STREAMLINING REGULATIONS DEVELOPMENT

IN THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

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Office of Inspector General

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This Report

Entitled "Streamlining Regulations Development in the Department of Health and Human Services," this report was conducted to examine rulemaking in HHS and describe best practices to help streamline the process.

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EXECUTIVE SUMMARY

Purpose: The purposes of this inspection were to examine the regulations development process in the Department of Health and Human Services (HHS), identify factors found to cause delays and describe best practices to help streamline the process.

Background: Federal agencies develop regulations to implement provisions of newly-enacted legislation and to establish or change program policies within existing legislative authority. The development of Federal regulations is governed by Federal laws and Executive Orders designed to allow public participation in the rulemaking process and control Federal paperwork burdens imposed on the public.

The HHS generally publishes two types of regulations in the Federal Register (FR).

- Notices of Proposed Rulemaking (NPRMs) let the public know that a regulatory change is being considered and allows time for public comment.
- Final Rules are prepared after consideration of public comments. Once published in the FR, final rules have the force of law.

There are three key players in the HHS rulemaking process.

- Operating Divisions (OPDIVs) develop program policies and write most rules. Staff Divisions (STAFFDIVs) in the Office of the Secretary (OS) also write some rules.
- The OS Executive Secretariat (ES) manages the review and clearance of proposed and final rules within OS STAFFDIVs and with other HHS program components.
- The Executive Office of Management and Budget (EOMB) reviews all rules before publication.

The development of regulations is a complex process which seldom runs smoothly. Every step can be time consuming. The process is meant to insure that all comments and any nonconcurrences will be resolved before FR publication. In addition, external events such as new legislation or court decisions can cause a draft rule to be withdrawn or revised and the entire process to be started again.

Some laws contain implementation deadlines. Rules written pursuant to these laws must be published by the statutory deadlines. For laws without deadlines, and for regulations initiated within existing legislative authority, OPDIVs establish the dates by which NPRMs and final rules will be published.

This inspection was conducted in response to concerns that some regulations may have taken an unreasonably long time to develop and publish. It consisted primarily of interviews with regulations staffs in the Health Care Financing Administration, the Social Security Administration and the Family Support Administration. Discussions were also held with OS/ES policy coordinators, selected OS STAFFDIV representatives and the EOMB. We also reviewed the systems used by OPDIVs and OS/ES to track regulations.

Findings:

- The rulemaking process is designed to insure that relevant legal, policy and program issues will be addressed and that final rules will be well-reasoned documents which can withstand public scrutiny. Although the process is complicated and many players are involved, all major steps and decision points are necessary and reasonable.

- While all OPDIVs reviewed follow the same basic steps in developing regulations, each has adapted the process to meet its own program and organizational requirements.

- Despite tight timeframes and often complicated issues, the OPDIVs reviewed meet virtually all budget deadlines for publication. Target dates for other high priority regulations are sometimes missed, however.

- Program priority changes and the complexity of issues covered were identified as the most common reasons for extending the time required to publish a regulation. Awaiting outcomes of pending legislation or court decisions, impact on multiple programs and a high volume of public comment were also cited as adding time to the process.

- Moreover, external pressures from advocacy groups and industry organizations, as well as media coverage prior to publication of proposed and final rules, have had a profound impact on rulemaking.

- The OS/ES has established an automated tracking system designed to monitor the rulemaking process and insure that established schedules are followed.

Recommendations

The OS/ES should:

- develop a systematic process to identify and begin tracking high priority regulations as soon as new legislation is passed; and

- establish a mechanism to systematically seek early involvement of affected components, both OPDIVs and STAFFDIVs, in issue identification and development of high priority regulations.

The OPDIVs should:

- hold their top managers accountable for timely regulations development by incorporating elements on timeliness in their merit pay plans; and

- take steps to reduce internal issue resolution and draft review times.

INTRODUCTION

Federal agencies develop regulations to implement provisions of newly-enacted legislation and to establish or change program policies within existing legislative authority.

The development of Federal regulations is governed by Federal laws and Executive Orders designed to allow public participation in the rulemaking process and control Federal paperwork burdens imposed on the public. A description of applicable laws and executive orders appears at Appendix A.

The Department of Health and Human Services (HHS) issues three types of regulations:

- Notice of Proposed Rulemaking (NPRM) -- announces to the public that regulatory change is being considered. Published in the Federal Register (FR), the NPRM describes the proposed changes and allows time for public comment.

- Final Rule -- developed after consideration of public comments. Once published in the FR, a final rule has the force of law.

- Interim Final Rule/Final Rule with Comment -- used in rare instances to go directly to a final rule. This technique is most often used when a new law requires regulatory action within a short time or where the agency has little or no policy discretion in developing the rule. If significant comments are received in response to the Interim Final Rule, the agency generally publishes a final rule that addresses the issues raised.

Regulations are written and cleared by the OPDIV and reviewed by OS STAFFDIVs and affected OPDIVs in a process managed by the OS/ES. After the initiating OPDIV makes revisions in response to these reviews, OS/ES reclears the rule, obtains Secretarial approval and submits the package to EOMB. Following EOMB review, NPRMs are published in the FR. After a public comment period, the OPDIV considers all comments and develops a final rule, making any revisions necessitated by those comments. The final rule must be reviewed again by OS/ES and EOMB before being published as a final rule.

The development of regulations is a complex process which seldom runs smoothly. Every step can be time consuming. Comments and nonconcurrences should be resolved before FR publication. In addition, external events such as new legislation or court decisions can cause a draft regulation to be withdrawn or revised and the entire process to be started again.

Some pieces of legislation contain implementation deadlines. Rules promulgated pursuant to these laws should be published and take effect by the statutory deadlines. For laws with no deadlines, and for regulations initiated within existing legislative authority, OPDIVs establish dates by which proposed and final rules will be published. Projected dates are published in two documents:

- Regulatory Program of the United States Government -- published annually by EOMB, it contains all planned regulations considered significant by all Federal agencies for a 1-year period, April 1 through March 31.

- HHS Semiannual Regulatory Agenda -- published in the FR in April and October of each year, it contains all regulations under development in HHS.

These documents are prepared at different times of the year. Due to changes in program priorities, unforeseen problems or other factors, projected publication dates for a particular rule may differ from one document to another. In the past, some regulations have taken far longer to publish than originally estimated.

This inspection was conducted in response to concerns that some regulations may have taken an unreasonably long time to develop and publish. Its purposes were to examine the regulations development process within HHS, identify factors found to cause delays and describe best practices to help streamline the process.

We selected three OPDIVs for inclusion in the inspection: the Health Care Financing Administration (HCFA), the Social Security Administration (SSA) and the Family Support Administration (FSA). These OPDIVs vary significantly in the type and volume of regulations for which they are responsible. The inspection consisted primarily of discussions with OPDIV regulations staffs, OS/ES policy coordinators, selected STAFFDIV representatives and the EOMB. We also reviewed the systems used by OPDIVs and OS/ES to track regulations through the development process.

