes legislative implementation for

appropriations law with the establishment of a subgroup, chaired by OLPA, with representation from OFM.

- OLPA, in conjunction with OMA, will conduct a periodic review to assess the effectiveness of the process.

**** Attachment Begins Here ****

1. Explanation of Material Transmitted: The attached issuance contains instructions on the legislative implementation process to coordinate and guide the development of a Legislative Implementation Action Plan (LIAP) for a legal and thoughtful implementation response to newly enacted Congressional legislation that affects NIH, including appropriations legislative language, such as restrictions on the use of appropriated funds (e.g., anti-lobbying), earmarks for particular programs or projects; and changes in the availability of funds (e.g., earmarks available until expended).

2. Filing Instructions:

- **Remove:** NIH Manual 1792, "Policy Development and Implementation (New Laws)" dated 9/28/89
- **Insert:** NIH Manual 1792, "Legislative Implementation" dated 12/31/97

3. Distribution: NIH Mailing Keys F-401 and F-402

PLEASE NOTE: For information on:

- **Content of this chapter,** contact the issuing office listed above.
- **NIH Manual Mailing Keys,** or for a paper copy of this chapter contact the Division of Support Services, ORS, on 496-4808.
- **NIH Manual System,** contact the Office of Management Assessment (OMA) on 496-2832.
- **On-line information,** enter this URL:
<http://www3.od.nih.gov/oma/manualchapters/>

A. Purpose: The purpose of the legislative implementation process is to coordinate and guide the development of a Legislative Implementation Action Plan (LIAP) for a legal, thoughtful, and timely response to newly enacted Congressional legislation that affects NIH, including appropriations legislative language, such as restrictions on the use of appropriated funds (e.g., anti-lobbying); earmarks for particular programs or projects; and changes in the availability of funds (e.g., earmarks available until expended).

B. Responsibilities:

1. Legislative Implementation Work Group:

a. The Legislative Implementation Work Group is a standing committee that determines requirements and responsibilities for implementation of recently-enacted legislation. The Work Group is chaired by the Office of Legislative Policy and Analysis (OLPA); permanent members include the Office of General Counsel (OGC), the Office of Management Assessment (OMA), and the Office of Financial Management (OFM). Rotating members (Term: One Congress) include two legislative contacts from an Institute, Center, or Division (ICD) with experience in legislative implementation and one legislative contact from an ICD with little or no experience. The Work Group shall meet within approximately 30 days after enactment of applicable legislation and at least twice a year (or as needed) to coordinate and guide the development of LIAPs for new laws that affect NIH, and to review the status of NIH's role in implementing such new laws. Concerning legislative language in appropriations law, a separate Appropriations Subgroup (see "b" below) will convene a meeting to assure that processes are in place to handle implementation expeditiously (the main Work Group will be updated periodically on the Appropriations Subgroup's actions). **Responsibilities of the Work Group include:**

- assisting in the interpretation of legislative language;
- identifying the "lead" ICDs and/or Offices responsible for implementation and the unit responsible for developing a LIAP (this includes laws for which another agency is the lead, but requires NIH compliance);
- ensuring the lead ICD or Office disseminates to all necessary parties information about the law; informs these parties of any policy changes for immediate compliance; and verifies that coordination takes place for required activities and enrolls other units as necessary to provide assistance, such as the Office of Science Policy, the Office of Extramural Research, and the intramural community;
- determining what LIAPs should be put on the fast track; and
- reviewing and commenting on the LIAP, monitoring the implementation process, and ensuring that implementation has been completed.

b. Appropriations Subgroup*: The Appropriations Subgroup is a standing committee which will ensure that legislative language in

appropriations law is implemented. Within approximately ten days after enactment of appropriations law, the subgroup, composed of representatives from OFM, OMA, OGC and chaired by OLPA, will meet to discuss actions and establish a framework, including time tables, for implementing legislative language. After consultation with the subgroup, OLPA will identify and notify the NIH entities responsible for implementation. The subgroup will monitor the implementation process and, when implementation is completed, provide documentation to the main implementation group for record keeping purposes.

** The subgroup specifically deals with legislative language (e.g., legislative bans) and will not deal with any language in the House or Senate reports accompanying the bill, unless it serves to describe or explain the language of the public law. Nor will the subgroup address the funding amounts associated with the ICs, OD, and Buildings and Facilities that are the responsibility of OFM.*

2. Office of Legislative Policy and Analysis (OLPA): OLPA tracks the progress of legislation affecting NIH. Responsibilities include: tracking relevant legislation; notifying the Legislative Implementation Work Group when legislation is enacted into law to initiate activity for the development of implementation plans; providing summary legislative and interpretative documentation; chairing Work Group meetings to determine the impact of the legislation on NIH, interpret the requirements of the legislation, and ascertain the ICDs and Offices that will be affected and involved in an implementation response; and facilitating formal communications regarding the new law and required processes to the relevant ICD/Office Directors, the ICD/Office legislative offices, and the Department as appropriate. OLPA has ultimate responsibility for ensuring that the LIAP is completed.

