

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Statement of Regulatory Priorities

Overall Regulatory Priorities

The Department of Health and Human Services (HHS) provides direct services or assistance to one of every five Americans. With emphasis on children, 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 to Americans. HHS activities are striking in their variety, 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 and welfare statistics to providing job training, health clinics, and Head Start services; and from the cutting edge of health research at the National Institutes for Health to regulating products that account for some 25 cents of every dollar spent by American consumers at the Food and Drug Administration.

HHS is committed to the Administration's initiatives to substantially reform existing regulations in order to reduce regulatory burden while meeting the health and human services responsibilities of the Department.

HHS began its comprehensive review of existing regulations with implementation of the President's Executive Order 12866 of September 30, 1993, on Regulatory Planning and Review. To assist in identifying priorities for HHS's review of existing regulations, the Department solicited recommendations from the public on plans for review in a January 20, 1994, Federal Register notice. More recently, on May 8, 1995, HHS again requested public comment on this Department's regulations in the Unified Agenda, seeking suggestions for furthering regulatory reform efforts.

HHS's review accelerated in 1995 with the establishment of regulatory reinvention task forces targeted at specific industries, under the leadership of the Vice President. HHS played a major role in two of these groups—one on drugs and medical devices and one on the health care industry. These efforts produced important reforms in regulations concerning clinical laboratories, hospitals, dialysis centers, drugs, biologics, and medical devices.

The Regulatory Reinvention Initiative

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.

These efforts have been a major undertaking of the Department. The changes in our regulations and 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 expect and deserve. As a result of this year's page-by-page review of HHS's portion of the Code of Federal Regulations (more than 6,900 pages), the Department plans to eliminate more than 1,000 pages by rulemaking (approximately 15%), as well as an additional 700 or so pages that will require statutory change, and reinvent another 2,200 pages (approximately 32%). In all, HHS plans to eliminate or reinvent over 50 percent of the pages.

These efforts have already produced a number of successes in reducing burden. For example, the Medicare program will no longer require the "attestation statements" that physicians had to sign before hospitals could submit claims for payment. These statements were abolished in a final rule published September 1, 1995. Ending this requirement eliminates 11 million forms a year, saving almost 200,000 hours of physician time and decreasing hospital administrative costs by approximately \$22,500 per hospital annually.

In another case, before a regulation was issued in July 1995 by the National Institute for Occupational Safety and Health (NIOSH), the only respirator for health care workers that met criteria for

the prevention of tuberculosis cost the purchaser approximately \$8. The first respirators certified under the new regulation range in price from about \$1 to \$3, according to manufacturers' data. Working closely with the industry, NIOSH developed a regulation that provides better protection for workers and increased savings for industry.

Other examples of reinvention of HHS regulations and approaches to rulemaking are discussed throughout this year's Regulatory Plan and Unified Agenda.

Consultation with our Partners

HHS has examined its approach to rulemaking in light of Executive Order 12866, the Regulatory Reinvention Initiative, Executive Order 12875 on Intergovernmental Partnerships, and the related legislation on Unfunded Mandates. As a result, HHS is undertaking more frequent and earlier consultation with those parties affected by rulemaking. HHS will use a number of innovative approaches as it works on developing the most effective strategies for consultation with State and local governments and the wide variety of other groups and individuals affected by regulations issued by this Department. For example, in the spring of 1995, senior HHS officials from the Food and Drug Administration, the Health Care Financing Administration, and the Administration for Children and Families held grassroots meetings at a number of locations around the Nation to hear first-hand the concerns of our regulatory partners regarding the issues facing the Department.

Last year for the first time, the Department used the negotiated rulemaking approach to develop rules in a consensual process. This process brings HHS together with the external interests who would be significantly affected by a new rule to reach consensus through open discussions on some or all issues under consideration before a rule is formally published as a notice of proposed rulemaking. HHS recently completed a negotiated rulemaking for reforming the Medicare hospice wage index and is now using the process to revamp the Indian health programs based on the Indian Self-Determination and Education Assistance Act.

HHS is taking a new approach to its relationship with State, local, and tribal governments. Pursuant to Executive Order 12875 "Enhancing the Intergovernmental Partnership" and the "Unfunded Mandate Reform Act of 1995," HHS is committed to avoiding,

where possible, imposition of mandates—funded, and particularly unfunded—and to consulting with appropriate levels of government as early as possible in the development of policies and regulations affecting them. HHS is carrying out its decisionmaking and consultation with a full appreciation of State, local, and tribal governments as partners in serving the public.

The Department's regulatory priorities also include initiatives related to implementation of the Department's strategic goals and enacted congressional legislation. For example, new Head Start regulations will not only strengthen the existing program as an investment in our Nation's children, but will also implement the new component for infants and toddlers through performance standards. Another regulatory initiative that will further the goal of investing in the future of our Nation's children is the Food and Drug Administration proposed rule restricting the sale and distribution of addictive tobacco products to children and adolescents.

Because of the significance of HHS's regulatory responsibilities, the Department believes that the principles of Executive Order 12866, the Regulatory Reinvention Initiative, and related efforts are particularly important in assuring that HHS's activities most effectively meet their objectives with as little burden as possible on the public. In ongoing efforts, HHS will emphasize regulating only where required by statute or to meet a compelling public need, fully considering the costs and benefits of regulatory alternatives, increasing consultation with affected public, and reducing regulatory burden.

Agency Plans

Virtually all HHS regulations are issued by a handful of agencies within the Department. Descriptions of priorities for these 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. Working closely with the public in developing new rules, HCFA has been conducting listening events around the country concerning specific regulations to collect ideas on partnerships from front-line regulators, those being regulated, and other

interested stakeholders. Some examples of specific successes follow.

Accomplishments

Even before the September 1, 1995, elimination of the physician attestation requirement mentioned above, HCFA eliminated the regulatory requirement that hospitals obtain a signed acknowledgement form from each attending physician every year. This form acknowledged that the physician understood the penalty for misrepresenting the information on an attestation statement relating to principal and secondary diagnoses and major procedures performed on patients. Beginning in April 1994, physicians are only required to sign a one-time acknowledgement statement upon being granted admitting privileges at a hospital.

As a result of a rule published July 25, 1994, the process for obtaining Medicaid home and community-based services waivers was simplified and now enables States to offer a wide variety of home and community-based services as cost-effective alternatives to more expensive institutional care. Without this regulatory change, joint State and Federal efforts to expand opportunities to provide cost-effective alternatives to institutional care would have been frustrated. The regulatory provisions were worked out in collaboration with the States, through the National Governor's Association.

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, 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, 1995.

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 September 1, 1995, 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 two 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.

HCFA's Regulatory Reform Initiatives Included in the 1995 Plan

The October 1995 Plan includes the President's and Vice President's initiatives for reinventing health care regulations. (One of the initiatives, eliminating the physician attestation form, was finalized in the September 1, 1995, annual rule on the hospital prospective payment system and is not included in the 1995 Plan.)

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 (HHAs), and end-stage renal disease (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.

HCFA will conduct a pilot project in four States to apply a different, less prescriptive set of rules to excellent ESRD facilities. Under the pilot project, an ESRD facility's performance will be measured using only three key patient care outcome indicators. Facilities that document sustained achievement in the outcome indicators over 6 consecutive

months will be awarded a HCFA certificate of excellence. Information about project results will be packaged in brochures and newsletters so that ESRD patients and nonparticipating ESRD facilities will be aware of the results.

HCFA will also conduct a pilot project that will evaluate the impact of the elimination of Medicare personnel requirements for ESRD facilities. The pilot project will be conducted in concert with the project establishing relaxed rules for ESRD facilities with good track records (see above). HCFA will collect information regarding the skills level of all personnel employed by those facilities participating in the project. Facilities will be informed that as part of the project Medicare will not apply any of the personnel requirements contained in the conditions for coverage. At the end of the 2-year project period, HCFA will re-collect information regarding the education and experience levels of all the facility's staff and evaluate the impact of the changes on predetermined measures of quality of care.

HCFA's Legislative Initiatives

Three of the initiatives from the July 1995 report will require statutory revisions before new regulations can be developed. First, Home Health Agencies are required by law to be surveyed yearly, even though historical data show that this frequency is excessive for many HHAs and does not improve care. Legislation is being proposed to allow flexible survey cycles.

Second, States must currently perform annual assessments of Medicaid nursing home residents with mental illness or mental retardation. This duplicates the requirement for Medicare- and Medicaid-certified nursing homes to assess their residents promptly after admission, after a significant change in condition, and no less often than annually. Under a legislative proposal, the redundant requirement for annual State reviews would be eliminated, reducing costly duplication. The assessments conducted by the nursing homes ensure that residents' continuing needs are properly evaluated and met.

Third, a legislative proposal would specify that a State could choose to approve a nurse aide training and competency evaluation program offered in (but not by) a nursing home, subject to an extended or partial extended survey or certain other sanctions, if the State determines that there is no other nurse aide training and competency evaluation program offered within a reasonable distance. This statutory

change would relieve a special problem encountered by rural nursing homes where alternate training programs may not be readily accessible. The proposal would alleviate this problem and still ensure patient health and safety.