FINDINGS

HOW ARE REGULATIONS DEVELOPED?

ALL OPDIVs FOLLOW THE SAME BASIC STEPS.

All HHS regulations are developed following the same basic steps. This chart highlights what are generally the major steps in the HHS rulemaking process.

REGULATIONS DEVELOPMENT PROCESS

ACTION STEP	RESPONSIBLE COMPONENT
1. Decision on need for rulemaking	OPDIV
2. Develop specifications, draft rule	OPDIV
3. Internal OPDIV and their GC clearances	OPDIV
4. OPDIV head approval, submit to OS/ES	OPDIV
5. STAFFDIV/OPDIV clearances, comments conveyed to OPDIV	OS/ES
6. Revise draft rule, resubmit to OS/ES for reclearance	OPDIV
7. Secretarial approval, submit to EOMB	OS/ES
8. EOMB review	EOMB
9. Revised draft rule	OPDIV
10. STAFFDIV/OPDIV clearance, submit revision to EOMB	OS/ES
11. EOMB final review	EOMB
12. Refer to Office of the Federal Register (OFR) for publication	OS/ES
13. FR publication (3 days after receipt)	OFR
14. Public comment period (usually 60 days)	
15. Consider all comments, revise rule	OPDIV
16. Repeat steps 3-13 for final rulemaking	

EACH OPDIV HAS ADAPTED THE PROCESS TO ITS OWN REQUIREMENTS.

We reviewed the regulations development process in HCFA, SSA and FSA. These OPDIVs differ in the type and volume of regulations for which they are responsible. The HCFA has approximately 150 rules in some stage of development at any given time, as compared with 75 for SSA and 30 for FSA. Well over half of HCFA's rules must be published by a specified statutory or budget deadline. In contrast, few if any SSA or FSA rules have external publication deadlines.

As described below, each OPDIV has adapted the process to meet its own program and organizational requirements.

Health Care Financing Administration

The HCFA has divided responsibility for regulations development between two offices: the Office of Regulations Management (ORM) in the Office of Executive Operations and the Regulations Staff (RS) located in the Bureau of Eligibility, Reimbursement and Coverage. The ORM manages the HCFA regulations process, including internal clearances, and is the official liaison with OS/ES for all matters relating to regulations development. The RS writes all rules based on regulation specifications from the responsible Bureau or Office and maintains the official regulations files.

The ORM coordinates the establishment of publication target dates for all rules, while ORM and RS develop work schedules with the responsible Bureau or Office to meet the publication target dates. Both offices maintain automated tracking systems capable of providing the status of all pending regulations instantaneously. These systems produce bi-weekly status reports for top HCFA management as well as a variety of other weekly and monthly reports covering every facet of HCFA regulations.

Social Security Administration

The Division of Regulations within the Office of the Deputy Commissioner for Policy and External Affairs serves as the focal point for all SSA regulations activity. While specifications are developed by substantive components, the Division actually writes NPRMs and final regulations, manages the clearance process, serves as SSA's liaison with OS/ES and prepares regulations for publication.

In consultation with the affected substantive components, the Division develops workplans which include a schedule for completing each step in the development of a regulation. An automated tracking system enables it to provide monthly reports to the Commissioner and Deputy Commissioner and bi-weekly reports to affected SSA components on status of regulations. In addition, bi-weekly meetings are held with

the SSA Office of General Counsel (OGC) to discuss all regulations pending in OGC.

Family Support Administration

The FSA does not have a separate office to coordinate its regulations activity. Each program component develops policy specifications, drafts its own rules and establishes its own target dates. The FSA Executive Secretariat (ES) coordinates clearances from other FSA components and the OGC, obtains the Administrator's signature and submits the approved package to OS/ES.

The FSA/ES has not found it necessary to establish a separate system to track regulations development within FSA. In fact, it generally does not become involved with an individual regulation until it receives the proposed draft from the responsible component.

While there is no regular schedule for regulations status reports, FSA/ES does provide reports to FSA management officials as needed and when significant events occur. In the past, such status reports have been issued at approximately 4 to 6 week intervals.

WHILE THE PROCESS CAN BE CUMBERSOME, ALL STEPS ARE NEEDED.

The current rulemaking process is designed to insure that all relevant legal, policy and programmatic issues will be addressed, that the public will have an opportunity for input, and that final rules will be well-crafted, high quality products which can withstand close public scrutiny. While the process is complicated and many players are involved, respondents believe strongly that all major steps and decision points are necessary and reasonable.

HOW LONG DO REGULATIONS ACTUALLY TAKE?

OPDIV PROCESSING TIMES ARE DIFFICULT TO MEASURE.

We asked OPDIVs to estimate the length of time usually taken internally to develop a typical draft rule before submission to OS/ES for review. The OPDIVs indicated that there are no typical rules. Instead, they feel that each rule is unique. Even a rule which all initially agree should be simple and straightforward can run into problems or complications which extend the time needed for development. For this reason, they saw little value in computing average times spent on each step.

The OPDIVs reviewed do not track regulations from the same starting point. The HCFA and the SSA begin tracking when the internal decision is made that a regulation is needed. The

FSA/ES begins tracking when it receives the draft regulation from the substantive component which prepared the draft.

Concerned about the length of time taken to publish some regulations, the OS/ES established an automated tracking system in late 1987. The system is designed to monitor progress on individual regulations as well as identify problems so that necessary corrective action may be taken.

The OPDIVs set publication target dates for regulations without statutory deadlines. These decisions are reviewed and approved by the Department through review mechanisms established for the Regulatory Program and the Unified Agenda. The OS/ES system begins tracking the regulation when agreement is reached to include a rule in one of these publications. The system has no mechanism for determining the rule's stage of development before that point.

If an OPDIV takes longer to draft a rule than originally planned, the clearance time available once the rule reaches OS/ES is reduced. Thus, OPDIVs and STAFFDIVs may be asked to review a complex draft rule which took months or years to develop in less than a week. This situation could be alleviated somewhat if the OS/ES identified and began tracking high priority rules as soon as new legislation is passed. Such a practice could also assist OPDIVs in prioritizing and planning their regulations workloads.

REVIEW TIMES HAVE REMAINED CONSTANT

In December 1987, OS/ES analyzed the times involved in the clearance and revision phases of 101 HHS regulations published during the previous 6 months. Of these, 38 were HCFA rules, 17 were SSA and 9 were published by FSA.

The OS/ES review found that OPDIVs took longer than STAFFDIVs to clear other OPDIV rules. During the 6 months studied, HCFA reviewed 9 rules averaging 24 days each. Both SSA and FSA reviewed one rule taking 11 days and 10 days, respectively, to comment. Most STAFFDIVs reviewed more rules in less time. Six STAFFDIVs with the highest volume of requests to review rules completed their reviews in times averaging 4.1 to 6.5 days for each rule. The number of rules reviewed by these STAFFDIVs ranged from 26 to 48.