3. Office of Management Assessment (OMA): OMA, in collaboration with OGC, determines whether there are action items in the legislation that need to be included in the NIH "Unified Agenda of Federal Regulatory and Deregulatory Actions" submission. When the legislation becomes law, OMA takes a lead role with the lead ICD/Office in identifying action items relevant to OMA's purview for inclusion in the LIAP. OMA then coordinates within a specified time frame the development or revision of regulations, guidelines, manuals, policies, delegations of authority, and the development of reorganization packages resulting from new laws. If another agency is implementing a law that will affect NIH programs, and regulations are published in the Federal Register in response to the law, OMA will forward the proposed regulations to the appropriate ICD/Office for review and comment. When final rules are published, OMA will ensure that appropriate ICDs/Offices are informed of the regulations and take action to ensure NIH's regulations, guidelines, manuals, policies, and delegations of authority are revised to reflect the law.

4. Office of the General Counsel (OGC): The major role of OGC is to interpret the legislation for a legal perspective and determine what actions will satisfy the new legislative requirements. No legislative implementation plan should be considered final for initiation of action until OGC has provided an analysis and clearance. OGC should participate in decisions concerning whether regulations and delegations to fulfill legal requirements or policy objectives are needed.

5. Office of Financial Management (OFM): OFM is responsible for coordinating the financial management activities of NIH including the planning, execution and implementation of budgetary law changes. OFM will assume the lead in setting forth the fiscal consequences of new laws and communicating this information throughout NIH. Because of statutory requirements related to the preparation of financial documents, OFM will proceed immediately with its responsibilities after enactment of appropriations laws. OFM also has responsibility for Congressional Appropriation Committee Reports. See NIH Manual 1161 (pending release) for instructions on these reports.

6. Lead ICD/Office for Legislative Implementation: The lead ICD/Office is responsible for developing the LIAP and submitting the plan for review by the Work Group. It will consult with the Work Group for assistance and guidance, coordinate with other entities as necessary, implement the legislation, and provide a final report to the Work Group informing them that the law has been implemented. In consultation with OMA, the lead ICD/Office will determine what regulations, guidelines, policy manuals, delegations of authority, and other information sources need to be updated. As appropriate, the lead ICD/Office will ensure that procedures are put in place in a timely fashion to inform affected parties of changes in policy through information sources such as memos, e-mail, home pages, announcements, etc.

C. Procedures: Preparation and implementation of LIAPs are to be coordinated by the ICD or Office that has lead responsibility as determined by the Legislative Implementation Work Group in consultation with the Work Group and other relevant ICDs and Offices. The required information and/or assistance to the implementing ICD or Office may be supplied by members of the Work Group or other organizations. Except in the case of legislation providing authorization for all units of the NIH, the LIAP should be kept as brief and concise as possible* (Appendix 1 is to be used as a template for the LIAP and can be obtained electronically from ICD legislative contacts). Similarly, with few exceptions, development and approval of a LIAP should not exceed a period of 120 calendar days from the time of assignment to a lead ICD or Office. (*Will vary with the scope of the legislation; e.g., one program area vs. authorization for all ICDs.) Appendix 2 is the status log for use by the NIH entity developing a LIAP. The status log provides a timeline to assist in guiding the legislative implementation process.

Criteria for Development of a Legislative Implementation Action Plan (LIAP):

An LIAP is required if:

- a new program is to be established that requires policy development, staffing and budget justification,
- the legislation will modify existing program policy, or
- the legislative requirements involve coordinating activities with another DHHS Operating Division (OPDIV) or Federal agency.

In the case of very comprehensive and/or complex legislation (e.g., revitalization), some items in the new law may meet the criteria for development of LIAPs while other items do not. In such cases, the LIAP should cover only those items that meet the criteria above.

Submission of LIAPs (see [Appendix 1](#) for format):

An LIAP should contain, at minimum, the following elements:

1. The lead ICD(s) or Office(s).
2. The title and Public Law number, and the date enacted/effective, and description of the legislation (provided to the lead ICD/Office by OLPA for inclusion in the Plan) which will include:
 - a. a brief summary of the purposes of the Act and legislative background that has bearing on the specific provision requiring action by PHS, and
 - b. the public law or relevant sections of the law, and, if appropriate, an analysis of the law.

In the case of broad-based legislation affecting many NIH units, the Work Group will prepare overview sections.

3. If it is determined by the Work Group that the new legislation must be reconciled with existing legislation (e.g., civil rights laws, the Privacy Act, the Freedom of Information Act), the relationship between the Acts should be delineated.
4. A description of the major actions required to implement the legislation, including steps taken to inform appropriate parties of changes in policy, and a timetable for each action (e.g., establishing a grant or loan program).
5. Any significant policy or procedural issues raised by the legislation. If there will be challenges in implementing the legislation, discuss the anticipated

problems and a strategy for resolving them.

6. Any significant legal issues raised by the legislation, together with any legal opinion that has been obtained from OGC, or a statement of what opinions should be obtained.