HCFA's Objectives

HCFA has made communication, cooperation, and partnership the guiding principles of the regulatory process, replacing the adversarial environment that often existed in the past. At a time when the American health care system is undergoing dramatic changes, HCFA is committed to putting the Federal Government's customers—the American people—first. The Nation can look forward to continued endeavors to reduce and eliminate unnecessarily burdensome regulations.

Food and Drug Administration (FDA)

FDA has made substantial progress toward carrying out vitally important regulatory reforms identified in response to the Clinton Administration's emphasis on reforming the Federal Government's regulatory processes with no sacrifice in public health and safety protections. FDA's reforms have three broad goals: to eliminate unnecessary burdens on the regulated industry, to get products to market more quickly, and to allow FDA to do its job more efficiently. The agency is well on its way toward accomplishing many of these reforms—others are in early stages of development, and still more potential reforms have been identified. For example, FDA has already outlined, in a report published by the Clinton Administration in April, a number of reforms that are under way in the regulation of drugs, biologics—including biotechnology products—and medical devices. The agency will propose further reforms in these areas and has identified and will propose reforms for human food products, new animal drugs, and medicated animal feeds.

Under the Prescription Drug User Fee Act of 1992, FDA has used the income from user fees to shorten substantially the review of new drugs, vaccines, and biotechnology products. Average review times dropped by more than 30 percent between 1992 and 1994—from 30 months to 20 months, and by 1997 FDA will be making decisions on these products in a year or less after applications are submitted—as fast, or faster than anywhere else in the world, with no sacrifice in quality. Medical devices and animal drugs are now

reviewed more efficiently as well, and a record number of 38 new animal drugs was approved in 1994.

Regulatory Reinvention Proposals

The reforms identified so far for drugs, biologics, and medical devices are estimated to save manufacturers \$500 million per year through measures such as:

- Allowing manufacturers of drugs and biologics to change the way they manufacture an approved product without submitting applications for FDA preapproval if the risk involved is negligible;
- Publishing a notice on April 6, 1995, clarifying that biologic manufacturers may use pilot or small-scale facilities (instead of building far more costly full-scale facilities) to conduct safety and efficacy studies of their products;
- Eliminating special requirements for insulin and antibiotics that are outdated and burdensome to manufacturers of these products;
- Excluding drug and biologic manufacturers from requirements for most environmental assessments, which cost tens of thousands of dollars and provide no real benefit to the environment;
- Exempting up to 125 categories of low-risk medical devices from premarket review, adding to the 441 categories already exempted from review (a final rule exempting 9 categories was published on July 28, along with a proposal to exempt 12 additional categories);
- Publishing a notice on June 2, 1995, eliminating the "Reference List" program by clarifying that marketing clearance of a device will not be deferred for uncorrected manufacturing violations unless there is a reasonable relationship between the violations and the application under review;
- Seeking authority to set up a user-fee program for medical devices, similar to the program that has shortened drug reviews, that would allow FDA to charge industry user fees and commit the agency to meet strict performance goals;
- Publishing a notice on August 1, 1995, clarifying FDA's effectiveness requirement for drugs and medical devices, to give industry a better understanding of how to go about developing new products and firmly refute a concern that FDA requires a new drug or device to be more effective than comparable therapies that are already approved; and
- Harmonizing FDA's drug and device testing requirements with those of

other countries, to reduce duplicative testing and expedite international marketing of new products.

Some of the reforms in the April report are facilitated by regulations included in the Unified Agenda, which appears elsewhere in this issue of the Federal Register. For example, for documents required to be maintained but not submitted to FDA, persons could use electronic records and signatures upon the effective date of a final rule. For documents submitted to FDA, persons could use electronic records and signatures if FDA has stated, in a public docket to be maintained for that purpose, that the intended receiving organization is prepared to accept the submission in electronic form. This step will simplify recordkeeping for industry and will support FDA's Submission Management and Review Tracking (SMART) Program, which aims to develop and implement a number of automated applications, including Establishment Licensing Applications for biologics firms, a gene therapy patient registry, and preapproval inspections.

In other Unified Agenda entries, FDA is proposing to expand the criteria for allowing the export of investigational medical devices to developed countries. The goals of this reform are to relax restrictions on exports of investigational products to industrialized nations, while leaving intact existing protections for countries that are not industrialized. FDA is also proposing to allow the name of the developer of a biologic (which must be listed as a selling agent or distributor) to be listed in product labeling with equal prominence as the name of the manufacturer. This will benefit small, innovative firms that develop important new therapies, but, because of a lack of capital, must rely on other firms to manufacture their therapies in commercial quantities.

Regulatory Plan Entries

FDA's Regulations Plan, which follows, contains initiatives that reflect the Clinton Administration'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 cut back significantly on the number of applications that drug and device manufacturers are required to submit, eliminate many pages of regulations that are outdated, duplicative, or otherwise in need of reform from the Code of Federal Regulations (CFR), seek to prevent children and adolescents from forming

a habit with long-term health consequences, protect the health of women by assuring the high quality of mammography, and set forth a voluntary program of disseminating to consumers important information on their prescription drugs.

Currently, sponsors of licensed biological products must obtain FDA approval of such changes as changes in product labeling, production process, equipment, and facilities by submitting supplements to approved marketing applications. This process has become burdensome, time-consuming, and unnecessarily rigid, and FDA is proposing a new process that will reduce the number of supplements that license holders must submit for these changes each year by an estimated 50 percent—from 1,000 to 500. The new process creates different categories for changes, based on their potential to adversely affect the product, and reporting requirements are tailored to each category.

FDA regulates 1,700 types of medical devices, and manufacturers of most of these types of devices must submit information to FDA and receive FDA clearance before marketing them. FDA has determined that, when such a device poses a low level of risk to patients, review is not necessary to protect the public health; it places an unnecessary regulatory burden on device manufacturers, and it delays introduction of new devices. Accordingly, FDA is proceeding to exempt low-risk medical devices from premarket notification requirements and, to date, has exempted 450 of them. The agency will issue a final rule exempting more than 100 additional types of devices so that, when this rulemaking is completed, one-third of the regulated devices will be exempted from premarket notification requirements.

In response to the President's charge to conduct a page-by-page review to identify regulations that are obsolete or otherwise in need of reform, FDA has determined that 941 pages of its regulations in the CFR should be deleted. Congressional approval will be sought for deletion of 735 of these pages, and FDA will propose to delete regulations that can be deleted administratively, including regulations that are actually statements of policy or guidance, that have been made inaccurate by changes in legislation or technology, or that are duplicative. FDA is proposing to delete a number of food standards for which there is little public interest, and regulations dealing with

substances no longer used in product formulations or products that are no longer marketed.

If children and adolescents are prevented from using nicotine-containing tobacco products habitually, they will avoid the serious health problems caused later in life by use and addiction to the nicotine in these products. FDA is proposing regulations that would affect the easy access and promotion and sale of nicotine-containing tobacco products to individuals at the young age when the majority of tobacco users take up the habit. The proposed rule would not restrict the use of tobacco products by adults.

Nearly half a million women will die of breast cancer during the nineties, and more than one and one-half million new cases will be diagnosed. Currently, the most effective method for detecting breast cancer is mammography. To assure quality in all aspects of mammography, FDA is proposing regulations to implement provisions of the Mammography Quality Standards Act (MQSA) that allow for oversight of all mammography facilities through a certification and inspection program. The proposed regulations set forth requirements for accreditation bodies, equipment, quality assurance, and personnel. The certification standards are existing private sector standards and allow implementation of the MQSA with minimum burden on mammography facilities.

In recognition of the importance of the individual participating in his or her own health care, FDA is proposing performance standards for drug labeling that will provide a readily available and understandable source of the information patients need in order to use their prescription drugs safely and properly. In accordance with the Administration's philosophy of fairly assessing a voluntary approach before imposing requirements through regulations, FDA is proposing that this information be disseminated through voluntary private sector initiatives. The goal of the proposal is for distribution of useful patient information to 75 percent of individuals receiving new prescriptions by the year 2000, and to 95 percent by the year 2006. Informing patients will reduce the potential for harm related to inappropriate prescription drug use and make it possible to realize substantial savings in health care costs.

Administration for Children and Families (ACF)

ACF is committed to a management and stewardship philosophy that fosters excellence through customer focus, results orientation, and the talents of staff. The agency has reinvented the way it conducts business: Redefining relationships with States, tribes, and other grantees; stressing creation of partnerships; and focusing on program outcomes that indicate improvement in the lives of children and families through efficient and effective means.