Recently, OS/ES updated its figures on clearance times for the period January through March 1988. All three OPDIVs interviewed during the inspection reduced the average time taken to review and clear other OPDIV rules. The HCFA showed the most dramatic improvement, reviewing 8 draft rules in an average of 11 days each. The FSA reviewed 4 rules, averaging 5 days each, while SSA reviewed 8 rules, reducing its average to 9 days each. Average STAFFDIV review times remained constant or increased during this review period. Thus,

despite some fluctuation in individual component review times, the overall average for all components has remained relatively constant at less that 8 days for each regulation. See Appendix B for additional detail.

One reason for longer OPDIV review times is that the OPDIV process often requires review by several different components to determine a rule's impact on their programs. Once completed, the comments must be distilled into a single response. This can be a time consuming process.

REVISION TIMES VARY SLIGHTLY

The OS/ES review also included the time taken for OPDIVs to revise rules after STAFFDIV/OPDIV review. The results for HCFA, SSA and FSA indicate an average of 23 to 29 days to complete this step of the process. Appendix C provides additional detail on this portion of the OS/ES review.

EOMB REVIEW TIME HAS INCREASED

Once approved within HHS, proposed draft and final rules are reviewed by EOMB. Appendix D shows average EOMB review times, by OPDIV, for HHS rules published between June 1987 and March 1988. The EOMB reviewed 42 HCFA rules, 14 SSA rules and 11 FSA rules, with review times averaging 44 to 49 days for each rule.

The EOMB has collected data on the average time taken to review HHS rules between 1981 and 1986. In 1981, the EOMB reviewed 117 rules, averaging 7 days per rule. In 1986, a total of 281 rules were reviewed, with an average review time of 36 days per rule.

Executive Order 12291 requires agencies to allow 60 and 30 days respectively for EOMB review of NPRMs and final versions of major rules. (A major rule is one which is expected to cost over $100 million annually, or is projected to have significant effects on employment, inflation or business competition.) Non-major rules (both NPRMs and finals) must be submitted to EOMB at least 10 days prior to publication.

The EOMB reviews major rules more quickly than non-major rules. In 1986, 15 of the 281 rules reviewed were major. The EOMB average of 19 days per rule was well within the 30 and 60 day guidelines. For the 266 non-major rules, however, EOMB exceeded the 10 day guideline, averaging 37 days review time for each rule. See Appendix E for additional detail.

WHY DO SOME REGULATIONS TAKE SO LONG TO PUBLISH?

MANY FACTORS CAN EXTEND REGULATION DEVELOPMENT TIME

We asked respondents why some regulations take longer to publish than originally planned. The factors mentioned, external as well as internal, are presented below.

- Changes in Priority -- Every OPDIV has more rules than it can work on at one time. Those with higher priority are developed before low priority rules. It is not unusual for a rule to change in priority at some point during its development. When this occurs, workload shifts can result in some rules being delayed.

- Complex or Difficult Issues -- Some rules deal with extremely complex issues involving divergent policy positions. In deciding how to proceed, all competing interests and opinions must be considered and resolved. This process may involve high level discussions dealing with Federal fiscal policy and the role of the Federal Government vis-a-vis State and local governments. While resolution of such issues can be time-consuming, they must be addressed before a regulation is approved.

- Pending Legislation or Court Decision -- Work on a rule can be held up when legislation or a court decision is pending on a related topic. An SSA regulation was put on hold for nearly a year while a related issue was being considered in the U.S. Supreme Court. The revised regulation is currently under development.

- Impact on Multiple Programs -- When multiple programs affect the same population, care must be taken to insure consistency between program requirements. For example, an SSA regulation affecting the Supplemental Security Income (SSI) program may also affect the Medicaid program administered by HCFA. Coordination between OPDIVs during rule development is a necessary step which may, due to different program requirements or competing workload demands, extend the time needed to draft proposed rules.

- High Volume of Public Comments -- The sheer volume of comments received in response to an NPRM can add time to the revision process. One NPRM published by HCFA generated some 36,000 comments, all of which had to be reviewed and addressed in developing the final rule.

- External Pressures -- Advocacy groups, industry organizations, and media coverage have had an impact on the rulemaking process, sometimes resulting in delays or alterations to final rules.

CASE STUDIES ILLUSTRATE THE COMPLEXITY OF RULEMAKING

We reviewed six individual regulations -- two from each OPDIV in the inspection -- to get a clearer sense of how long rulemaking actually takes and why delays occur. Two high priority rules (one of which had a legal deadline) met their publication target dates. As highlighted below, the remainder encountered a variety of situations which resulted in substantial delays.

- FY 1988 PPS Update -- This high priority rule updating Medicare hospital payment rates was developed and published in just 9 months, meeting the legal deadline imposed by Congress. The HCFA's past experience and familiarity with the need for annual updates, as well as OS/ES' commitment to quick OS review and comment resolution, may have contributed to the rule's timely development.

- Payments to Institutions -- Originally an agency priority, this rule's status changed several times before publication. It was delayed by an inconsistency with another regulation, consideration of various policy options and the identification of a paperwork burden. Nearly 4 years elapsed between publication of the NPRM and final regulations, due to these and other minor factors.

- Consultative Examinations -- The legal deadline for this regulation was April 1985. However, a congressional hearing, changes in paperwork burden decisions and an unresolved payment issue delayed NPRM publication 2 years until April 1987. The final has not yet been published.

- Multiple Impairments -- This rule was first published as an interim final in March 1985. Public comments necessitated development of a new draft. A pending Supreme Court decision put the rule on hold for a year and the final rule is yet to be published.

- Essential Persons -- This agency priority rule was published as an NPRM 15 months after work began. The final will clarify the definition of family members eligible for AFDC benefits under the Essential Persons provision. At the time of our study, FSA was awaiting administrative decisions on appropriate responses to the public comments received.

- COBRA ADP -- This low priority rule was delayed twice by discussions over its necessity and effectiveness before finally being withdrawn entirely.

See Appendix F for detailed descriptions of these cases.

DO REGULATIONS TAKE TOO LONG?

BUDGET RULES ARE PUBLISHED ON TIME

While all respondents agreed that some regulations have taken far longer to publish than originally estimated, they also pointed out that they usually meet publication deadlines for budget regulations. This is true even when there are serious disagreements or complex issues to resolve.

Budget regulations are considered to be the highest priority. It is not unusual for work on other rules to be set aside temporarily to insure that budget publication deadlines will be met. Data from OS/ES confirm that publication deadlines for budget regulations are met in virtually all cases.

