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01949 - [A1252249]

Report to the Secretary of Health, Education, and Welfare on Fundamental Improvements Needed for Timely Promulgation of Health Program Regulations. HRD-77-58; B-164031(5). May 5, 1977. 83 pp.

Report to Secretary, Department of Health, Education, and Welfare; by Gregory J. Ahart, Director, Human Resources and Development Div.

Issue Area: Health Programs: Compliance With Financing Laws and Regulations (1207).
Contact: Human Resources and Development Div.
Budget Function: Health (550).
Congressional Relevance: House Committee on Interstate and Foreign Commerce: Health and the Environment Subcommittee; Senate Committee on Human Resources.
Authority: Health Maintenance Organization Act of 1973 (P.L. 93-222; 42 U.S.C. 300e et seq.). Social Security Act, as amended; Social Security Amendments of 1967, sec. 301; Social Security Amendments of 1972 (P.L. 92-603; 42 U.S.C. 703(2), 704(2); 42 U.S.C. 711; 42 U.S.C. 1395u; 42 U.S.C. 1396a). National Health Planning and Resources Development Act of 1974 (P.L. 93-641; 42 U.S.C. 3001). Nurse Training Act of 1971; Public Health Service Act, as amended (42 U.S.C. 296d; 42 U.S.C. 3801, as amended). 21 C.F.R. part 1, 3. CMB Circular A-85.

The Chairman of the House Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce, requested a review of the Department of Health, Education, and Welfare's (HEW's) System for developing and promulgating health program regulations. Fourteen regulations were studied, 12 initiated as a result of legislation and 2 instituted to change the administration of current programs. Findings/Conclusions: No final regulations were published within the deadline time of 6 months after enactment of enabling legislation, and, instead, are being published up to 3 years late. Delays in publishing regulations were primarily caused by weaknesses in HEW's policies and procedures for developing and processing proposed regulations, but sometimes the delays were caused by HEW's conscientiousness in resolving policy issues and encouraging public participation. Limited staff and resources, diffused responsibilities and lack of authority, low priority assigned regulations by some officials, and failure to monitor and take effective measures, also delay publication. Recently announced changes to policies and procedures will help somewhat, but additional changes are needed. Compliance with CMB Circular A-85 is not required, and the policies for forwarding proposed regulations to the Advisory Committee on Intergovernmental Relations (ACIR) are interpreted differently by the health agencies. Recommendations: HEW staff and resources should be

developed to levels that are sufficient to participate in developing and processing regulations, and the need for public comment should be reevaluated. Comments from appropriate congressional committees on proposed and final regulations should be requested. The computerized system for monitoring the processing of regulations within the Office of the Secretary should be modified to include both developing and processing of all regulations. Preclearance policies and procedures to expedite final processing should be formalized, and revisions, unresolved issues, or questions on program criteria and proposed regulations should be highlighted. The Commissioner of Food and Drugs should establish developing and processing limits. The policy and procedures for forwarding regulations to ACIR, obtaining comments from State and local government associations, and resolving differences of opinion should be clarified. (Author/SS)

UNITED STATES
GENERAL ACCOUNTING OFFICE

Report To The Secretary Of Health, Education, And Welfare On Fundamental Improvements Needed For Timely Promulgation Of Health Program Regulations

Department of Health, Education, and Welfare

Some programs operate for years without required regulations. Delays in publication of regulations are primarily caused by weaknesses in the Department's policies and procedures for developing and processing proposed regulations.

The Secretary announced a comprehensive body of new policies and procedures for issuing regulations July 25, 1976. These new policies and procedures will result in some improvement but additional changes are needed for timely publication of regulations.

HRD-77-58

MAY 5, 1977

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

B-164031(5)

The Honorable
The Secretary of Health,
Education, and Welfare

Dear Mr. Secretary:

At the request of the Chairman of the House Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce, we reviewed the Department of Health, Education, and Welfare's (HEW's) system for developing and promulgating health program regulations. We found that some HEW programs operate for years without the regulations required by enabling legislation, the Administrative Procedure Act, or Department policy, or deemed necessary by Department officials for prudent administration.

We issued our report to the Chairman on February 4, 1977, without obtaining formal comments from the Department. However, responsible HEW officials were informed of the matters discussed in the report, and their comments were considered. The report provided recommendations for the timely publication of health program regulations and to increase State and local government involvement and participation in their development.

On April 1, 1977, the Chairman forwarded to you a copy of our report. He requested your comments on the report, its findings, and its recommendations.

As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House Committee on Government Operations and the Senate Committee on Governmental Affairs not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

To assist you in preparing your comments to the Chairman and the statement required by section 236, we are providing you with the recommendations and the 14 case studies (App. I through XIV) on which our findings and conclusions are based.

NATURE OF THE REVIEW

For the limited number of regulations studied, we determined that delays in publishing regulations could be attributed to the same or similar causes. In accordance with the Chairman's request and subsequent arrangements with his office, we studied 14 regulations--12 initiated as a result of legislation and 2 initiated to change the administration of current programs. Six of the regulations were reviewed to determine

--the adequacy of the procedures for public participation and disposition of public comments,

--involvement of other Federal agencies, departments, and State and local officials, and

--HEW's willingness to issue regulations consistent with congressional intent and within the scope and authority of the enabling legislation.

We found that delays were primarily caused by weaknesses in HEW's policies and procedures for developing and processing proposed regulations. However, a portion of the delay in publishing regulations was because of HEW's conscientious efforts to resolve policy issues resulting from statutory requirements and to encourage public participation in the regulatory process.

Within the scope of our review we found no examples of regulations promulgated to implement a law which were clearly contrary to congressional intent or went beyond the scope and authority of the enabling legislation. When congressional intent was questioned either on the basis of our review or in public comments on draft regulations, the questions raised resulted from the language of the law and not from any apparent or deliberate efforts by HEW to circumvent or evade enabling legislation.

REGULATIONS CAN BE DEVELOPED AND PROCESSED IN A MORE TIMELY MANNER

Although Department policy requires that final regulations be published in the Federal Register within 6 months after enactment of enabling legislation, no final regulation

included in our study was published by the date due. Of the 12 regulations directly resulting from legislation,

--1 was published within a year of enactment of the legislation,

--5 were published between 1 and 2 years after enactment,

--3 were published between 2 and 3 years after enactment, and

--3 were or will be published over 3 years after enactment.

Publication was delayed for one or more of the following reasons:

--Known policy issues were not addressed and resolved on a priority basis.

--Extended delays were encountered in developing a regulation due to limited staff and resources.

--Some offices ignored established processing dates and placed a low priority on the review of proposed and final regulations.

--Responsible officials did not take effective measures when a proposed or final regulation was delayed.

NEW POLICIES AND PROCEDURES COULD FURTHER DELAY PUBLISHING REGULATIONS

On July 25, 1976, HEW announced a comprehensive body of new policies and procedures for issuing regulations. Although it is too early to assess how effective these new policies and procedures will be in streamlining the development and processing of regulations, we believe that several of the problems identified in this report will not be corrected. For example, the new policies and procedures:

--Require public comment on policy issues identified before or during development of a regulation. Since a regulation should not be drafted until policy issues are tentatively decided and because developing or processing stops until new issues are resolved, extended delays in the promulgation of a regulation could occur.

--Delegate responsibility for monitoring and processing regulations, although no system for this monitoring has been developed. Also, the new policies make no mention of the authority of responsible officials to take effective measures, when necessary, to avoid delays in promulgating regulations.

--Imply that pools of professionally competent and trained persons to draft regulations will be developed from existing staff and resources. This would be possible only to the extent that these resources are not now being fully utilized in other administrative aspects of the programs.

--Do not state how internal clearance disputes are to be resolved nor do they identify the redundant processes to be eliminated.

HEW'S PROCEDURES FOR REFERRAL TO THE ADVISORY COMMISSION ON INTERGOVERNMENTAL RELATIONS (ACIR) NEED CLARIFICATION AND REVISION

The Office of Management and Budget (OMB) Circular No. A-85 establishes a process for promoting early consultation on regulations among Federal agencies and departments and State and local governments. The circular provides that chief executives of State and local governments be given a reasonable opportunity to comment on proposed Federal rules, regulations, standards, procedures, and guidelines which have a significant and nationwide effect on State and local governments. Procedures for implementing the ACIR process are set forth in the HEW General Administration Manual.

HEW officials responsible for the regulations included in our study were either not aware of the policies and procedures contained in OMB Circular A-85 or did not adhere to HEW's procedures for referral to ACIR. One or more of the following problems were identified. The officials:

--Forwarded drafts of proposed regulations to ACIR simultaneously with or after their publication in the Federal Register, frustrating the hope for early consultation.

--Employed "self exemptions" from compliance with the process.

--Did not forward summaries along with drafts of regulations to ACIR for circulation as required.

--Did not forward drafts of final regulations to ACIR for circulation.

--Did not provide ACIR with explanations of why major changes requested by government associations were rejected.

CONCLUSIONS

Publication of the approximately 600 health program regulations within HEW is delayed for weeks, months, and sometimes years because prescribed policies and procedures are not adhered to and weaknesses are inherent in those policies and procedures. Limited staff and resources, diffused responsibility and lack of authority, low priority assigned regulations by some officials, and failure to monitor and take effective measures, when necessary, delay publication. Recently announced changes to policies and procedures will result in some improvement, but additional changes can further expedite the promulgation of regulations. Also, HEW's policies and procedures do not require compliance with OMB Circular A-85, and the policies and procedures for forwarding proposed regulations to ACIR are interpreted differently by the health agencies.

RECOMMENDATIONS TO THE SECRETARY OF HEW

To expedite the publication of health regulations, and to increase State and local government involvement and participation in the development of regulations, we recommend that the Secretary of HEW make further changes to and clarify policies and procedures relating to the promulgation of regulations. More specifically, the Secretary should:

--Develop staff and resources within HEW to levels that are sufficient to participate in developing and processing regulations, as well as fulfilling other responsibilities.

--Evaluate the need for public comment before rendering a decision on significant policy issues. An alternative would be to discuss all policy issues and the preferred decisions in the preambles to proposed regulations; those not previously discussed would be identified in the final regulations. Public comment should be solicited on both proposed and final regulations.

--Request comments from appropriate congressional committees on proposed and final regulations published in the Federal Register to gain coordination with cognizant committees.

--Require that the computerized system for monitoring the processing of regulations within the Office of the Secretary be modified to include both developing and processing of all regulations. Furthermore, consideration should be given to delegating to responsible officials the authority to take effective measures, when necessary, to avoid delays in promulgating regulations.

--Formalize preclearance policies and procedures to expedite final processing. Criteria for preclearance could include significant policy issues, time constraints, or strategy considerations.

--Highlight revisions made, unresolved issues, or questions on program criteria and proposed regulations so that subsequent review can focus on those provisions.

--Direct the Commissioner of Food and Drugs to establish developing and processing limits that provide for the timely publication of regulations.

--Clarify the Department's policy and procedures for forwarding regulations to ACIR, obtaining comments from State and local government associations, and resolving differences of opinion. The need for ACIR review should be identified early in regulation development and documented on monthly status or other monitoring reports.

We are sending copies of this report to the Chairmen of the following committees: House Committee on Government Operations and Senate Committee on Governmental Affairs; House and Senate Committees on Appropriations; House Committees on Interstate and Foreign Commerce, and Ways

and Means; and the Senate Committees on Human Resources and Finance. A copy is also being sent to the Director, Office of Management and Budget.

Sincerely yours,

Gregory J. Ahart
Director

CASE STUDY

REGULATIONS TO IMPLEMENT EMPLOYEES' HEALTH BENEFITS PLANS FOR HEALTH MAINTENANCE ORGANIZATIONS

Legal Citation: Title 42--Public Health

Chapter I--Public Health Service
Department of Health, Education, and Welfare

Part 110--Health Maintenance Organizations

Employees' Health Benefits Plans
October 28, 1975

The Health Maintenance Organization Act of 1973 (42 U.S.C. 300e, et seq.) approved on December 29, 1973, amended the Public Health Service Act to assist and encourage the establishment and expansion of health maintenance organizations (HMOs). Section 1310 provides that every employer with at least 25 employees, who provides health benefits to his employees and is required to pay the minimum wage, must offer the option of joining a qualified HMO. This is the dual choice provision.

HEW officials considered the section 1310 regulation one of the two most important HMO regulations. Without it many potential applicants for assistance under the HMO Act would be hindered in becoming federally qualified HMOs.

An HEW Office of the General Counsel opinion stated that while the statute was effective in 1974, it was not applicable until the Secretary issued regulations prescribing the manner in which the HMO option was to be offered. Tardiness in publishing regulations not only discouraged potential applicants but was a major contributing factor to several HMO bankruptcies.

A proposed regulation was published in the Federal Register on February 12, 1975. The final regulation was published on October 28, 1975.

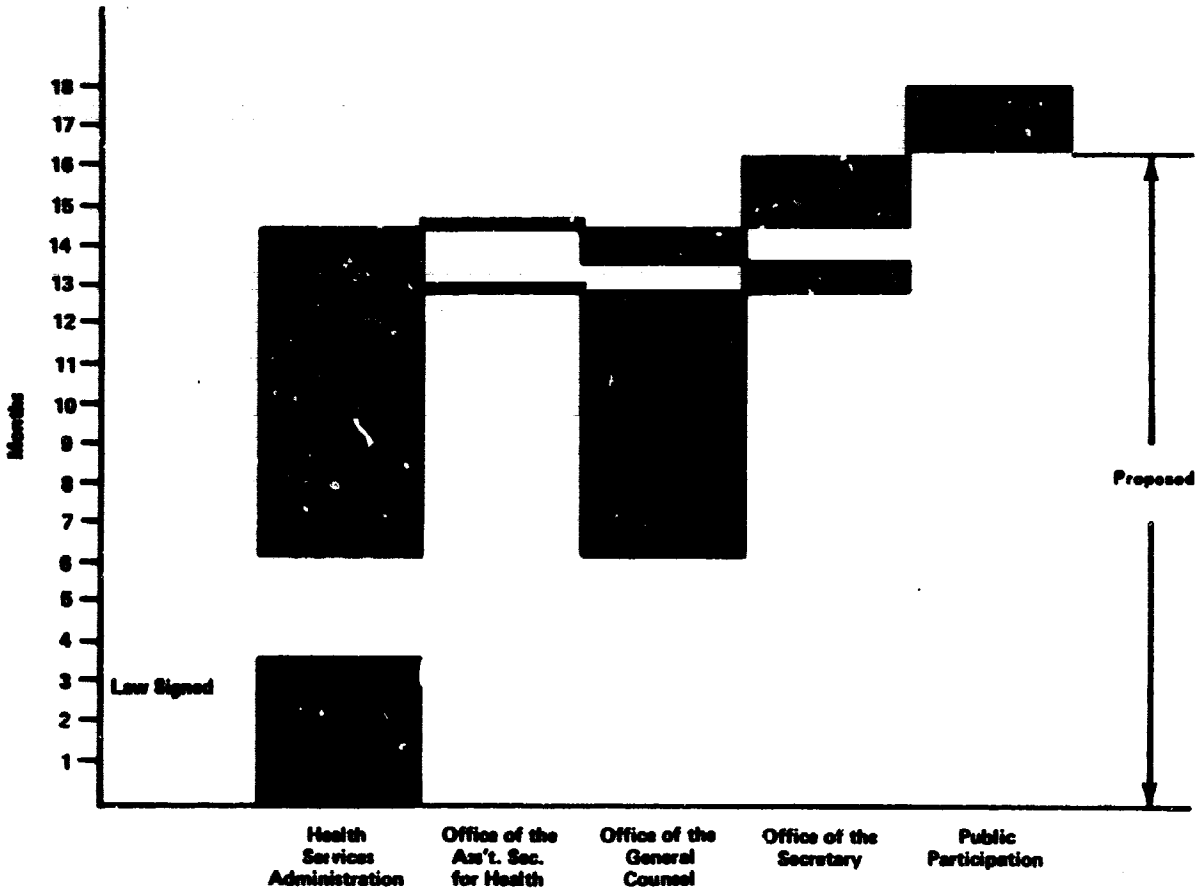
The chart on the following page indicates the approximate periods for developing and processing the proposed regulation. Shading for two or more levels during the same period indicates interaction between these levels.

SIGNIFICANT POLICY ISSUES NOT RESOLVED

Promulgation of the proposed regulation was delayed while HEW tried to resolve a significant policy issue. A controversy developed between HEW and the Department of Labor (DOL) involving the offering of an HMO option to individual employees after it had been rejected by the appropriate union representative. DOL believed the collective bargaining representative had the authority to accept or decline the HMO offer on behalf of all represented employees, while HEW believed that employees should be permitted to individually accept or reject the HMO option.

APPENDIX I

HEALTH SERVICES ADMINISTRATION
HEALTH MAINTENANCE ORGANIZATIONS – EMPLOYEES'
HEALTH BENEFIT PLANS UNDER SECTION 1310
OF THE HMO ACT OF 1973
P.L. 93-222



The issue was addressed by a task force comprised of representatives from industry, labor unions, DOL, and HEW in April 1974. The issue was also discussed by the General Counsels of HEW, DOL, and the National Labor Relations Board in May 1974. On October 25, 1974, a draft of the proposed regulation, including HEW's position, was forwarded to DOL and the Board for review and comment. Beginning in November 1974, HEW's General Counsel held meetings with DOL and Board officials in an attempt to resolve this policy issue.

However, the issue had not been resolved when the proposed regulation was forwarded to the Secretary for approval on December 17, 1974. A memorandum requesting a Secretary's decision to resolve the policy issue accompanied the proposed regulation. The memorandum recommended approval of a General Counsel developed approach to offering the HMO option individually to each employee. It also noted that DOL was not inclined to negotiate a compromise. In commenting on the proposed regulation, the Assistant Secretary for Legislation recommended resolving the issue with DOL prior to publication. However, on February 4, 1975, 7 weeks after the regulation had been forwarded for approval, the Secretary accepted the General Counsel recommendation and approved publication with the dual choice issue highlighted in the preamble.

Five months after the proposed regulation was published, continued efforts still had not resolved the dual choice issue. Finally, the Domestic Council and the Counsel to the President concluded that the position of DOL was consistent with the law. They recommended that HEW review the issue and if further examination of the legal question was required, an opinion of the Department of Justice should be solicited.