Regulatory reform is an important element of ACF's reinvention strategy. The agency has already undertaken a comprehensive, page-by-page review of its regulations and eliminated hundreds of unnecessary pages. More importantly, a cultural change in the agency has taken place that will improve the approach taken in future rulemakings. All ACF regulatory efforts will, without fail, respond to the needs of State and local partners and the public at large by routinely employing a consultative process that is open and reaches out to all involved parties. In tandem with this, ACF is actively seeking to reduce burden and focus on outcome rather than process.

The benefits of this strategy will be evident in a key upcoming initiative to establish performance standards with respect to Head Start services provided to children 0 to 5 years old, as well as in the adoption of final rules proposed in the last regulatory planning period, including a computer systems rule designed to reduce reporting and recordkeeping burdens on States and Family Preservation and Family Support rules that provide a consultative and coordinated approach to service planning, consolidating two service programs under title IV-B of the Social Security Act. ACF will continue to create partnerships with the stakeholders of all new regulatory initiatives to effect improved services and outcomes for children and families.

HHS—Substance Abuse and Mental Health Services Administration (SAMHSA)**FINAL RULE STAGE****26. BLOCK GRANTS FOR PREVENTION AND TREATMENT OF SUBSTANCE ABUSE (TOBACCO PROVISIONS)****Priority:**

Other Significant

Legal Authority:

42 USC 300x-21

CFR Citation:

45 CFR 96; 45 CFR 130

Legal Deadline:

None

Abstract:

Sets procedures for the Secretary to determine compliance under section 1926 of the PHS Act regarding State enforcement of laws against sale of tobacco products to minors as a condition of full funding of Federal block grants for prevention and treatment of substance abuse.

Statement of Need:

Section 1932(d) of the Public Health Service (PHS) Act requires the Secretary to publish regulations on the standards that will be used in approving Substance Abuse Prevention and Treatment Block Grant applications. Section 1926 of the PHS Act requires that States, as a condition of receiving a grant, must have in place a law that prohibits the sale and distribution of tobacco products to minors. It further requires the States to enforce the provision in a manner that can reasonably be expected to reduce the availability of tobacco products to minors, and to conduct annual, random, unannounced inspections to ensure compliance with the law.

In addition States are required to report as part of their application for Block Grant funds the activities carried out in the previous year for enforcing the provision, the State's success in reducing the availability of tobacco products to minors, and the activities it plans to carry out during the year for which it is seeking funds. If the Secretary determines that a State has not complied with the requirements of section 1926, the Secretary shall penalize the State 10 percent of its allotment the first year, 20 percent the

second, 30 percent the third, and 40 percent the fourth and all subsequent years.

These regulations set the criteria and standards for the Secretary's determination of compliance with section 1926.

A notice of proposed rulemaking was issued on August 26, 1993 and the public was given 60 days to comment. The Department will respond to those comments and amend the proposed rule as appropriate.

Alternatives:

The Department has minimal discretion in establishing the criteria and standards to use for establishing compliance. States are statutorily required to carry out random inspections of outlets in a manner that provides an accurate, reliable and valid measure of how successful the enforcement of the provisions is being conducted throughout the State. The results of these inspections constitute an objective measure for the Secretary's use in determining compliance.

Anticipated Costs and Benefits:

The NPRM was considered a major rule for the purposes of carrying out an economic impact analysis. With regard to the States enforcing the State laws on the availability of tobacco products to minors and for conducting the inspections, States may only use the 5 percent of their allocation that they currently use for the purposes of administering the block grant. Thus little or no Federal funds are available to the States to enforce their statute.

We estimate the cost of a substantial enforcement effort at \$50 million nationwide. The costs of training staff, moving vending machines, etc., we estimate will cost businesses about \$100 million nationwide. The costs of carrying out the inspections we believe will be between \$1 and \$2 million nationwide. This suggests a total cost of a maximum effort at \$152 million nationwide.

The annual benefit of the provision is in reduction of medical bills incurred by those who choose to stop smoking; reduced sick leave and group life-insurance subsidies, increased productivity and the taxes realized from people choosing to stop smoking; the value of lives gained; reduced costs for fire damage that would have been caused by the smokers; and the lives saved from those fires that would not happen. We estimate these savings at one-sixth to one-third of a billion dollars per year.

Risks:

Implementation of the above-cited statute leaves the Department no option other than issuing a regulation in this area. In any case, the risks in not acting against illegal sales of tobacco products are great. The Centers for Disease Control and Prevention (CDC) estimate that at present approximately 500,000 minors become regular smokers each year. A major cause is ready access to illegal tobacco. Three fourths or more of all outlets sell illegally to minors, due in part to insufficient enforcement efforts by many States, which encourage a scofflaw attitude among merchants. CDC estimates that 73 percent of all over-the-counter outlets and 96 percent of all vending machine outlets sell tobacco products to minors.

Timetable:

Action	Date	FR Cite
NPRM	08/26/93	58 FR 45156
NPRM Comment Period End	10/25/93	58 FR 45156
Final Action	12/00/95	

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

State, Tribal

Additional Information:

Previously reported under RIN 0905-AE05.

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HHS—Food and Drug Administration (FDA)**PRERULE STAGE****27. • FOOD STANDARDS OF IDENTITY, QUALITY, AND FILL OF CONTAINER; COMMON OR USUAL NAME REGULATIONS: REQUEST FOR COMMENTS ON EXISTING REGULATIONS****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:

21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 348; 21 USC 349; 21 USC 371; 21 USC 376

CFR Citation:

21 CFR 102 to 103; 21 CFR 130 to 131; 21 CFR 133; 21 CFR 135 to 137; 21 CFR 139; 21 CFR 145 to 146; 21 CFR 150; 21 CFR 152; 21 CFR 155 to 156; 21 CFR 158; 21 CFR 160 to 161; 21 CFR 163 to 166; 21 CFR 168 to 169

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is considering amending, revising, or revoking its food standards of identity, quality, and fill of container and its common or usual name regulations for nonstandardized foods to make them less burdensome on industry. A notice of proposed rulemaking that published October 13, 1995, identified, among other obsolete or otherwise unnecessary regulations, 17 specific CFR sections on food standards for possible revocation. In addition an advance notice of proposed rulemaking (ANPRM) would request comments on other such standards from all interested parties, including consumers, consumer groups, academia, the regulated food industry, food distributors, importers, and exporters on these regulations. The agency would seek comments on the benefits or lack of benefits of such regulations in facilitating domestic, as well as international, commerce and on their value to consumers, less costly alternative means of accomplishing the

statutory objective of food standards, that is, to promote honesty and fair dealing in the interest of consumers, in the manufacture and sale of food products covered by these regulations.

Statement of Need:

Standards of identity, quality, and fill of container are designed to protect consumers from manufacturing, packaging, and labeling practices that could result in economic deception, such as substitution of water or filler for more valuable constituents in a food or the use of substandard ingredients. Common or usual names are designed to ensure that the food products will bear names that are appropriately descriptive of the food so that consumers will be provided with sufficient information to make informed purchasing decisions in the marketplace. The agency has received complaints that some of these regulations should be amended, particularly some food standards, because they are overly restrictive and inhibit product development. Others may be obsolete and should be revised or revoked.

Summary of the Legal Basis:

Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) provides that food standards of identity, quality, and fill of container may be established when such action will promote honesty and fair dealing in the interest of consumers. Section 403(i) of the act which requires, among other things, that a nonstandardized food bear on its label the common or usual name of the food, and if the food is fabricated of two or more ingredients, the common or usual name of each such ingredient; and section 201(n) that provides, among other things, that an article (food, drug, or cosmetic) is alleged to be misbranded if its labeling or advertising fails to reveal material facts about the nature of the article, provide the agency with authority to establish common or usual name regulations. These regulations are promulgated under section 701(a) of the act (notice and comment rulemaking), except that actions for amendments or repeal of any dairy standards that are accomplished under section 701(e) of the act (formal rulemaking).

Alternatives:

This ANPRM requests public comment on ways to make existing regulations more flexible and less burdensome on industry. It also requests comment on alternatives to these regulations that

will provide comparable consumer protection.

Anticipated Costs and Benefits:

A proper assessment of the costs and benefits to be derived from this ANPRM is premature.

Timetable:

Action	Date	FR Cite
ANPRM	11/00/95	
ANPRM Comment Period End	03/00/96	
NPRM	00/00/00	
Final Action	00/00/00	

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

State, Federal

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HHS—FDA

PROPOSED RULE STAGE

28. MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992

Priority:

Other Significant

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 set regulatory 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 has proceeded with the development of proposed regulations to replace the interim rules. The agency now plans to issue 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 offer services commensurate with the value of mammography in the abstract. To ensure quality control compliance, the Congress enacted the MQSA.

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 an advisory committee to set regulatory quality standards and also provides for the establishment of surveillance systems to evaluate breast cancer screening programs.

