DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Statement of Regulatory and Deregulatory Priorities

Departmentwide Priorities

The Department of Health and Human Services (HHS) promotes the health and well-being of every single American. With emphasis on children, working families, the elderly, disabled persons, the poor, and others who are most vulnerable, HHS is the Federal Government's principal agency for protecting health and providing essential human services.

HHS activities are strikingly diverse, ranging from some of the largest programs in Government (Medicare, Medicaid) to some of the smallest; from improving infant health to providing care for the elderly; from gathering basic national health statistics to providing front-line clinical and Head Start services; from conducting biomedical research to ensuring the safety of products that account for 25 cents of every dollar spent by the American people.

While continuing to meet its statutory responsibilities, HHS has been a major participant in President Clinton's initiative to reduce regulatory burden by producing more targeted, focused, and cost-effective regulations.

HHS began a comprehensive review of existing regulations with its implementation of President Clinton's Executive Order 12866 ''Regulatory Planning and Review.'' To assist in identifying priorities for this review, the Department solicited recommendations from the public in a January 20, 1994, Federal Register notice. On November 28, 1995, and again on May 13, 1996, HHS requested public comment on the Department's regulations through the Unified Agenda of Federal Regulatory and Deregulatory Actions, seeking suggestions for furthering regulatory reform efforts.

With the President's March 4, 1995, memorandum on the ''Regulatory Reinvention Initiative,'' HHS joined the Governmentwide effort to pursue additional steps to reduce unnecessary regulatory burden and to increase cooperation and coordination with its customers. Specifically, the President asked that the Department:

- Conduct a page-by-page review of HHS regulations, with the goal of eliminating or revising those that are outdated or otherwise in need of reform;
- Change the way performance is measured by agencies and frontline regulators to focus on results rather than on process and punishment;
- Create ''grassroots partnerships'' by getting out of Washington and convening groups of frontline regulators and the people affected by regulations to discuss issues of concern; and
- Increase use of consensual rulemaking.

Efforts to comply with this directive have been a major undertaking of the Department. The changes in our rulemaking approach are reducing burden, as well as promoting better communication, consensus building, and a less adversarial environment, while maintaining the critical health and safety protections the American people rightly expect. Agency heads and other senior officials have held many meetings with medical care providers, social service providers, food companies, and others to discuss opportunities to minimize burden on small businesses and other small entities (as also mandated by the newly amended Regulatory Flexibility Act).

The Department has participated in numerous sector-specific regulatory reinvention task forces led by the Vice President. These efforts continue to produce important reforms in regulations concerning clinical laboratories, hospitals, dialysis centers, foods, medical devices, biotechnology-derived drugs, cancer drugs, and animal drugs, while protecting public health and safety.

Here are some brief descriptions of a few illustrative examples:

- A new Medicare regulation focused in on a highly specific problem—that of lack of coverage for medical devices which use new versions of proven technologies. The regulation established criteria for identifying such devices as ''non-experimental'' for Medicare coverage purposes. Medicare beneficiaries thus have gained access to the medical benefits of emerging technologies, and manufacturers of medical devices were given new incentives for continuing technological breakthroughs.
- The Department issued new regulations significantly modernizing the way seafood products are regulated: The Department and seafood companies now collaborate to protect the public health through a state-of-the-art system of preventive controls, put in place by industry and monitored by the Food and Drug Administration, to reduce the risk of food-borne illness.
- On August 28, the Department issued a final rule restricting the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents. The rule restricts the ability of children and adolescents to obtain cigarettes and smokeless tobacco and reduces the appeal of such products.
- In the biotechnology area, a significant overhaul of regulatory requirements is reducing paperwork by thousands of pages and cutting drug development time by months, without diminishing the safety and effectiveness of biotech therapies.

We have given special attention to the President's directive for a line-by-line review of all existing regulations with a view to eliminating or reinventing those that are obsolete or otherwise in need of reform. Regulations occupying over 1000 pages in the Code of Federal Regulations have been eliminated, and another 1500 pages' worth of rules have been reinvented. Eight hundred additional pages are slated for elimination or reinvention as soon as appropriate legislative action is taken.

HHS has examined its approach to rulemaking in light of Executive Order 12875 ''Enhancing the Intergovernmental Partnership'' and of the provisions of the Unfunded Mandate Reform Act of 1995. The Department is committed to avoiding the imposition of unfunded mandates on State, local, and tribal governments. Where such mandates cannot be avoided, we are committed to advance consultation with the affected levels of government. HHS components have been directed to carry out ''both the letter and the spirit'' of E.O. 12875 by considering the effect of all issuances and actions—not just formal regulations—on the State, local, and tribal levels.

The Department has for the first time successfully used the negotiated rulemaking approach to develop rules in a consensual process. This process brings Federal officials together with representatives of the constituencies to be significantly affected by a new rule to reach consensus on some or all issues through open discussions before a formal notice of proposed rulemaking is published. HHS recently completed a successful effort at reforming the Medicare hospice wage index through negotiated rulemaking, with publication of a proposal on September 4, 1996. Earlier in 1996, the Department used the ''regneg'' approach to create a regulatory framework through which

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administrative responsibility for Indian health programs may be smoothly turned over to those tribes who wish to exercise such responsibility through a contractual relationship.

The large majority of regulations issued by HHS are associated with the Health Care Financing Administration or the Food and Drug Administration. Descriptions of priorities for those components of the Department are as follows:

Health Care Financing Administration (HCFA)

HCFA has improved its regulations by focusing on rulemakings that reduce unnecessary burden, while ensuring continual improvement in the quality of services to Medicare and Medicaid beneficiaries. Within existing regulation programs, HCFA is following the President's July 1995 directives to communicate, not dictate, innovate more than regulate, and educate not dictate. Working closely with the public in developing new rules, HCFA has conducted listening events around the country concerning specific regulations to collect ideas on partnerships from front-line regulators, those being regulated, and other interested stakeholders.

HCFA successfully completed negotiated rulemaking for the wage index that is used to adjust payment rates to hospices under the Medicare program. As part of the agreement with the members of the negotiating committee, incorporated in the proposed rule published on September 4, 1996, the hospice wage index will rely on the most recent data from the hospital wage index published in the Medicare hospital prospective payment systems rule published on September 1, 1996.

In response to requests from States and pharmaceutical manufacturers, HCFA used alternative dispute resolution procedures to resolve disputes over rebated payments under the Medicaid Rebate Program. With the assistance of the HHS Departmental Appeals Board, HCFA developed the Dispute Resolution Pilot (DRP) that resulted in the resolution of disputes over millions of dollars in rebates formerly at issue between the 6 New England States and 30 drug manufacturers. Building on the New England success, HCFA is expanding the DRP to 14 western States. Through this innovative approach, we have clearly improved communication between States, private industry, and HCFA and turned the situation into a negotiated partnership arrangement.

HCFA plans to conduct two pilot projects concerning end stage renal disease (ESRD) facilities. The goal of one pilot is to improve the quality of care to Medicare beneficiaries with ESRD by tracking specific quality indicators. Over a 2-year period, we will collaborate with hemodialysis providers to design a measurement system to assist facilities in their efforts to improve care and, when fully operating, lessen the regulatory burden on these facilities. Facilities that successfully complete this project will be recognized as ''Facilities of Achievement'' that have demonstrated the capacity and commitment to improve patient care through use of a quality measurement system.

