NIH Policy Manual

1792 - Legislative Implementation

Issuing Office: OD/OLPA **Phone:** (301) 496-3471

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Transmittal Notice

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 thoughtful, comprehensive, and timely response to newly enacted, NIH-related Congressional legislation that best reflects Congressional mandates and intent.
2. **Filing Instructions:**

   Remove:NIH Manual 1792, "Legislative Implementation" dated 07/05/05.
   Insert:NIH Manual 1792, "Legislative Implementation" dated 03/24/14.

PLEASE NOTE: For information on:

- **Content of this chapter**, contact the issuing office listed above.
- **NIH Manual System**, contact the Office of Management Assessment (OMA) on 301-496-2832, or enter this URL: http://oma.od.nih.gov/public/MS/manualchapters/pages/default.aspx

A. Purpose

It is imperative that NIH implement newly enacted legislation in a thoughtful, comprehensive, and timely manner. The Legislative Implementation Action Plan (LIAP) is the mechanism that NIH has put in place to coordinate and guide the legislative implementation process. LIAPs encompass all NIH-related legislation, including appropriations legislative language, restrictions on the use of appropriated funds (e.g., lobbying), earmarks for particular programs or projects; and changes in the availability of funds (e.g., earmarks making funds available until expended). This manual chapter does not apply to requests in appropriations report language, known as Congressional Appropriations Committee Reports (CACRs) and Significant Items (SIs).

B. Responsibilities

1. **Office of Legislative Policy and Analysis (OLPA)**: OLPA notifies the relevant Institute, Center or Office of the Director (IC/OD) legislative contact of newly enacted laws that require a LIAP, monitors implementation, and ensures that implementation is

completed. OLPA shall provide the lead IC/OD office with a template LIAP and provide general guidance.

2. **Legislative Implementation Work Group**:

    a. **The Legislative Implementation Work Group** (Work Group) is a standing committee that determines requirements and responsibilities for implementing recently enacted legislation. The Work Group is chaired by OLPA. Permanent members include representatives from the Office of the General Counsel (OGC), the Office of Management Assessment (OMA), the Office of Budget (OB), the Office of Extramural Research (OER), and the Office of Science Policy (OSP). Rotating members include three IC legislative contacts, whose term will be the length of one Congress. Responsibilities of the Work Group include:

        i. assisting in the interpretation of new legislation;
        ii. determining whether a LIAP is required and determining which LIAPs should be expedited;
        iii. identifying the lead IC/OD office responsible for developing a LIAP (if another agency leads implementation, but some aspect requires NIH compliance, the Work Group will advise the relevant IC/OD office to work with that agency);
        iv. ensuring the lead IC/OD 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, such as OSP, OER, and the intramural community, as necessary, to provide assistance; and
        v. reviewing and commenting on LIAPs.

    b. **Appropriations Subgroup:** The Appropriations Subgroup is a standing subcommittee of the Work Group, chaired by the Associate Director for Budget and composed of representatives from OLPA, OGC, and OMA, that has the responsibility within the Work Group for ensuring that legislative language in appropriations law (e.g.. lobbying ban) is implemented. The Subgroup does not deal with language in House or Senate committee reports accompanying a bill, unless it serves to describe or explain language of the law. The Subgroup also does not address funding amounts associated with the ICs, OD, or Buildings and Facilities, which are the responsibility of OB. An implementation table that lists the legislative provision, responsible office for implementation, and action taken to implement the provision, is completed in lieu of a Legislative Implementation Action plan unless the Subgroup determines otherwise.

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 the lead role in collaborating with the appropriate IC/OD office to identify action items relevant to OMA's functional areas, available at http://oma.od.nih.gov/public/Pages/OMA-

Services.aspx, for inclusion in the LIAP. OMA then coordinates the development or revision of regulations, guidelines, policy manuals, 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 the agency publishes proposed regulations in the Federal Register in response to the law, OMA will forward the proposed regulations to the appropriate IC/OD office for review and comment. When the agency publishes final rules, OMA will inform the appropriate ICs/OD offices. Additionally, OMA, in collaboration with appropriate ICs/OD offices, will coordinate the revision of NIH regulations, guidelines, policy manuals, and delegations of authority, as necessary.

OMA will inform OLPA if they receive a Delegation of Authority from HHS to implement a new law or a provision within a law on behalf of the Department. OLPA will then notify the Legislative Implementation Work Group, who will determine whether a LIAP is necessary.