The implementation of these regulations will 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:

Direct Federal costs in fiscal year 1995 are \$13 million. Yearly costs to mammography facilities, over a 10-year period, were estimated to range from a high of approximately \$88.8 million to \$24.3 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 \$50.5 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:

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 11/00/95

Mammography Quality Standards Act of 1992; Inspection Fees

Notice 03/17/95 (60 FR 4584)

Personnel Requirements

NPRM 11/00/95

Quality Standards for Mammography Equipment and QA

NPRM 11/00/95

Quality Standards for Mammography Facilities

Interim Final Rule 12/21/93 (58 FR 67565)

Requirements for Accreditation Bodies and Quality Standards

Notice (Advisory Committee) 12/21/94 (59 FR 65776)

NPRM 11/00/95

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

State, Federal

Additional Information:

Previously reported under RIN 0905-AE07.

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RIN: 0910-AA24

HHS—FDA

29. • REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO PRODUCTS TO PROTECT CHILDREN AND ADOLESCENTS

Priority:

Economically Significant

Legal Authority:

21 USC 351; 21 USC 360; 21 USC 360j; 21 USC 371; 21 USC 374

CFR Citation:

21 CFR 801; 21 CFR 803; 21 CFR 804; 21 CFR 897

Legal Deadline:

None

Abstract:

The Food and Drug Administration is proposing new regulations governing the sale and distribution of nicotine-containing cigarettes and smokeless tobacco products to children and adolescents, in order to address the serious public health problems caused by the use of and addiction to these products. The proposed rule would reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and would significantly decrease the amount of positive imagery that makes these products so appealing to them. The proposed rule would not restrict the use of tobacco products by adults.

The objective of the proposed rule is to meet the goal of the report "Healthy People 2000" by reducing roughly by half children's and adolescents' use of tobacco products. If this objective is not met within 7 years of the date of publication of the final rule, the agency will take additional measures to help achieve the reduction in the use of tobacco products by young people. In the proposed rule, the agency is requesting comment regarding the type of additional measures that would be most effective.

Statement of Need:

Approximately 50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco products. These tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illnesses, heart disease, and other health problems. On average, smokers who die from a disease caused by smoking have lost 12 to 15 years of life because of tobacco use.

Summary of the Legal Basis:

The FDA has conducted an extensive investigation and has engaged in comprehensive legal analysis regarding the agency's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. The results of that inquiry and analysis support a finding at this time that nicotine in cigarettes and smokeless tobacco products is a drug, and that these products are drug delivery devices within the meaning to the Food, Drug, and Cosmetic Act. Traditionally, the FDA has initiated enforcement actions in cases where the agency determines that a product is a drug or a delivery device. Because the agency has elected to embark on this initiative through rulemaking, no enforcement action will be brought pending completion of that process.

Alternatives:

FDA is proposing to regulate cigarettes and smokeless tobacco products by employing its restricted device authority, which affords the most appropriate and flexible mechanism for regulating the sale, distribution, and use of these products. Rather than banning tobacco products for the millions of Americans who are currently addicted to them, this regulation focuses on preventing future generations from developing an addiction to nicotine-containing tobacco products.

One alternative considered by the agency was a far more prescriptive monitoring requirement for tobacco manufacturers. Under the alternative, each manufacturer of tobacco products would have been required to adopt a system for monitoring the sales and distributions of retail establishments. The additional cost for this monitoring was estimated at about \$85 million per year. FDA rejected this alternative, because it was decided that the industry might employ its resources more efficiently if permitted to choose among alternative compliance modes. It is possible, however, that the industry might implement certain features of this approach in order to avoid the optional performance-based provision that would become effective if the "Healthy People 2000" goals were not met.

A second alternative considered by the agency was to require package inserts containing educational information in cigarette and smokeless tobacco products. A preliminary projection of one-time costs of this rule were about \$490 million and annual operating costs of about \$54 million. FDA did not select this alternative as the agency was not certain that the benefits of this provision would justify the large compliance costs.

FDA also considered setting the permissible age for purchase at 19 rather than 18, because many 18-year-old adolescents are still in high school, where they can easily purchase tobacco products for classmates. This alternative would have added costs of about \$34 million annually, mostly due to lost producer profits. The proposed regulation restricts access to regulated tobacco products for persons under the age of 18, because most adult smokers have already become regular smokers by the age 18, and because that age limit is already consistent with most State and local laws.

The agency also considered restricting rather than prohibiting sales from vending machines. However, studies indicated that measures such as placing locks on vending machines or restricting their placement failed to prevent young people from purchasing cigarettes from vending machines.

Anticipated Costs and Benefits:

To comply with the initial requirements of the rule, FDA projects that manufacturers and retailers of tobacco products would incur one-time costs ranging from \$26 to \$39 million and annual operating costs of about \$227 million. Achieving the "Healthy People 2000" goals, however could demand still further efforts by tobacco manufacturers to restrict youth access to tobacco products. Moreover, FDA plans to propose additional requirements that would become effective only if these goals were not met.

Each year, an estimated 1 million adolescents begin to smoke cigarettes. It is estimated that at least 24% of these youngsters will ultimately die from causes related to their nicotine habit. Other studies suggest even higher rates of excess mortality. As a result, FDA projects that the achievement of the "Healthy People 2000" goals would prevent well over 60,000 early deaths, gaining over 900,000 future life-years for each year's cohort of teenagers who would otherwise begin to smoke. The estimated monetary value of these benefits is projected to total from about \$28 to \$43 billion per year. In addition, the proposed rule would prevent numerous serious illnesses associated with the use of smokeless tobacco products.

Risks:

Cigarettes kill more Americans each year than acquired immune deficiency syndrome (AIDS), alcohol, car accidents, murders, suicides, illegal drugs, and fires combined. If even only a small fraction of the goals of the "Healthy People 2000" report were achieved, the benefits would be substantial. For example, it is estimated that halting the onset of smoking for only 1/20 of the 1 million adolescents who become new smokers each year would provide annual benefits valued at from \$2.9 to \$4.3 billion a year.

Timetable:

Action	Date	FR Cite
NPRM	08/11/95	60 FR 41314
NPRM Comment Period Extended to 01/02/96	10/16/95	60 FR 53560

Action	Date	FR Cite
NPRM Comment Period End	11/09/95	
Final Action	00/00/00	
Jurisdictional Analysis		
Notice 08/11/95 (60 FR 41453)		

Small Entities Affected:

Businesses

Government Levels Affected:

State

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HHS—FDA

30. • REVOCATION OF CERTAIN REGULATIONS

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will eliminate existing text in the CFR.

Legal Authority:

21 USC 321 to 394; 21 USC 41 to 50; 21 USC 141 to 149; 21 USC 467F; 21 USC 679; 21 USC 821; 21 USC 1034; 42 USC 202; 42 USC 262; 42 USC 263B; 42 USC 264; 15 USC 1451 to 1461; 5 USC 551 to 558; 5 USC 701 to 721; 28 USC 2112

CFR Citation:

21 CFR 100 to 101; 21 CFR 103 to 105; 21 CFR 109; 21 CFR 137; 21 CFR 161; 21 CFR 163; 21 CFR 182; 21 CFR 186; 21 CFR 197; 21 CFR 505; 21 CFR 507 to 508; 21 CFR 601; 21 CFR 620; 21 CFR 630; 21 CFR 640 to 660; ...

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is proposing to revoke certain regulations that either do not achieve public health goals or do not need to be codified as regulations to do so. These regulations include regulations that are actually statements of policy or guidance, that are duplicative, that

are obsolete, or that have been made inaccurate by changes in legislation and technology.

FDA is taking this action in response to President Clinton's directive of March 4, 1995, to all Federal agencies to conduct a page-by-page review of their regulations and to eliminate or revise those that are outdated or otherwise in need of reform. As a result of its regulations review, FDA is proposing to eliminate 36 percent of its regulations that it has determined are obsolete or no longer necessary to achieve public health goals (735 pages of which will first require Congressional action). In addition, FDA plans to revise or modify an additional 45 percent of its remaining regulations to ease the burden on regulated industry and the consumer without sacrificing public health protection. For those regulations requiring Congressional permission to eliminate or reform, the Administration is seeking legislation. This proposal contains deletions that can be accomplished administratively. Examples include regulations that refer to substances no longer used in product formulations or to products that are no longer marketed; and regulations that codify product standards that can be more flexibly handled and updated within the context of the review process. FDA is providing a 90-day period for public comment on these proposed deletions.

Statement of Need:

This proposal represents FDA's most recent effort toward achieving for all products under its jurisdiction a set of regulations that is leaner and more clearly focused. By eliminating regulations that are out of date, or duplicative, or that amount to mere statements of policy and guidance, the agency is eliminating the potential for confusion with respect to its requirements.

Summary of the Legal Basis:

FDA's authority to promulgate and withdraw regulations, as stated in the agency's Administrative Practices and Procedures regulations, is grounded in the Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Fair Packaging and Labeling Act.

Alternatives:

One alternative to revoking the regulations that are the subject of this proposal would be to leave them untouched. Inasmuch as these regulations have been identified as either no longer serving useful public health goals, or as not requiring

codification as regulations to do so, leaving them intact would amount to allowing them to take up space in the Code of Federal Regulations, which is printed at a cost to taxpayers, for no useful purpose. Another alternative would be to substantially rewrite these regulations in an effort to make them more useful. However, if they could be usefully rewritten, these regulations would not be proposed for deletion.