The other ESRD pilot project will be a demonstration that would grant approximately six to eight carefully selected ESRD facilities a 2-year waiver of the staffing requirements set forth in regulations, which would only be granted after determining that patient health and safety would not be jeopardized. This is part of the Administration's overall strategy to reduce regulatory burdens on the American public and an opportunity to further carry out HCFA's commitment to the goals of regulating only when necessary and in a cost-effective manner, while maintaining and improving quality health services to our customers.

HCFA and the Centers for Disease Control and Prevention (CDC), which share responsibility for the Clinical Laboratory Improvement Act (CLIA) program, have continually taken actions to reduce burden and improve the entire CLIA system. A flexible survey system for good performers, which has already been initiated for certain laboratories, allows for self-attestation and off-site reviews. Information requirements and paperwork have been eliminated, steps have been taken to make personnel requirements more flexible, and the inspection process has been streamlined. Additional burden reductions have been undertaken that will virtually eliminate oversight for certain appropriate laboratories, establish performance standards in place of process requirements, and use information and education as a substitute for sanctions.

As of October 1, 1996, six private accrediting organizations have been approved for Federal accrediting status (''deemed'' status) because their accreditation standards are as stringent as those of CLIA. In addition, exemption from CLIA requirements has been granted to laboratories in three States because the States in which they are located have requirements equal to or more stringent than CLIA's. The impact of these actions is to reduce Federal inspections, offer laboratories oversight by peers, and allow States with strong licensure programs to be approved for exemption from CLIA.

On August 21, 1996, the President signed into law the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) under which HCFA will have major implementation responsibilities. HCFA will have a major role under title I of the new law when it comes to ensuring that the American people have health care access, portability, and renewability across all health insurance markets. HCFA will also have a role in fighting fraud and abuse and ensuring that administrative simplification procedures are implemented and followed under the new program.

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 changes the link between Medicaid eligibility and welfare. HCFA will develop Medicaid regulations to implement these changes.

October 1996 Regulatory Plan Entries

The October 1996 Regulatory Plan includes the President's and Vice President's initiatives for reinventing health care regulations. CLIA regulations are being revised to reduce unnecessary burden and improve the CLIA system by rewarding good performance by laboratories, creating incentives for manufacturers to develop more reliable testing equipment, and using proficiency testing as an outcome measure to monitor laboratory performance.

New regulations for hospitals, home health agencies, and ESRD facilities will focus on the outcomes of care and replace unnecessary process requirements. These three proposed rules would provide for the collection and analysis of patient care data needed for continuous quality improvement and performance evaluation, increase consistency of requirements across providers, and ask the customer to provide input on what the outcome measures should be and evaluate the services they received.

A new HCFA entry in The Regulatory Plan would simplify, expedite appeals, and improve protections afforded to beneficiaries under managed health care plans; i.e., health maintenance

organizations, competitive medical plans, and health care prepayment plans. In keeping with HCFA's now standard practice under the President's and Vice President's reinventing government and regulatory reform initiatives, input will be sought from all affected interests (i.e., beneficiaries, managed care contractors, and others) during the development of this rule.

Food and Drug Administration (FDA)

FDA's regulatory efforts continue to reflect the Administration's emphasis on reforming the Federal Government's regulatory practices without sacrificing public health and safety protections.

FDA's regulatory program has three broad goals: (1) To eliminate unnecessary burdens on the regulated industry, (2) to get products to market more quickly, and (3) to allow FDA to do its job more effectively.

For example, on November 27, 1995, FDA published a proposed rule in the Federal Register that would streamline the requirements for exporting unapproved devices for investigational use (60 FR 58308). The proposed rule would eliminate unnecessary submissions to FDA without affecting the agency's ability to determine whether exportation of the device was contrary to public health or safety.

On December 18, 1995, FDA published a final rule in the Federal Register that would significantly change the way seafood products are regulated. The regulations were based on principles of a system called Hazard Analysis Critical Control Points (HACCP) to keep unsafe products from reaching consumers. HACCP is a system of preventative controls put in place in industry and monitored by FDA to reduce the risk of food-borne illness. Under HACCP, firms perform a science-based analysis of their potential safety hazards that would make seafood hazardous, monitor critical control points to minimize risks, and keep a record of the results so Government inspectors can have a clear, systematic view of how well firms are doing. Thus, under the seafood HACCP regulations, Government and industry work together to protect the public health; this represents a significant advancement over the pre-existing system where safety problems were addressed only after they had occurred.

Other accomplishments by FDA include issuance of final rules regarding humanitarian use devices (June 26, 1996). These are devices that are intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in less than 4,000 individuals in the United States annually.

The agency also revoked hundreds of pages of regulations that were outdated or obsolete (see, e.g., 61 FR 37682; July 19, 1996).

More recently, on August 28, 1996 (61 FR 44396), the agency issued a final rule restricting the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents. The rule restricts the ability of children and adolescents to obtain cigarettes and smokeless tobacco and reduces the appeal of such products.

Regulatory Plan Entries

FDA's regulations plan, which follows, contains initiatives that reflect the President's goal of providing traditional public health protections through a streamlined regulatory process that is focused on minimizing burdens on those who are regulated. Regulations included in the plan protect the health of women by assuring a high quality of mammography, take steps to prevent the development of bovine spongiform encephalopathy (BSE) in cattle in the United States, and streamline the process for reporting changes to a biological product.

Administration for Children and Families

The Administration for Children and Families (ACF), as part of its strategy to better serve its client populations, has made regulatory reform one of its key principles. All ACF regulatory efforts will respond to the needs of States, tribes, and local partners through a consultative process that is open and reaches out to all involved parties. This philosophy will guide ACF as the Agency seeks to fulfill its responsibilities in implementing the provisions of the newly enacted welfare reform legislation, The Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

The enactment of this law is an opportunity to continue the work already begun to change the culture of welfare in this country so that it focuses on work, provides the supports necessary to ensure a successful transition to work, demands greater responsibility from those participating in the system, and protects children. ACF is committed to working with the States, wherever possible, to facilitate this process and assure that the goals of welfare reform can be achieved.

Initially, ACF will promulgate two regulations which are significant in implementing the Temporary Assistance for Needy Families (TANF) Block Grant under welfare reform. These regulations will clarify States' responsibilities for assuring that work participation rates are being achieved and will address the consequences when States are not able to get people to work or meet other key expectations of the legislation.

We will continue to work with our partners to identify any other significant regulatory initiatives which may be necessary for implementation of the welfare reform legislation.

HHS—Food and Drug Administration (FDA)

PROPOSED RULE STAGE

26. MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

PL 102-539 Mammography Quality Standards Act of 1992; 42 USC 263b

CFR Citation:

21 CFR 900

Legal Deadline:

Final, Statutory, July 27, 1993.

Standards for accreditation bodies are required by July 27, 1993.

Abstract:

The purpose of the Mammography Quality Standards Act of 1992 (MQSA), enacted October 27, 1992, is to assure quality in all aspects of the practice of mammography. The primary mechanism for this is oversight of all mammography facilities through a certification and inspection program. Only facilities certified by the Secretary are permitted to produce, process, or interpret mammographic images. The statute also required the establishment of an advisory committee to advise on appropriate quality standards and also provided for the establishment of surveillance systems to evaluate breast cancer screening programs.

The agency published interim regulations on December 21, 1993, which were drafted and implemented so as to maximize lawful operation by facilities under existing quality standards, and to ensure adequate examinee access to quality

mammography during the transition to more comprehensive national standards.

Concurrent with the implementation of the interim rules, FDA proceeded with the development of proposed regulations to replace the interim rules. The agency recently issued proposed rules, with the advice and consultation of the National Mammography Quality Assurance Advisory Committee, on requirements for accreditation bodies, equipment and quality assurance requirements, facility requirements, and personnel requirements.