On September 10, 1975, in a memorandum to the Secretary, the Assistant Secretary for Health recommended adopting DOL's position. The Secretary approved the recommendation and the final regulation was published on October 28, 1975.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

HEW's Office of the General Counsel was instrumental in developing the regulation. Its early involvement included participation in task force meetings beginning in April 1974, and conversations with interested parties, including DOL's Office of Solicitor and the National Labor Relations Board's General Counsel.

On July 30, 19[illegible] the proposed regulation was forwarded to HEW [illegible]sel for review and comment. Discussions were held an[illegible] were made based on the Counsel's comments. A revise[illegible]c, incorporating the Counsel's comments, was forwarde[illegible]preclearance on October 25, 1974, nearly 3 months after t[illegible]e initial draft was received. On October 25, 1974, the Counsel sent the proposed regulation to the National Labor Relations Board and DOL for preclearance. The Counsel concurred with the proposed regulation on December 20, 1974.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

The responsible Health Services Administration bureau prepared a plan to identify task force responsibility areas and a sequence for development. However, an overall schedule for developing, preparing, and coordinating the regulation was not established and milestones within specific time limits were not identified.

Department regulations status reports used to monitor development established a target date of October 1974 for publication of the proposed regulation. The target date was later revised to November 29, 1974, with no explanation for the delay provided.

PRECLEARANCE EXPEDITED FINAL PROCESSING

The proposed regulation was precleared by five Assistant Secretary for Health staff offices, two Secretary staff offices, the Social Security Administration and the Social and Rehabilitation Service. The Assistant Secretary for Health's Office of Regional Operations commented on the preclearance due date, and the Office of the Assistant Secretary for Planning and Evaluation informally commented 2 days later. Receipt of the other four Assistant Secretary for Health staff offices' comments and one Secretary staff office response could not be verified by available documentation. The Social and Rehabilitation Service and the Social Security Administration commented over 1 and 2 weeks after the preclearance due date, respectively.

Since the proposed regulation had been precleared, the final draft was circulated to two Assistant Secretary for Health staff offices, with 1 day afforded for review and comment. Both offices concurred that day. The final draft

was then routed to five Secretary staff offices and the Office of the General Counsel with 8 days for review and comment. Two of the staff offices and the General Counsel concurred within the specified time limit. The other three staff offices concurred within 3 days after the due date.

PROCEDURES FOR PUBLIC PARTICIPATION

In October 1973, prior to the passage of the HMO Act, task forces were established to prepare issue papers used in developing the regulations. A task force including industry and labor union officials met in April 1974 to discuss issues involving the dual choice regulation.

The Health Services Administration notified 760 organizations and individuals, including the media, by distributing a press release which described the proposed regulation and advised the recipients of the opportunity to comment. The proposed regulation was published in the Federal Register on February 12, 1975, with a 47-day comment period. A wide variety of reactions from many diverse interest groups was anticipated. One hundred and seventy-one comments were received. The Health Services Administration mailed a form letter acknowledging receipt and advising each individual or organization that the comments would be considered in drafting the final regulation.

INVOLVEMENT OF OTHER FEDERAL AGENCIES

Starting in February 1974, HEW briefed DOL on HMOs including the issues identified by the various task forces. Both DOL and the National Labor Relations Board were invited to participate on the section 1310 task force which met in April 1974. An official from DOL's Wage and Hour Division became a member of the task force while the Board's involvement remained more informal. During development HEW's Office of the General Counsel held meetings, discussions, and correspondence with DOL, Board, and Civil Service Commission (CSC) officials concerning the regulation and unresolved policy issues.

DOL, the Board, and OMB were requested to comment on preclearance and final drafts of the proposed regulation. Drafts were also forwarded to the Department of Commerce and CSC for comment.

DOL disagreed with the preclearance and final drafts due to the dual choice provision. The position of the Board was unclear. CSC's General Counsel commented on the preclearance draft. There was no record of a response from OMB on either of the two drafts or from the Department of Commerce on the final.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

The need for Advisory Commission on Intergovernmental Relations (ACIR) review was identified on Department regulations status reports. However, ACIR received the proposed regulation and summary 3 days after Secretary approval and 5 days before publication in the Federal Register, frustrating the hope for early consultation.

APPENDIX II

CASE STUDY

REGULATIONS TO IMPLEMENT PROJECT GRANTS TO INSTITUTIONS OF HIGHER LEARNING FOR MATERNAL AND CHILD HEALTH AND CRIPPLED CHILDREN'S SERVICES

Legal Citation: Title 42--Public Health

Chapter 1--Public Health Service
Department of Health, Education, and Welfare

Subchapter D--Grants

Part 51a--Grants for Maternal and Child Health and Crippled Children's Services

Subpart D--Project Grants to Institutions of Higher Learning

March 20, 1975

Section 301 of the Social Security Amendments of 1967 approved on January 2, 1968, amended title V of the Social Security Act (42 U.S.C. 703(2), 704(2), and 711) to provide grants to public or other nonprofit institutions of higher learning for special projects of regional or national significance, which may contribute to the advancement of maternal and child health or services for crippled children, and for training personnel for health care and related services for mothers and children. Although the regulation was developed in 1968, reorganizations affecting the maternal and child health and crippled children's programs, and higher priorities within the Office of the General Counsel and other HEW staff offices delayed publication.

On July 1, 1973, the programs were transferred to the Health Services Administration. In August 1973 the responsible Health Services Administration bureau revised an

earlier draft of the regulation based on comments by the General Counsel and an ad hoc bureau committee. A proposed regulation was published in the Federal Register on August 19, 1974. The final regulation was published on March 20, 1975.

The chart on the following page indicates the approximate periods for developing and processing the proposed and final regulations. Shading for two or more levels during the same period indicates interaction between these levels.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The General Counsel took almost 7 weeks to prepare the proposed regulation for publication in the Federal Register. Subsequent revision and concurrence was accomplished in about a week.

The General Counsel reviewed and revised the final regulation preamble developed by the Health Services Administration, and also prepared the final regulation for publication in the Federal Register in 2 months' time. Further revisions based on staff offices' comments took an additional 2 weeks. In all, the proposed and final regulations were within the Office of the General Counsel for over 4 months.

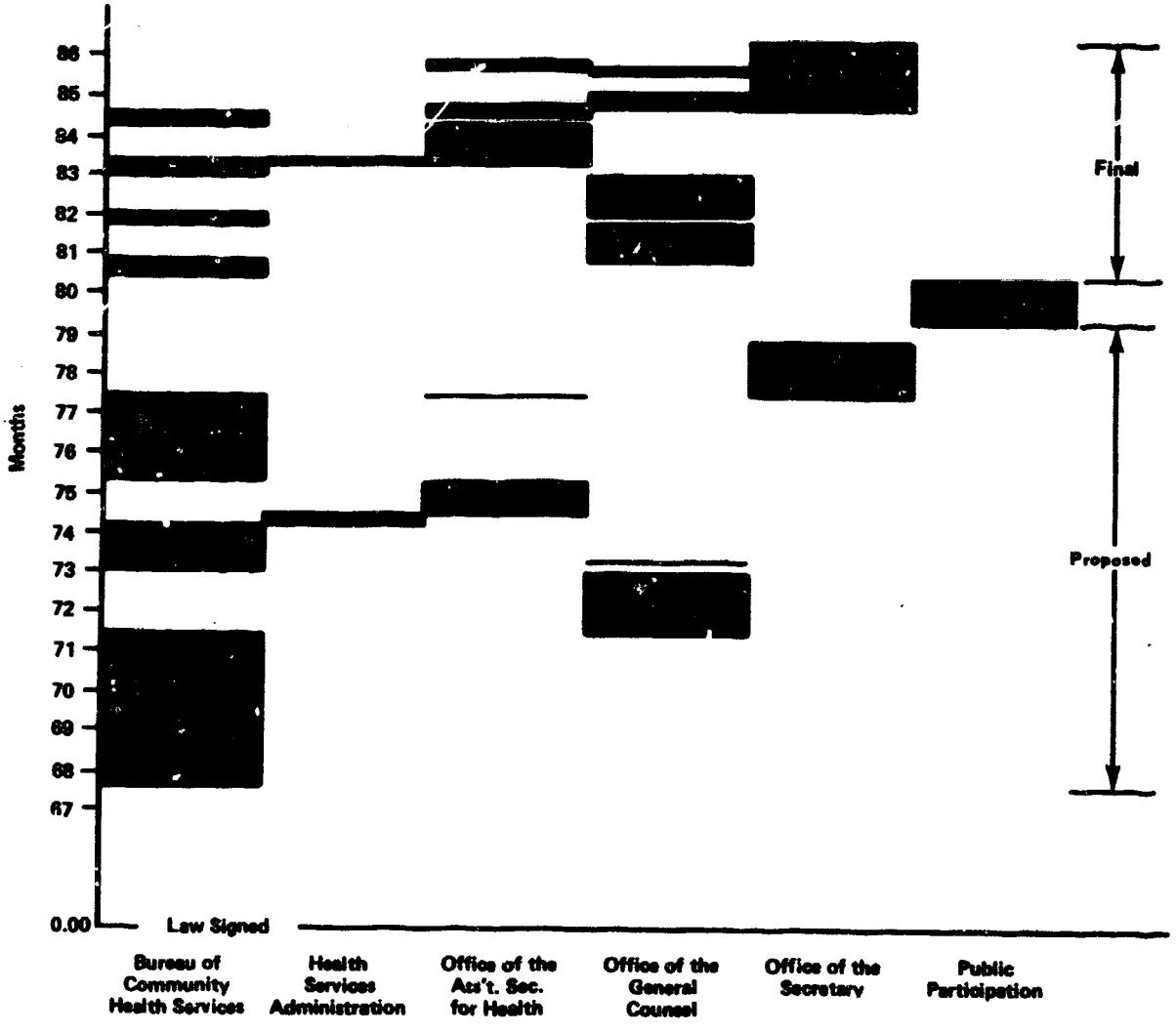
AWARDING GRANTS PRIOR TO PUBLICATION OF REGULATIONS DIMINISHED THE NEED FOR THEIR PROMULGATION

Through March 20, 1975, when the final regulation needed to codify the practices and policies was published, approximately $213 million was obligated for 1,390 grants under sections 503(2), 504(2), and 511, as amended. Until then draft guidelines were used for awarding grants.

The Health Services Administration official primarily responsible for the regulation stated that HEW policy is to require regulations before awarding grants. However, development of the regulation was delayed for several years due to higher priorities within the Office of the General Counsel and other HEW staff offices.

APPENDIX II

HEALTH SERVICES ADMINISTRATION
PROJECT GRANTS TO INSTITUTIONS OF HIGHER LEARNING FOR MATERNAL AND CHILD HEALTH AND CRIPPLED CHILDREN'S SERVICES AND TRAINING UNDER SECTION 301 OF P.L. 90-248



APPENDIX II

EXTENDED DELAYS IN DEVELOPING THE REGULATION

During the 5-1/2 years between the enactment of the enabling legislation and August 1973, several drafts were prepared after reorganizations had affected the maternal and child health and crippled children's programs. Despite this advance preparation, development of the proposed regulation within the Health Services Administration bureau took almost 4 months. The bureau took another 3-1/2 months to revise, redraft, and retype the proposed regulation based on internal HEW comments.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

The Health Services Administration bureau developed an internal schedule for the regulation's development. However, a schedule for the overall development of the regulation within the Health Services Administration was not established and milestones within specific time limits were never identified.

Department regulations status reports used to monitor development established a February 1974 target date for publication of the proposed regulation. This date subsequently changed, without explanation, to July 1974. The proposed regulation was finally published in August 1974. Publication of the final regulation was postponed from June 1974 to December 1974, then to March 1975. The status reports provided no explanation for the delays.

PROCESSING TIME LIMITS NOT MET

The final draft of the proposed regulation was circulated to only one Assistant Secretary for Health staff office with a week provided for review and comment. The staff office concurred within the specified time limit. However, the Health Services Administration had sent the proposed regulation to the Assistant Secretary for Health about a week before its circulation. Also, the Assistant Secretary for Health did not approve the proposed regulation until about a week after the staff office had concurred. Processing of the proposed regulation at the Assistant Secretary for Health level should have been accomplished in about a week. Instead, 3 weeks were required.

The proposed regulation was then circulated to four Secretary staff offices and the Office of the General Counsel and they were given 8 days for review and comment. Two offices and the General Counsel concurred by the due date. The Office of the Assistant Secretary for Planning and Evaluation and the Office of the Assistant Secretary for Administration and Management concurred 3 days and over 3 weeks after the due date, respectively. In all, processing of the proposed regulation at the Secretary's level took 5 weeks even though no nonconcurrences or comments were received.

The final regulation was circulated to the same Assistant Secretary for Health staff office that had concurred with the proposed regulation. Eight days were provided for review and comment. The staff office concurred over a week after the due date. An additional 2-week delay at the Assistant Secretary for Health level was encountered when the Office of Public Affairs disapproved the press release.

The final regulation was then circulated to the Office of the General Counsel; five Secretary staff offices; and the Director, Office for Civil Rights. Eight days were provided for review and comment. All five of the staff offices concurred without comment. However, only two concurred within the specified time limit. The Office of the Assistant Secretary, Comptroller, and the Office of the Assistant Secretary for Administration and Management concurred 3 and 4 days later, respectively. The Office of the Assistant Secretary for Planning and Evaluation concurred 10 days after the due date.

The Office for Civil Rights, which had not been requested to concur with the proposed regulation, commented on the final regulation 2 weeks after the due date. The comments resulted in two new subsections which required an additional week to prepare and process. These delays contributed to a processing period of over 5 weeks at the Secretary's level.

In addition, the Office for Civil Rights identified other issues which would have required revisions to the regulation. Further delay was avoided when the Office, noting that the regulation was in final processing and the issues identified had not been previously raised, did not hold up its concurrence in order to have them included. At the same time, the Office believed that they should have been considered prior to publication.

PROCEDURES FOR PUBLIC PARTICIPATION

The proposed regulation was published in the Federal Register on August 19, 1974. A period of 30 days was provided for interested persons to submit comments, suggestions, or objections concerning the proposed rules. In addition, the responsible Health Services Administration bureau mailed over 2,000 copies of the proposed regulation to external organizations and other interested groups.

Three individuals commented before the end of the 30-day period. Specific requests and suggestions for revisions, including the disposition of each, were summarized in the preamble to the final regulation. However, the comments did not result in changes to the regulation. Each individual received a letter expressing appreciation for the comments and, if suggestions were made, reasons were given why the suggestions were not reflected in revisions to the regulation.

In addition, the final regulation was accompanied by a press release to inform the general public about its publication and content.

INVOLVEMENT OF OTHER FEDERAL AGENCIES

No other Federal agencies or departments, including OMB, were involved in developing and processing the proposed and final regulations.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

Although grants can be made to public institutions of higher learning for special projects of regional or national significance, HEW officials determined that ACIR review was not required. This determination was documented on Department regulations status reports.

QUESTIONS RELATING TO CONGRESSIONAL INTENT DUE TO LANGUAGE OF ENABLING LEGISLATION

Questions were raised about congressional intent while resolving an internal Public Health Service issue concerning the prohibition on charges for diagnostic services. Based in part on specifically identified congressional actions to eliminate potential barriers to the availability of diagnostic services, the issue was resolved in favor of continuing the prohibition on charges.

APPENDIX II

According to a responsible Health Services Administration bureau official, the language of the committee reports and legislative history dictated that section 511 funds and the amount transferred under provisions of section 502 be allocated for grants to institutions which had previously received other Federal funds. This criterion is not contained in the law or reflected in the regulation. It was and is, however, being used to award grants. Approximately 90 percent of the funds allocated under section 511 in fiscal year 1975 were awarded to federally constructed facilities.

Because this criterion is not contained in the enabling legislation or reflected in the regulation, it was not addressed in the public comments on the proposed regulation. If this limitation had been known, the public may have objected.

CASE STUDY

REGULATIONS TO DESIGNATE AND FUND HEALTH SYSTEMS AGENCIES

Legal Citation: Title 42--Public Health

Chapter 1--Public Health Service
Department of Health, Education, and Welfare

Part 122--Health Systems Agencies

Designation and Funding
March 26, 1976

On January 4, 1975, the National Health Planning and Resources Development Act of 1974 (42 U.S.C. 3001) was approved. Part B, section 1515 requires that the Secretary of HEW, after consulting with the Governor of a State, designate either a private nonprofit corporation or a public entity as the health systems agency responsible for health planning and development in a designated health service area. The legislation specifies minimum criteria for the legal structure, staff, governing body, and functioning of a health systems agency.