Anticipated Costs and Benefits:

FDA finds that this proposed rule is neither an economically significant nor significant regulatory action. It would result in no new requirements on regulated industries, but would, in many instances, delete requirements that are no longer meaningful and out of date and that may generate confusion as a result. Information contained in regulations that have been identified as statements of policy or guidance will continue to be available to the regulated industry. The proposed rule raises no new policy issues. Its significance lies in the fact that it is part of a larger effort to streamline, clarify, and reduce the burden on industry and consumers of FDA regulation with no sacrifice in public health protection. The benefit of the proposed regulation is that it would simplify and clarify FDA's regulation in all product areas.

Risks:

FDA is aware of no risk to public health and safety posed by regulations that this proposal would delete. Their deletion would leave in the Code of Federal Regulation a body of regulations that would provide a clearer statement of regulatory requirements that are needed to carry out FDA's mandate.

Timetable:

Action	Date	FR Cite
NPRM	10/13/95	60 FR 53480
NPRM Comment Period End	01/11/96	
Final Action	04/00/96	

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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HHS—FDA

31. • STREAMLINING PROCEDURES FOR CHANGES IN PRODUCTION OF BIOLOGICS

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 proposing to revise 21 CFR 601.12, which deals with proposed 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 proposed revision, 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. Proposed procedures for reporting changes in production are: No supplements to approved applications will be required. Firms

would notify FDA of changes and dates of implementation in an annual report. License holders would notify FDA not less than 30 days prior to implementing a change.

Changes would require FDA approval prior to implementation.

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 proposed system 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 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 proposed revision for such changes.

Anticipated Costs and Benefits:

FDA is specifically requesting comment and information that can be used to calculate the costs and benefits to licenseholders. In general, the proposed revision is expected to reduce significantly the burden of preparing supplements for proposed changes by eliminating this requirement for a number of changes. The proposed revision 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 proposed new reporting system are minimal. In addition to stating in the proposed 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	01/00/96	

Small Entities Affected:

Businesses

Government Levels Affected:

None

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HHS—FDA

32. • PROTECTION OF HUMAN SUBJECTS; INFORMED CONSENT

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:

21 USC 321; 21 USC 346; 21 USC 346a; 21 USC 348; 21 USC 352; 21 USC 353; 21 USC 355 to 357; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 381

CFR Citation:

21 CFR 50; 21 CFR 56; 21 CFR 312; 21 CFR 314; 21 CFR 601; 21 CFR 812; 21 CFR 814

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is proposing to amend its current informed consent regulations to permit harmonization of FDA and National Institutes of Health (NIH) policies on emergency research, and to reduce confusion as to when such research can proceed without obtaining informed consent. The regulation provides a narrow exception to the requirement for obtaining and documenting informed consent from each human subject prior to initiation of an experimental treatment. The exception would apply to a limited class of research activities involving human subjects who, because of their life-threatening medical condition and the unavailability of legally authorized persons to represent them, are in need of emergency medical intervention and cannot provide legally effective informed consent.

The proposed rule would permit an Institutional Review Board (IRB) to approve an emergency research protocol if the IRB finds and documents that (a) the human subjects will be in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine what particular treatment is most beneficial; (b) obtaining informed consent is not feasible; (c) the opportunity for the subjects to participate in the research is in the

interest of the subjects because treatment is required, and the risk is "reasonable" given what is known about the risks and benefits of experimental treatment, the current therapy, and the medical condition; (d) the research could not practically be carried out without the waiver; (e) additional protection of the rights and welfare of the subjects will be provided; and, (f) the IRB has reviewed and approved an informed consent document for use with subjects for whom consent is possible.

The proposed rule provided that, when possible and at the earliest possible opportunity, each subject will be informed about the details of the study and permitted to discontinue participation at any time without penalty. The rule also incorporates additional patient protections, including: FDA review of the protocol; consultation with representatives of the communities from which the subjects will be drawn; public disclosure prior to the study sufficient to describe the study and its risks and benefits; the establishment of an independent data and safety monitoring board; and public disclosure following completion of the study sufficient to apprise the community and researchers of the study and its results.

FDA, in coordination with NIH, developed this proposal because of concerns expressed by the research community and patient advocacy groups that emergency research is at a virtual halt pending a revision of both FDA's informed consent regulations and a waiver of HHS regulations for the protection of research subjects. HHS intends to bring both policies into harmony on this matter at the time this rule is made final.

Statement of Need:

FDA is proposing this action in response to growing concerns that current rules are making high-quality acute care research activities difficult or impossible to carry out at a time when the need for such research is increasingly recognized. There are many conditions, such as heart attacks, closed head wounds, and spinal cord injuries, where current medicine cannot save many of the patients. For example, each year, approximately 350,000 people in the United States suffer a sudden cardiac arrest. Most die, while many others are irreversibly harmed by complications such as brain damage. Given the large number of sudden cardiac arrests annually in the United States alone, even small improvements

in care offer enormous life-saving potential. This proposed rule is intended to permit emergency care professionals to conduct appropriately designed clinical trials to validate or discredit current or innovative treatments.

Summary of the Legal Basis:

Sections 505(i), 507(d), and 520(g) of the Federal Food, Drug, and Cosmetic Act direct the Secretary (and, in accordance with section 903 of the act (21 USC 394), FDA) to issue regulations establishing conditions under which investigational use of drugs and devices by qualified experts will be permitted. For drugs (including biological drugs and antibiotics) and devices, the statute specifies that the agency must include among these conditions that the product manufacturer or sponsor require the expert studying the product to obtain informed consent from the subjects or their representatives. The only exceptions from the informed consent requirement for drugs are where the investigators "deem it not feasible or, in their professional judgment, contrary to the best interests" of the subjects (sections 505(i) and 507(d) of the act). The only exceptions from the informed consent requirements for devices are where the investigator determines "there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative" (section 520(g)(3)(D) of the act). In addition, "unless immediate use of the device is required to save the life of the human subject," and there is insufficient time to obtain the concurrence of a licensed physician must concur in the determination. The exceptions to require informed consent are "subject to such conditions as the Secretary may prescribe." The agency has analyzed the provisions of the proposed rule and found that they satisfy all of the statutory criteria of sections 505(i), 507(d), and 520(g) of the act for permitting exceptions to the informed consent requirements for investigational drug and device use.

Alternatives:

FDA considered whether a reinterpretation of its existing regulations would meet the needs of persons in life-threatening situations and the research community. It concluded against such a reinterpretation for a number of

reasons, including: it would not make the FDA regulations and the HHS regulations congruent; it would not provide prospective protections to subjects participating in such research; it would be difficult if not impossible to enforce additional safeguards that the agency believes are essential to protect subjects involved in such research activities; and it would not adequately eliminate the confusion that currently exists within the research community as to the standards that must be applied to this research. The sole benefit of a reinterpretation of existing regulations would be to permit this limited class of research to move forward quickly, rather than delaying until a new regulation could be written. The agency has, thus, placed priority on developing this proposed regulation in order to permit the ethical conduct of a limited class of emergency research.

Anticipated Costs and Benefits:

FDA does not believe that this rule will have a significant economic impact on a substantial number of small entities. This is because this proposed rule is a deregulatory action insofar as it will permit research to proceed which could not proceed under existing regulations, and because relatively few research projects will need to meet the requirements of this rule.

By permitting certain controlled clinical trials to be conducted with the involvement of human subjects who are confronted by a life-threatening condition and who are also unable to give informed consent because of that condition, the agency expects to provide individual access to potentially beneficial treatment. The agency also expects that research to result in advancement and improvement of therapies used in emergency medicine situations that currently have poor clinical outcome. As a result of this rule, many individuals confronted by life-threatening situations will benefit immediately. Survival of these individuals may be enhanced by their participation in controlled trials. As described previously, there are many conditions where current medicine cannot save many of the patients. For example, each year, approximately 350,000 people in the United States suffer a sudden cardiac arrest. Even small improvements in emergency medical care offers enormous life-saving potential.

Risks:

Modern trauma care is based on the "golden hour" following acute injury.

Most patients who die from injury in the first 24 hours do so from processes set in motion at the time of injury. Because of this, any therapeutic intervention must be begun immediately to interrupt the injury-induced cascade of body reactions that lead to death. There are many conditions, such as heart attacks, closed head wounds, and spinal cord injuries, where current medicine cannot save many of the patients. For example, currently, despite efforts to instill basic life support education, only a small percentage of individuals who suffer sudden out-of-hospital cardiac arrests are resuscitated by bystanders. Few survive to leave the hospital. This percentage may be as low as 1 to 3 percent in some large metropolitan areas, with the best results estimated to be only in the 25 percent range. Given the large number of sudden cardiac arrests annually in the United States alone, even small improvements in care offer enormous life-saving potential.