Statement of Need:

Nearly 50,000 women die each year from breast cancer. While much research into causes and treatments still needs to be done, we do know that, for women over 50, mortality for lesions found by mammography is 30 percent less than for larger lesions identified by physical examination. Unfortunately, not all mammography facilities have offered services commensurate with the value of mammography in the abstract. The Congress enacted the MQSA to ensure quality mammography services for all women.

The primary mechanism established by the MQSA to ensure quality in mammography is oversight of all mammography facilities through a certification and inspection program. Only facilities certified by the Secretary will be permitted to produce, process, or interpret mammographic images. The statute also requires the establishment of a committee of experts to offer advice about regulatory quality standards and also provides for the establishment of surveillance systems to evaluate breast cancer screening programs.

The implementation of these regulations will help ensure that mammograms are properly administered and interpreted to provide adequate protection, diagnosis, and treatment of breast cancer among women. FDA has worked with the Health Care Financing Administration, the Centers for Disease Control, and State and local radiation control officials to coordinate mammography quality assurance activities and the development of policies and regulations for implementation of the MQSA, and will continue to coordinate its efforts with these agencies as appropriate.

Summary of the Legal Basis:

The MQSA established a comprehensive statutory scheme for the certification and inspection of mammography facilities to ensure that, after October 1, 1994, only those facilities that comply with minimum Federal standards for safe, high-quality mammography services may lawfully continue to operate. Operation after that date is contingent on receipt of an FDA certificate attesting that the facility meets the minimum mammography quality standards promulgated under section 354(f) of the Public Health Service Act. The standards are intended to apply equally to screening and diagnostic mammography. The MQSA required: (a) accreditation of mammography facilities by private, nonprofit organizations or State agencies meeting FDA established standards; (b) annual physics surveys of mammography facilities; (c) annual inspections of mammography facilities; (d) qualification standards for interpreting physicians, radiologic technologists, medical physicists, and mammography facility inspectors; (e) specification by FDA of boards or organizations eligible to certify mammography personnel; (f) quality standards for mammography equipment and practices, including quality assurance; (g) establishment of the National Mammography Quality Assurance Advisory Committee; and (h) standards governing recordkeeping for examinee files and requirements for mammography reporting and examinee notification by physicians.

Alternatives:

The statute is prescriptive and does not allow for a substantially different regulatory approach than is being taken by FDA. It allows for discretion in the details of individual standards, and FDA has sought to avoid unnecessary burden in devising these standards. In order to reduce the burden of complying with the MQSA regulations on mammography facilities, FDA incorporated existing standards to the maximum extent possible; issued Federal certificates, which are required for facilities to legally operate after October 1, 1994, to facilities already accredited by the American College of Radiology; required facilities to submit information for certification only to the accrediting body--not to FDA; and allowed flexibility to accrediting bodies in developing their standards by requiring that accrediting body standards be ‘‘substantially the same as’’ FDA’s standards, rather than identical.

Anticipated Costs and Benefits:

Yearly costs to mammography facilities, over a 10-year period, were estimated to range from a high of approximately $203.2 million to $25.2 million. Yearly costs differed due to the phased implementation dates for some proposed requirements. Overall, average annualized costs of the proposals are preliminarily estimated at $61.4 million.

There are many benefits associated with these proposed rules. High-quality mammography could significantly reduce breast cancer mortality. Early detection could reduce the morbidity associated with treating later-stage disease. There may be a reduction in the number of malpractice claims filed for failure to diagnose early breast cancer. In addition, because of improved mammography quality, the agency expects a reduction in the number of follow-up procedures in nondiseased patients, resulting in a reduction of annual medical costs. By themselves, the health care cost savings are expected to substantially exceed the expected average annualized costs.

Risks:

The motivation for the MQSA was public response to concerns about breast cancer and to concerns about the quality of mammography services relied on for early detection of breast cancer. Breast cancer is the most prevalent nonskin cancer among women (and the second most deadly) with over 175,000 new cases and 45,000 breast cancer-related deaths occurring annually. The disease is most treatable in the early stages. Missed diagnosis of early lesions due to factors such as poor image quality or incorrect interpretation of images could result in delayed treatment, leading to otherwise avoidable increases in mortality or more complex and costly remediations.

Timetable:

Alternative Approaches
NPRM 04/03/96 (61 FR 14856)
Review of Comments 01/00/97

Approval of Accrediting Bodies
Interim Final Rule 12/21/93 (58 FR 67558)

Draft Proposed Quality Standards
Notice of Availability 01/26/95 (60 FR 5152)

Draft X-Ray and Medical Physicist Standards Proposals
Notice of Availability; 12/30/94 (59 FR 67710)

General Facility Requirements
NPRM 04/03/96 (61 FR 14870)
Review of Comments 01/00/97

Mammography Quality Standards Act of 1992; Inspection Fees
Notice 03/17/95 (60 FR 4584)

Personnel Requirements
NPRM 04/03/96 (61 FR 14898)
Review of Comments 01/00/97
Quality Standards for Mammography Equipment and QA
NPRM 04/03/96 (61 FR 14908)
Review of Comments 01/00/97
Quality Standards for Mammography Facilities
Interim Final Rule 12/21/93 (58 FR 67565)
Quality Standards/Certification Rqmts.
Interim Final Rule 09/30/94 (59 FR 49808)
Requirements for Accreditation Bodies and Quality Standards
Notice (Advisory Committee) 12/21/94 (59 FR 65776)
NPRM 04/03/96 (61 FR 14884)
Review of Comments 01/00/97

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

State, Local, Federal

Additional Information:

Previously reported under RIN 0905-AE07.

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HHS—FDA

27. ● SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED; PROTEIN DERIVED FROM RUMINANTS PROHIBITED IN RUMINANT FEED

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal governments.

Legal Authority:

21 USC 321; 21 USC 342; 21 USC 348; 21 USC 371

CFR Citation:

21 CFR 589.2000

Legal Deadline:

None

Abstract:

The Food and Drug Administration is proposing rules providing that animal protein derived from ruminant and mink tissues are not generally recognized as safe (GRAS) for use in ruminant feed and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act. Therefore, protein derived from ruminants and mink are prohibited from use in ruminant feed. The proposed rule would establish a flexible system of controls to ensure that ruminant feed does not contain animal protein derived from ruminant and mink tissues in a manner that is cost effective and encourages innovation. While BSE has not been diagnosed in the United States, this rule is intended to prevent the development and amplification of bovine spongiform encephalopathy (BSE) in cattle to protect the health of animals and to minimize any risk which might be posed to humans.

Statement of Need:

The Food and Drug Administration (FDA) is proposing this action to protect the health of animals and to minimize any risk which tfght be posed to humans, through the transmission of transmissible spongiform encephalopathies (TSEs). While BSE has not been diagnosed in the United States, this rule is intended to prevent the development and amplification of bovine spongiform encephalopathy in cattle in the United States. Ruminant and mink tissues present a risk of transmitting spongiform encephalopathies. These tissues have been found through experimental trials and bioassays to transmit spongiform encephalopathies. Epidemiological evidence gathered in the United Kingdom (UK) suggests an association between an outbreak of BSE, a ruminant TSE, and the feeding to cattle of protein derived from sheep infected with scrapie, another TSE. The causative agent was further spread in the UK cattle population as a result of feeding rendered products to cattle. In addition, scientists have postulated an epidemiological association between BSE and a variant form of human TSE, Creutzfeldt-Jakob Disease (v-CJD) reported recently in England. FDA is not aware of a practical assay for the presence of ruminant protein in rendered products. Nor is FDA aware of a reliable deactivation procedure in the rendering process which is used to produce the proteins.