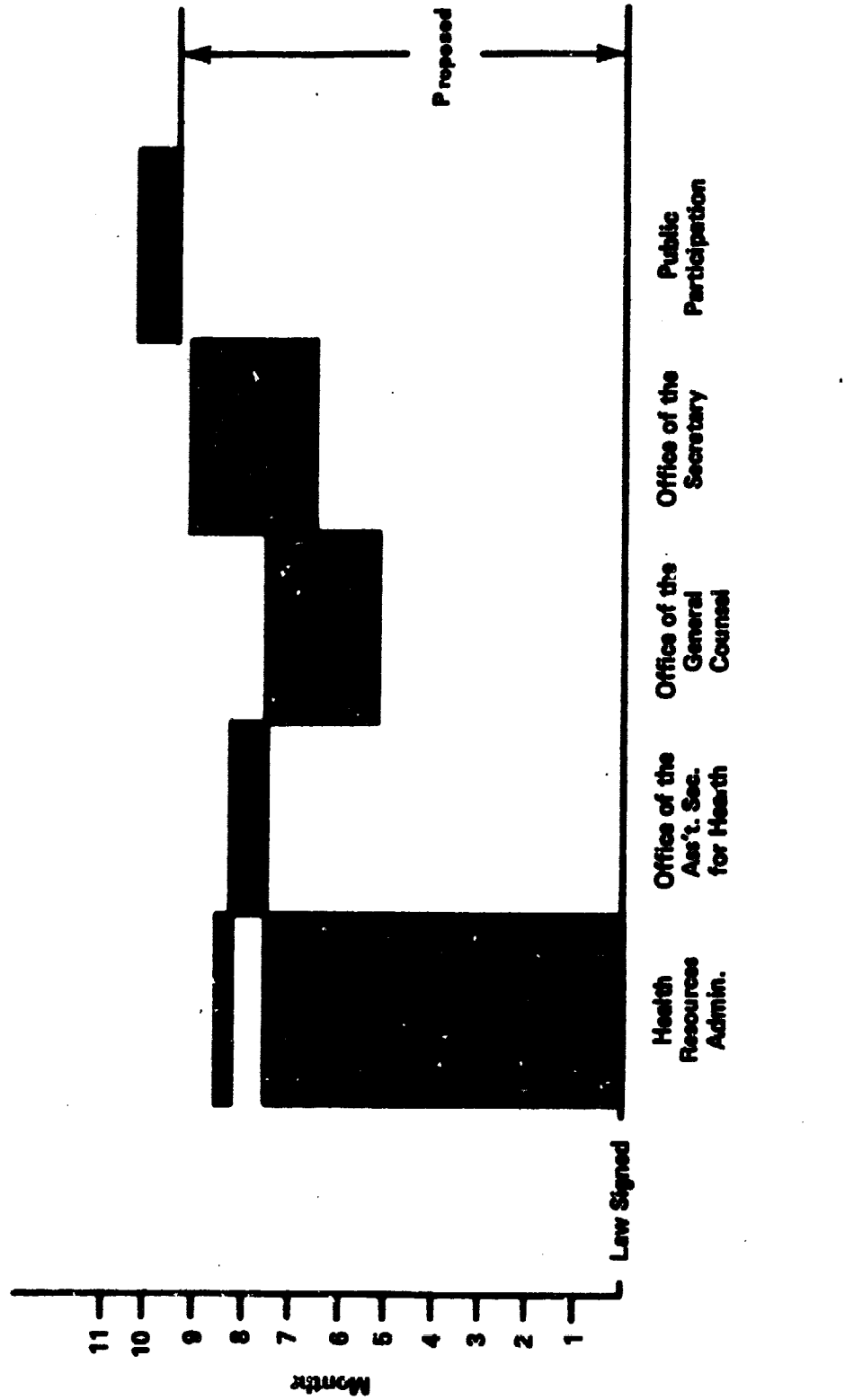
The legislation requires the Secretary to designate health systems agencies within 18 months. A proposed regulation (1) setting forth the eligibility and operational requirements for health systems agencies and (2) establishing regulations for making grants to designated agencies was published in the the Federal Register on October 17, 1975. The final regulation was published on March 26, 1976, less than 15 months after enactment of the enabling legislation.

The chart on the following page indicates the approximate periods for developing and processing the proposed regulation. Shading for two or more levels during the same period indicates interaction between these levels.

SIGNIFICANT POLICY ISSUES NOT RESOLVED

Significant policy issues were raised before development of the proposed regulation. The responsible Health Resources

APPENDIX III



Administration bureau followed internal HEW procedures designed for early detection and resolution of the issues. However, when the specifications for the regulation were forwarded to the Office of the General Counsel for drafting, some issues had not been resolved. Initial drafts of the regulation by the Counsel did not include provisions for such pertinent items as standards for contracts, advisory council agreements, and the relationship between the governing body of a public health systems agency and the sponsoring agency's governing board.

The schedule for publishing the regulation afforded 1 month for the General Counsel to draft the proposed regulation based on the specifications provided. However, some policy issues still had not been resolved when the final draft was returned to the bureau over 2 weeks after the due date.

The single most controversial issue concerned the relationship between the governing body of a public health systems agency and the sponsoring agency's governing board. The provisions of the pertinent statute were in direct conflict with the language of Senate and House debates. Although this issue was raised in February 1975, a Secretary's decision was not rendered until September 16, 1975, a day after the proposed regulation had been approved by the Assistant Secretary for Health and forwarded to the Secretary.

As late as July 25, 1975, the Assistant Secretary for Health recommended that the language of the debates be accepted over the provisions of the statute if the General Counsel could support its legality. During this period the responsible Health Resources Administration bureau requested the General Counsel to develop two options--one fully reflecting the debates and another reflecting the debates to the greatest extent possible without violating the language of the statute. A General Counsel opinion on August 7, 1975, stated that implementing the regulation based on the language of the debates was not a legally viable option.

Approximately 2 weeks after the General Counsel opinion had been rendered, it was still considered a viable option to include the language of the debates in the regulation. The Secretary reviewed the available options and suggested another which also reflected the language of the debates. Meanwhile the proposed regulation had been developed and processed on the assumption that the Secretary would accept the Health Resources Administration option of including the provisions of the statute but reflecting the language of the debates to the greatest extent possible.

If the Secretary had not adopted this option the proposed regulation would have been returned to the Health Resources Administration for revision. As it was, an issue identified before initial development of the regulation was not resolved until every procedure other than processing the proposed regulation within the Office of the Secretary had been completed.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Office of the General Counsel became involved early in the regulation's development. In trying to comply with the legislatively mandated time limit, guidelines were promptly developed for designating health service areas. The Counsel reviewed and approved the guidelines on March 18, 1975. On April 28, 1975, the Counsel attended a policy issue work session and rendered a legal opinion concerning the eligibility of organizations for designation as health systems agencies.

The designation and funding specifications were forwarded to the Counsel in nonregulation form on June 13, 1975. Four meetings were subsequently held with bureau officials to resolve Counsel comments on the specifications. The Counsel returned preliminary drafts of the planning grants and designation regulations to the bureau for comment on July 10, 1975, and July 22, 1975, respectively. The Counsel revised the drafts after considering comments submitted by the bureau on July 16, 18, and 25, 1975, and informal comments made by telephone. The Counsel returned another draft of the proposed regulation to the bureau for comment on August 1, 1975. The Counsel concurred with the proposed regulation on August 22, 1975.

REQUIREMENT TO PUBLISH REGULATION BEFORE ENTERING INTO AGREEMENTS HASTENED DEVELOPMENT

Developing and processing was expedited because of the legislative mandate requiring the Secretary to enter into agreements for the designation of health systems agencies no later than 18 months after enactment of the enabling legislation, and because of the need to publish the proposed regulation before accepting applications for health systems agency designations.

The proposed regulation stated that applications would be accepted and appropriate amendments to the applications would be allowed if the final regulation differed from the

proposed rule. By taking this approach, HEW expected to designate the great bulk of the health systems agencies in March 1976. Since the final regulation was not published until March 26, 1976, it was doubtful that the new agencies could have been designated prior to the legislative mandated date of July 1976 if applications had not been accepted based on the proposed regulation.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

A plan identifying policy issues and problems influencing implementation and operation of the enabling legislation and presenting strategy for satisfying them was prepared before developing the proposed regulation. A schedule for developing, preparing, coordinating, and processing the regulation was established. Milestones within specific time limits were also identified.

The responsible Health Resources Administration bureau constructed a tentative schedule for publishing the proposed regulations, indicating the sequence, grouping and projected Federal Register publication dates. This April 24, 1975, schedule projected July 15, 1975, and September 30, 1975, as the dates for publication of the proposed and final regulation, respectively. A February 1975 Department status report also identified July 1975 as the month for publication of the proposed regulation. However, an undated timetable revised the target dates to August 21, 1975, for the proposed regulation and November 20, 1975, for the final regulation. An August 19, 1975, timetable projected publication on October 24, 1975, and January 23, 1976, respectively. Neither the undated nor the August 19, 1975, timetable provided an explanation for the time extensions.

PROCESSING TIME LIMITS NOT MET

The final draft of the proposed regulation was circulated to the Alcohol, Drug Abuse, and Mental Health Administration; the Center for Disease Control; the Health Services Administration; the National Institutes of Health; and six Assistant Secretary for Health staff offices. Eleven days were provided for review and comment. Five of the six staff offices, the Health Services Administration, and the National Institutes of Health concurred within a day after the due date. The Center for Disease Control commented indicating neither concurrence nor nonconcurrence within the same time period. The comments did not result in any revisions and

were forwarded verbatim to the Health Resources Administration for use in developing the final regulation.

Two of the ten HEW regional offices commented on the proposed regulation through an Assistant Secretary for Health staff office. Although these comments were received after the due date, the two offices believed them important enough to recommend nonconcurrence. Their comments were not resolved prior to Assistant Secretary for Health concurrence. Additional Health Services Administration comments, none of which affected the Administration's concurrence, were received 2 weeks after the due date. The regional offices' and the Health Services Administration's additional comments were also forwarded to the Health Resources Administration for use in developing the final regulation. There was no record of a response from the Alcohol, Drug Abuse, and Mental Health Administration.

The final draft of the proposed regulation was then routed to five Secretary staff offices, the Social Security Administration, the Social and Rehabilitation Service, and the Office of the General Counsel. Four days were provided for review and comment. Staff offices were requested to talk to operating agency personnel and possibly resolve any questions involving the proposed regulation before submitting comments.

One staff office and the General Counsel concurred within the specified time limit. The other four staff offices, the Social Security Administration, and the Social and Rehabilitation Service concurred within a week after the due date.

Final processing of the proposed regulation took only about 3 weeks at both the Assistant Secretary for Health and the Office of the Secretary levels. The proposed regulation was expeditiously processed because late comments were not considered or resolved prior to publication.

PROCEDURES FOR PUBLIC PARTICIPATION

In February and March 1975 the responsible Health Resources Administration bureau distributed a preliminary list of major policy issues to approximately 160 health agencies, HEW regional offices, and a wide variety of national groups and interested individuals. Their comments and suggestions served as a basis for identifying the most controversial issues. Work sessions attended by individuals outside the

Department were held to discuss policy issue options. The objective was to provide the Department with a complete set of coherent policy options for consideration.

Once specifications were finalized and recommendations concerning policy issue options were made to the Secretary, discussions and the exchange of information with outside organizations and individuals ceased.

The Health Resources Administration notified 2,757 interested organizations and individuals by distributing a press release which described the proposed regulation and advised the recipients of the opportunity to comment. The proposed regulation was published in the Federal Register on October 17, 1975, with a 30-day comment period. The Public Health Service expected extensive written public comments due to the controversial issues addressed and the fragmentation of the required regulations into several proposed rules.

INVOLVEMENT OF OTHER FEDERAL AGENCIES AND STATE AND LOCAL OFFICIALS

The list of major policy issues prepared in February 1975 was distributed to State officials and organizations identified as having a signficant interest in health systems agencies. The only Federal agency included in the distribution was the Appalachian Regional Commission. Based on available documentation, OMB was not consulted during the development of the proposed regulation.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

Although the health systems agencies regulation was considered a major Federal regulation which would have a considerable, nationwide effect on State and local governments, Department status reports stated that ACIR review was not required.

However, the Assistant Secretary for Health, realizing that ACIR review was required, forwarded 25 copies of the proposed regulation and a summary to the Secretary about a month before publication in the Federal Register. The Department Regulation Coordinator determined that this summary was insufficient to meet OMB requirements and it was subsequently redrafted by the responsible Health Resources Administration bureau. ACIR was finally notified less than 2 weeks

before publication of the proposed regulation, frustrating the hope for early consultation.

In the memorandum accompanying the revised summary, the bureau official stated that

> "the summary originally transmitted * * * is apparently insufficient to meet the purpose of OMB Circular A-85 which evidently requires that ACIR * * * always be provided a substantive summary of proposed regulations which affect intergovernmental relations."

This terminology indicates that the bureau official was either unaware of the procedures required by Circular A-85 or the reason for preparing a substantive summary for the proposed regulation.

CASE STUDY

REGULATIONS TO IMPLEMENT NURSING SPECIAL PROJECT GRANTS

Legal Citation: Title 42--Public Health

Chapter I--Public Health Service
Department of Health, Education, and Welfare

Part 57--Grants for Construction of Health Research Facilities (Including Mental Retardation Research Facilities), Teaching Facilities, Student Loans, Educational Improvement and Scholarships

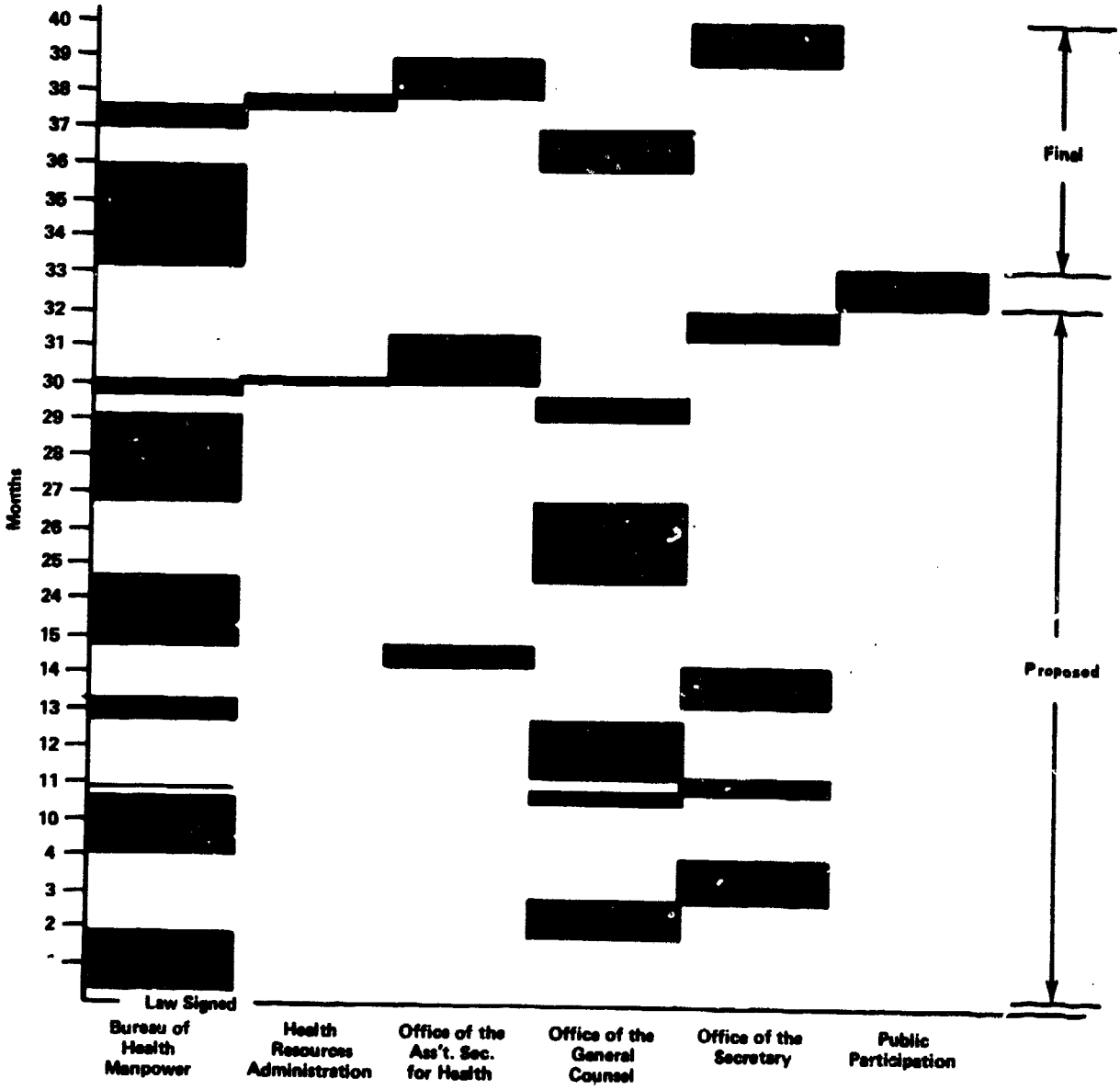
Nursing Special Project Grants
March 21, 1975

The Nurse Training Act of 1971 (42 U.S.C. 296d) approved on November 18, 1971, amended or repealed certain provisions of the Public Health Service Act. Section 3(b) revised and expanded the existing authority (section 805(a)) for special project grants in nursing to public or other nonprofit private schools of nursing, agencies, organizations, and institutions. The act also extended the authority for special project grants for 3 fiscal years (1972 - 1974). Grants were awarded in fiscal year 1975 under authority of a Continuing Resolution (42 U.S.C. 3801, as amended). A proposed regulation was published in the Federal Register on July 31, 1974. The final regulation was published on March 21, 1975.

The chart on the following page indicates the approximate periods for developing and processing the proposed and final regulations. Shading for two or more levels during the same period indicates interaction between these levels.

APPENDIX IV

HEALTH RESOURCES ADMINISTRATION
NURSING SPECIAL PROJECT GRANTS UNDER
SECTION 3(b) OF P.L. 92-158



OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The initial draft of the proposed regulation was forwarded to the Office of the General Counsel in nonregulation form. The Counsel prepared the document as a final regulation for publication in the Federal Register and returned it to the responsible bureau within a week. However, the Counsel subsequently redrafted the document to conform to a proposed regulation and OMB Circular A-102 retention-of-records requirements. The Counsel also revised, commented on, and concurred with changes made by the Health Resources Administration. This process took approximately 20 weeks. The Counsel took an additional month to prepare the final regulation for publication in the Federal Register. The Counsel concurred with the final regulation in 3 days. In all, the proposed and final regulations remained within the General Counsel for about 6 months.

AWARDING GRANTS BEFORE PUBLICATION OF FINAL REGULATIONS DIMINISHED THE NEED FOR THEIR PROMULGATION

From July 1, 1971, through March 21, 1975, when the final regulation was published, approximately $72 million was obligated for 800 grants and contracts under section 805(a), as amended. By the time the proposed regulation reached the Office of the Secretary for review, the program had been operating for nearly 3 years, the original authority had expired, and new legislation which would require new regulations had been introduced in the Congress. Grants were being awarded under authority of a Continuing Resolution for almost 9 months before a final regulation was published.

The Nursing Training Act of 1975 (42 U.S.C. 296K), approved July 29, 1975, revised the criteria for awarding special project grants in fiscal year 1976. Therefore, the regulation published in March 1975 was not applicable 4 months later. A new regulation is being developed by the Health Resources Administration.

A Health Resources Administration official stated that the agency is aware of HEW's policy requiring the publication of final regulations before awarding grants under enabling legislation. However, the agency chose to award grants under guidelines based on a previously published regulation rather than return the appropriated funds.

APPENDIX IV

EXTENDED DELAYS IN DEVELOPING THE REGULATION

After specifications for the regulation were approved by the Secretary, the responsible Health Resources Administration bureau took over 6-1/2 months to complete the initial draft of the proposed regulation. The proposed regulation did not contain substantive revisions to a regulation previously published to implement a prior grant program, nor were there revisions to the interim guidelines issued. About 12-1/2 months elapsed while the bureau revised, redrafted, and retyped the proposed regulation before forwarding it for final approval. The bureau took about 3 months to dispose of the four sets of comments.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

The implementation plan prepared did not include a schedule or milestones within specific time limits.