Timetable:

Action	Date	FR Cite
NPRM	09/21/95	60 FR 49086
NPRM Comment Period End	11/06/95	
Final Action	09/00/96	

Small Entities Affected:

None

Government Levels Affected:

None

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HHS—FDA**33. • MEDICAL DEVICE EXEMPTIONS FROM PREMARKET NOTIFICATION****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:

21 USC 351; 21 USC 360; 21 USC 360c;
21 USC 360e; 21 USC 360j; 21 USC
371

CFR Citation:

21 CFR 862; 21 CFR 866; 21 CFR 868;
21 CFR 870; 21 CFR 872; 21 CFR 874;
21 CFR 876; 21 CFR 878; 21 CFR 880;
21 CFR 882; 21 CFR 884; 21 CFR 886;
21 CFR 888; 21 CFR 890; 21 CFR 892

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) regulates some 1,700 types of medical devices and places them in classes, depending on the level of risk they present. Currently, manufacturers of most medical devices are required to submit information to FDA and receive FDA clearance before putting a device on the market, even if the device poses an extremely low risk. FDA has determined that, for devices that pose a low level of risk to patients, review is not necessary to protect the public health, places an unnecessary regulatory burden on device manufacturers, and delays introduction of new devices.

Accordingly, FDA is proceeding, through notice and comment rulemaking, to exempt low-risk medical devices from premarket notification requirements. Of these, 450 types of low-risk devices (such as stethoscopes, hernia supports, and surgical microscopes) have already been exempted. On July 28, 1995, FDA proposed to exempt 12 more types of low-risk devices and, at the same time, to reclassify an additional 112 types of devices as low-risk (Class I) and to exempt them from premarket notification requirements as well. FDA receives some 700 submissions each year for devices in the categories affected by this rulemaking and will be able to redirect resources for the review of these products to more complex products. This final regulation will complete the rulemaking, at which time one-third of all categories of devices will be exempted from premarket notification requirements. Examples of affected devices include arterial blood sampling kits, therapeutic humidifiers for home use, dental floss, and otoscopes for examining the ear.

Statement of Need:

Premarket notification is burdensome to manufacturers of low-risk devices, and review of such notification is time-

consuming, delaying marketing of the devices, and represents an inefficient use of FDA resources. Exempting low-risk devices from premarket notification allows new devices to be brought to market more quickly and allows FDA to use its resources to better protect the public health.

Summary of the Legal Basis:

Section 513(d) of the Food, Drug, and Cosmetic Act (21 USC 360d) authorizes FDA to exempt, by regulation, a generic type of class I device from, among other things, the requirement of premarket notification in section 510(k) of the act (21 USC 360K). Pursuant to section 513(e)(1) of the act, based on new information respecting a device, FDA may, upon its own initiative, by regulation change a device's classification and revoke, because of the change in classification, any regulation or requirement in effect with respect to such device under sections 514 or 515 of the act (21 USC 360d or 21 USC 360e).

Alternatives:

The exemption process is an ongoing one, and 450 categories of devices have been exempted so far. This action has reduced burden on manufacturers, allowed FDA resources to be redirected more usefully, and has not been shown to affect public health protection. The alternative to the exemptions and reclassifications included in this regulation would be to do nothing, in effect, and continue to require premarket notification. This has been shown to be burdensome to manufacturers and to make inefficient use of FDA resources without offering meaningful public health protection.

Anticipated Costs and Benefits:

The proposal will not impose any costs on manufacturers, but will relieve them of the burden of submitting premarket notification submissions for certain devices. FDA will also benefit by receiving approximately 700 fewer submissions per year and will be able to redirect its resources to more complex products.

Risks:

In view of the low level of risk presented by these devices, the likelihood of their causing harm or injury to patients is slight. Exemption from premarket notification is not an exemption from any of the other general controls under the act, including current good manufacturing practices. In addition, under the reporting provisions of the Safe

Medical Devices Act, actual or probable harm to patients and malfunction must be reported to FDA, and thus FDA will be able to monitor these devices and take appropriate remedial action if necessary.

Timetable:

Action	Date	FR Cite
NPRM	07/28/95	60 FR 38902
NPRM Comment Period End	10/11/95	
Final Action	12/00/95	

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

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RIN: 0910-AA65

HHS—FDA

FINAL RULE STAGE

34. FINAL REGULATION TO ESTABLISH PROCEDURES FOR THE SAFE AND SANITARY PROCESSING AND IMPORTING OF FISH AND FISHERY PRODUCTS

Priority:

Economically 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:

21 USC 342 Federal Food, Drug, and Cosmetic Act; 21 USC 371 Federal Food, Drug, and Cosmetic Act; 21 USC 374 Federal Food, Drug, and Cosmetic Act; 42 USC 264 Public Health Service Act; 21 USC 321; 21 USC 343; 21 USC 346; 21 USC 348; 21 USC 379e; 21 USC 381; 42 USC 241; 42 USC 242l; 42 USC 300u-1; 42 USC 216; 42 USC 243

CFR Citation:

21 CFR 123; 21 CFR 1240

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is adopting regulations to ensure the safe and sanitary processing and importing of fish and fishery products. These procedures include the monitoring of selected processes in accordance with Hazard Analysis Critical Control Point (HACCP) principles. HACCP is a preventive system of hazard control that can be used by food processors. FDA is adopting these regulations because a system of preventive controls is the most effective and efficient way to ensure that these products are safe.

Statement of Need:

Ensuring the safety of seafood to consumers poses a unique challenge to both the industry that produces it and to regulators. Seafood involves more than 300 highly diverse species from around the world. It is the most perishable of all flesh foods. As stocks of traditionally consumed fish decline, the pressure to find new species increases. Most seafood is still wild caught, the range of possible human food safety hazards includes every hazard in the marine environment as well as those associated with aquaculture. It is essential that those who process seafood for consumers understand the hazards and the controls for those hazards. As a general rule, however, such knowledge is not a prerequisite for doing business. Preventive controls for ensuring safety are not always employed and good sanitation is not always practiced. Preventable illnesses from seafood do occur. Moreover, it is questionable whether the current regulatory system, which was developed for the general food supply, is best suited for the seafood industry. The current system provides the agency with a "snapshot" of conditions at a facility at the moment of the inspection. The reliability of the regulators' assumptions about conditions in the plant during the intervals between inspections creates legitimate concerns about the adequacy of the system. Moreover, the system places an undue burden on the regulator to find problems, rather than placing responsibility on the industry to demonstrate that it understands the human food safety hazards and is employing appropriate controls for those hazards. The HACCP system solves these problems. Processors design preventive controls that are

tailored to their products and processes. In accordance with HACCP principles, these controls provide processors with immediate information about whether they are controlling hazards. The records generated by the monitoring of critical control points enable the plant and the regulator to observe key safety operations over time, rather than at a single moment.

Summary of the Legal Basis:

FDA's application of HACCP is intended for the efficient enforcement of sections 402(a)(1) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, which applies to products that contain substances that may render the product injurious to health and to processing conditions that are insanitary and that could render a product injurious to health.

Alternatives:

Continuing the current system of highly generalized good manufacturing practices (GMPs) for seafood processors and intermittent inspections based on these GMPs would be less efficient and effective than a HACCP-based system for the reasons stated above.

Continuous visual inspection is not a viable alternative. Few hazards associated with seafood are detectable through visual inspection. Moreover, the costs of such a system would likely exceed the nearly half-billion dollar public outlay now required to operate this kind of system for meat and poultry.

Another alternative would be to direct significant additional resources toward greatly increasing the frequency of FDA's inspection of seafood, as well as increasing the agency's sampling, laboratory analysis, and related regulatory activities with respect to seafood. Even if the funds for increased inspection and sampling were available, this approach alone would not be the best way for the agency to spend its resources on protecting the public health because the current form of inspection is inherently less efficient and effective than a HACCP-based inspection. Increased reliance on end-product testing, moreover, would involve a certain amount of inefficiency that would require very large sample sizes to overcome.

Anticipated Costs and Benefits:

Costs, first year, 69 million to 168 million, benefits first year 73-108 million, total discounted costs at 6 percent discounting: 677 million to 1,488 million. Total discounted benefits

at 6 percent: 1,435 million to 2,561 million.

Risks:

If this regulation is not adopted the U.S. industry will lose or be significantly hampered in exporting to the European Union market. In addition an opportunity to adopt an efficient and highly effective means of manufacturing and monitoring the safety of seafood will be lost. Finally, a major opportunity to significantly reduce the number of seafood related illnesses in the United States will also have been lost.

Timetable:

Action	Date	FR Cite
NPRM	01/28/94	59 FR 4142
NPRM Comment Period End	03/29/94	
Final Action	12/00/95	

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

Previously reported under RIN 0905-AD60.