Summary of the Legal Basis:

A substance used in food (including animal feed) that is not generally recognized as safe is a ''food additive'' under section 201(s) of the Food, Drug, and Cosmetic Act. A food additive is unsafe under section 409 of the Act unless a food additive regulation or an exemption is in effect for the substance. An unsafe food additive is adulterated under section 402(a)(2)(c) of the Act. Section 701(a) of the Act provides authority to issue regulations for the efficient enforcement of the Act, including regulations that determine substances to be food additives.

Alternatives:

The agency considered a number of alternatives regarding the feeding of animal protein to ruminants; including a prohibition of feeding protein derived from adult sheep and goats, restricting the prohibition only to ruminant tissues that had been demonstrated to be potentially TSE infective, and a prohibition of feeding of protein derived from mammalians. In addition the agency considered not taking any action regarding the feeding on animal proteins. The grave potential consequences of exposure to TSE and the apparent small intake of the agent needed to achieve infection in small animals encourage a conservative regulatory policy.

Anticipated Costs and Benefits:

The affected industry sectors are predicted to incur total direct compliance costs ranging from $21.4 to $48.2 million per year. The benefits of prohibiting ruminant proteins in ruminant feeds are the reduced risks to animal and human health and to the economic health of the U.S. livestock and livestock dependent industries. For analytical purposes, these benefits can be expressed as the expected value of the future disease related costs that would be averted by the present implementation of the proposed rule. The realized benefits depend primarily on two factors: 1) the risk that BSE will occur in the U.S. (or currently exists undetected), and 2) the incidence rate of BSE once it becomes established. The proposed measure is aimed both at reducing the first risk, and at eliminating the second if the first should occur. The UK will destroy an additional 1 million cattle in 1996 for this reason, or about 8.7 percent of its cattle stock. Risks are inherently lower in the United States. Similar measures in the U.S., if they occurred immediately upon detection of the disease, would result in the one-time destruction of $4.58 billion worth of cattle, with a present value of $3.49 billion.

Risks:

Based on the scientific information that is available at the present time, the primary health concern related to animal feed is the possibility of transmission of TSE infectively from BSE-infected bovines, with the risk of that threat increasing through the recycling of ruminant tissues. Furthermore, there exists the theoretical possibility of the transmission of a TSE in animals to a TSE in humans. The possibility of other TSE transmissions between species, in addition to the postulated transmission of a sheep TSE (scrapie) to cattle, supports the agency's concern about TSE transmission and infectivity both in animals and humans. The typically long incubation period and the potentially devastating effect that a BSE outbreak would have on animal health and U.S. agribusiness, support a conservative regulatory approach aimed at prevention. While no BSE has been diagnosed in the United States, and the current level of exposure to products derived from animals with a TSE is extremely low or absent, the potential consequences of such exposure and the apparent small intake of the agent needed to achieve infection in some animals further encourage a conservative regulatory policy.

Timetable:

Action	Date	FR Cite
ANPRM	05/14/96	61 FR 24253
ANPRM Comment Period End	06/15/96	
NPRM	12/00/96	

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

FINAL RULE STAGE

28. CHANGES TO AN APPROVED APPLICATION

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

15 USC 1451 to 1461; 21 USC 321; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360u to 360j; 21 USC 371; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262 to 263

CFR Citation:

21 CFR 601

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is issuing a final rule to revise 21 CFR 601.12, which deals with changes in the production of licensed biological products--for example, product labeling, production process, equipment, facilities, and responsible personnel. Currently, licenseholders must obtain FDA preapproval of all such changes through supplements to approved applications. In the final rule, FDA sets forth a process that is intended to reduce the burden on licenseholders by reducing the number of supplements submitted for changes and to result in more timely approval of changes in their products. The new process creates different mechanisms for reporting changes, based on their potential to affect adversely the safety, purity, potency, or effectiveness of the product.

Statement of Need:

The present system has been shown to be burdensome to both licenseholders and to FDA in that licenseholders must submit supplements for every proposed change, and FDA must review them. The present system is also time-consuming--manufacturers may wait from 6 to 12 months for approval of supplements--and unnecessarily rigid. FDA estimates that the final rule would reduce by 50 percent--from 1,000 to 500--the number of supplements submitted annually for biologics and reviewed by FDA, allowing for more expeditious agency review of supplements that are submitted.

Summary of the Legal Basis:

The Public Health Service Act (42 USC 216 et seq.) and the Federal Food, Drug, and Cosmetic Act (21 USC 321 et seq.) authorize FDA to regulate the distribution of biological products so that the products are safe, pure, potent, and effective. These acts authorize FDA to promulgate regulations designed to ensure that the public is not exposed to biological products that may not be safe, pure, or potent for their intended uses. In order to carry out the public health protection purposes of the FD&C Act, FDA (a) reviews and approves applications for licenses to manufacture biological products; (b) inspects establishments involved in manufacturing activities; and (c) reviews and approves important changes that have the potential to adversely affect the biological product.

Alternatives:

FDA considered two alternatives. The first alternative was allowing license holders to submit summary data and a certification of validation and lack of adverse effect on the product's safety, purity, potency, or efficacy. FDA believes this alternative is appropriate for some changes, but not adequate or sufficient for changes with substantial potential to have an adverse effect.

The second alternative would have required license holders to keep validation data and certification of lack of adverse effect, and allowed them to report changes to FDA in an annual report. FDA believes this alternative is appropriate for changes that have only a minimal potential for adverse effect on the product. It is incorporated into the final rule.

Anticipated Costs and Benefits:

In general, the final rule is expected to reduce significantly the burden of preparing supplements for proposed changes by eliminating this requirement for a number of changes. The final rule will accordingly reduce the number of supplements requiring FDA review and allow for more expeditious handling of supplements that are submitted. Licenseholders are expected to incur no additional costs as a result of the proposal; on the other hand it will allow for more timely implementation of changes by licenseholders--for example,

streamlining and updating manufacturing facilities.

Risks:

FDA believes the risks posed by the new reporting system are minimal. In addition to stating in the revision which changes are considered to have substantial, moderate, and minimal potential for adverse effects, FDA will provide thorough supplementary guidance to manufacturers to help assure adequate assessment of the potential for adverse effects.

Timetable:

Action	Date	FR Cite
NPRM	01/29/96	61 FR 2739
NPRM Comment Period End	04/29/96	
Final Action	05/00/97	

Small Entities Affected:

Businesses

Government Levels Affected:

None

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RIN: 0910–AA57

HHS—Health Resources and Services Administration (HRSA)

FINAL RULE STAGE

29. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK RULES

Priority:

Other Significant

Legal Authority:

42 USC 1320b-8 sec 1138 of the Social Security Act; 42 USC 274 sec 372 of the Public Health Service Act

CFR Citation:

42 CFR 121

Legal Deadline:

None

Abstract:

Section 1138 of the Social Security Act requires Medicare and Medicaid participating hospitals that perform organ transplants to be members of and abide by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) as established by section 372 of the Public Health Service Act. Section 1138 also requires that for organ procurement costs attributable to payments to an Organ Procurement Organization (OPO) to be paid by Medicare or Medicaid, the OPO must be a member of and abide by the rules and requirements of the OPTN. No other entity (for example, a histocompatibility laboratory) is required to be a member of or abide by the rules of the OPTN under the provisions of the statute. It is the Department's position that no rule, requirement, policy, or other issuance of the OPTN will be considered to be a ''rule or requirement'' of the Network within the meaning of section 1138 unless the Secretary has formally approved that rule. The OPTN is currently in operation and these rules will impose no further cost or provide any benefit other than that which now exists.