4. **Office of the General Counsel (OGC):** OGC is responsible for providing legal advice and interpretation throughout the implementation process, including advising NIH when regulations and delegations are needed to fulfill legal requirements or policy objectives. No LIAP is final until OGC has cleared it.
5. **Office of Budget (OB):** OB is responsible for coordinating the budget of NIH, including the planning, execution, and implementation of laws affecting the budget. OB assumes the lead role in establishing the fiscal consequences of new laws and communicating this information throughout NIH. Because of statutory requirements related to the preparation of financial documents, OB proceeds immediately with its responsibilities after a new appropriations law is enacted. Separate from the implementation process, but related to annual appropriations measures, OB is responsible for preparing CACRs and SIs.
6. **Lead IC/OD Office:** The lead IC/OD office is responsible for developing and submitting assigned LIAPs to OLPA through the IC/OD office legislative contact no later than 120 calendar days from the date when the lead IC/OD office received the assignment. The lead IC/OD office consults with the Work Group for assistance and guidance, coordinates implementation activities, implements the law, and provides written documentation to OLPA confirming completion or providing a status of all activities in the LIAP within a year of enactment. In consultation with OMA, the lead IC/OD office determines which new or revised regulations, guidelines, policy manuals, delegations of authority, and other information sources are needed. As appropriate, the lead IC/OD office ensures that procedures are put in place to promptly disseminate to all appropriate parties information about the law; informs the parties of any policy changes for immediate compliance; verifies that coordination takes place for required activities; and enrolls other units, such as OSP, OER, and the intramural community to provide assistance as necessary.

C. Procedures

1. **Notifying Work Group and Appropriations Subgroup of Enacted Legislation:**

    a. **Authorizing Legislation:** OLPA is responsible for notifying the Work Group of newly enacted NIH-related authorizing legislation and scheduling a meeting with the Work Group no later than 30 days after enactment of such law to determine if a LIAP is needed.
    b. **Appropriations Legislation:** Within ten working days after an annual appropriations law is enacted, the Appropriations Subgroup shall meet to assure that processes are in place to handle expeditious implementation of appropriations legislative language and to identify NIH entities responsible for taking appropriate action. OB is responsible for notifying the budget community and OD offices responsible for implementation and compliance of legislative language in appropriations law after consulting with the Subgroup, monitoring implementation of the process as necessary, and updating the main Work Group on the status of implementation. In addition, OB shall:

        i. prepare a table to identify provisions in the law that require implementation or compliance and actions taken to implement or comply with the provision, and
        ii. provide on the OB SharePoint site a listing of legislative mandates that describe the public law and NIH-related policies.

2. **Determining Whether a LIAP is Needed:** At the initial meeting, the Work Group shall determine, by majority vote, whether a LIAP is required by analyzing whether the newly enacted legislation:

    a. requires establishment of a new program that would necessitate policy development, staffing, and budget justification,
    b. modifies existing program policy, or
    c. involves coordinating activities with another Department of Health and Human Services (HHS) Operating Division (OPDIV) or federal agency.

    If the legislation meets the criteria of any of the elements above, then a LIAP is required. In such cases, OLPA shall inform the lead IC/OD office. OLPA shall schedule meetings as needed to coordinate and guide the development of the LIAP and to review the status of the lead IC/OD office's role in implementing the LIAP. In cases of complex legislation where some items meet the criteria requiring a LIAP while others to do not, the LIAP shall cover only those items that meet the criteria.

3. **Developing a LIAP:** The lead IC/OD office, in consultation with the Work Group, is responsible for preparing and implementing each LIAP. OLPA shall provide the lead IC/OD office with a template LIAP. LIAPs may vary based on the scope of legislation (e.g. one program vs. an NIH reauthorization measure) but should be as brief and

concise as possible. *A LIAP should contain, at a minimum, the following elements*:

a. The name/s of lead IC(s)/OD office(s).
b. The title and public law number, the date enacted or effective, and a description of the legislation, which includes:

    i. a brief summary of the purposes of the Act and legislative background that has bearing on the specific provision requiring action by NIH; and
    ii. the public law or relevant sections of the law, and, if appropriate, an analysis of the law.