42 USC 264; 42 USC 271

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RIN: 0910-AA10

HHS—FDA

35. PRESCRIPTION DRUG PRODUCT LABELING; MEDICATION GUIDE

Priority:

Other Significant

Legal Authority:

21 USC 321; 21 USC 352; 21 USC 371;
21 USC 355; 42 USC 262

CFR Citation:

21 CFR 201; 21 CFR 208; 21 CFR 314;
21 CFR 600

Legal Deadline:

None

Abstract:

Inadequate access to appropriate patient information is a major cause of inappropriate use of prescription medications, resulting in serious personal injury and related costs to the health care system. The Food and Drug Administration (FDA) believes that it is essential that patients receive information accompanying dispensed prescription drugs. This information needs to be widely distributed and be of sufficient quality to promote the proper use of prescription drugs. Therefore, FDA is proposing performance standards that would define acceptable levels of information distribution and quality, and to assess supplied information according to these standards. In accordance with the Administration's philosophy of fairly assessing a voluntary approach before imposing requirements through regulations, FDA is proposing that this information be disseminated through voluntary private-sector initiatives. Preliminary evidence suggests recent increases in the distribution of privately produced patient medication information with dispensed prescriptions; however, estimated distribution rates indicate that significant numbers of patients still do not receive information with their medications. FDA analyses also indicate that there is a high variability in the quality of this information. FDA believes that, with greater encouragement and clear objectives, the private sector will substantially improve the quality and distribution of patient information. Therefore, in concert with Healthy People 2000, FDA is proposing that private-sector initiatives meet the goal of distributing useful patient information to 75 percent of individuals receiving new prescriptions by the year 2000 and 95 percent of individuals receiving new prescriptions by the year 2006. FDA is proposing two alternative approaches to help ensure that these goals (performance standards) are achieved. FDA would periodically evaluate and report on achievement of these goals. If the goals are not met in the specified timeframes, FDA would either (a) implement a mandatory comprehensive Medication Guide program, or (b) seek public comment on whether the comprehensive program should be implemented or whether, and what, other steps should be taken to meet patient information goals.

Regardless of the approach chosen, a mandatory Medication Guide program would initially be limited to instances

where a product poses a serious and significant public health concern requiring immediate distribution of FDA-approved patient information. FDA believes that substantial health care cost savings can be realized by ensuring that consumers obtain the inherent benefits of proper use of prescription drugs, and by reducing the potential for harm caused by inappropriate drug use by the patient.

Statement of Need:

A fundamental principle of an effective health care system is that patients have a right and responsibility to participate actively in decisions affecting their own health. This requires that patients receive their own information, including information about their medicines. Despite the existence of numerous voluntary programs designed to improve patient knowledge, however, FDA has concluded that the number of consumers who receive patient information with their prescription drug products is unacceptably low. This rule will establish a program of patient information distribution through voluntary programs that is designed to ensure that consumers achieve maximum benefits from the use of prescription drugs and reduce the potential for harm caused by inappropriate patient drug use.

FDA is proposing that useful written information, in nontechnical language that is directed to the patient, be developed by the private sector for dispensing with prescription drug and biological products that are used primarily on an outpatient basis without direct supervision by a health care professional. The patient labeling would inform the patient about the drug product and would include information such as the product's approved uses, contraindications, proper administration, adverse drug reactions, and cautions for specific populations (including pregnant women and children).

Summary of the Legal Basis:

The Federal Food, Drug and Cosmetic Act (21 USC 321 et seq.) authorizes FDA to regulate the marketing of drug products so that the products are safe and effective for their intended uses and are properly labeled. In order to carry out the public health protection purposes of the act, FDA (a) monitors drug manufacturers and distributors to help make certain that drug products are manufactured and distributed under conditions that ensure their identity, strength, quality, and purity; (b)

approves new drugs for marketing only if they have been shown to be safe and effective; and (c) monitors drug labeling and prescription drug advertising to help ensure that they provide accurate information about drug products.

The act authorizes FDA to promulgate a regulation designed to ensure that patients using prescription drugs will receive information that is material with respect to the consequences which may result from the use of a drug product under its labeled conditions. This interpretation of the act and the agency's authority to require patient labeling for prescription drug products has been previously upheld.

Alternatives:

FDA considered several alternative programs that could meet the objectives of this proposed regulation.

One alternative was to offer patients access to patient labeling through a catalogue or computer data base at the pharmacy or practitioner's office, but not necessarily dispense individual labeling with each product. FDA decided against this alternative because not all patients would be aware of or able to obtain sufficient information about the drug product, and because the information is needed at home where the drug product is consumed.

A second alternative was to provide patient labeling with both new and refill prescriptions. FDA decided against this alternative because of the relatively large economic burden it would place on pharmacists.

Anticipated Costs and Benefits:

FDA has analyzed the economic consequences of the proposed rule and has determined that patient labeling will have associated costs well below the \$100 million threshold that defines a significant regulatory action.

However, even though the rule is below this threshold, in accordance with Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed a preliminary regulatory impact analysis (PRIA). The PRIA concludes that, even when utilizing very conservative benefit estimates, implementation costs will be more than offset by the health care savings that result from an increase in compliance with prescribed drug therapy, and a decrease in the number of adverse drug reactions.

Risks:

FDA has concluded from a review of the current literature that patient noncompliance with prescribed drug

regimens ranges from 30 to 50 percent. Patients who do not comply with prescribed regimens are subject to two types of risks: risk of therapeutic failure and risk of adverse drug reaction or drug interaction with other drugs and foods. Both types of risk are potentially very serious. The seriousness of therapeutic failure depends on the seriousness of the illness being treated, while the effects of drug reaction or interaction may range from mild and transitory to long-lasting and even life-threatening.

Timetable:

Action	Date	FR Cite
NPRM	08/24/95	60 FR 44182
Final Action	06/00/96	

Small Entities Affected:

Businesses

Government Levels Affected:

State, Federal

Additional Information:

Previously reported under RIN 0905-AE43.

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RIN: 0910-AA37

HHS—Health Resources and Services Administration (HRSA)

FINAL RULE STAGE

36. 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

Action	Date	FR Cite
NPRM Comment Period End	12/07/94	59 FR 46482
Final Action	03/00/96	

Small Entities Affected:

None

Government Levels Affected:

None

Additional Information:

Previously reported under RIN 0905-AD26.

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RIN: 0906-AA32

HHS—Indian Health Service (IHS)

PROPOSED RULE STAGE

37. REVISION OF INDIAN SELF-DETERMINATION REGULATIONS

Priority:

Other Significant

Legal Authority:

PL 93-638; PL 100-202; PL 100-446; PL 100-472; PL 100-581; PL 101-301; PL 103-413; 25 USC 450

CFR Citation:

42 CFR 36; 48 CFR 380.4; 48 CFR 352.280-4

Legal Deadline:

Final, Statutory, March 1996.

Abstract:

Public Law 93-638, passed in 1975, requires the Indian Health Service (IHS) to turn over administrative responsibility for service delivery programs to tribes so requesting, using the mechanism of contracting. Public Law 93-638 also authorizes the IHS to make grants to tribes for the planning, development, and/or operations of health programs. Public Law 100-472, enacted October 5, 1988, made significant changes to the statute and

required that regulations implementing the amendments be promulgated in final within 10 months of enactment. The NPRM was published on January 20, 1994. The 120-day comment period was extended until August 20, 1994. On October 26, 1994, Public Law 103-413 was enacted. These amendments superseded the published NPRM and authorized the Secretaries of Interior and Health and Human Services to publish joint regulations only in specified areas. These regulations would be developed using the negotiated rulemaking procedure and are to be published within 18 months of the passage of the authorizing legislation.

Statement of Need:

In response to the long-standing Indian interest in self-determination, Congress enacted the Indian Self-Determination and Education Assistance Act in 1975. The Indian people have long sought more meaningful participation in the planning, conduct, and administration of their programs and devices. The Act reflects a commitment to preserving the Federal relationship with and responsibility to the Indian people by promoting efforts to transfer the operation of service delivery programs of the Federal Government to Indian tribes. The 1975 Act requires the Indian Health Service (IHS) to contract with Indian tribal organizations for the operation of IHS service delivery programs.

The Act also authorizes IHS to make grants to tribes for the planning, development, and/or operation of Health Programs. On October 5, 1988, Congress amended the Act to expand its coverage and authorize a new nonprocurement contracting process which required revision of existing regulations. The Amendments (Public Law 100-472) provided that the regulations be developed with the participation of and in consultation with Indian tribes and tribal organizations.

Summary of the Legal Basis:

As mentioned above, on October 26, 1994, Public Law 103-413 was enacted. The amendments superseded the published NPRM and authorized the Secretaries of Interior and Health and Human Services to publish joint regulations only in specified areas.

Alternatives:

Public Law 103-413 authorizes the secretaries of Interior and HHS to publish joint regulations in certain specified areas, but does not require

publication of any regulation. Regulations are under development using the negotiated rulemaking process. Therefore, the Secretaries and the tribes will jointly determine the nature and extent of the regulations.