Statement of Need:

These regulations are required by law.

Summary of the Legal Basis:

Section 1138 of the Social Security Act (42 USC 1320b-8) requires Medicare and Medicaid participating hospitals that perform organ transplants to be members of and abide by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) as established by section 372 of the Public Health Service Act (42 USC 274).

Alternatives:

The alternative was to continue without codifying existing policies.

Anticipated Costs and Benefits:

There are no anticipated costs beyond the cost of preparing the regulations (approximately $100,000.00). The anticipated benefit is that the regulations will make mandatory adherence to the policies set forth in the regulations.

Risks:

None known.

Timetable:

Action	Date	FR Cite
NPRM	09/08/94	59 FR 46482
NPRM Comment Period End	12/07/94	
Final Action	03/00/97	

Small Entities Affected:

None

Government Levels Affected:

None

Additional Information:

Previously reported under RIN 0905-AD26.

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RIN: 0906–AA32

HHS—Health Care Financing Administration (HCFA)

PROPOSED RULE STAGE

30. REVISION OF MEDICARE HOSPITAL CONDITIONS OF PARTICIPATION (BPD-745-P)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 1395x; 42 USC 1302; 42 USC 1395(cc); 42 USC 1395(hh)

CFR Citation:

42 CFR 482

Legal Deadline:

None

Abstract:

This proposed rule would revise the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The revised requirements focus on patient care and the outcomes of that care, reflect a

cross-functional view of patient treatment, encourage flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are necessary to reflect advances in health care practices since the requirements were last revised in 1986. This regulation is part of the Administration's reinventing government and regulatory reform initiatives.

Statement of Need:

The purpose of the hospital conditions of participation is to protect patient health and safety and help assure that quality care is furnished to all hospital patients. Hospitals must meet the conditions of participation in order to participate in Medicare or Medicaid. Revised conditions are necessary to ensure that our regulations focus primarily on the actual quality of care furnished to patients, and the outcomes of that care, rather than on procedural compliance. These changes are intended to give hospitals the flexibility needed to achieve high-quality outcomes in the most cost-effective manner.

In addition, the regulations are intended to promote a cross-functional, interdisciplinary approach to hospital performance, instead of an approach geared towards evaluating each department of a hospital as a stand-alone entity. This approach is in line with current best practices in hospitals, in which patients routinely encounter many caregivers and services that often cut across department lines.

Summary of the Legal Basis:

Section 1861(e) of the Social Security Act (the Act) provides that a hospital participating in the Medicare program must meet certain specified requirements. In addition, section 1861(e)(9) of the Act specifies that a hospital also must meet such requirements that the Secretary finds are necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in regulations the requirements that a hospital must meet to participate in Medicare. These requirements are set forth in regulations at 42 CFR Part 482, Conditions of Participation for Hospitals. Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii), hospitals generally are required to meet the Medicare conditions of participation in order to participate in Medicaid.

Alternatives:

HCFA considered the possibility of revising individual sections of the current hospital regulations. However, we determined that the best means of achieving the systematic changes needed in the regulations was to revise the hospital conditions in their entirety. The specific areas that are likely to form the core of the revised requirements include patient rights, patient assessment, patient care, quality assessment and improvement, and information management.

Anticipated Costs and Benefits:

There would not be significant costs associated with this proposed rule. The benefits that would be derived from the rule are discussed in the Need section, above.

Risks:

By revising these regulations to focus on the quality of the actual care given to an individual and the effectiveness of that care for the individual patient, we hope to reduce risks to beneficiaries' health and safety. Revised procedures can better focus on ensuring that the care being given to a patient is the care that is actually necessary and effective for that patient. No quantitative estimates of risk reductions are available yet.

Timetable:

Action	Date	FR Cite
NPRM	01/00/97	

Small Entities Affected:

Undetermined

Government Levels Affected:

Undetermined

Additional Information:

BPD-745

Agency Contact:

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RIN: 0938–AG79

HHS—HCFA

31. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (BPD-819-P)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bbb

CFR Citation:

42 CFR 484

Legal Deadline:

None

Abstract:

This proposed rule would revise home health agency conditions of participation to center on the patient, using outcome-oriented measures. Most of the current HHA conditions of participation have remained unchanged since home health services became a Medicare benefit in 1966. Some limited modifications have been made over the years to comply with legislative changes. As a result, most of the conditions of participation continue to be structure and process oriented. They do not effectively support the mandate of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) to develop a patient-centered, outcome-oriented survey process that focuses on the organization and delivery of quality care services. This proposed rule is part of the Administration's Reinventing Government and Regulatory Reform Initiatives.

Statement of Need:

Because the existing survey process continues to focus on structure and process measures, the discrepancy between a Congressional mandate for outcome-oriented care and the authority for measuring the actual performance capabilities of HHAs in patient care services remains a problem. It presents difficulties for both providers and surveyors in areas of survey/certification, medical review, developing data based performance standards for HHA management and monitoring, and implementing a continuous quality improvement system for outcomes of care.

Regulations containing the Medicare HHA conditions of participation must be revised in order to provide a regulatory basis for a patient-centered, outcome-oriented system of home health quality assurance. The implementation of such a system will enhance Medicare's ability to ensure that high-quality care is furnished to the patients of Medicare-certified home health agencies. The Social Security Act authorizes us to regulate this area and no improvements in the survey process can be made without underlying regulatory authority.

The Health Care Financing Administration has already met with a variety of provider and consumer representatives to discuss the development of revised standards. Representatives of consumers, providers, and States participated in this effort. Additional consultations are ongoing.

Alternatives:

Congress has mandated the implementation of an outcome-oriented quality assurance system for home health. Therefore, the Medicare home health agency conditions of participation must be revised to provide the basis for implementation of such a system. Because of this mandate, no alternatives to this action have been considered.

Anticipated Costs and Benefits:

The primary benefit of this rule will be the implementation of a more effective, efficient, and patient-centered system of quality assurance for HHAs. Costs and benefits associated with the implementation of the rule have not yet been estimated, but costs should not be significant.

Risks:

This rule would have the potential for reducing risks to patient health and safety. No quantitative estimates are available yet.

Timetable:

Action	Date	FR Cite
NPRM	01/00/97	

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

Undetermined

Additional Information:

BPD-819

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RIN: 0938–AG81

HHS—HCFA

32. END-STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (BPD-818-P)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 1395rr

CFR Citation:

42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 412; 42 CFR 413; 42 CFR 414; 42 CFR 489; 42 CFR 492

Legal Deadline:

None

Abstract:

This proposed rule would revise current conditions of coverage for end-stage renal disease (ESRD) services covered by Medicare. It would update the conditions to reflect new developments in outcome-oriented standards technology and equipment, emphasize the total patient experience with dialysis and develop performance expectations for the facility that result in quality, comprehensive care for the dialysis patient. This rule is part of the Administration's Reinventing Government and Regulatory Reform Initiatives.

Statement of Need:

Section 1881(b)(1) of the Social Security Act stipulates that payment is made to individuals, providers of services, and renal dialysis facilities that meet the requirements for institutional dialysis services and supplies that are determined by the Secretary. These requirements are the end-stage renal disease (ESRD) conditions of coverage.