OTHER SIGNIFICANT RULES ARE SOMETIMES DELAYED

Publication deadlines for other significant regulations are sometimes missed. In March 1988, the OS/ES reviewed the status of HHS commitments to publish 128 significant regulations included in the 1987 Regulatory Program of the United States Government. As shown in Appendix G, 37 percent had been published, 30 percent were not yet due, and 33 percent were overdue. About one-third of the overdue regulations were delayed for reasons beyond the Department's control. The remaining two-thirds, or about 20 percent of the total, are considered by OS/ES to be overdue, as there were no identifiable external impediments which caused deadlines to be missed.

LOWER PRIORITY RULES OFTEN TAKE LONGER TO PUBLISH.

The OPDIV representatives interviewed indicated that they often miss target dates, even for regulations initially considered to be relatively uncomplicated and straightforward. This is true even in those instances where the OPDIV establishes its own preliminary work schedule and target dates. Since this appears to occur frequently, it is possible that for these rules at least, the OPDIVs are underestimating the time and work required and setting unrealistic target dates.

All respondents were aware of regulations that had taken several years to publish. In general, however, most felt that with limited staff resources, management must prioritize the regulations workload, and accept the fact that lower priority rules will take longer to publish than high priority rules. They agreed that extended development times for lower priority rules should not pose major problems for the Department. Through periodic reviews of those rules under development, the OPDIV or OS can reassess its regulations workload and reprioritize as necessary.

HOW CAN THE PROCESS BE STREAMLINED?

While respondents indicated that the current rulemaking process is generally sound, all agreed that it can be improved. We received suggestions for streamlining the process from every respondent interviewed. Suggestions fell into four areas: early identification of priority regulations, early involvement by affected components, increased management accountability and reduced issue resolution and draft review times.

IDENTIFY PRIORITY REGULATIONS EARLY

The sheer volume of regulations developed by HHS means that some will be written sooner than others. In some cases, the OS/ES, with OPDIV and STAFFDIV input, identifies regulations which are high priority to the Department. Before the responsible OPDIV begins development, OS/ES convenes meetings to identify issues and agree on general direction and approach. Respondents suggested that this be done systematically, rather than on the current ad hoc basis. The identification of high priority regulations as soon as legislation is passed could streamline development of these rules.

The same approach can be used within each OPDIV, at the Administrator or Commissioner level, to identify priority regulations. One OPDIV reviewed is successfully using this approach.

Priorities are reevaluated during the development of HHS submissions to the annual Regulatory Program and the semiannual HHS Unified Agenda. Some respondents suggested that this reevaluation take place more often, to facilitate quick response to internal and external factors which may necessitate a change in priorities.

INVOLVE AFFECTED COMPONENTS EARLY IN DEVELOPMENT

Several respondents suggested that early STAFFDIV and affected OPDIV involvement could streamline the process, especially for controversial, high priority or crosscutting regulations which impact on more than one program or component. They cautioned, however, that a careful balance must be maintained between early involvement and the OPDIV's authority to develop its own regulations independently.

One OPDIV reported it seeks OGC input throughout the process to minimize problems relating to legal sufficiency. Two OPDIVs with related program responsibilities have entered into an agreement to share early drafts at the staff level on rules which impact on the other's programs. This is seen as one way to identify potential program inconsistencies early

in the process. Given the success of this approach, it may be beneficial for all OPDIVs with related program responsibilities to adopt the practice of sharing early drafts for review and comment.

In addition, there are some instances when it would be helpful to have comments from OPDIVs and STAFFDIVs in the early stages of regulation development. The OS/ES is the logical unit to coordinate early involvement of this nature, possibly through a process of simultaneous review and comment before formal submission of the rule by the lead OPDIV to OS.

HOLD OPDIV MANAGEMENT ACCOUNTABLE

Along with prioritizing the regulations workload, several respondents saw a need for OPDIV heads to hold their managers accountable for timely completion of high priority rules.

One OPDIV has demonstrated top management's commitment to timely rulemaking by incorporating a timeliness element into the performance plans of senior management staff. The same OPDIV has included timely review of draft rules in OGC performance plans. The OGC review step had been identified as one where delays were likely to occur. The OGC response times improved immediately after this action was taken.

Discussions of progress on priority regulations at senior staff meetings is seen as another way to convey top management's commitment to timely rulemaking.

REDUCE INTERNAL OPDIV ISSUE RESOLUTION AND DRAFT REVIEW TIME

The OPDIV respondents identified several approaches which have been used successfully to reduce internal processing times. One OPDIV requires that an issue which cannot be resolved at the staff level within a certain period of time be elevated to the next level. This process of elevating unresolved issues continues until a decision is made.

All three OPDIVs save time by doing concurrent rather than sequential reviews. One OPDIV does this for all rules; the other two use the technique only for high priority rules which need to be published quickly. All OPDIVs felt that concurrent reviews have been effective and should continue.

Virtually all draft regulations are returned to the OPDIV for revision after the initial review. For minor technical revisions, one OPDIV saves time by delegating approval authority to senior policy officials. Substantive revisions, however, still require approval by the OPDIV head.

The OPDIVs may wish to consider these and other ways to reduce internal processing times.

RECOMMENDATIONS

The OS/ES should:

- develop a systematic process to identify and begin tracking high priority regulations as soon as new legislation is passed; and

- establish a mechanism to systematically seek early involvement of affected components, both OPDIVs and STAFFDIVs, in issue identification and development of high priority regulations.

The OPDIVs should:

- hold top managers accountable for timely regulations development by incorporating elements on timeliness in their merit pay plans; and

- take steps to reduce internal issue resolution and draft review times.

APPENDICES

	APPENDIX
LAWS AND EXECUTIVE ORDERS AFFECTING DEVELOPMENT OF FEDERAL REGULATIONS	A
AVERAGE CLEARANCE TIME (DECEMBER 1987 AND MARCH 1988)	B
REVISION OF REGULATIONS (Regulations revised 6/1/87 - 11/24/87)	C
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LAWS AND EXECUTIVE ORDERS AFFECTING DEVELOPMENT OF FEDERAL REGULATIONS

Federal Register Act of 1935 -- Established a uniform system for handling regulations, including submitting documents to the Office of the Federal Register; placing documents for public inspection; publishing documents in the Federal Register; and codifying rules in the Code of Federal Regulations.

Administrative Procedure Act of 1946 -- Gave the public the right to participate in the rulemaking process by requiring agencies to publish certain rules initially as proposals and to consider public comments; also required that the effective date for a regulation be not less than 30 days from the publication date unless there is good cause for an earlier date. Grant programs are specifically exempted from these requirements.

Paperwork Reduction Act of 1980 -- Established policies and procedures to control paperwork burdens imposed on the public by Federal agencies.

Regulatory Flexibility Act of 1980 -- Required Federal agencies to reduce the burden of government regulations and paperwork requirements on small business, small organizations and small governmental jurisdictions. In developing regulations, agencies must identify those rules which will have a significant economic impact on a substantial number of small entities.