An April 1972 Department regulations status report showed July 1, 1972, as the date for publishing the final regulation. A September 1972 report stated that publication of a proposed regulation had been waived by the Secretary and the target date for publication of the final regulation was revised without explanation to November 1, 1972. The proposed regulation was not published until July 31, 1974.

The target date for publication of the final regulation changed from November 1974 to March 1975. A February 1975 report attributed the delay to the disposition of extensive public comments. However, the four sets of comments received on the proposed regulation were neither extensive or voluminous and required no substantive revisions. The delay was due primarily to the reluctance of the Health Resources Administration and the Office of the General Counsel to include State or areawide health planning agency review as a criteria for awarding grants.

PROCESSING TIME LIMITS NOT MET

The proposed regulation was distributed to two Assistant Secretary for Health staff offices and 5 days were provided for review and comment. Both offices responded within the specified time limit. One office concurred but the Office of Administrative Management did not concur, and three weeks were required to resolve the disagreement. After discussions

with the General Counsel, the Office of Administrative Management concurred with the original document.

The proposed regulation was then circulated to four Secretary staff offices and the Office of the General Counsel with 9 days provided for review and comment. Two staff offices and the General Counsel concurred within the specified time limit. The Office of the Assistant Secretary, Comptroller, concurred within 2 weeks after the due date when informed that grants were being awarded under authority of the Continuing Resolution, and publication of the regulation was required. The Assistant Secretary for Administration and Management also concurred within 2 weeks after the due date.

Final processing of the proposed regulation took over 5 weeks and 3 weeks at the Assistant Secretary for Health and Secretary levels, respectively.

The final regulation was circulated to four Assistant Secretary for Health staff offices with 6 days provided for review and comment. Two offices concurred within the specified time limit. When the other two responses were not received by the due date, the two offices were contacted by phone. Both offices informally concurred with the regulation within a week. The Acting Assistant Secretary for Health approved the final regulation about 3 weeks later.

The final regulation was then circulated to the Office of the General Counsel and the same four Secretary staff offices which had concurred with the proposed regulation. Eleven days were provided for review and comment. All four staff offices and the General Counsel concurred. However, the Assistant Secretary for Planning and Evaluation concurred 10 days after the due date.

Final processing of the final regulation took about 5 weeks and 4 weeks at the Assistant Secretary for Health and the Secretary levels, respectively. Both the proposed and the final regulation took approximately 2 months to be processed. While conflicting opinions were received and questions were raised during the processing of the proposed regulation, there was no discernable time variance between it and the processing of the final regulation which was concurred with by every staff office.

PROCEDURES FOR PUBLIC PARTICIPATION

The special project grant program in nursing was widely publicized by HEW through regional meetings with schools of

nursing and organizations concerned with nursing education. Also news releases, fact sheets, and other methods were used for publicity. The policies reflected in the regulation were considered and approved by the National Advisory Council on Nurse Training. The proposed regulation was published in the Federal Register and 30 days were provided for comment.

Four individuals commented on the proposed regulation. Their specific requests and suggestions for revisions and the disposition of each were summarized in the preamble to the final regulation. Two of the four suggestions were adopted and the regulation was revised accordingly. A third suggestion was not adopted because participation was limited by the law. The fourth individual commented after the comment period and the suggestion was considered in drafting the final regulation but it was not adopted. The individual received a letter of appreciation explaining why the suggestion was rejected.

Because the program had been so widely publicized, publication of the proposed and final regulations was not accompanied by a press release.

INVOLVEMENT OF OTHER FEDERAL AGENCIES AND STATE AND LOCAL OFFICIALS

According to a Health Resources Administration official, no other Federal agencies, including OMB or State and local officials, were involved in developing and processing the regulation. As stated previously, the proposed regulation was redrafted to conform to the OMB Circular A-102 retention-of-records requirements.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

Although public schools of nursing are eligible for the special project grants, HEW officials determined that ACIR review was not required. This determination was documented on Department regulations status reports.

CASE STUDY

REGULATIONS TO IMPLEMENT SPECIAL PROJECT GRANTS AND CONTRACTS FOR DRUG ABUSE PREVENTION ACTIVITIES

Legal Citation: Regulations Had Not Been Published as of December 31, 1976

Section 410 of the Drug Abuse Office and Treatment Act of 1972 (Public Law 92-255) authorizes the Secretary to award grants and enter into contracts for a broad range of drug abuse prevention functions including training, prevention and education, treatment and rehabilitation, and research. The law, approved on March 21, 1972, also established the Special Action Office for Drug Abuse Prevention in the Executive Office of the President. The Director of the Special Action Office was responsible for developing a comprehensive, coordinated long-term Federal strategy for all drug abuse prevention functions and all drug traffic prevention functions conducted, sponsored, or supported by any department or agency of the Federal Government.

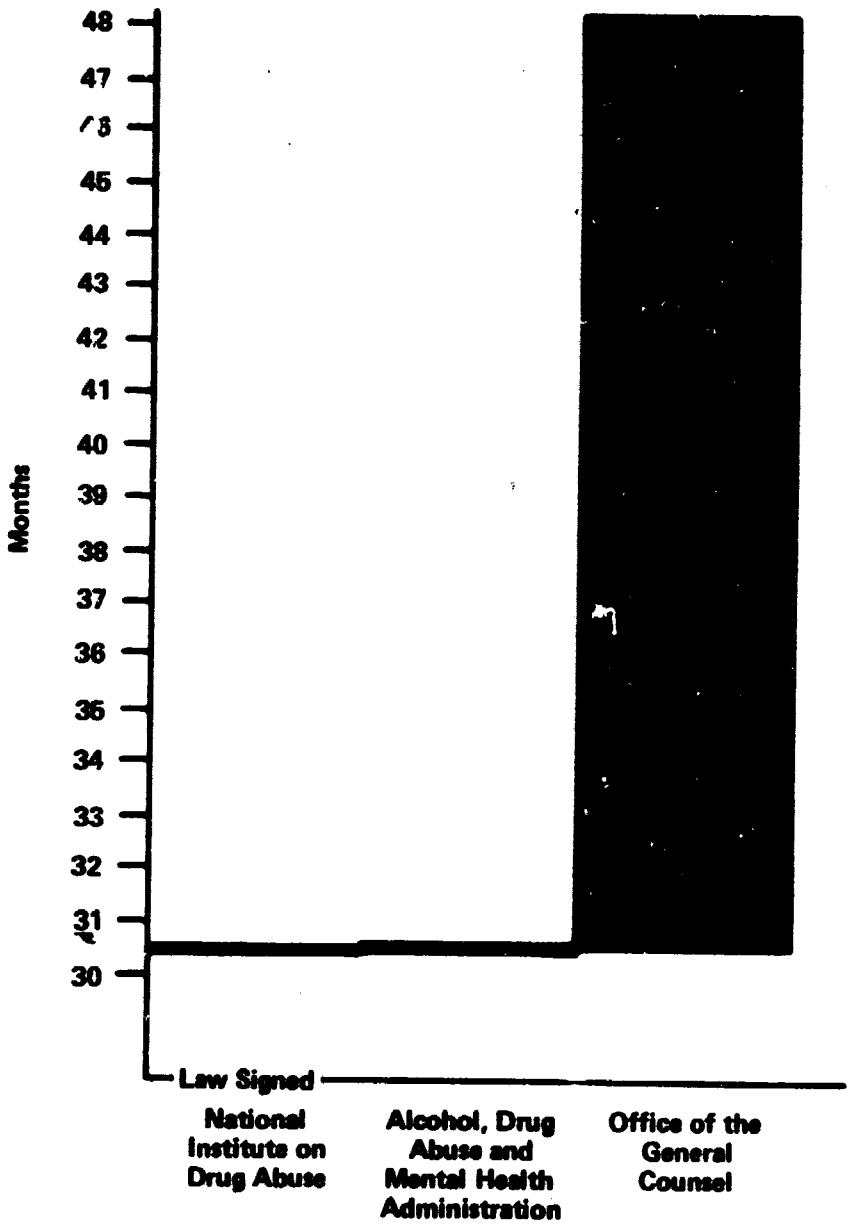
As of December 31, 1976, a proposed regulation had not been developed. The chart on the following page indicates the approximate periods for developing the proposed regulation through March 31, 1976.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Alcohol, Drug Abuse, and Mental Health Administration forwarded specifications for the regulation to the General Counsel in October 1974. As of March 31, 1976, the specifications had remained in the Office of the General Counsel for over 17 months. A proposed regulation had not been developed due to (1) the low priority given the regulation by both the Counsel and the Administration, (2) the apparent lack of HEW interest or public pressure to publish the regulation, and (3) the lack of a precedent or guideline which made the initial drafting complex and time consuming. The Counsel admitted that even after an initial draft has been prepared, considerable review and revision will be required prior to publication. However, the attorney responsible for drafting the regulation stated that he will continue to devote his time and effort to those regulations that are of higher priority or that have initial drafts already prepared.

APPENDIX V

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION SPECIAL PROJECT GRANTS AND CONTRACTS FOR DRUG ABUSE PREVENTION ACTIVITIES UNDER SECTION 410 OF P.L. 92-255



Note: Memorandum of specifications still in the Office of the General Counsel as of 3-31-76.

AWARDING GRANTS PRIOR TO PUBLICATION OF FINAL REGULATIONS DIMINISHED THE NEED FOR THEIR PROMULGATION

From fiscal year 1973 through fiscal year 1975, the Alcohol, Drug Abuse, and Mental Health Administration obligated over $248 million for 563 special project grants and contracts under the Drug Abuse Prevention Activities Program. The agency did not request a waiver of HEW's policy requiring publication of final regulations prior to awarding grants. An Alcohol, Drug Abuse, and Mental Health Administration official informed us that exceptions to this policy occur frequently and most programs award grants before publishing final regulations.

EXTENDED DELAYS IN DEVELOPING THE REGULATION

The proposed regulation had to be developed in accordance with particular Special Action Office for Drug Abuse Prevention policy directives. These directives were released on March 28, 1973. Even then the Administration anticipated that considerable negotiations with the Special Action Office would be necessary. The Special Action Office had stated that its top priority was the formula grant (section 409) program and that its staff would not be available to discuss other regulations until the policy issues concerning the formula grant regulation were resolved. The final section 409 regulation was not published before abolishment of the Special Action Office on June 30, 1975.

The responsible Alcohol, Drug Abuse, and Mental Health Administration institute did not begin drafting the specifications for the special project grants and contracts program until October 1974, over 18 months after the national drug abuse policy directives were released. The specifications were drafted within a week but were not reviewed by or discussed with the Special Action Office. The delay in drafting the specifications was attributed to the same reasons given by the Office of the General Counsel--the low priority given the regulation and the apparent lack of HEW interest or public pressure to publish the regulation.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

A schedule for developing, preparing, and coordinating the regulation was not established and milestones within specific time limits were not identified.

APPENDIX V

Department regulations status reports used to monitor development were misleading, inaccurate, and incomplete. An April 1972 Department regulations status report identified a September 1972 target date for publishing the proposed regulation, and a November 1972 target date for publishing the final regulation. A November 1974 report stated that the proposed regulation was backlogged in the Office of the General Counsel and the target date was revised to February 1975. The report failed to mention that the specifications had not been forwarded to the Counsel until the previous month. A February 1975 report stated that the initial draft of the proposed regulation would be completed within the month when actually the Counsel had not begun to draft the document. Status reports prepared in September 1975, October 1975, November 1975, December 1975, and January 1976 identified a January 1976 target date for publishing the proposed regulation. As of March 31, 1976, the General Counsel still had not begun to draft the proposed regulation.

PROCEDURES FOR PUBLIC PARTICIPATION

A proposed regulation will be published in the Federal Register and interested persons will be requested to submit comments, suggestions, or objections.

INVOLVEMENT OF OTHER FEDERAL AGENCIES AND STATE AND LOCAL OFFICIALS

The Alcohol, Drug Abuse, and Mental Health Administration institute official responsible for drafting the specifications did not consult with State and local officials. As stated previously, the specifications were never reviewed by or discussed with the Special Action Office before its abolishment.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

The Department regulations status reports dated April 1972 through February 1975 stated that the regulation would require ACIR review. However, since September 25, 1975, the status reports no longer identify the need for ACIR review.

CASE STUDY

REGULATIONS TO ESTABLISH CONFIDENTIALITY OF PATIENT RECORDS FOR ALCOHOL AND DRUG ABUSE PROGRAMS

Legal Citation: Title 42--Public Health

Chapter I--Public Health Service
Department of Health,
Education, and Welfare

Subchapter A--General
Provisions

Part 2--Confidentiality of
Alcohol and Drug Abuse
Patient Records

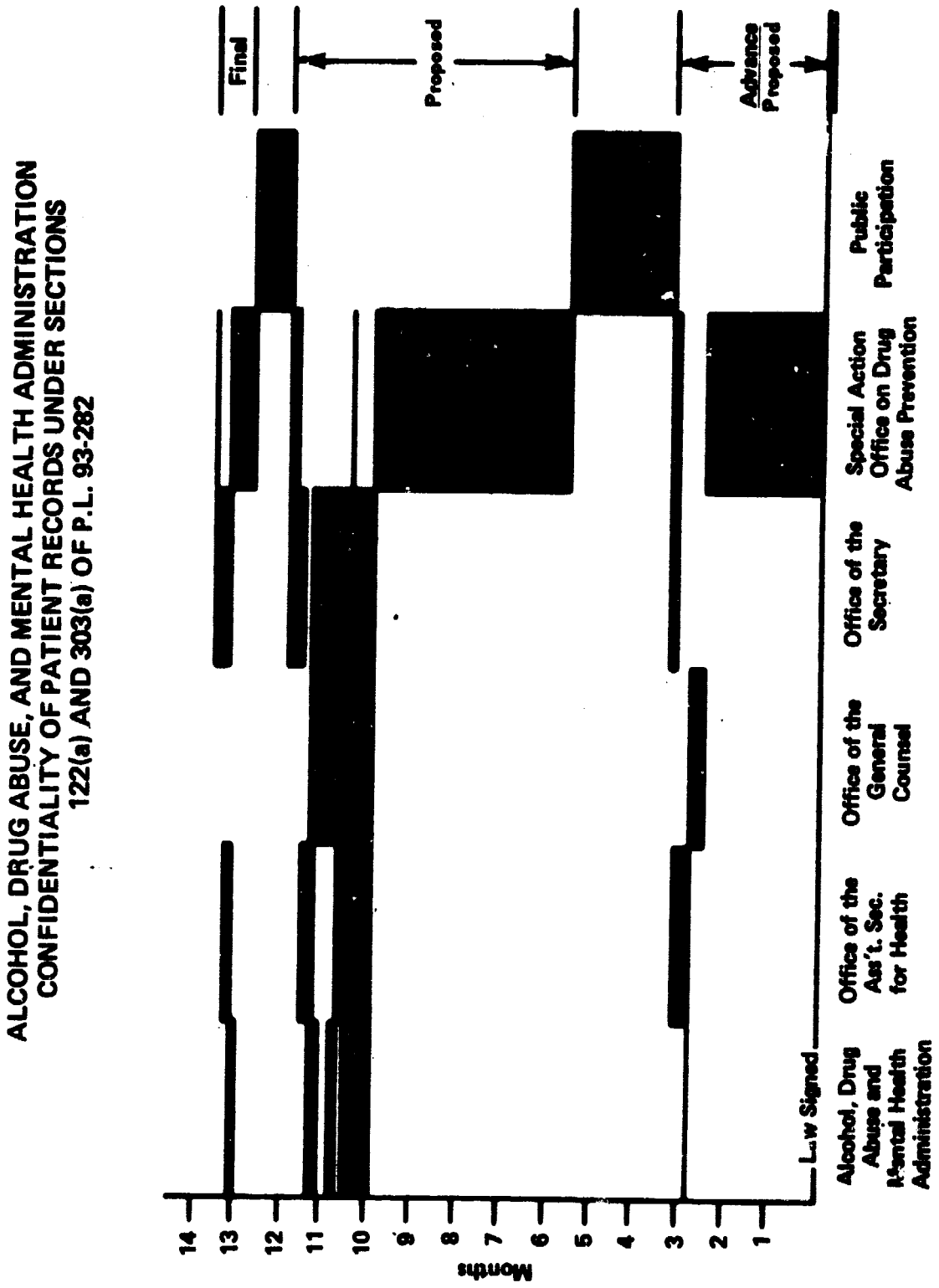
July 1, 1975

The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974, approved on May 14, 1974, amended section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582) and section 408 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175), resulting in substantially similar confidentiality provisions for alcohol and drug abuse. A passage from the legislative history suggested the promulgation of a joint regulation. The Special Action Office for Drug Abuse Prevention in the Executive Office of the President was responsible for section 408, as amended. The Alcohol, Drug Abuse, and Mental Health Administration is responsible for section 333, as amended. Both agencies recommended a joint regulation with the Special Action Office responsible for development.

An advance notice of the proposed regulation was published on August 22, 1974. The proposed and final regulations were published on May 9, 1975, and July 1, 1975, respectively.

The chart on the following page indicates the approximate periods for developing and processing the advance notice, the proposed regulation, and the final regulation. Shading for two or more levels during the same period indicates interaction between these levels.

APPENDIX VI


ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
CONFIDENTIALITY OF PATIENT RECORDS UNDER SECTIONS
122(a) AND 303(a) OF P.L. 93-282
Final
Proposed
Advance Proposed
Months
14
13
12
11
10
9
8
7
6
5
4
3
2
1
Law Signed
Alcohol, Drug Abuse and Mental Health Administration
Office of the Ass't. Sec. for Health
Office of the General Counsel
Office of the Secretary
Special Action Office on Drug Abuse Prevention
Public Participation

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Special Action Office's General Counsel was responsible for drafting the regulation. HEW's General Counsel redrafted the preamble of the advance notice and concurred with the proposed process for issuing the regulations. HEW's General Counsel also reviewed, commented on, and concurred with the proposed and final regulations.

DELAYS IN DEVELOPING THE REGULATION

In a letter to the Secretary, the Special Action Office's General Counsel stated that 13 months was more than enough time to obey a statutory direction to prescribe regulations, especially when there was a real need for their issuance. He noted several instances where developing and processing the regulations had been delayed by HEW.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

Department regulations status reports used to monitor development were misleading, inaccurate, and incomplete. A November 1974 report did not identify the advance notice as being a joint publication nor did it state that lead responsibility for drafting the regulation had been assigned to the Special Action Office. A February 1975 report stated that the Alcohol, Drug Abuse, and Mental Health Administration was responsible for reviewing public comments on the advance notice and making revisions where appropriate, but actually this task had been assumed by the Special Action Office. The Administration's role was limited to providing HEW approval, usually informal, on drafts, revisions, and decisions made by the Special Action Office. The responsible Alcohol, Drug Abuse, and Mental Health Administration institute did not formally review and comment on the advance notice or the final regulation and did not respond to a request for comment on the proposed regulation.