The ESRD conditions for coverage regulations have not been comprehensively revised since their inception in the late 1970s. The current regulations primarily focus on process-oriented requirements, which are unnecessarily burdensome. They do not provide adequate support for a modern survey system based on an outcome-oriented approach. As a result, revised regulations must be issued to bring the ESRD conditions for coverage up to current standards of practice in the ESRD community. They must also reflect new developments in technology and equipment, as well as addressing the outcome-oriented standards process.

The regulations would focus on the patient and the results of the care provided to the patients with the emphasis on total patient experience with dialysis and quality improvement. The revised regulations should focus on patient-centered, outcome-oriented standards where appropriate. In addition, they should emphasize patient functional well-being and indicate continuous quality improvement. Patient rights and satisfaction will also be key areas in the regulation. The revised regulations would develop performance expectations for the facility that would result in quality, comprehensive care for the dialysis patient.

In keeping with the Administration's policy of working with our private sector partners, we held a meeting with the industry to discuss the focus of revisions to the conditions for coverage. Following publication of the proposed rule, we will consult further with the industry.

Alternatives:

In the past, HCFA has revised pieces of the ESRD regulations. However, we have determined that a complete and thorough revision would be a more effective mechanism for developing a comprehensive approach to quality care for the dialysis patient. In addition, this approach provides greater potential for successful implementation. Another option is to update the current regulations and maintain the process-oriented standards without developing an outcome-oriented approach. However, for the reasons discussed, we believe it is important to move forward with the outcome-oriented approach.

Anticipated Costs and Benefits:

The purpose of this proposed rule is to ensure that ESRD beneficiaries are receiving quality care in the areas of

dialysis and transplantation. We believe that revised regulations are necessary to ensure that all facilities are using the most effective technology and equipment. The primary benefit of updating the conditions for coverage is the development of performance expectations for the facility that would result in the comprehensive, integrated care and outcomes the patient needs and wants. As a result, the beneficiaries would receive an improved quality of care. In addition, the revised regulations would address the issue of adequacy of dialysis, which would have a significant impact on ensuring that patients are not being underdialyzed.

Items that have the potential to affect the cost of the ESRD program include data gathering and infection control. However, at this time the cost or savings to the Medicare program have not yet been established, but costs should not be significant.

Risks:

If the ESRD regulations are not updated, our regulations will not reflect new developments in technology and equipment, thereby denying the improved protections to patients' health care that would result from this proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	01/00/97	

Small Entities Affected:

Undetermined

Government Levels Affected:

Undetermined

Additional Information:

BPD-818

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RIN: 0938–AG82

HHS—HCFA

33. • CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 1998 RATES (BPD-878-P)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1395ww

CFR Citation:

42 CFR 412; 42 CFR 413

Legal Deadline:

NPRM, Statutory, May 1, 1997. Final, Statutory, September 1, 1997.

Abstract:

Medicare pays for hospital inpatient services under a prospective payment system (PPS) in which payment is made at a predetermined specific rate for the operating and capital-related costs associated with each discharge. These rules would announce the prospective payment rates for operating and capital-related costs for FY 1998. We would also revise the Medicare hospital inpatient prospective payment systems for operating costs and capital-related costs to implement necessary changes arising from our continuing experience with the systems. In addition, we would set forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the prospective payment systems. These changes would be applicable to discharges occurring on or after October 1, 1997.

Statement of Need:

Section 1886(e)(5) of the Social Security Act requires the Secretary to publish a proposed rule on prospective payment system policies and payment rates in the Federal Register by May 1 and a final rule by September 1.

Summary of the Legal Basis:

As noted above, publication of proposed and final rules concerning hospital PPS policies and payment rates is required by law. The statute sets forth several specific requirements concerning what must be included in the PPS proposed and final rules (See sections 1886(b)(3)(B), 1886(d)(1)(A), 1886(d)(2)(H), 1886(d)(3)(A), 1886(d)(3)(E), 1886(d)(4)(C), 1886(e)(4), 1886(e)(5), and 1886(g)(1)(A) of the Act.)

Alternatives:

Publication of these rules is not discretionary. Thus, no alternatives exist.

Anticipated Costs and Benefits:

We are unable to estimate at this time the costs and benefits associated with these rules.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	05/00/97	
Final Action	09/00/97	

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

State, Federal

Additional Information:

BPD-878

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RIN: 0938–AH55

HHS—HCFA

34. • IMPROVEMENTS TO THE APPEAL PROTECTIONS OFFERED BY MEDICARE CONTRACTING HMOS/CMPS (OMC-025-P)

Priority:

Other Significant

Legal Authority:

42 USC 1395mm(c)(5)(A)

CFR Citation:

42 CFR 417 subpart Q

Legal Deadline:

None

Abstract:

Medicare contracting Health Maintenance Organizations (HMOs) and Competitive Medical Plans (CMPs) as well as Health Care Prepayment Plans (HCPPs) are required to provide Medicare enrollees with a decision (called an ''initial organization

determination'') as to whether a service will be provided or a claim paid. Contracting health plans must also provide a second level of review (called a ''reconsideration'') if the initial decision is adverse to the beneficiary and the Medicare enrollee requests the reconsideration. At both levels, the health plan has a regulatory 60-day time frame for responding to the beneficiary, regardless of whether it is a service denial or a retrospective claims denial. This regulation would revise these time frames and distinguish service-related decisions (i.e., preservice denials, terminations of services, and reductions in services) from claims for payment, as well as establish an expedited review requirement. This regulation would require, at both the initial and reconsideration levels, that: standard service-related decisions be made with 20 working days; review of expedited cases be made within a time period appropriate to the situation but, generally, not exceeding 72 hours; and claims within an appropriate period not to exceed 60 days.

Statement of Need:

Results of HCFA's efforts to gain more beneficiary input and studies by various external organizations clearly indicate the need for more rapid turnaround on decisions involving medically necessary, covered services. Delays in such decisions could affect quality of care and the health status of Medicare enrollees. In addition, the need for expedited review in cases where a beneficiary's life, health status, or ability to function could be in serious jeopardy has been identified, and is becoming increasingly available to under-65 enrollees of managed care plans. Last, there has been confusion as to the appeal rights of Medicare enrollees who have received covered services, particularly from skilled nursing facilities and home health agencies, but for whom such services are subsequently terminated or reduced. This rule would clarify the Medicare enrollee's right to appeal in these situations.

Summary of the Legal Basis:

Section 1876(c)(5)(A) of the Social Security Act requires that the contracting HMO/CMP provide meaningful procedures for hearing and resolving grievances between the organization and the member. Subpart Q of 42 part 417 sets forth specific regulatory requirements for implementation of this provision. In a final regulation issued in November 1994, HCPPs were required to provide the appeal protections of this subpart.

Alternatives:

Various time frames for conducting preservice and other service-related denials were considered. This regulation proposes following time frames being recommended for adoption by the National Association of Insurance Commissioners (NAIC) in their Health Carrier Grievance Procedure Model Act, which will likely be used by State legislatures as a licensure requirement for HMOs and other managed care plans. Conformity with NAIC model requirements will enhance consumer/beneficiary understanding and utilization of appeal protections, eliminate confusion on the part of health plan staff responsible for the appeals process, and improve plan performance in this area.