Executive Order 12291, issued February 17, 1981 -- Established new requirements to reduce the burden of regulations, increase agency accountability for regulatory actions and insure that regulations are cost beneficial. It also strengthened the oversight role of EOMB in the regulatory process. Major provisions include:

- Agencies must determine whether a proposal meets the threshold criteria for a "major rule." A major rule is one likely to result in:
  - annual effect on the economy of $100 million or more;
  - major cost increases for consumers, industries, units of government or geographic regions; and

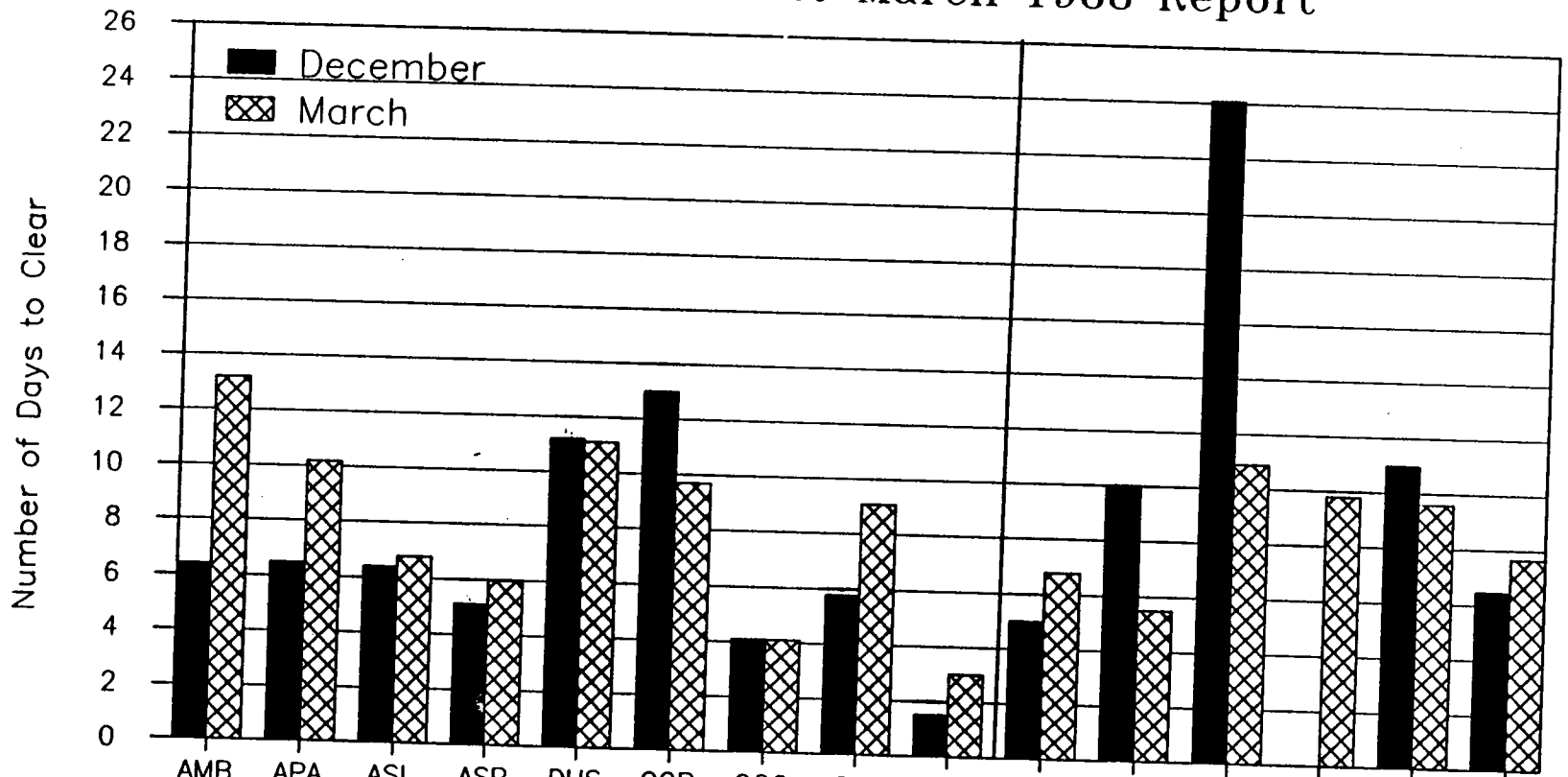
- significant adverse effects on competition, employment, investment, productivity, innovations, or the ability of U.S. businesses to compete with foreign businesses.

o All notices of proposed rulemaking (NPRMs), final rules and interim final rules must be submitted to EOMB for review.

o Each agency must publish a Semi-Annual Unified Agenda of Regulations in the Federal Register in April and October of each year. The Unified Agenda contains all rules the agency plans to work on during the next 6 months.

Executive Order 12498, issued January 4, 1985 -- Required annual publication of the Regulatory Program of the United States Government. The purpose of this publication was to improve regulatory decisionmaking and coordination within the executive branch, and to provide Congress and the public with an advance view of the most important regulatory decisions for the forthcoming year.

AVERAGE CLEARANCE TIME
Multiple Clearance Rounds Included
December 1987 to March 1988 Report



Number of Clearances	AMB	APA	ASL	ASP	DUS	OCR	OGC	OIG	PER	ASH	FSA	HCF	HDS	SSA	WGT AVERAGE
December	37	26	29	44	06	03	48	31	02	23	01	09	0	01	260
March	33	16	26	49	11	03	61	28	03	22	04	08	06	08	278