HEW waived many of its processing procedures so that the final regulation could be published before abolishment of the Special Action Office on June 30, 1975. For example, the advance notice was not reviewed or concurred with by the Alcohol, Drug Abuse, and Mental Health Administration or any of its institutes; Assistant Secretary for Health staff offices; or Office of the Secretary officials prior to publication in the Federal Register.

Due to the urgent circumstances that existed, the proposed and final regulations were precleared while development continued. Although the proposed regulation was precleared at the Assistant Secretary for Health level within 2 weeks, Secretary staff offices took over a month. Late comments were not considered prior to the Acting Secretary's approval of the proposed regulation. Because the comments were not considered, the proposed regulation was approved over objections by one Secretary staff office and the Executive Secretary. Both offices were assured that the comments would be considered in drafting the final regulation. The final regulation was concurred with simultaneously by Assistant Secretary for Health and Secretary staff offices in less than a week. As previously stated, institutes within the Alcohol, Drug Abuse, and Mental Health Administration did not review or concur with the final regulation.

PROCEDURES FOR PUBLIC PARTICIPATION

The advance notice was published on August 22, 1974, with 74 days provided for comment. Hearings were held in 11 cities throughout the United States in accordance with a schedule published in the advance notice. Eighty-four witnesses testified and 173 sets of comments were received.

The proposed regulation, published on May 9, 1975, reflected the Special Action Office's consideration of the comments and testimony received. Another 30 days were provided for comment. In addition, the Special Action Office's General Counsel attended drug abuse and criminal justice system conferences in an effort to persuade affected parties that the proposed rules were reasonable and workable.

Sixty-nine sets of comments were received on the proposed regulation. The preamble to the final regulation discussed two substantive changes to the proposed regulation. One of the changes was a direct result of extensive written comment and oral communications on the provision as presented in both the advance notice and the proposed regulation. Our review of the 69 sets of comments received on the proposed regulation indicates that 27 were critical of the revised provision. Although neither the proposed nor the final regulation attributed the other substantive change to public comment, 15 of the 69 sets of comments made reference to the revised provision. The final regulation also included minor policy, technical, clarifying, and conforming changes made to the proposed regulation which were addressed in the public comments received. Two other provisions on which numerous comments and views were critical remained unchanged. However,

the final regulation reflected a consideration of these comments and justification for their rejection.

The advance notice and the proposed and final regulations were accompanied by press releases to inform the general public about their publication and content.

INVOLVEMENT OF OTHER FEDERAL AGENCIES

Available documentation indicated that the Department of Justice, the Veterans Administration, and the Civil Service Commission were consulted prior to enactment of the enabling legislation. The law required the Special Action Office to consult the Administrator of Veterans Affairs and other Federal departments and agencies. No similar requirement was imposed on HEW.

HEW did not seek concurrence with the advance notice or proposed regulation from any other Federal departments or agencies. The Veterans Administration and the Drug Enforcement Administration were consulted by the Public Health Service before publishing the final regulation. Neither of the agencies objected.

The final regulation states that the Administrator of Veterans Affairs and the heads of other Federal departments and agencies substantially affected by the regulation were consulted. However, since consultation with other Federal departments and agencies was the responsibility of the Special Action Office, HEW officials were not aware of this interaction.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

Although Department regulations status reports identified the need for ACIR review, the advance notice had to be requested by ACIR. In a letter to OMB, ACIR stated that neither the Special Action Office nor the Alcohol, Drug Abuse, and Mental Health Admininistration was aware of the review procedures afforded State and local governments through OMB Circular A-85. ACIR was concerned that there were still Federal agencies unaware of the A-85 process.

QUESTIONS RELATING TO CONGRESSIONAL INTENT DUE TO LANGUAGE OF ENABLING LEGISLATION

Public comments on the proposed regulation questioned whether the regulations went beyond the scope and authority of the enabling legislation and the intent of Congress. Two issues of public concern were:

1. Whether programs which begin with direct Federal assistance and later continue with State aid and private contributions are subject to the regulations.

2. Whether all programs and activities of a State or local government are indirectly assisted by Federal revenue sharing or other unrestricted grants, and therefore meet the statutory criteria for coverage.

The applicable sections of the law state that records maintained in conjunction with any program, activity, or function "conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall * * * be confidential." The regulation specifies that it is applicable to records maintained in conjunction with any function

> "which is assisted by funds supplied by any department or agency of the United States, whether directly through a grant, contract, or otherwise, or indirectly by funds supplied to a State or local government unit through the medium of contracts, grants of any description, general or special revenue sharing or otherwise."

The public expressed concern that because the regulation was being applied to programs indirectly receiving Federal funds, it exceeded the Federal Government's legal and constitutional rights and infringed on State rights. They felt that in enacting the relevant statutory provisions, the Congress did not intend that they be applied to all patient records relating to drug abuse or alcohol abuse treatment. According to the public comments received, the law, as stated, does not extend coverage to all treatment situations and all patient records.

The final regulation stated that the wording of the law strongly suggests an intention to provide the broadest coverage consistent with the literal terms of the statutes. The

coverage therefore includes (1) programs for which all direct Federal assistance has terminated and (2) programs which are indirectly assisted by revenue sharing or other unrestricted grants. Since most State and local governments receive some funds from the Federal Government, this decision means that virtually all programs are covered, including those which have direct dealings only with a State or local government.

CASE STUDY

REGULATIONS TO IMPLEMENT A CLINICAL CANCER EDUCATION PROGRAM

Legal Citation: Title 42--Public Health

Chapter 1--Public Health Service
Department of Health,
Education, and Welfare

Part 52d--National Cancer
Institute
Clinical Cancer
Education Program

September 29, 1975

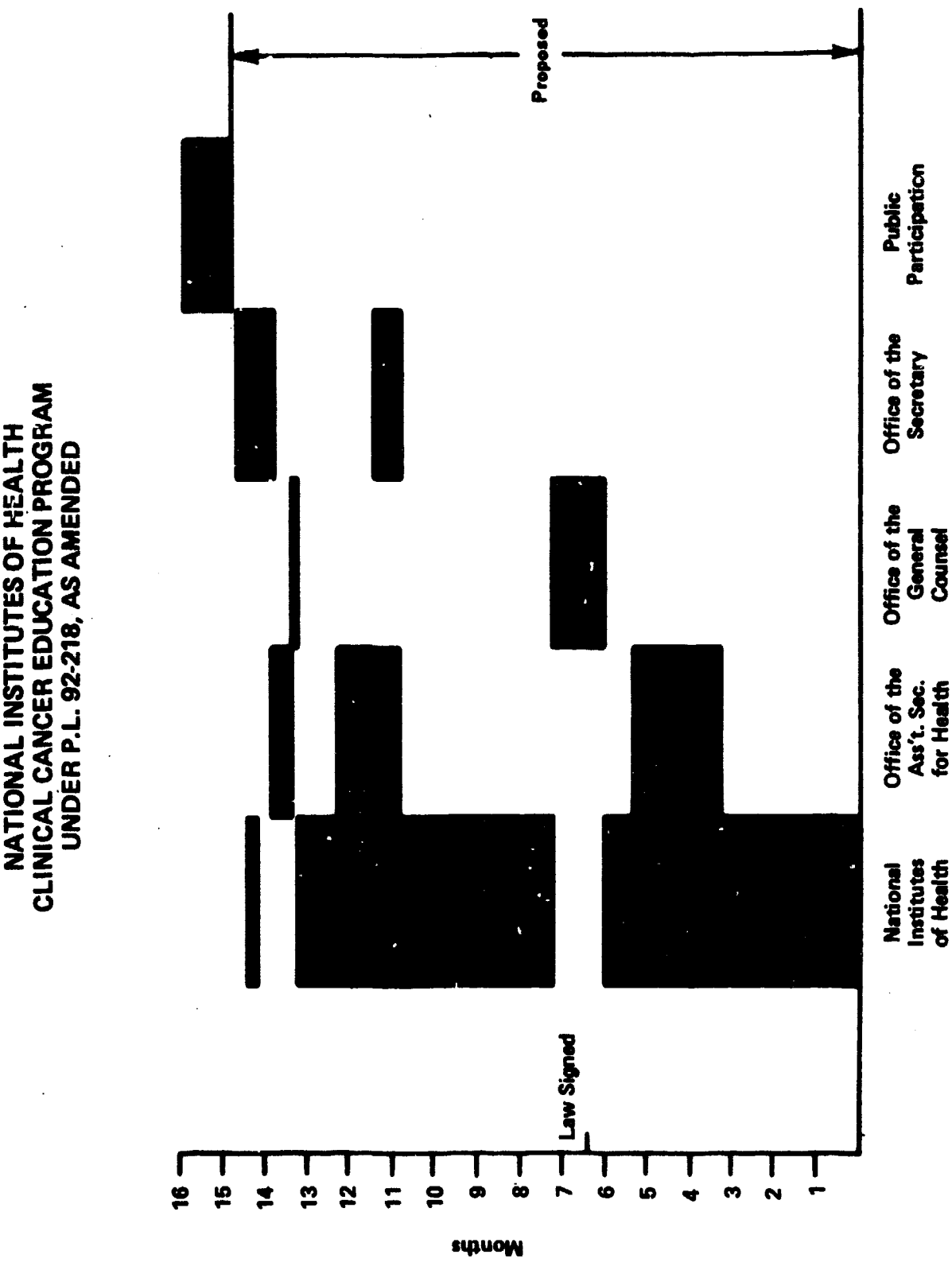
The Clinical Cancer Education Program was originally developed under the broad authority of section 301 and title IV, part A, of the Public Health Service Act as amended (42 U.S.C. 241, 281 et seq.). The National Research Service Award Act of 1974 (Public Law 93-348) and the National Cancer Act Amendments of 1974 (Public Law 93-352) enacted on July 12, 1974, and July 23, 1974, respectively, amended section 407 (b)(7) of the Public Health Service Act (42 U.S.C. 286a(b)(7)). Section 407 (b)(7) then became the sole authority for awarding grants.

The Clinical Cancer Education Program can support training programs designed to provide staff from which to select investigators, physicians, and allied health professions personnel for clinical programs relating to cancer, including the use of training stipends, fellowships, and career awards.

Plans and guidelines for the Clinical Cancer Education Program were approved by the Assistant Secretary for Health in June 1974, 1 month prior to the enactment of Public Law 93-348 and Public Law 93-352. A general notice announcing the program was published in the Federal Register on November 29, 1974. The proposed and final regulations were published on March 25, 1975, and September 29, 1975, respectively.

The chart on the following page indicates the approximate periods for developing and processing the proposed regulation. Shading for two or more levels during the same period indicates interaction between these levels.

APPENDIX VII



OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

On July 1, 1974, prior to the enactment of Public Law 93-348 and Public Law 93-352, the National Institutes of Health forwarded background data relating to the Clinical Cancer Education Program to the General Counsel for use in drafting a proposed regulation. The Counsel prepared an initial draft and returned it in 5 weeks. After the initial draft was returned, interaction between these organizations continued. Although most of the Counsel's further involvement was informal, limited documentation indicated intermittent formal interaction. The General Counsel concurred with the proposed regulation on March 3, 1975.

REQUIREMENT TO PUBLISH REGULATION BEFORE AWARDING GRANTS HASTENED DEVELOPMENT

Although grant applications were solicited, no new or competing grants were awarded until the final regulation was published.

EXTENDED DELAY IN DEVELOPING THE REGULATION

The National Institutes of Health took almost 4 months to review, revise, and resolve problems relating to the press release and the proposed regulation's initial draft prepared by the Office of the General Counsel.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

A schedule for developing, preparing, and coordinating the regulation was not established and milestones within specific time limits were not identified. The original target date for publication of the proposed regulation was December 1974. A revised target date of January 1975 was identified on a November 1974 Department regulations status report used to monitor development. The report provided no explanation for the target date change. A February 1975 status report subsequently identified a publication target date of April 1975. Again the report provided no explanation for the change. A chronology based on available documentation and interviews with HEW officials showed that between August 1974 and February 1975, the proposed regulation remained within the National Institutes of Health.

PRECLEARANCE EXPEDITED FINAL PROCESSING

The National Institutes of Health precleared the proposed regulation with the Health Resources Administration; the Alcohol, Drug Abuse, and Mental Health Administration; two Assistant Secretary for Health staff offices; and four Secretary staff offices. The Alcohol, Drug Abuse, and Mental Health Administration and two Secretary staff offices concurred within the 2 weeks provided. The other two Secretary staff offices concurred informally through unrecorded telephone calls, the dates of which are unknown. The Health Resources Administration never responded to the preclearance request. Both Assistant Secretary for Health staff offices requested and received time extensions. The Office of Administrative Management concurred with comments over 1 week after the due date. The Office of Policy Development and Planning concurred without comment 3 weeks after the due date.

During formal processing the Assistant Secretary for Planning and Evaluation, a Secretary staff office, reconsidered the concurrence given during preclearance and raised 12 questions. The questions were resolved 4 days after the the due date and the Assistant Secretary for Planning and Evaluation concurred with the proposed regulation. The Assistant Secretary for Health and the Secretary approved the proposed regulation in about 2 weeks and 3 weeks, respectively.

PROCEDURES FOR PUBLIC PARTICIPATION

A general notice announcing the program was published in the Federal Register on November 29, 1974, followed by the press release on December 19, 1974. One comment about the notice was received. The American Association of Colleges of Podiatric Medicine protested the omission of schools of podiatric medicine from institutions eligible for the program. A National Institutes of Health official met with the organization to explain HEW's position.

A proposed regulation was published on March 24, 1975. No comments were received during the comment period. Since the American Association of Colleges of Podiatric Medicine also did not comment, the National Institutes of Health and the Office of the General Counsel assumed that the organization was satisfied with the explanation provided at the meeting.

INVOLVEMENT OF OTHER FEDERAL AGENCIES

No other Federal agencies, including OMB, were involved in developing and processing this proposed regulation.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

Although public institutions of higher learning are eligible for stipends, fellowships, and awards under the program, National Institutes of Health officials determined that ACIR review was not required. This determination was documented on Department regulations status reports.

QUESTIONS RELATING TO CONGRESSIONAL INTENT DUE TO LANGUAGE OF ENABLING LEGISLATION

Our review raised a question relating to congressional intent. The National Cancer Act of 1971 (Public Law 92-218) signed on December 23, 1971, amended title IV, part A, of the Public Health Service Act (42 U.S.C. 281 et seq.) by adding section 407. The act stated that the National Cancer Program should support staff training programs, including the use of training stipends, fellowships, and career awards, where appropriate. HEW determined that stipends, fellowships, and career awards would not be used and denied the responsible institute the opportunity to conduct such training.

The National Research Service Award Act of 1974 (Public Law 93-348) and the National Cancer Act Amendments of 1974 (Public Law 93-352) enacted during July 1974 amended section 407 by striking "where appropriate," making the authority unambiguous. By striking "where appropriate," the Congress intended to prevent curtailment of training stipends, fellowships, and career awards by HEW or OMB. However, HEW's Clinical Cancer Education Program continues to exclude such financial aid.

CASE STUDY

REGULATIONS TO IMPLEMENT NATIONAL RESEARCH SERVICE AWARDS

Legal Citation: Title 42--Public Health

Chapter 1--Public Health Service
Department of Health,
Education, and Welfare

Part 66--National Research
Service Awards

May 2, 1975

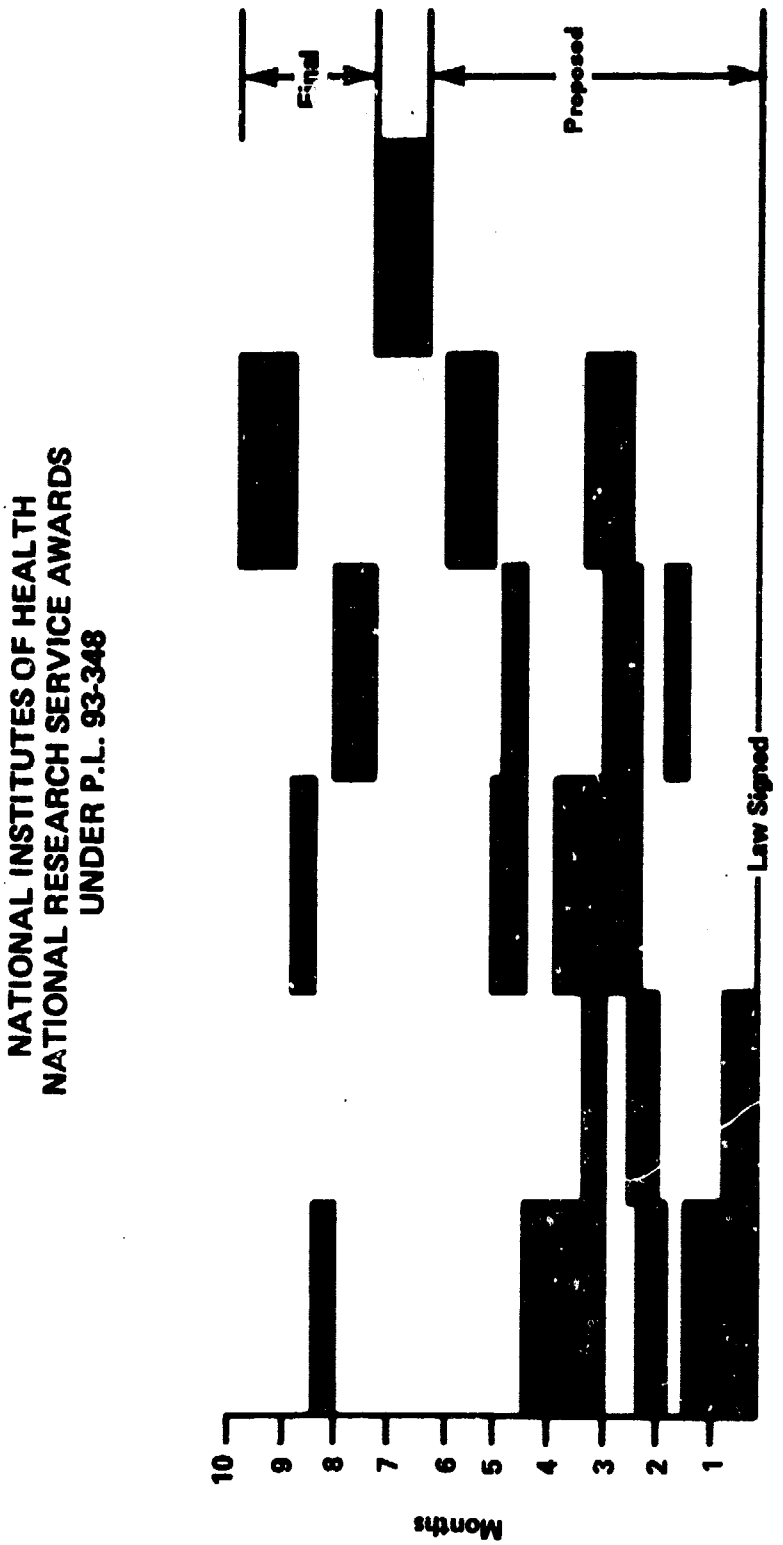
On July 12, 1974, the National Research Act (42 U.S.C. 2891-1) was approved. Title I consolidated the research training authorities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration into a single National Research Service Awards. A proposed regulation was published in the Federal Register on January 17, 1975. The final regulation was published on May 2, 1975.