Anticipated Costs and Benefits:

Although the costs and benefits associated with this rulemaking have not yet been estimated, no significant budgetary impact is anticipated. Medicare contracting health plans would experience additional costs associated with these appeals improvements, including a higher volume of appeals. These costs would be absorbed within the plans' Medicare payment amount. HCFA will experience some additional administrative costs associated with expansion of its reconsideration contract. These costs are justified by the improved protections available to beneficiaries who choose Medicare managed care. The appeals process is an integral and critical component to prepaid, managed systems of care. That is, the incentives of prepaid health plans to manage utilization of services is balanced by quality checks and balances, including the appeals process. A strong appeals process helps ensure that Medicare enrollees receive all medically necessary covered services.

Risks:

There is bipartisan and industry support for this rule and there are no apparent risks.

Timetable:

Action	Date	FR Cite
NPRM	12/00/96	

Small Entities Affected:

None

Government Levels Affected:

Federal

Additional Information:

OMC-025

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RIN: 0938–AH62

HHS—HCFA

FINAL RULE STAGE

35. REVISIONS TO REGULATIONS IMPLEMENTING CLIA (HSQ-226-F)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 263a

CFR Citation:

42 CFR 493

Legal Deadline:

None

Abstract:

This rule would respond to public comments received on a final rule published on February 28, 1992. The rule revised regulations applicable to laboratories and implemented provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578. The regulations apply to laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. They specify the performance requirements, based on test complexity and risk factors related to erroneous test results as required by CLIA, that apply to laboratories that are subject to CLIA. They also list requirements that permit waiver of the certification and inspection requirements for laboratories performing only limited testing. This rule is part of the Administration's

reinventing government and regulatory reform initiatives.

Statement of Need:

On October 31, 1988, the Congress enacted comprehensive changes to existing laboratory regulations in CLIA. This statute requires the regulation of any facility (including physician offices) that performs tests on human beings for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. Historically, the Department had regulated laboratories by ''location,'' rather than by the types of tests they performed. CLIA requires that the Department regulate by test, using what is commonly referred to as the ''complexity model'' to categorize individual laboratory tests based on the experience, skills, and judgment required to perform each test accurately. Requirements vary as a function of the complexity of the tests the laboratory conducts.

The law requires the Secretary to implement the numerous provisions through regulation to ensure the quality of laboratory testing, regardless of where it is provided or who is providing the testing. The law also requires the CLIA program be operated through the assessment of user fees paid by entities subject to these requirements.

On May 21, 1990, the Department published proposed rules to implement CLIA and received public comments from over 60,000 commenters. Based on analysis of these comments, the Centers for Disease Control and Prevention with the Health Care Financing Administration developed a final rule with comment period that set forth standards for all entities performing laboratory testing based on test complexity. This rule was published on February 28, 1992, and was effective September 1, 1992. This regulation was revised by regulations with comment period published on January 19, 1993, December 6, 1994, and April 24, 1995.

Issues that will be addressed in this rule include quality control, quality assurance, personnel standards, cytology requirements; proficiency testing (PT) requirements; employee workplace drug testing; and other issues raised by commenters based on experience with CLIA implementation.

The Clinical Laboratory Improvement Advisory Committee (CLIAC), which is composed of members of professional organizations and private citizens, is actively involved in making recommendations regarding technical and scientific aspects of the regulations. In addition, we actively solicit comments from outside organizations such as the American Medical Association, the Association of State and Territorial Public Health Laboratory Directors, and other professional and medical organizations regarding the interpretive guidelines for surveyors.

Summary of the Legal Basis:

This rule summarizes and responds to CLIAC recommendations and public comments to four previously published CLIA regulations.

Alternatives:

HHS is currently developing a final rule that will address comments received on the final rule with comment period published February 28, 1992, and further comments received in response to the January 19, 1993, December 6, 1994, and April 24, 1995 rules with comment period. Based on these comments, modifications to improve the cost-effectiveness of the CLIA standards are under consideration.

Anticipated Costs and Benefits:

It is not possible to project costs and benefits of the rule at this time. These regulations serve to ensure consistent, reliable laboratory testing that is an integral part of ensuring that individuals receive appropriate treatment.

Risks:

Inferior and inappropriate laboratory testing can result in misdiagnosis causing patient harm. CLIA reduces the potential for inaccurate diagnosis resulting from poorly performed laboratory testing since entities must meet requirements (e.g., quality assurance, proficiency testing, quality control, personnel requirements) that have a direct impact on laboratory testing results. Overly stringent standards could, however, discourage needed testing and reduce early detection of health problems. The Department does not at this time have an estimate of the magnitude and severity of these types of risks, but believes that both the original regulations and the revisions will on balance contribute to better diagnosis.

Timetable:

Action	Date	FR Cite
NPRM	05/21/90	55 FR 20896
NPRM Comment Period End	09/21/90	
Final Rule With Comment Period	02/28/92	57 FR 7002
Comment Period End	04/28/92	
Effective Date	09/01/92	
Final Rule Effective Date	01/19/93	
Final Rule With Comment Period	01/19/93	58 FR 5215
Comment Period End	03/22/93	
Final Action	09/00/97	

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

HSQ-226

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RIN: 0938–AE47

HHS—HCFA

36. CLIA PROGRAM: CATEGORIZATION OF WAIVED TESTS (HSQ-225-F)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 263a

CFR Citation:

42 CFR 493.2; 42 CFR 493.7; 42 CFR 493.9; 42 CFR 493.15; 42 CFR 493.20; 42 CFR 493.25; 42 CFR 493.35; 42 CFR 493.37; 42 CFR 493.39; 42 CFR 493.45; 42 CFR 493.47; 42 CFR 493.49; 42 CFR 493.53; 42 CFR 493.1775

Legal Deadline:

None

Abstract:

As part of the CLIA program (see RIN: 0938-AE47), this rule will revise our

current process of evaluating tests against generic criteria. A waiver will be granted to any test that meets the statutory criteria, provided that scientifically valid data are submitted verifying that the criteria were met.

Statement of Need:

This final rule will clarify and expand the waiver criteria and streamline the waiver process so that more tests may be categorized as waived; that is, free from CLIA performance and personnel requirements.

Summary of the Legal Basis:

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was established to advise and make recommendations on technical and scientific aspects of the regulations. The CLIAC recommended that the criteria for categorizing tests as waived be better defined. As a result of the comments concerning waived tests and the CLIAC recommendations, the Centers for Disease Control and Prevention developed criteria for placing tests in the waived category as outlined in this proposal.

Alternatives:

Performance standards based on current analysis specific criteria would have limited technology and impeded innovative ideas.

Anticipated Costs and Benefits:

This regulation decreases burden, especially for physician office laboratories due to virtually no regulatory oversight. It increases access to a greater variety of tests. Physician office laboratories may expand the range of tests they perform without an increase in costs/burden. The regulation creates incentives for manufacturers to develop more test systems that meet the clarified waiver criteria and criteria for approval for home use. It eliminates inspection fees for many of the 60,000 physician offices and other small laboratories performing tests that will fall into the expanded waived category.

Risks:

The expansion of the waived criteria and development of a process protocol will provide for consistent application of detailed standards in order to ensure that tests categorized as waived preclude any reasonable risk of harm to patient as a result of testing error.

Timetable:

Action	Date	FR Cite
NPRM	09/13/95	60 FR 47534
NPRM Comment Period End	11/13/95	
Final Action	04/00/97	

Small Entities Affected:

None

Government Levels Affected:

None

Additional Information:

HSQ-225

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RIN: 0938–AG99

HHS—HCFA

37. MEDICARE PROGRAM: REVISIONS TO PAYMENT POLICIES AND FIVE-YEAR REVIEW OF AND ADJUSTMENTS TO RELATIVE VALUE UNITS UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1997 (BPD-852-FC)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1395w-4

CFR Citation:

42 CFR 41O; 42 CFR 415; 42 CFR 410; 42 CFR 411; 42 CFR 412; 42 CFR 413; 42 CFR 414; 42 CFR 415; 42 CFR 417; 42 CFR 489

Legal Deadline:

Final, Statutory, January 1, 1997.