STAFFDIV REVIEW OF OPDIV RULES

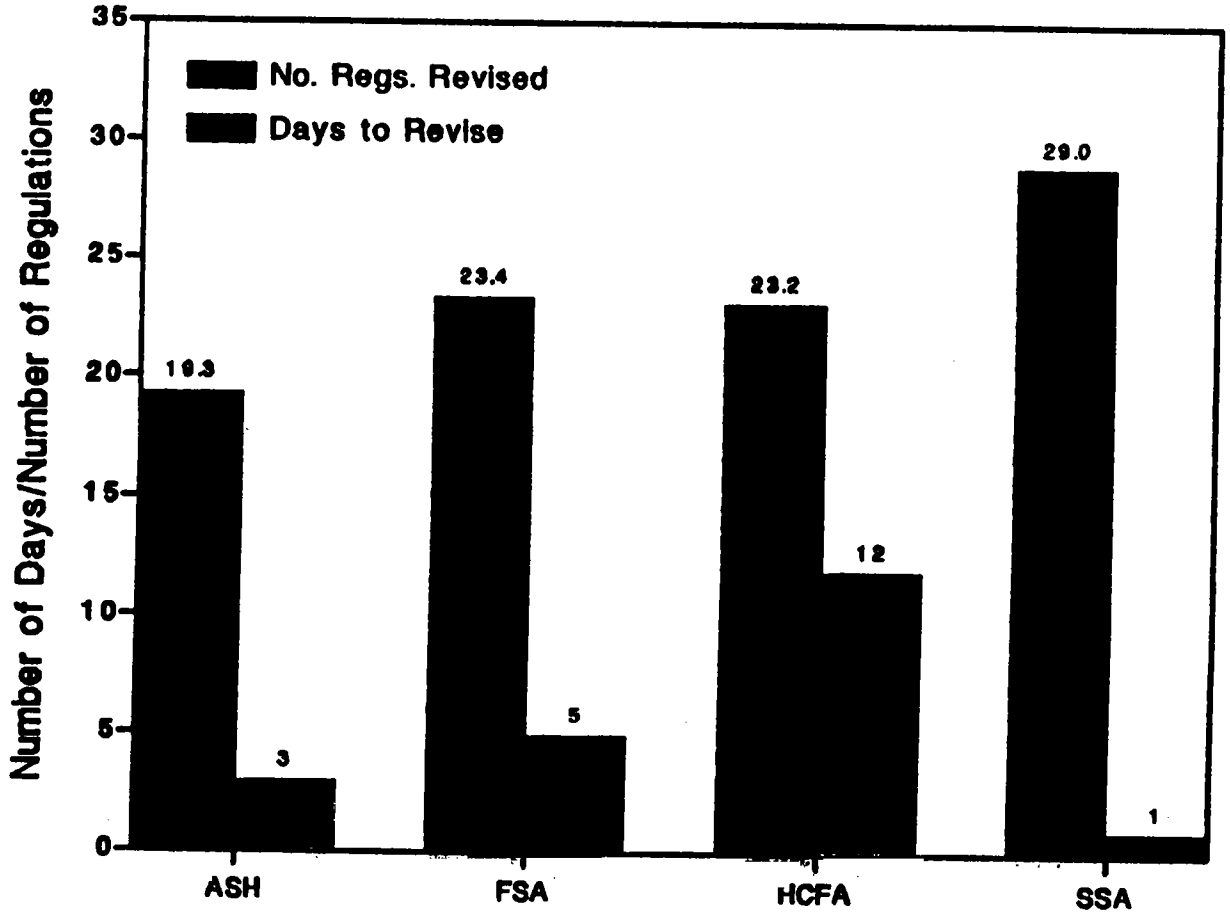
OPDIV REVIEW OF OTHER AGENCY RULES

Chart Date 3/26/88

APPENDIX B

(Chart provided by OS/ES)

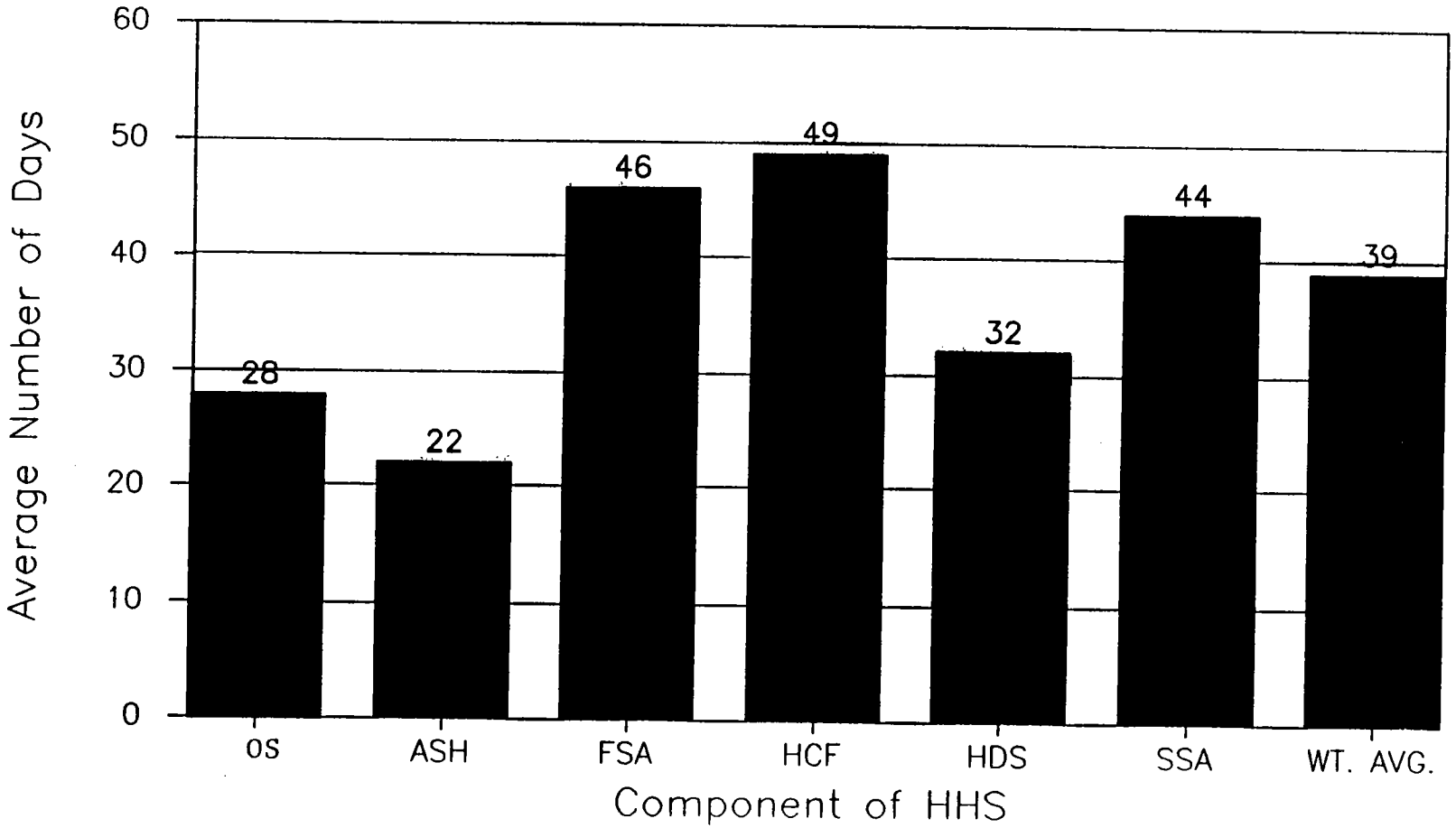
REVISION OF REGULATIONS
(Regulations Revised 6/1/87-11/24/87)



(Chart provided by OS/ES)

APPENDIX C

AVERAGE REVIEW TIME AT OMB
For Regulations Published June 1987 – March 1988



	OS	ASH	FSA	HCF	HDS	SSA	WT. AVG.
Number of Regulations	17	18	11	42	2	14	104

Chart Date: 3/26/88

APPENDIX D

(Chart provided by OS/ES)

AVERAGE EOMB REVIEW TIME FOR HHS RULES
MAJOR AND NON-MAJOR RULES

YEAR	RULES REVIEWED	AVERAGE REVIEW DAYS		
		Major	Non-Major	All
1981	117	8	7	7
1982	272	21	10	11
1983	294	35	18	19
1984	198	3	33	33
1985	212	74	46	47
1986	281	19	37	36

SOURCE: Regulatory Program of the United States Government, April 1, 1987 - March 31, 1988, Appendix 4, pages 626 and 632.