The chart on the following page indicates the approximate periods for developing and processing the proposed and final regulations. Shading for two or more levels during the same period indicates interaction between these levels.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The General Counsel, responding to a National Institutes of Health request, prepared the proposed regulation for publication in the Federal Register. Due to the high priority assigned the regulation, the Counsel prepared the initial draft in 3 weeks. The Counsel took another 3 weeks to revise the proposed regulation based on comments by the National Institutes of Health. The Counsel also revised the proposed regulation while it was being reviewed by Assistant Secretary for Health staff officials. The Counsel prepared the final regulation in 17 days.

APPENDIX VIII



REQUIREMENT TO PUBLISH REGULATION BEFORE MAKING AWARDS HASTENED DEVELOPMENT

The developing and processing was expedited because no new or competing grants could be awarded until the final regulation was published, and only applications and project supplements which were approved, but not funded in 1973 were awarded using impounded 1973 funds. These awards were made under existing terms and conditions.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

A schedule for developing, preparing, and coordinating the regulation was not established and milestones within specific time limits were not identified.

A November 1974 status report identified a target date of February 1975 for submission of the final regulation to the Secretary. The comment period on the proposed regulation did not end until February 1975. A February 1975 status report stated that the final regulation still had not been published. Between the November 1974 report and the February 1975 report, no other status reports were prepared and development of the proposed regulation was not monitored. Development of the final regulation also was not monitored.

PRECLEARANCE EXPEDITED FINAL PROCESSING

The proposed regulation was precleared with selected Assistant Secretary for Health and Secretary staff offices. Development continued during the preclearance.

Six days after formal processing had begun at the Assistant Secretary for Health level, the Office of the General Counsel revised the proposed regulation. Even with this delay the Assistant Secretary for Health approved the proposed regulation in about 3 weeks. Secretary's approval of the proposed regulation was received in about 4 weeks. The final regulation was approved by the Assistant Secretary for Health and the Secretary in about 2 weeks and 3 weeks, respectively.

PROCEDURES FOR PUBLIC PARTICIPATION

The proposed regulation was published in the Federal Register with 30 days provided for comment. Ten sets of

comments were received. One organization's comments were not considered in drafting the final regulation because they were received about 3 weeks after the comment period had ended and 3 days after the National Institutes of Health had forwarded the final regulation to the Assistant Secretary for Health for approval. However, the National Institutes of Health promptly notified the organization and explained why their comments were not considered.

Specific requests and suggestions for revisions were summarized in the preamble to the final regulation. However, the revisions were primarily editorial and technical in nature, and did not change the basic provisions of the proposed regulation. Three comments were adopted, five were rejected and one required no change. An explanation was provided for each comment rejected.

Both the proposed and final regulation were accompanied by a press release to inform the general public of their publication and content. The National Research Service Awards were also included in the National Institutes of Health Guide for Grants and Contracts published at irregular intervals. The Guide explains policy and procedures to individuals and organizations, including information about requirements and changes in grants and contracts activities.

INVOLVEMENT OF OTHER FEDERAL AGENCIES

No other Federal agencies, including OMB, were involved in developing and processing this regulation.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

Although the National Research Service Awards have a considerable nationwide effect, National Institutes of Health officials determined that ACIR review was not required. This determination was documented on Department regulations status reports.

QUESTIONS RELATING TO CONGRESSIONAL INTENT DUE TO LANGUAGE OF ENABLING LEGISLATION

Although comments received on the proposed regulation did not question congressional intent, there was some concern over provisions of the statute. Because the requirements were mandated by the legislation, and therefore not discretionary in terms of rulemaking, the comments did not dispute the necessity for their implementation in the regulation.

CASE STUDY

REGULATIONS TO PROVIDE STANDARDS FOR LABELING OF PRESCRIPTION DRUGS USED IN MAN

Legal Citation: Food and Drug Administration [21 C.F.R. Parts 1, 3]

Labeling for Prescription Drugs Used in Man

Proposed Format for Prescription Drug Advertisements

Proposed April 7, 1975

The Commissioner of Food and Drug has determined that considerable improvements should be made in drug labeling to provide the essential information that a practitioner needs to use a drug safely and effectively in the care of patients. The purpose of the labeling regulation is not to establish new regulatory requirements but to provide standards so that all package inserts can be brought up to the level of the best ones written in the past.

A notice of intent to solicit comments was published in the Federal Register on March 7, 1974. A proposed regulation was published on April 7, 1975. The final regulation has not been published.

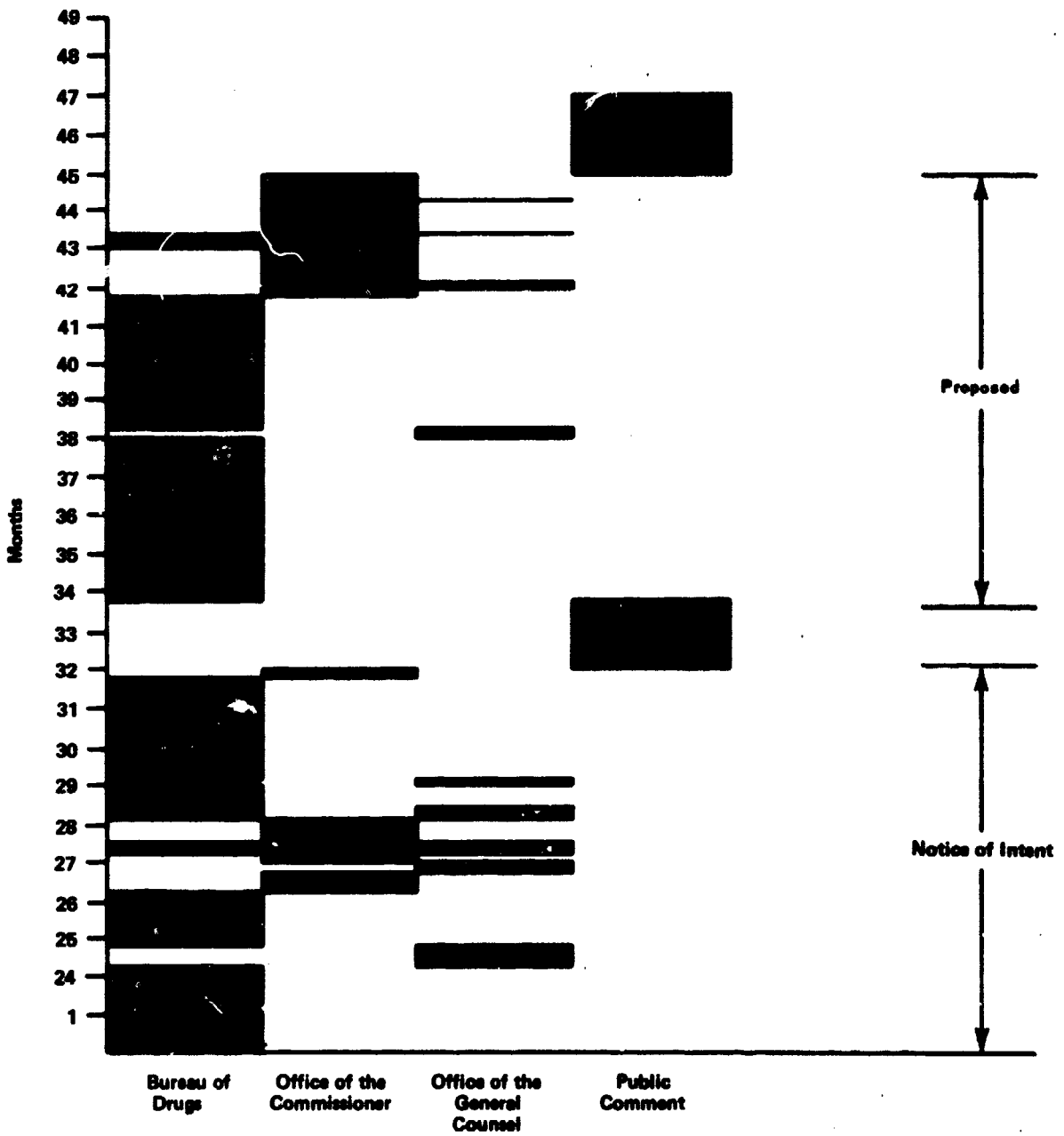
The chart on the following page indicates the approximate periods for developing and processing a notice of intent and the proposed regulation. Shading for two or more levels during the same period indicates interaction between these levels.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Food and Drug Division of the Office of the General Counsel reviewed and commented on the notice of intent on three separate occasions. The average turnaround time was less than 2 weeks. The Counsel also met with Food and Drug Administration officials twice during development of the notice to discuss changes. This interaction took about 2 weeks.

APPENDIX IX

FOOD AND DRUG ADMINISTRATION
LABELING FOR PRESCRIPTION DRUGS USED IN MAN



The Counsel took over 3 weeks to review and comment on two drafts of the proposed regulation. The Counsel concurred with both the notice of intent and the proposed regulation in 1 day.

EXTENDED DELAYS IN DEVELOPING THE REGULATION

Although this regulation was given a high priority, the Food and Drug Administration took over 2 years to complete the initial draft of the notice of intent. In addition to the 2 years, the Administration also took nearly 8 months to redraft the regulation based on 59 sets of public comments and comments received from the General Counsel.

Internal review at the Office of the Commissioner took about 5 weeks and 9 weeks for the notice of intent and the proposed regulation, respectively.

MONITORING DEVELOPMENT OF THE REGULATION

Beginning with the week of October 13, 1973, the Commissioner's Weekly Report on Status of Selected Federal Register Announcements accurately tracked the proposed regulation's development and processing.

PROCEDURES FOR PUBLIC PARTICIPATION

Substantial comment on the proposed regulation was expected because the revision of prescription drug labeling affects the medical profession, the drug industry, and the Food and Drug Administration's staff. The Administration, therefore, published a notice of intent to solicit comments in the Federal Register with 50 days provided for comment. The purpose of this notice was to obtain comments from various professional, scientific, trade, and consumer organizations before publishing the proposed regulation.

Fifty-nine sets of comments were received from physicians, professional societies, drug manufacturers, trade associations, and individual consumers. The proposed regulation included some changes to the notice of intent based on the comments. The proposed regulation was published in the Federal Register with an additional 60 days provided for comment. Although the preamble to the proposed regulation did not address all the comments received on the notice of intent, it included the major legal issues that were raised. The preamble to the proposed regulation stated that comments not addressed or

satisfactorily answered, as indicated by additional comments, would be addressed in the final regulation.

As of December 30, 1975, the Food and Drug Administration had received 98 sets of comments on the proposed regulation.

INVOLVEMENT OF OTHER FEDERAL AGENCIES

No other Federal agencies, including OMB, were involved in developing and processing the notice of intent and the proposed regulation.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

The Food and Drug Administration's Administrative Practices and Procedures published in the Federal Register do not include ACIR review. Food and Drug officials were not familiar with OMB Circular A-85. To their knowledge ACIR requirements do not apply to them, and proposed and final regulations are not forwarded for ACIR review.

APPENDIX X

CASE STUDY

REGULATIONS TO PROVIDE STANDARDS FOR ADOPTION OF FOREIGN CLINICAL INVESTIGATIONS ON DRUGS

Legal Citation: Title 21--Food and Drugs

Chapter 1--Food and Drug Administration
Department of Health,
Education, and Welfare

Subchapter D--Drugs for
Human Use

Part 312--New Drugs for
Investigational Use

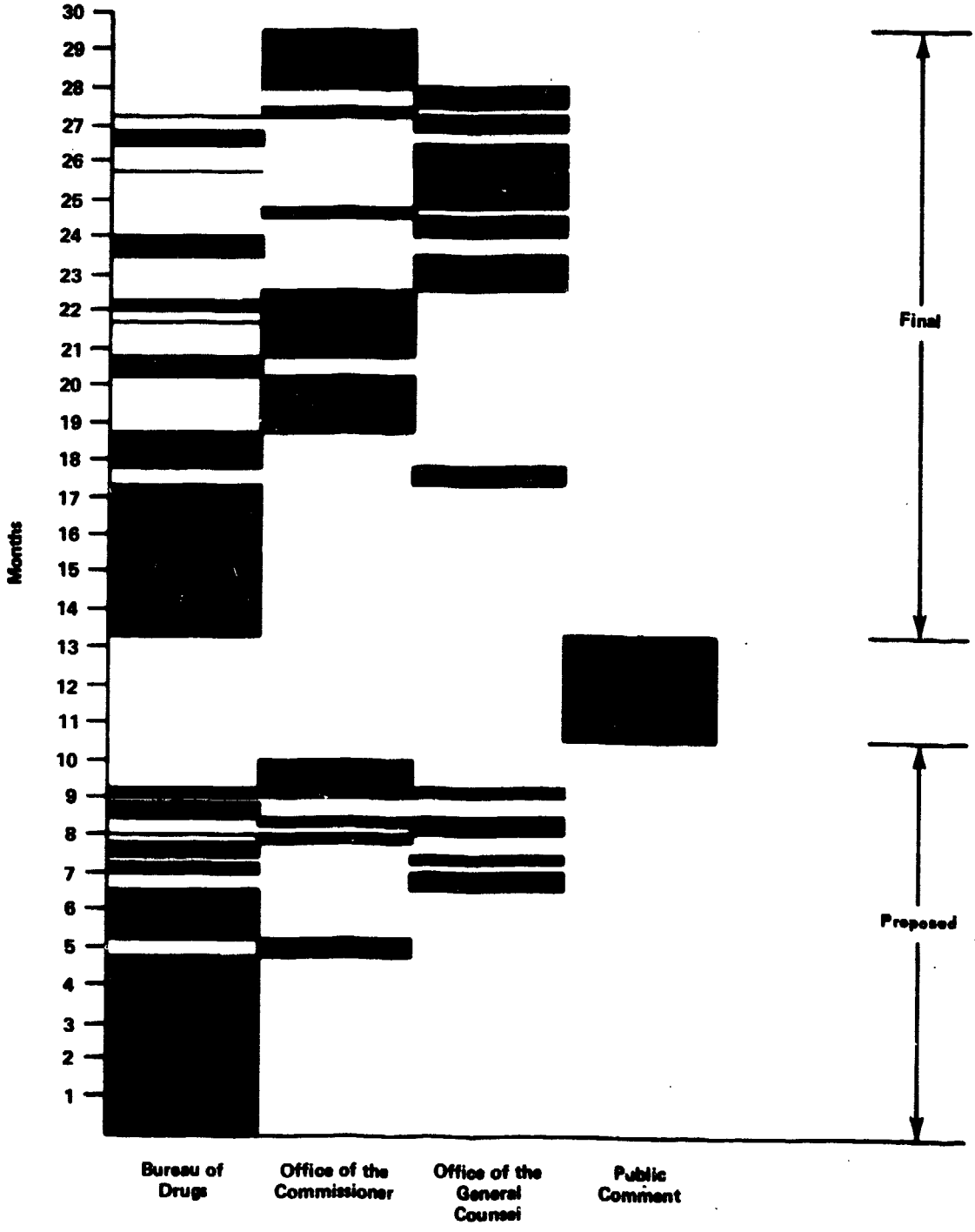
Adoption of International Clinical Research Standards; Acceptance of Foreign Data

April 9, 1975

The Food and Drug Administration was concerned over the failure to utilize clinical data from well-conceived, controlled studies performed by qualified experts abroad in the new drug approval process. Therefore, on September 6, 1973, a proposed regulation was published in the Federal Register under which the results of clinical investigations on drugs generated outside the United States would be acceptable in support of a new drug's approval. The final regulation was published on April 9, 1975.

The chart on the following page indicates the approximate periods for developing and processing the proposed and final regulations. Shading for two or more levels during the same period indicates interaction between these levels.

FOOD AND DRUG ADMINISTRATION
ADOPTION OF INTERNATIONAL CLINICAL RESEARCH
STANDARDS; ACCEPTANCE OF FOREIGN DATA



SIGNIFICANT POLICY ISSUE NOT RESOLVED

Publication of the final regulation was delayed for 4-1/2 months while the issue of whether foreign clinical investigations should be reviewed by committees before acceptance was being resolved by the Office of the General Counsel and the responsible Food and Drug Administration bureau. Staff officials within the Office of the Commissioner were not actively involved in the controversy and a Commissioner's decision was never rendered on the issue.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Food and Drug Division of the Office of the General Counsel formally reviewed and commented on four drafts of the proposed regulation. The average turnaround time was about a week. The Counsel concurred with the final draft in a day. The Counsel reviewed and commented on six drafts of the final regulation. However, as stated above, an extensive amount of time (4-1/2 months) was required to resolve one controversial issue.

EXTENDED DELAYS IN DEVELOPING THE REGULATION

The responsible Food and Drug Administration bureau took over 4 months to revise the regulation based on 12 sets of comments received on the proposed regulation. The overwhelming majority of the comments favored the basic principles set forth in the proposed regulation. In all, development of the final regulation took about 16 months.

The Office of the Commissioner took over 5 weeks to review four drafts of the proposed regulation and 19 weeks to review seven drafts of the final regulation. Review of two final regulation drafts took almost 13 weeks because other regulations were assigned higher priority.