Abstract:

This rule discusses several changes affecting policies for specific physician services and the relative value schedule for calendar year 1997 including locality changes and Medicare payment for diagnostic services and transportation in connection with furnishing diagnostic tests. The rule implements section 1848 of the Social Security Act.

Statement of Need:

The Omnibus Budget Reconciliation Act (OBRA) of 1989 changed the basis of the Medicare physician payment system from reasonable charge to a fee schedule based on relative value units (RVUs). The fee schedule was first implemented in 1992. This regulation will announce the RVUs upon which Medicare payment for physician services will be based in 1997. The public was given a 60-day period to comment on the interim values. It will also explain the process by which the interim RVUs were reviewed and, in some cases, revised as a result of public comments.

After four full years of experience with the physician fee schedule, we continue to reevaluate related payment policies. Proposed revisions to these policies were announced in a notice of proposed rulemaking on July 2, 1996. This final rule will respond to the public comments received on those proposals and announce the final policy decisions. Thus, it will discuss changes in payment localities; special rules for the payment of diagnostic tests, including diagnostic radiology procedures; transportation in connection with furnishing diagnostic tests; changes in the status of certain services; and technical changes in our rules for payments to supervising physicians in teaching settings.

In addition, this regulation will discuss the changes made as a result of the 5-year review of physician work relative values mandated by the statute. In this regard, we have and will continue to work with the physician community through the American Medical Association Specialty Society Relative Value Update Committee.

Summary of the Legal Basis:

42 USC 1395w-4

Alternatives:

An alternative to this rulemaking would be to continue to base payments on 1996 RVUs. This would continue inappropriate payments for certain services and would not allow a national basis for paying for new rule. By not revising the payment policies described in this notice, we would continue inadequate or inequitable payments for certain physician services.

Anticipated Costs and Benefits:

Section 1848(c)(2)(B) of the Social Security Act requires that adjustments to RVUs for a year may not cause the amount of expenditures to differ by more than $20 million from the amount of expenditures if the adjustments had not been made. In general, the payment policies and other revisions included in

this rule will be implemented in a budget-neutral manner. Although this is viewed as an economically significant rule under 5 USC 801, total Medicare expenditures will not be increased or decreased as a result of most of these changes.

Risks:

Not applicable

Timetable:

Action	Date	FR Cite
NPRM	07/02/96	61 FR 34614
NPRM Comment Period End	09/03/96	
Final Rule with Comment Period	01/00/97	

Small Entities Affected:

None

Government Levels Affected:

None

Additional Information:

BPD-852

Agency Contact:

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RIN: 0938–AH40

HHS—HCFA

38. ● HEALTH INSURANCE REFORM: PORTABILITY AND NONDISCRIMINATION IN THE GROUP INSURANCE MARKET; PORTABILITY IN THE INDIVIDUAL INSURANCE MARKET; REQUIREMENTS ON STATE FOR ALTERNATIVE MECHANISMS FOR REG

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 104-191, sec 102; PL 104-191, sec 111

CFR Citation:

Not yet determined

Legal Deadline:

Final, Statutory, April 1, 1997.

Abstract:

This interim final rule will include policies for group and individual markets on portability, availability, and renewability. It will: (1) guarantee access to health insurance for firms with fewer than 51 employees and to all individuals in those groups; (2) limit the use of pre-existing conditions exclusions in the group market; (3) guarantee access to individual converage for people who lose their group coverage; and (4) set forth requirements imposed on health insurance issuers. It will also establish rules that would apply to a State where its alternative mechanism is disapproved or its is determined that the State is not substantially enforcing the portability provisions governing health insurance issuers in the State.

Statement of Need:

The Health Insurance Portability and Accountability Act of 1996, (HIPPA, or Pub. L. 104-191) requires the Secretaries of Labor, Treasury, and Health and Human Services to promulgate implementing regulations for that Act by April 1, 1996. If this is not done timely, the effective date of the protections under the law shall be delayed, with potential harm to protected eligible individuals.

Summary of the Legal Basis:

HIPAA includes provision at a new section 2792 of the Public Health Service Act requiring and authorizing the Secretary of Health and Human Services to promulgate such regulations as may be necessary or appropriate to carry out the provisions of the Act. Other provisions of the Act specify implemented through regulation.

Alternatives:

HIPAA requires that its provisions be implemented through regulations. This is a new area for Federal oversight, and no related prior regulations exist.

Anticipated Costs and Benefits:

These rules will benefit eligible individuals by assuring them of continuity of health coverage when they lose coverage under a group health plan as a result of termination of employment, or as a result of certain other events, of the individul or of a person under whose coverage the individual had been a dependent. As a result, many people will not become uninsured, and many others will be able to maintain coverage without the imposition of new pre-existing condition limitations on coverage. This regulation will assist small employers by assuring that they will have access to group coverage for their employees in the small group market. It also will impose costs on small insurance companies. Overall, there may some increase in premium costs for all participants in the small group and individual insurance markets.

A full cost analysis is not complete. Congressional Budget Office analyses of the impact on plans and insurers of mandated coverage showed the cost of that coverage would be on the order of $400 million annually.

Risks:

The promulgation of there regulaitons will put in place protections in the insurance market that will assure eligible individuals continuity of coverage and relief of new pre-existing condition limits. Failure to timely promulgate these regulations will delay their effect, and will result in harm to some of those individuals who would otherwise have been protected.

Timetable:

Action	Date	FR Cite
Interim Final Rule with Comment Period	04/00/97	

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

State, Local, Federal

RIN: 0938–AH75

HHS—Administration for Children and Families (ACF)

PROPOSED RULE STAGE

39. ● TANF AUDITS/PENALTIES AND CORRECTIVE ACTIONS

Priority:

Other Significant

Legal Authority:

PL 104-193

CFR Citation:

45 CFR 201

Legal Deadline:

None

Abstract:

This regulation will discuss the audit and penalty requirements of TANF and

will include a discussion of the reasonable cause exception, a description of corrective compliance plans, and provide information on an appeals process.

Statement of Need:

This regulation is necessary to implement the provision of the new welfare reform legislation requiring penalties and corrective actions be taken in certain, specified situations.

Summary of the Legal Basis:

Section 409 and section 410 of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Alternatives:

There are no viable alternatives.

Anticipated Costs and Benefits:

No additional costs to the public.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	01/00/97	

Small Entities Affected:

None

Government Levels Affected:

State, Tribal, Federal

Agency Contact:

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RIN: 0970–AB76

HHS—ACF

40. ● TANF WORK REQUIREMENTS

Priority:

Other Significant

Legal Authority:

PL 104-193

CFR Citation:

45 CFR 204

Legal Deadline:

None

Abstract:

This regulation will describe the work participation rate requirements of welfare reform, discuss the two-year time limit for receiving TANF benefits, and will explain how participation rates can be reduced based on caseload reductions.

Statement of Need:

This regulation is necessary to help States fully understand their responsibilities to assure welfare recipients will be able to leave welfare and enter the work force within prescribed periods of time.

Summary of the Legal Basis:

Section 407 of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Alternatives:

There are no viable alternatives.

Anticipated Costs and Benefits:

No additional costs to the public.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	03/00/97	

Small Entities Affected:

None

Government Levels Affected:

State, Tribal, Federal

Agency Contact:

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