SELECTED CASE STUDIES

All respondents interviewed made a point of emphasizing that there is no such thing as an average or typical regulation. The cases presented below illustrate just how different one regulation can be from another. We selected a total of six case studies -- two from each OPDIV included in the inspection. Examples 1. and 5. are high priority rules which, although involving complex issues, were published by the legal or internally established deadline. The remaining examples illustrate a few of the many possible causes for delay.

1. Title: FY 1988 PPS UPDATE
   Legal Deadline: Implementation: Sept. 1, 1987
   NPRM: June 1, 1987
   Final Rule: Sept. 1, 1987
   NPRM Published: June 10, 1987
   Final Published: September 1, 1987
   Total Time Elapsed: 9 months
   Major Reasons for Delay: None

   Medicare legislation requires annual payment rate updates for the hospital prospective payment system (PPS). The current PPS rule established payment rates applicable for FY 1988.

   Development of this rule began in HCFA in January 1987. The proposed rule was circulated within HCFA March 2 and was cleared in less than a week. In April, the rule was submitted to OS/ES for clearance. Clearance was completed quickly and OS approval was accomplished in just over 2 weeks.

   The rule was at EOMB for nearly a month while HCFA addressed EOMB's policy options. It was published as an NPRM on June 10, 1987.

   Work on the final package began immediately. A total of 200 comments had been received when the public comment period ended August 11. All comments were considered and the final rule was circulated throughout HCFA in 24 hours. The OS and EOMB review began August 20 and was completed in a week. The final rule was published in the FR September 1, 1987.

2. Title: PAYMENTS TO INSTITUTIONS
Significance: Agency Priority
NPRM Published: March 13, 1985
Final Published: February 8, 1988
Total Time Elapsed: 5 years, 9 months
Major Reasons for Delay: Various policy options to consider, paperwork burden.

The Payments to Institutions (PTI) rule allows States to deduct non-covered medical expenses from an institutionalized Medicaid recipient's income in determining how much income to apply to the cost of institutional care. Prior regulations made such deductions mandatory. The rule also implements a provision of Public Law 99-272 which requires States using a special income standard for institutionalized individuals to begin Medicaid eligibility on the first day of a period of at least 30 consecutive days of institutionalization.

The first draft of the proposed rule was completed in May 1982 and internal clearances began in July. In August, various policy options were considered. The HCFA Administrator approved the regulation in May 1983.

The OS approval process, including comment resolution, took several months. In July 1983, two STAFFDIVs raised concerns which led to HCFA revisions. Revised cost estimates had to be developed and the entire package was recleared within HCFA. The revised rule was submitted to OS in December.

The OS comments reached HCFA in January 1984 and the regulation was revised. The rule was cleared within HCFA once again and submitted to OS in September. The Secretary approved it October 2, 1984.

The EOMB received the NPRM October 3. In its comments to HHS at the end of November, EOMB raised significant policy options. The NPRM was revised by HHS and reviewed again by EOMB before being published in the FR March 13, 1985.

The NPRM comment period ended May 20, 1985. The draft final was completed in December and HCFA circulation began in March 1986. The COBRA of 1985 necessitated development of new cost estimates and impact data.

In June 1986, in response to a request for complete reanalysis and revision from a substantive component, the package was reworked. The revised package was submitted to the HCFA Administrator in September, but identification of a paperwork burden held up final approval until December 1986.

The OS received the PTI regulation from HCFA in mid-December. In February 1987, the OS raised various policy concerns. The HCFA revised the rule and developed new cost estimates and impact data. The HCFA cleared these changes in July 1987.

The Secretary approved the final rule in November 1987. It was reviewed by EOMB and was published in the FR February 8, 1988.

3. Title: CONSULTATIVE EXAMINATIONS
Legal Authority: 1984 Disability Amendments
Legal Deadline: April 8, 1985
NPRM Published: April 20, 1987
Total Time Elapsed: 3 years, 8 months
Major Reasons for Delay: Paperwork burden*, policy issues, and major revisions following a congressional hearing.

Consultative Examinations (CEs) are medical examinations purchased from private physicians to assist in making Social Security disability determinations. The proposed rule would establish standards for determining when a CE is needed. It also prescribes the types of referrals to be made, the referral process and monitoring procedures.

The SSA began work on the CE rule in mid-October 1984. Internal clearance of the NPRM was completed in April 1985 -- 2 weeks after the legal publication deadline. In May 1985, OS and SSA determined jointly that the rule involved a paperwork burden. The draft rule was revised to remove the burden. Nevertheless, in November 1985, further paperwork burden concerns had to be considered.

A month later, results of a congressional hearing required major revisions to the rule. The revisions were recleared in HHS and submitted to EOMB in April 1986, where it was again found to have a paperwork burden. Three more months passed while the rule was recleared.

In August 1986, the rule was revised again in response to various policy questions. In February 1987, the rule was submitted to OS and EOMB. Reviews were completed within 3 months and the NPRM was published April 20, 1987.

As of mid-February 1988, the draft final was being circulated with SSA for internal review. The target date for final publication is September 1988.

*The Paperwork Reduction Act of 1980 requires Federal agencies to control paperwork burden imposed on the public. When a determination is made that the proposed rule has a paperwork burden, the agency must change the rule to eliminate the burden or obtain EOMB approval before publication. Either course of action can involve substantial additional workload.

4. Title: MULTIPLE IMPAIRMENTS
Legal Authority: 1984 Disability Amendments
Interim Final Rule Published: March 5, 1985
Total Time Elapsed: 3 years, 6 months
Major Reason for Delay: Pending Supreme Court decision delayed action for one year.

The Multiple Impairments (MI) regulation states that in determining disability SSA now considers the combined severity of a person's impairment rather than assessing the effect of each impairment separately.

Work began on this rule in October 1984. It was first published as an interim final on March 5, 1985 with a 60-day comment period. The draft final was completed in December 1985 and circulated within SSA for comments. All comments were received by mid-March 1986. Internal SSA clearance of the revised final was nearly complete by August 1986, when SSA was notified that the Justice Department did not want the MI rule published until the Supreme Court issued its decision on a related case. Consequently, the MI rule was put on hold for almost a year pending the Supreme Court's decision.