7. In consultation with OMA (496-2832), a list of all new or revised regulations, guidelines, policies, manuals, information sources, etc. that will be required. Provide projected timetables for needed new or revised regulations and, if required, identify other organizations that should participate in preparing them.

a. State when specifications for regulations, or draft of the regulations, are expected to be completed by the program in collaboration with OMA and forwarded to OGC.

b. State when the Notice of Proposed Rulemaking and final regulations are expected to be sent to Office of the Secretary.

8. In consultation with OMA, an identification of new delegations of authority, if needed, including the authority or authorities, specifying by and to whom the delegation(s) should be made. Provide projected timetables for development of needed documents to request delegation(s).

9. When the legislation authorizes or reauthorizes programs of Federal financial assistance and/or direct Federal development (except R&D and training programs), the LIAP is to contain an analysis provided by OMA (OGC or OER, as appropriate) concerning the program's applicability to the intergovernmental review requirements of Executive Order 12372, as implemented in 45 CFR Part 100.

10. If a report to the Congress is required, the title, subject, due date, and the office responsible for preparing the report should be included. OFM has responsibility for Congressional Appropriations Committee Reports. See NIH Manual 1161 (pending release) for instructions on these reports.

11. If the law requires participation of another agency, office, or DHHS OPDIV, the lead ICD/Office should identify and coordinate with the organization concerned, and provide an overview of coordination efforts in the LIAP. Indicate the nature and scope of the involvement (e.g., "Funding in the amount of \$ for the first year will be provided by agency Y via a Memorandum of Agreement"). State the total dollar authorization and appropriation level for each year and indicate, if required by the statute, the amount to be used for each section of the law. If the Office of the Secretary or some other Federal agency is to provide funds, indicate the amount and source of funds. If a supplemental budget request is needed, state the amount and the date by which the request must be submitted.

12. In consultation with OMA, indicate any proposed organizational changes required by the legislation. State when functional statements will be submitted to OMA by the affected ICD/Office. If additional personnel are needed, indicate how many, and how they will affect the organization, including estimated additional cost.

13. In consultation with OFM, consideration should be given to the resource availability to support implementation of the legislation. In addition, any funding amounts mentioned in the LIAP must be coordinated with OFM and the appropriate ICD budget office(s).

14. State whether any advisory committees will be needed and, if so, their scope of responsibilities. Consult with the Committee Management Office on need for concurrence.

D. Records Retention & Disposal: For this chapter, records (e-mail and non-e-mail) pertaining to "Legislative Implementation Planning" are retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records," Items 1100-A and 1100-H-3. See Manual for specific instructions.

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 ICD 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.

E. Management Controls: The purpose of this manual issuance is to implement a process to coordinate and guide the development of a LIAP to respond to newly enacted Congressional legislation that affects NIH.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter (Issuing Office): OLPA

2. Frequency of Review (in years): Annual
3. Method of Review:
Other Review (describe): Annual Compliance Assessment conducted by Legislative Implementation Work Group. This assessment will ensure targeted offices are complying with this policy and the requirements as outlined in the LIAP.
4. Review Report to be sent to: Deputy Director for Management

Appendix 1: LEGISLATIVE IMPLEMENTATION ACTION PLAN

1. Lead and Other ICDs/Offices:
2. Public Law & Title:
 - Date/Effective Date:
 - Description and Section Summary (Attached as Appendix) (OLPA):
3. Relationship with Current Legislation:
4. Required Actions & Timetable(s) by Applicable Section:
5. Policy Issues:
6. Legal Interpretations (Attached as Appendix) (OGC):
7. New/Revised Regulations (OMA) Timetable(s):
8. New/Revised Delegations of Authority Needed (by OMA) with timetable(s):

9. Financial Assistance Review (Attached as Appendix) (OMA/OGC/OER):

10. Report to Congress Required: Title, Due Date:

11. Other Agencies/Coordination:

12. Organizational Changes; Added Staff Needed? (OMA):

13. Availability of Funds (OFM):

14. Advisory Committees Needed (CMO concurrence if necessary):

Appendix 2: LEGISLATIVE IMPLEMENTATION ACTION PLAN STATUS LOG

Public Law No. _____ Title:

*** There should be a separate status log for each requirement stipulated in the Public Law.*

Section Requirements:

Lead ICD/ Office:

Other ICDs/ Offices:

**Due Date Completion Completed By
 Date**

Work Group
Initiation (OLPA)

Initial Review of
Legislation
(OGC/OMA/OER)

Action Assignment

Feedback:
Assignment/
Coordination
(ICD/ Office)

Draft Plan
Submitted by
ICD/Office to
Work Group

Final OGC/ OMA
Review

Work Group
Review

Final LIAP
Submitted by
ICD/Office to
Work Group

LIAP Submitted or
Included in Unified
Agenda (OLPA /
OMA)

LIAP Received by
Reviewing
Office(s) (DHHS,
OMB, etc.)

Amended LIAP
(Anticipated New
Completion Date)

Implementation
Initiated

Semi-Annual
Status of
Uncompleted
Items (Attach as
Appendix)

Implementation
Completed (Attach
Description as
Appendix)

Final Report to
Work Group

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