c. The relationship between different laws, in those cases where the Work Group has determined that the new legislation must be reconciled with existing legislation (e.g., civil rights laws, the Privacy Act, the Freedom of Information Act).
d. A description of the major actions required to implement each applicable section of the legislation, including steps taken to inform appropriate parties of changes in policy, and a timetable for each action (e.g., establishment of a grant or loan program, development of research plan, coordination of activities).
e. Any significant policy or procedural issues raised by the legislation. Include the anticipated problems and a strategy for resolving them if there are any challenges in implementing the legislation.
f. Any significant legal issues raised by the legislation, together with any legal opinion obtained from OGC, or a statement of the opinions that should be obtained.
g. A list of all new or revised regulations, guidelines, policies, manuals, and information sources, to be compiled in consultation with OMA (301-496-2832). Provide projected timetables for any new or revised regulations and, if required, identify other organizations that should participate in preparing them. This section should specifically state when:

    i. specifications for regulations, or draft regulations, are expected to be completed by the program in collaboration with OMA and forwarded to OGC; and
    ii. the Notice of Proposed Rulemaking and final regulations are expected to be sent to the Office of the Secretary, HHS.

h. Any new necessary delegations of authority, including the authority or authorities, to be compiled in consultation with OMA and specifying by and to whom the delegation(s) are made. Provide projected timetables for the development of needed documents to request delegation(s).
i. A justification provided by OER (made in consultation with OGC, if appropriate) on the program's applicability to the intergovernmental review requirements of Executive Order (EO) 12372, as implemented in 45 Code of Federal Regulations (CFR) part 100, for those cases in which the new legislation authorizes or reauthorizes programs of federal financial assistance or direct federal

development (except R&D and training programs). This EO established a national program that encourages coordination between federal agencies, states, and local governments to provide opportunities for local units of government to learn about and comment on selected projects affecting their jurisdictions. For the most part, the types of grants that require review under this EO are service-oriented, and therefore, would not affect most NIH programs. A copy of the EO and CFR can be obtained from OLPA.

j. The title, subject, due date, the date that the OD Executive Secretariat was notified of the report requirement, and the office responsible for preparing the report, for those cases where a report to Congress is required.

k. An overview of coordination efforts with other agencies, offices, or HHS OPDIVs, if the law requires participation with entities outside NIH. 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 used for each section of the law. If the Office of the Secretary or some other federal agency is to provide funds, indicate the amounts and source(s). If a supplemental budget request is needed, state the amount and the submission date of the request. If applicable, please refer to NIH Manual 1165 - Agency Agreements.

l. Any proposed organizational changes required by the legislation, identified in consultation with OMA. Include an overview of the proposed organizational change, including a list of each organizational component with the Standard Administrative Code (SAC) that is undergoing an organizational change, how the functions will continue (if transferring functions from one component to another) or are no longer needed (if abolishing a function), and the approval authority for the organizational change. Provide an overview of the budget and personnel impact from the organizational change and how they will be addressed. Provide a timeframe for when the draft organizational change package will be submitted to OMA.

m. The availability of resources to support implementation of the legislation as identified in consultation with OB. Also identify coordination between OB and the appropriate IC budget office of any funding amounts.

n. Any advisory councils (or other committees, such as interagency committees) that may be needed and their scope of responsibilities. Consult with the Office of Federal Advisory Committee Policy on the need for concurrence.

4. **Time-Frame for Competing a LIAP:** With few exceptions, development and approval of a LIAP shall not exceed 120 calendar days from the date when the lead IC/OD office received the assignment. If an IC/OD office cannot meet this deadline, it must submit an extension request to OLPA before the due date.

D. Records Retention and 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," multiple Items in Sections 1100-A, 1100-D (as appropriate), 1100-F, 1100-H-3, and 2100-A. See Manual for specific instructions.

NIH e-mail 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. Pursuant to General Records Schedule 20, Item 14 - Electronic Mail Records, e-mail messages which meet this definition should be copied to a record keeping system--either hard copy or electronic--and then deleted from the e-mail system.

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. Back-up files are subject to the same requests as the original messages.

E. Internal Controls

The purpose of this manual issuance is to have 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 Internal Controls Relative to this Chapter (Issuing Office):** OLPA
2. **Frequency of Review (in years):** One year after a new law is enacted.
3. **Method of Review:** IC/OD office provides written documentation to OLPA providing a status or confirming completion of all activities in the LIAP.
4. **Review Report to be sent to:** Associate Director for Legislative Policy and Analysis.