The Supreme Court rendered its decision in July 1987. Later that month, SSA staff met to discuss how to proceed with the final in response to the Supreme Court decision. The revised rule was being cleared internally by mid-October 1987.

Since that time, SSA has been considering whether a final rule is needed or whether the interim final is sufficient to implement the Supreme Court decision. As of March 1988, a final decision had not been made on this issue.

5. Title: DEFINITION OF ESSENTIAL PERSONS
NPRM Published: October 5, 1987
Total Time Elapsed: 1 year, 3 months
Major Reasons for Delay: None

Essential Persons (EP) was originally part of a regulations package developed at the request of the FSA Administrator under the title, "Least Costly." The purpose of the rule is to make more restrictive the definition of a person considered essential to a family receiving benefits under the Aid to Families with Dependent Children (AFDC) program. The designation of essential person status allows the State to provide for the needs of an otherwise ineligible individual. The loose definition of this term in existing regulations has permitted States to include any household member as an essential person.

The rule would eliminate benefits for certain individuals currently included as an essential person, as well as making some AFDC families ineligible. Thus, it has the potential for savings in Federal funds. For these reasons, a decision was made to develop the EP as a separate rule.

Work began on the EP rule in August 1986. The completed draft rule was circulated within FSA in November 1986. The FSA circulation and revision process was finished in January 1987 and the rule was sent to OGC for clearance on January 13. After further revisions, the package was recleared by FSA in mid-May 1987.

Clearance in OS began June 1, 1987 and was completed August 9. The EOMB reviewed revisions and reclearance in FSA and OS was necessary. The OS approval came in mid-September. The NPRM was then submitted to EOMB and was published in the FR October 5, 1987.

6. Title: COBRA ADP
Legal Authority: Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985
Total Time Elapsed: 1 year, 7 months
Major Reasons for Delay: Held at EOMB for 5 months, debate over need to regulate.

A provision of COBRA 1985 requires the Secretary to recoup the incentive portion of Federal funding expended by a State for automated data processing (ADP) systems development if that State does not implement its system by the date specified in its advance planning document. The effective date of this provision is April 7, 1986 and incentive funding can be recovered only as far back as that date.

Discussion on the need for this regulation began in April 1986. The Family Assistance Management Informations Systems (FAMIS) program funds States to develop ADP systems. The FAMIS had previously been amended to allow FSA to suspend a State's project and retrieve the incentive portion of Federal money if the State did not meet its planned milestone dates.

In July 1986, FSA decided to proceed with the rule. The draft was submitted to OGC on May 8, 1987 and reviewed in OS 3 weeks later. The rule was revised in response to comments received and cleared by OS at the end of June. On July 9, the rule was submitted to EOMB where it remained for 5 months. On December 24, EOMB requested that the regulation be withdrawn because the existing FAMIS regulation are more specific and effective. The FSA withdrew the rule in early 1988.

1987 REGULATORY PROGRAM
Status of HHS Commitments
March 1988
N = 128

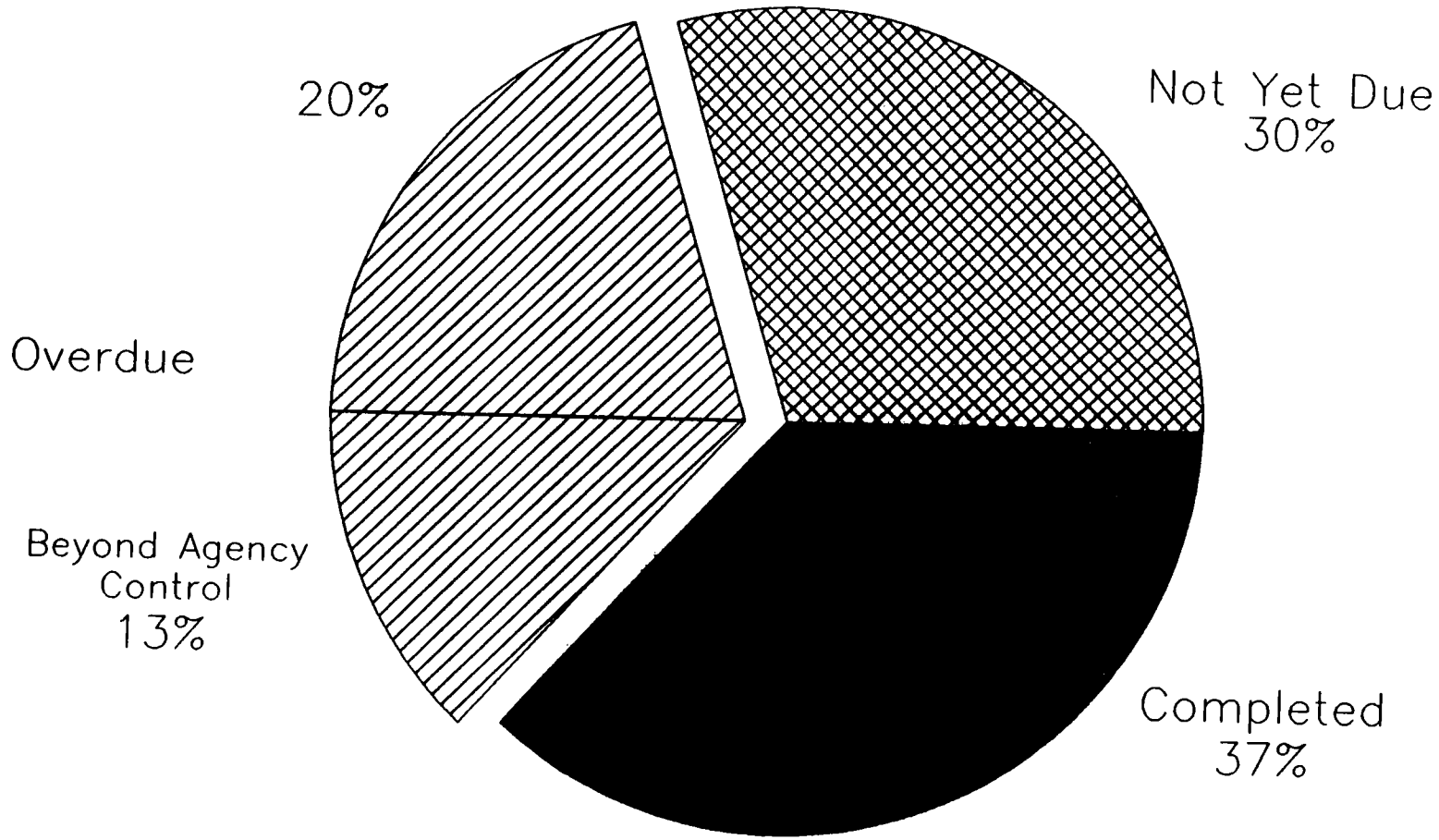


Chart Date: 3/26/88

APPENDIX G

(Chart provided by OS/ES)