MONITORING DEVELOPMENT OF THE REGULATION

Beginning in June 1973 the Commissioner's Weekly Report on Status of Selected Federal Register Announcements traced the development of the proposed and final regulations. The weekly report accurately traced review and comment by the General Counsel, revisions and review by the responsible

Food and Drug Administration bureau, internal processing at the Office of the Commissioner and approval at all 3 levels.

PROCEDURES FOR PUBLIC PARTICIPATION

The guidelines for the regulation were the result of dialogue with foreign regulatory agencies, foreign clinical investigators, and drug firms.

The proposed regulation was published in the Federal Register with 90 days provided for comment. Twelve sets of comments were received. Specific requests and suggestions for revisions and clarifications and the Commissioner's responses were summarized in the preamble to the final regulation.

The Commissioner also stated that data submitted under the provisions of the final regulation will be continually monitored, and if experience indicates exploitation of foreign subjects, changes will be proposed, comments considered, and the regulation revised. Additional comments were requested on the final regulation if there was still concern that domestic research was being adversely affected. The final regulation was accompanied by a press release to inform the general public about its publication and content.

INVOLVEMENT OF OTHER FEDERAL AGENCIES

The proposed regulation was discussed with the Department of State. No other Federal agencies, including OMB, were involved in developing and processing the proposed and final regulations.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

The Food and Drug Administration's Administrative Practices and Procedures published in the Federal Register do not include ACIR review. Food and Drug officials were not familiar with OMB Circular A-85. To their knowledge ACIR requirements do not apply to them and proposed and final regulations are not forwarded for ACIR review.

APPENDIX XI

CASE STUDY

REGULATIONS TO LIMIT PAYMENTS FOR DRUGS UNDER MEDICAID

Legal Citation: Title 45--Public Welfare

Chapter II--Social and Rehabilitation Service (Assistance Programs)

Department of Health, Education, and Welfare

Part 250--Administration of Medical Assistance Programs

Limits on Payments for Drugs

August 15, 1975

On October 30, 1972, the Social Security Amendments 1972 (Public Law 92-603) were approved. Section 224(a) amended section 1842(b)(3) of the Social Security Act (42 U.S.C. 1395u) by adding limits to Federal financial participation under Medicaid. Items or services that do not generally vary greatly in quality from one supplier to another are limited to the lowest charge levels at which they are widely and consistently available in a locality, except as otherwise specified by the Secretary.

Pointing to comparisons between the price of brand name drugs and their generic equivalents, proponents of generic prescribing have suggested that where multisource products are involved, considerable savings could result if prescribing and dispensing choices are directed toward the lowest priced product of acceptable quality. HEW estimated that the new policy could cut Federal and State expenditures by at least $89 million a year.

A proposed regulation was published in the Federal Register on November 27, 1974. The final regulation was published on August 15, 1975.

The chart on the following page indicates the approximate periods for developing and processing the proposed regulation. Shading for two or more l[illegible]s during the same period indicates interaction between those [illegible]els.

SIGNIFICANT POLICY ISSUES NOT RESOLVED

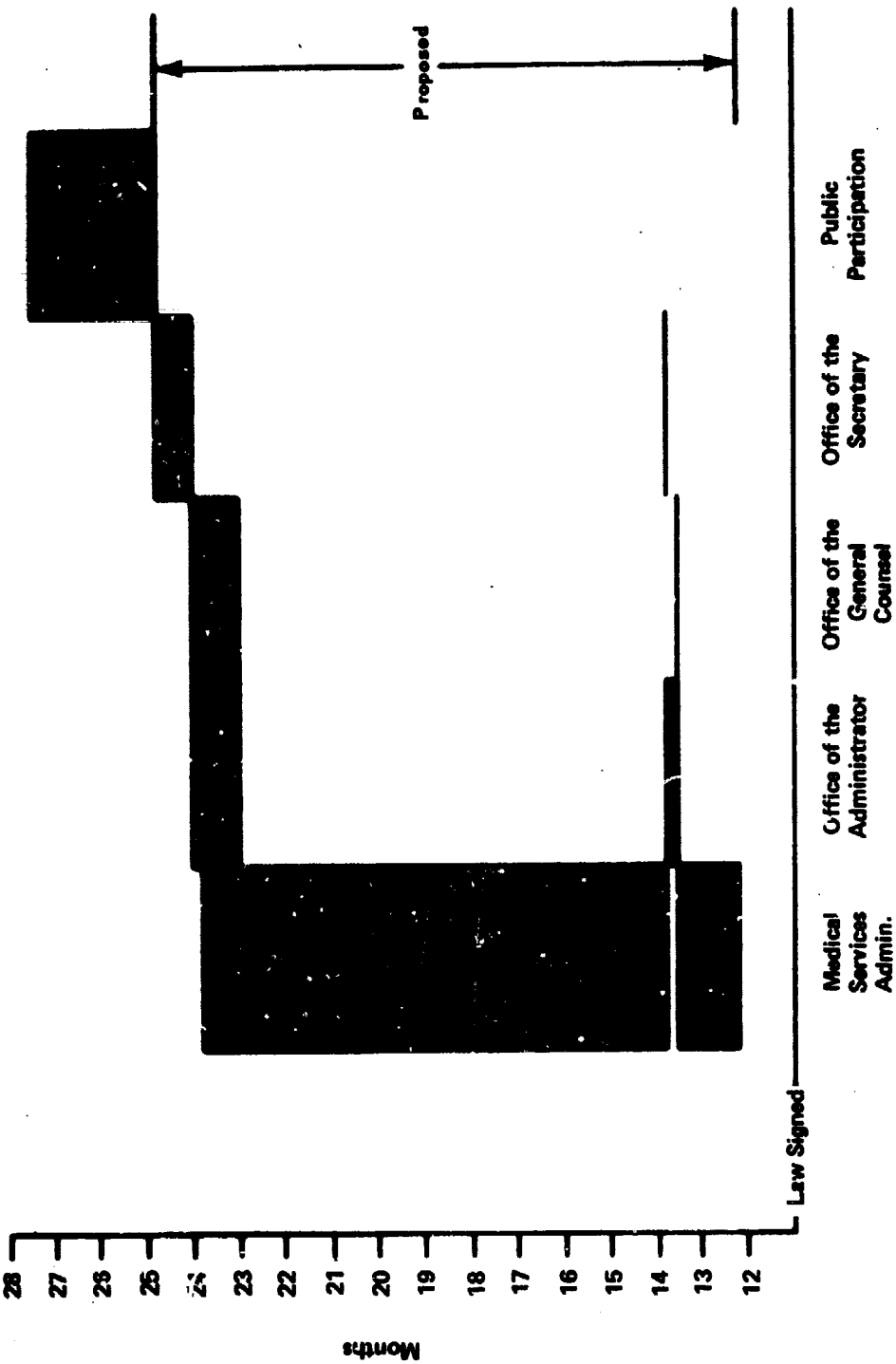
A draft of the proposed regulation was forwarded to the Secretary on December 14, 1973, before all policy issues had been resolved, and so it was unacceptable. In January 1974, an interagency HEW work group under Office of the Secretary leadership was established to resolve the issues. Meetings were held with State representatives and comments were requested from pharmaceutical organizations, other interested groups and individuals, and HEW officials. In J[illegible]e 1974, a memorandum was prepared describing the policy issues, alternative solutions, and recommended alternatives. On October 30, 1974, the Social and Rehabilitation Service forwarded another draft of the proposed regulation implementing the work group's recommendation to the Secretary for approval. The 10-1/2 month lapse between submissions was due primarily to the time taken to resolve policy issues.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Office of the General Counsel made changes to the preamble of the initial draft of the proposed regulation. On October 30, 1974, the Counsel concurred with the proposed Social and Rehabilitation Service regulation forwarded to the Secretary for approval. On November 1, 1974, the Counsel rendered legal opinions on establishing maximum allowable cost limits for drug reim[illegible]ursement, and the legality of not providing separate maximum allowable costs for each locality.

During Secretary staff office review and comment on the the proposed Social and Rehabilitation Service regulation, the Counsel agreed with comments suggesting that the regulation be withheld until a proposed departmental regulation implementing the same provisions of the law had been forwarded for Federal Register publication. The proposed Departmental regulation was published on November 15, 1974, and the Secretary approved the proposed Social and Rehabilitation Service regulation on November 21, 1974.

APPENDIX XI


MEDICAL SERVICES ADMINISTRATION
PROPOSAL TO LIMIT REIMBURSEMENT FOR
PRESCRIBED DRUGS UNDER SECTION 224
OF P.L. 92-603
Months
28
27
26
25
24
23
22
21
20
19
18
17
16
15
14
13
12
Law Signed
Proposed
Medical Services Admin.
Office of the Administrator
Office of the General Counsel
Office of the Secretary
Public Participation

EXTENDED DELAY IN DEVELOPING THE REGULATION

The Medicaid program was one of the two programs on which regulations governing maximum allowable cost would have their greatest fiscal impact. However, procedures for identifying policy issues before developing the proposed regulation did not begin until about a year after enactment of the enabling legislation.

MONITORING DEVELOPMENT OF THE REGULATION LIMITED

A schedule for developing, preparing and coordinating the regulation was not established and milestones within specific time limits were not identified.

PROCEDURES FOR PUBLIC PARTICIPATION

As previously stated, the HEW work group requested comments on known policy issues from pharmaceutical organizations and interested groups and individuals. Based on requests from interested parties and others who wished to comment, the comment period on the proposed regulation was extended from 2 to 2-1/2 months. In addition to the more than 2,600 sets of comments received on the proposed departmental regulation, 150 sets of comments were received on the proposed Social and Rehabilitation Service regulation.

INVOLVEMENT OF OTHER FEDERAL AGENCIES AND STATE AND LOCAL OFFICIALS

The interagency HEW work group pursued the resolution of issues through meetings with State representatives. Prior to publication of the proposed regulation, the Department briefed OMB, the Department of Commerce, the Department of Defense, the Veterans Administration, the Treasury Department, and the President's Council of Economic Advisors. A copy of the proposed Social and Rehabilitation Service regulation was forwarded to OMB for review. There was no record of an OMB response.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

On November 21, 1974, the date the Secretary approved the proposed regulation, the Department Regulations Coordinator requested an explanation from the Social and Rehabilitation

Service as to why ACIR review was not required. The Department subsequently determined that the proposed departmental regulation sent to ACIR for review would suffice and no ACIR review of the proposed Social and Rehabilitation Service regulation was needed.

CASE STUDY

REGULATIONS TO IMPLEMENT COST SHARING CHARGES IN MEDICAID

Legal Citation: Title 45--Public Welfare

Chapter 11--Social and Rehabilitation Service (Assistance Programs)

Department of Health, Education, and Welfare

Part 248--Coverage and Conditions of Eligibility for Medical Assistance

Part 249--Services and Payment in Medical Assistance Programs

Cost Sharing in Medicaid

March 13, 1974

On October 30, 1972, the Social Security Amendments of 1972 (Public Law 92-603) were approved. Section 208 amended section 1902(a)(14) of the Social Security Act (42 U.S.C. 1396a) to require Medicaid premiums, enrollment fees, or similar charges relating to income to be imposed on the medically needy. State medical assistance programs also may elect to impose nominal co-payments, deductibles, or similar charges on the categorically needy in return for optional services under the State's title XIX plan and on the medically needy for any service under the plan. The law stated that section 208 would become effective on January 1, 1973, or earlier if State plans so provide. Cost sharing in Medicaid represented one of the largest cost-savings provisions in the 1972 amendments.

Publications of the cost sharing in Medicaid regulation was deemed urgent since considerable budget savings were predicted. In April 1973 the Assistant Secretary, Comptroller asserted that a potential $44 million in fiscal year 1973 savings had been lost because the regulation had not been

published. He also estimated that the cost sharing regulation would reduce fiscal year 1974 Federal Medicaid expenditures by $130 million.

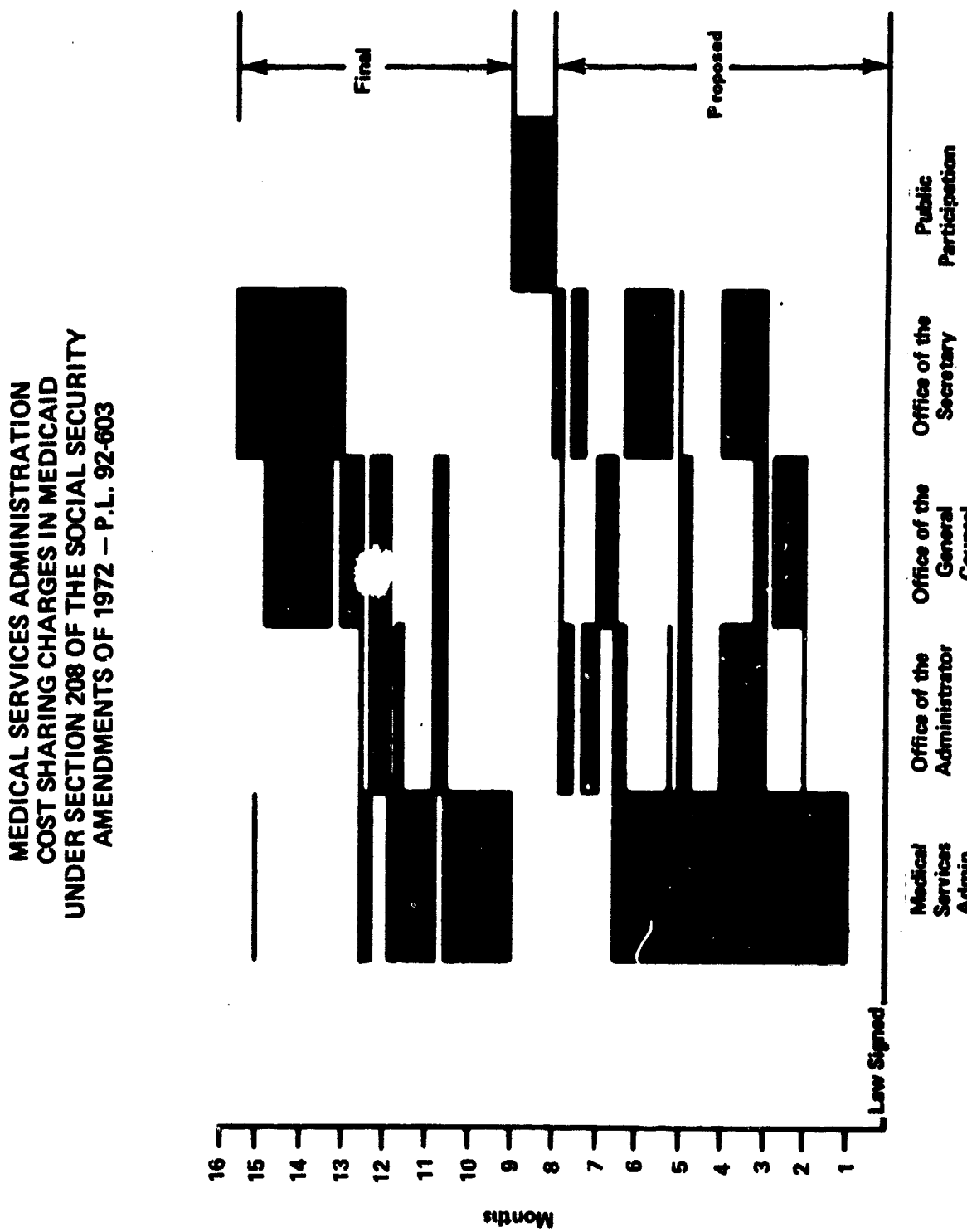
A proposed regulation was published in the Federal Register on July 2, 1973. The final regulation was published on February 13, 1974. Using the HEW estimate, a potential $81.2 million in fiscal year 1974 savings was lost because the final regulation was not published until over 15 months after enactment of the enabling legislation.

The chart on the following page indicates the approximate periods for developing and processing the proposed and final regulations. Shading for two or more levels during the same period indicates interaction between these levels.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Office of the General Counsel took approximately 1 month to review and comment on the issue memorandum and a week to concur with the revision. The Counsel concurred with the proposed regulation in 2 weeks.

APPENDIX XII



The General Counsel disagreed with the final regulation and then agreed with comment on the revision. The Counsel's difference of opinion delayed forwarding the final regulation to the Secretary for approval for over 2 weeks. During review and comment by Secretary staff offices, the Counsel agreed with comment on the final regulation over a month after the due date. A preamble revision resulting from a General Counsel comment brought about another 2-week delay.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

A schedule for developing, preparing, and coordinating the regulation was not established and milestones within specific time limits were not identified.

PROCESSING TIME LIMITS NOT MET

Only four of the eight Social and Rehabilitation Service staff offices responded to a request for comments on the policy issue memorandum. Of these four, one concurred by the due date while the other three responded within 5 days after the due date. In addition to the Office of the General Counsel, five Secretary staff offices were requested to review and comment on the issue memorandum. Only two of the five responded to the request. One of the two commented by the due date and the other disagreed on a date that could not be determined.

Review and comment by Social and Rehabilitation Service staff offices on the proposed regulation could not be determined because of limited documentation. Also, no due date for Secretary staff office review and comment could be identified.

The Assistant Secretary for Planning and Evaluation was one of the two Secretary staff offices that commented on the issue memorandum. The Assistant Secretary commented again during final processing of the proposed regulation. The Assistant Executive Secretary for Health noted that the changes requested by the Assistant Secretary had not been discussed when the issue memorandum was reviewed. The decision to incorporate the comments resulted in at least a week delay.

The final regulation was circulated to two Social and Rehabilitation Service staff offices and to the Office of General Counsel with 4 days provided for review and comment.

Although the General Counsel commented by the due date over a month was required to discuss the comments and revise the regulation. The revised final regulation was then circulated to four Social and Rehabilitation Service staff offices and the General Counsel with 5 days provided for review and comment. Only the General Counsel responded to the request. The Counsel concurred with the final regulation about a week after the due date. The Social and Rehabilitation Service assumed that the four staff offices, by their lack of response, concurred with the final regulation.

The final regulation was then forwarded to four Secretary staff offices and the Office of the General Counsel with a week provided for review and comment. Two of the four staff offices concurred by the due date. The other two concurred without comment 3 days and over 2 weeks after the due date. As stated previously, the General Counsel commented and concurred over a month after the due date.

PROCEDURES FOR PUBLIC PARTICIPATION

The policy issue memorandum developed by the Medical Service Administration was distributed to public health organizations for review and comment. The proposed regulation published in the Federal Register provided 30 days for comment. Forty-eight sets of comments were received.

During final processing by Secretary staff offices, the General Counsel questioned the manner in which public comments were addressed in the preamble to the final regulation. The Counsel asserted that the preamble should be intelligible and should fully inform the public as to what was being done, why it was being done, and why other alternatives were not followed. The Counsel felt that the mere promulgation of a regulation is simply not adequate to achieve those goals. The Secretary supported the Counsel's suggestion and the preamble was revised.

INVOLVEMENT OF OTHER FEDERAL AGENCIES

The Cost of Living Council was contacted twice during the comment period on the proposed regulation. The Council gave the Medical Services Adminstration guidance in applying the President's price freeze regulations to cost sharing in Medicaid and clarified the status of Medicaid cost sharing under Phase IV insurance regulations.

APPENDIX XII

During final processing of the final regulation, the Social and Rehabilitation Service forwarded a copy of the regulation to the National Center for Social Statistics for review and comment. OMB was not given an opportunity to comment on the proposed or final regulation.

PROCEDURES FOR REFERRAL TO ACIR NEED CLARIFICATION AND REVISION

The ACIR did not receive copies of the proposed regulation until 3 days before its publication in the Federal Register, thus frustrating the hope for early consultation.

CASE STUDY

REGULATIONS TO ESTABLISH AN ECONOMIC INDEX TO LIMIT INCREASES IN PHYSICIAN CHARGES UNDER MEDICARE

Legal Citation: Title 20--Employees' Benefits

Chapter III--Social Security Adminstration

Department of Health, Education, and Welfare

(Regs. No. 5, further amended)

Part 405--Federal Health Insurance for the Aged and Disabled

Subpart E--Criteria for Determination of Reasonable Charges; Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians

Economic Index

June 16, 1975

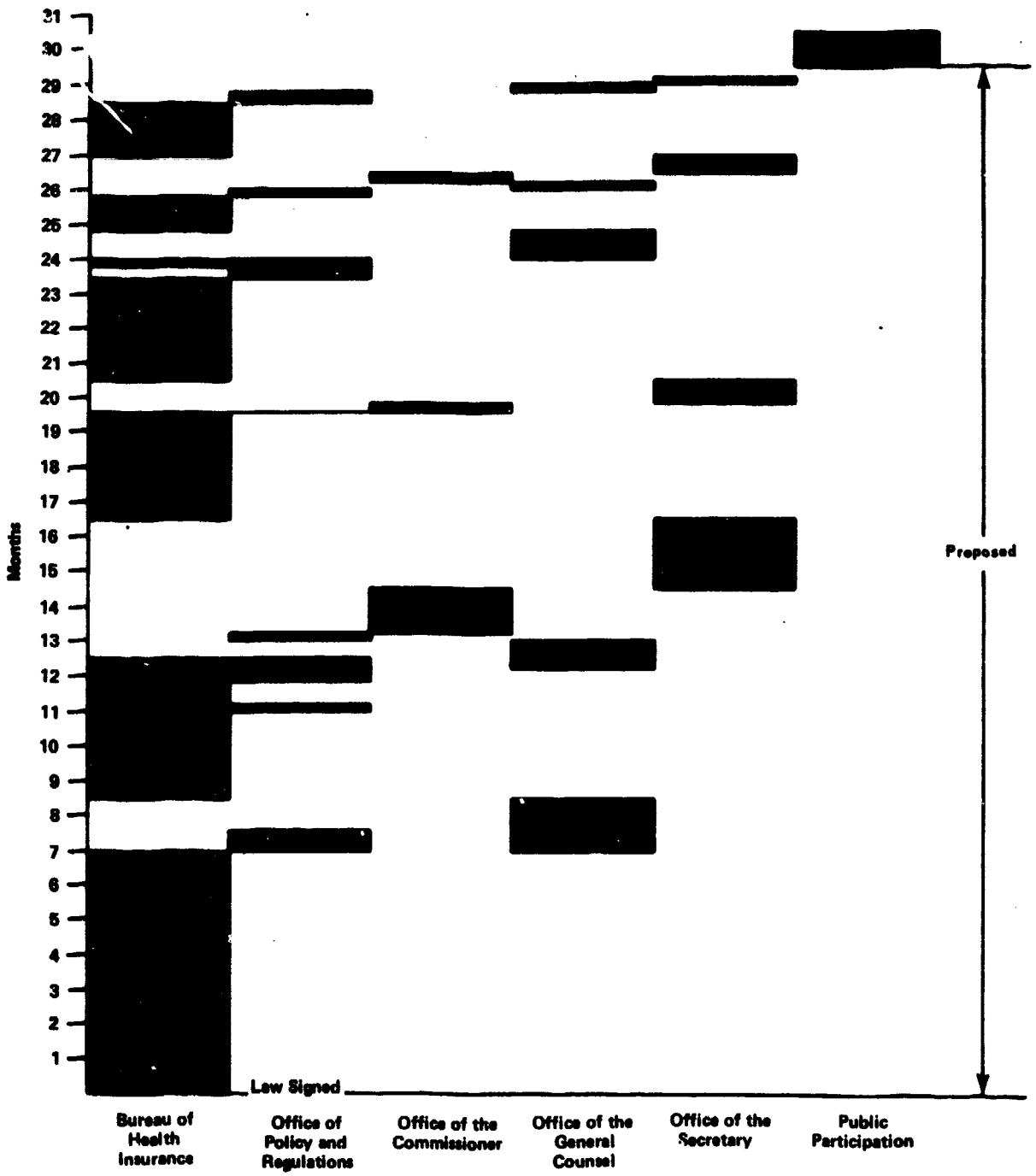
On October 30, 1972, the Social Security Amendments of 1972 (Public Law 92-603) were approved. Section 224(a) amended section 1842 (b)(3) of the Social Security Act (42 U.S.C. 1395u) by adding limits to Federal financial participation under Medicare. Economic index provisions under section 224(a) limit increases in prevailing physician charges to increases justified by economic changes.

A proposed regulation was published in the Federal Register on April 14, 1975. The final regulation was published on June 16, 1975.

The chart on the following page indicates the approximate periods for developing and processing the proposed

APPENDIX XIII

BUREAU OF HEALTH INSURANCE AMENDMENTS TO IMPLEMENT THE ECONOMIC INDEX PROVISIONS OF SECTION 224(a) OF P.L. 92-603



regulation. Shading for two or more levels during the same period indicates interaction between these levels.

SIGNIFICANT POLICY ISSUES NOT RESOLVED

Publication of the proposed regulation was delayed for about 8 months because policy issues relating to the nature and structure of the index were not resolved.

Policy issues and proposed alternatives were addressed by the Bureau of Health Insurance in November 1972, prior to development of the proposed regulation. Bureau reports noted that efforts to resolve the issues continued while the proposed regulation was being developed.

The proposed regulation, forwarded to the Secretary for approval on January 16, 1974, was returned to the Bureau on March 8, 1974, because the policy issues relating to the nature and structure of the index had not been resolved. It was only then that the Bureau began to prepare a memorandum describing each issue and the alternative solutions.

On June 20, 1974, a revised proposed regulation describing the economic index provisions in general terms was forwarded to the Secretary for approval. On July 12, 1974, the Secretary again returned the proposed regulation to the Bureau because the policy issues had not been resolved. The Bureau then forwarded a memorandum on August 27, 1974, describing the issues and alternatives to the Secretary for decision. The Secretary made his decisions within 2 weeks.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Social Security Division of the Office of the General Counsel formally reviewed and commented on five drafts of the proposed regulation. The Counsel took over 6 weeks to review and comment on the initial draft. The average turnaround time for the other four drafts was about 2 weeks. The Counsel concurred with the final draft of the proposed regulation in 4 days.

The 6-week delay can be attributed to only one attorney within the Social Security Division of the Counsel assigned responsibility for reviewing all regulations developed by the Bureau of Health Insurance to implement the Social Security Amendments of 1972.

APPENDIX XIII

EXTENDED DELAYS IN DEVELOPING THE REGULATION

Besides the 6-week delay in the Office of the General Counsel, the Bureau of Health Insurance took 7 months to develop its initial draft of the proposed regulation. The Bureau took another 14 weeks to redraft the proposed regulation based on comments by Social Security Administration staff offices and the General Counsel. Redrafting was delayed due to higher priorities within the Bureau.

On three occasions the Secretary returned the proposed regulation to the Bureau. The document remained there for a total of about 7 months while policy issues were being resolved and revisions made. In addition, the Office of Policy and Regulations took a total of about 2 months to review 10 drafts of the proposed regulation.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

A schedule for developing, preparing, and coordinating the proposed and final regulations was established within the Office of the Commissioner. Milestones within specified time limits were also identified. However, the schedule and milestones were continually revised as delays were encountered.

In addition, the schedule and milestones for development were not applicable to the Bureau of Health Insurance. Development of the proposed and final regulations took about 32 months instead of the average 33 weeks. The Commissioner's regulatory staff office did not monitor development of the regulations within the Bureau and lacked the authority to take effective measures, when necessary, to avoid delays in promulgating the final regulation.

PROCESSING TIME LIMITS NOT MET

A draft of the proposed regulation was forwarded to the Commissioner for approval on December 4, 1973. The draft remained in the Office of the Commissioner for about 6 weeks, as opposed to the established 2 weeks. The reason for the delay was that a timely agreement could not be reached on a resolution to be forwarded with the proposed regulation.

A draft of the proposed regulation remained in the Office of the Secretary for over 7 weeks. This delay was due primarily to 39 days allowed Secretary staff offices for review and comment.

APPENDIX XIV

CASE STUDY

REGULATIONS TO DISALLOW COSTS RELATED TO CERTAIN CAPITAL EXPENDITURES FOR HEALTH FACILITIES

Legal Citation: Title 20--Employees' Benefits

Chapter III--Social Security Administration

Department of Health, Education, and Welfare

Part 405--Federal Health Insurance for the Aged and Disabled (1965__)

Nonallowable Costs Related to Certain Capital Expenditures, Provider Appeals Concerning Classifications for, Exceptions to, and Exemptions From Cost Limits

August 4, 1975

On October 30, 1972, the Social Security Amendments of 1972 (Public Law 92-603) were approved. Section 221(a) added section 1122 to Title XI of the Social Security Act (42 U.S.C. 1301). Under this section, designated planning agencies within the states must review proposed capital expenditures to determine their consistency with State or local health facility plans. The Secretary is authorized to exclude amounts from reimbursement for depreciation, interest, return on equity, and other costs related to capital expenditures which were not submitted to the designated planning agency for review, or which were determined to be inconsistent with health facility planning requirements.

A proposed regulation was published in the Federal Register on January 3, 1975. The final regulation was published on August 4, 1975.

APPENDIX XIV

The chart on the following page indicates the approximate periods for developing and processing the proposed and final regulations. Shading for two or more levels during the same period indicates interaction between these levels.

SIGNIFICANT POLICY ISSUE NOT RESOLVED

The Social Security Administration assumed lead responsibility for developing this regulation prior to enactment of the enabling legislation. The Bureau of Health Insurance proceeded with development of the proposed regulation assuming that the Social Security Administration would be delegated the authority to implement section 221(a).

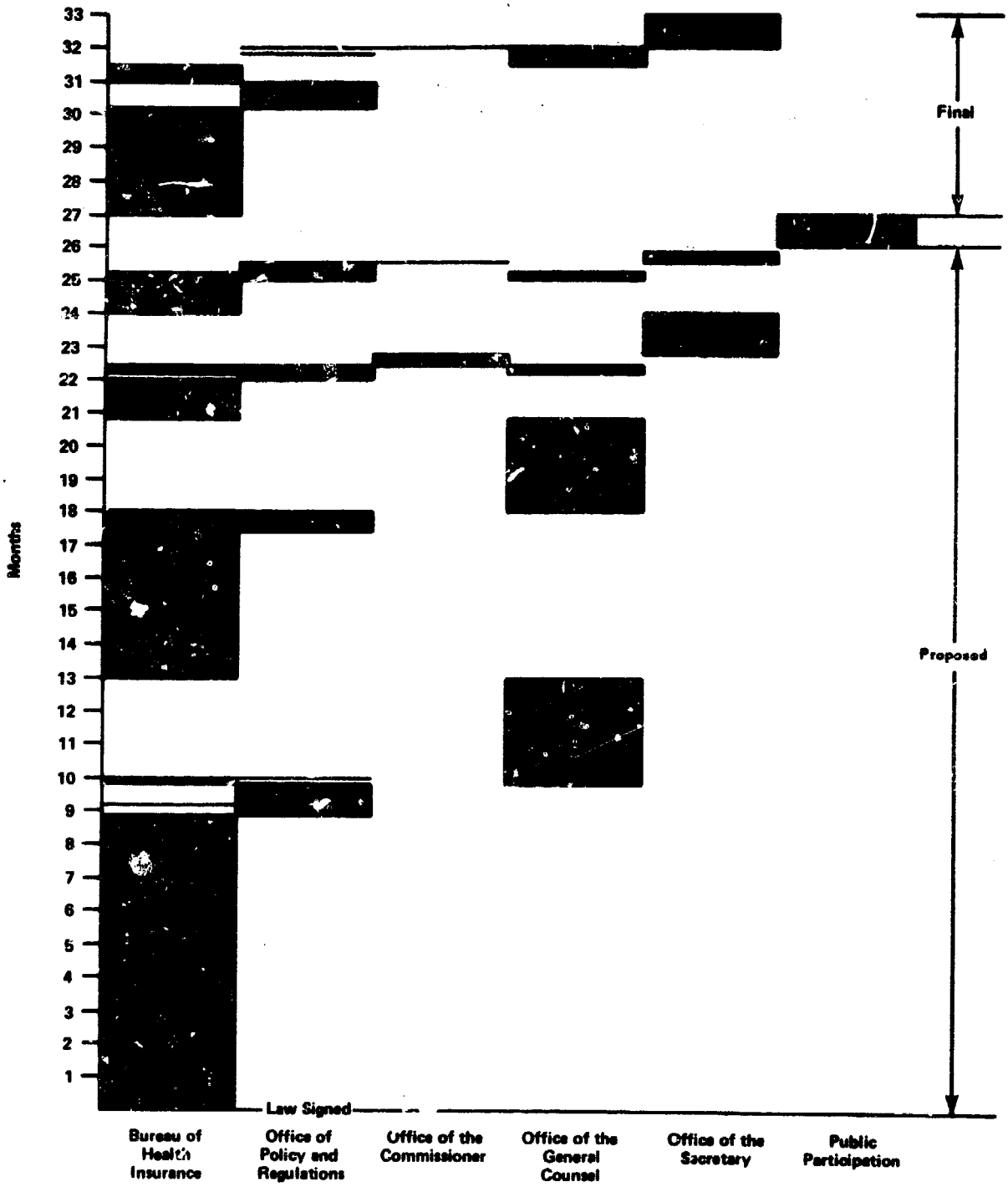
On April 25, 1973, the Assistant Secretary for Health requested an Under Secretary's decision on which HEW agency--the Public Health Service or the Social Security Administration--should have responsibility for managing the section 221(a) provisions. On May 10, 1973, the Under Secretary delegated responsibility for managing section 221(a) to the Public Health Service. The Bureau of Health Insurance then ceased its efforts to develop a model State agreement and to delegate authority to the Social Security Administration. Since responsibility for managing section 221(a) was not delegated until over 6 months after enactment of enabling legislation, valuable time and efforts were wasted.

The Bureau of Health Insurance continued its effort to develop an implementing regulation for the Social Security Administration. An initial draft of the proposed regulation was forwarded to the Office of the Commissioner for approval on July 23, 1973. The proposed regulation was returned to the Bureau over 4 months later to be revised to conform to the final regulation published by the Public Health Service on November 13, 1973. Since the proposed regulation was extensively revised to conform to the Public Health Service's final regulation, much of the Bureau's time and efforts to develop the initial draft were wasted.

OFFICE OF THE GENERAL COUNSEL RESPONSIBILITIES

The Social Security Division of the Office of the General Counsel reviewed and commented on four drafts of the proposed regulation. The Counsel did not concur with the initial draft because it did not conform to the Public Health Service final regulation. The Social Security Administration forwarded a revised draft to the Counsel on April 30, 1974.

**BUREAU OF HEALTH INSURANCE
NONALLOWABLE COSTS RELATED TO CERTAIN
CAPITAL EXPENDITURES UNDER SECTION 221(a)
OF P.L. 92-603**



The Counsel took almost 3 months for review and comment. They were primarily concerned with the effective date of the regulation and its retroactive effect. The Counsel took only 4 days to review and comment on a third draft incorporating its previous comments, and 4 days to concur with a draft forwarded to the Secretary for approval. The Counsel also concurred with the final draft of the proposed regulation in 4 days.

The Counsel reviewed, commented on, and concurred with drafts of the final regulation in less than 2 weeks.

EXTENDED DELAYS IN DEVELOPING THE REGULATION

The Bureau of Health Insurance took almost 9 months to develop the initial draft of the proposed regulation which was subsequently returned by the Office of the General Counsel. The Bureau took an additional 20 weeks to redraft the proposed regulation to conform to the Public Health Service final regulation.

The Bureau took over 5 weeks to revise the proposed regulation based on Office of the General Counsel comments and another 5 weeks to revise the proposed regulation based on Office of the Secretary comments.

The Bureau took an additional 3 months to incorporate public comments and suggestions on the proposed regulation, some of which expressed full agreement. The Office of Policy and Regulations took a total of 2 months to review 10 drafts of the proposed regulation.

MONITORING DEVELOPMENT OF THE REGULATION WAS LIMITED

A schedule for developing, preparing, and coordinating the proposed and final regulations was established within the Office of the Commissioner. Milestones within specific time limits were also identified. However, the schedule and milestones were continually revised as delays were encountered.

In addition, the schedule and milestones for development are not applicable to the Bureau of Health Insurance.

APPENDIX XIV

Development of the proposed and final regulations took about 33 months instead of the average 33 weeks. The Commissioner's regulatory staff office did not monitor development of the regulations within the Bureau and lacked the authority to take effective measures, when necessary, to avoid delays in promulgating the final regulation.

PROCESSING TIME LIMITS NOT MET

The proposed regulation, forwarded to the Secretary for approval on September 23, 1974, was returned to the Bureau for revision on November 1, 1974. The reason for this delay was that the Social and Rehabilitation Service failed to respond to the request for review and comment until almost 3 weeks after the due date.