Anticipated Costs and Benefits:

No additional costs are associated with this regulation. It is anticipated that Indian tribes and tribal organizations will benefit from having regulations required for "638" contracts and grants in one title of the Code of Federal Regulations.

Risks:

There are no public health risks addressed by this rule.

Timetable:

Action	Date	FR Cite
NPRM	12/00/95	
NPRM Comment Period End	01/00/96	

Small Entities Affected:

None

Government Levels Affected:

Tribal

Additional Information:

Previously reported under RIN 0905-AE68.

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HHS—Health Care Financing Administration (HCFA)

PROPOSED RULE STAGE

38. 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 HCFA's regulatory reform initiative.

Statement of Need:

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 OBRA '87 to develop a patient-centered, outcome-oriented survey process which focuses on the organization and delivery of quality care services.

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 and will continue during the development of the regulation.

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	12/00/95	

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

Undetermined

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RIN: 0938-AG81

HHS—HCFA

39. END-STAGE RENAL DISEASE (ESRD) CONDITIONS OF 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

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 HCFA's regulatory reform initiative.

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-of-coverage regulations have not been comprehensively revised since the regulation's inception in the late 1970s.

The current regulations are written in an outdated style that primarily focuses 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 coverage conditions up to current standards of practice in the ESRD community. The revised regulations must reflect new developments in technology and equipment, as well as addressing the outcome-oriented standards process.

The regulations need to be revised to reflect the innovations in the dialysis and transplant community. The purpose of revising the regulations is to focus on the patient and the results of the care provided to the patient. Thus, the emphasis should be on the 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.

The Health Care Financing Administration held an industry meeting to discuss the focus of the conditions of coverage revision. Additional discussions with the ESRD community will occur during the regulations process.

Alternatives:

In the past, HCFA has revised portions of the ESRD regulations. However, it was 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 the regulation with greater potential for future application. Another option is to update the current regulations and maintain the process-oriented standards without developing an outcome-oriented approach. However, we believe it is important now to move forward with the outcome-oriented approach.

Anticipated Costs and Benefits:

The purpose of this final rule is to ensure that ESRD beneficiaries are receiving quality care in both the areas of dialysis and transplantation. We

believe that this regulation is a necessary step to ensure that all facilities are using the most effective technology and equipment. The primary benefit of updating the conditions of coverage is the development of performance expectations for the facility that will result in the comprehensive, integrated care and outcomes the patient needs and wants. As a result, the beneficiaries will receive an improved quality of care. In addition, the revised regulations will address the issue of adequacy of dialysis, and this 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 are speculative.

Risks:

If the ESRD regulations are not updated, the 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	03/00/96	

Small Entities Affected:

Undetermined

Government Levels Affected:

Undetermined

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RIN: 0938-AG82

HHS—HCFA

40. CATEGORIZATION AND CERTIFICATION REQUIREMENTS FOR A NEW SUBCATEGORY OF MODERATE COMPLEXITY TESTING (HSQ-222-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 263a

CFR Citation:

42 CFR 493.2; 42 CFR 493.3; 42 CFR 493.5; 42 CFR 493.18; 42 CFR 493.20; 42 CFR 493.21; 42 CFR 493.25; 42 CFR 493.43; 42 CFR 493.45; 42 CFR 493.48; 42 CFR 493.49; 42 CFR 493.51; 42 CFR 493.53; 42 CFR 493.638

Legal Deadline:

None

Abstract:

This rule would develop criteria for simple and easy-to-use test systems that have demonstrated accuracy and precision through scientific studies. It would waive the routine 2-year survey of users of accurate and precise technology (APT) tests, conducting surveys only if there are indications of problems or complaints. A small number of surveys would be conducted to validate the criteria for determining APT and to assure quality.

Statement of Need:

This rule would add a subcategory of moderate complexity tests called "accurate and precise technology" (APT) tests that clinical laboratories may perform under the CLIA program. These tests would have to meet less stringent requirements because they will have demonstrated accuracy and precision through scientific studies evaluated by the Centers for Disease Control and Prevention. The purpose of adding this subcategory is to provide regulatory relief to laboratories that perform testing using methodologies that have been determined to be precise and accurate.

Summary of the Legal Basis:

The proposal, based on consultation and in response to public comments, establishes less stringent regulatory requirements for tests that have demonstrated accuracy and precision through scientific studies.

Alternatives:

Laboratories would have to meet the requirements applicable to moderate complexity testing, incurring expenses for personnel, paperwork, and routine biennial inspections. Continual regulatory updates would be required

to reflect innovative technological advances. The performance standards currently in place would potentially limit technology.

Anticipated Costs and Benefits:

This rule creates incentives for manufacturers to develop more reliable testing equipment by stimulating demand for accurate and precise technological testing systems. It reduces paperwork and costs for providers, especially for physician office laboratories, as well as reducing costs of program management. It includes specific requirements for the test system manufacturer or producer to include instructions to laboratories for meeting the CLIA requirements, thus lessening operating requirements, supervisory staff qualifications, and the need for routine survey activities.

Risks:

Less oversight reduces assurance that users are following manufacturers instructions and producing reliable results. Technology may not perform as reliably as expected in all workplace settings. Test systems may not perform as expected in different users' hands. Specimen procurement and handling may affect the reliability of testing. We expect no clinically meaningful change in test accuracy, or patient health, from this proposal.

Timetable:

Action	Date	FR Cite
NPRM	00/00/00	60 FR 47982
NPRM Comment Period End	11/14/95	
Final Action	00/00/00	

Small Entities Affected:

None

Government Levels Affected:

None

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RIN: 0938-AG98

HHS—HCFA

41. CLIA PROGRAM: CATEGORIZATION OF WAIVED TESTS (HSQ-225-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 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:

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

Statement of Need:

This proposed regulation would 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. CLIA requirements would also be waived for tests approved for home use by the Food and Drug Administration.

Summary of the Legal Basis:

The Clinical Laboratory Improvement Advisory Committee (CLIAAC) was established to advise and make recommendations on technical and scientific aspects of the regulations. The CLIAAC recommended that the criteria for categorizing tests as waived be better defined. As a result of the comments concerning waived tests and the CLIAAC 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 proposed expansion of the waived criteria and development of a process protocol would 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	60 FR 47534
Final Action	00/00/00	

Small Entities Affected:

None

Government Levels Affected:

None

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HHS—HCFA**42. • CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM AND FISCAL YEAR 1997 RATES (BPD-847-P)****Priority:**

Other Significant

Legal Authority:

42 USC 1395ww

CFR Citation:

42 CFR 412; 42 CFR 413

Legal Deadline:

NPRM, Statutory, May 1, 1996. Final, Statutory, September 1, 1996.

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 will announce the prospective payment rates for operating and capital-related costs for FY 1997. We will 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 system. In addition, we will set forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the prospective payment systems. These changes are applicable to discharges occurring on or after October 1, 1996.

Statement of Need:

Section 1886(e)(5) of the Social Security Act requires the Secretary to publish a proposed notice of 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	05/00/96	

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

State, Federal

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RIN: 0938-AH34

HHS—HCFA**FINAL RULE STAGE****43. MEDICARE, MEDICAID, AND CLIA PROGRAMS: REGULATIONS IMPLEMENTING THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA '88) (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:

Historically the Department regulated by "location," rather than by the types of tests they performed. CLIA changes this approach. CLIA requires that the Department "regulated by test," using what is commonly referred to as the "complexity model." A final rule with comment period was published February 28, 1992, that set forth standards for all laboratories, based on complexity, and responded to public comments on the proposed standards. The regulation was revised by rules with comment period published on January 19, 1993, December 6, 1994, and April 24, 1995. A final rule, which will respond to these public comments, will be issued.

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 any analysis of these comments, the Public Health Service (PHS) with the Health Care Financing Administration (HCFA) 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 and experience with implementation.

With respect to PT requirements, it is important to note that the July 1995 report of the President and Vice President on Reinventing Health Care Regulations indicated that we will use PT "failures" for education and as an outcome indicator in laboratory quality. (PT is testing samples of known values to assess the accuracy of a laboratory's results.) Sanctions (for example, loss of Medicare payment or loss of approval to do testing) are imposed only in cases of immediate jeopardy or when the laboratory has refused to correct the problem or has had repeated failures on PT. This final rule with comment period will provide clarification on this issue.

The Clinical Laboratory Improvement Advisory Committee (CLIA), 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 CLIA 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 notices 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 omnibus rule at this time. These regulations serve to ensure consistent, reliable laboratory testing which 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) which 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	55 FR 34289
Final Rule With Comment Period	02/28/92	57 FR 7002
Comment Period End	04/28/92	
Effective Date	09/01/92	
Effective Date	01/19/93	58 FR 5215
Final Rule With Comment Period	01/19/93	58 FR 5215
Comment Period End	03/22/93	58 FR 6215
Final Action	06/00/96	

Small Entities Affected:

Businesses

Government Levels Affected:

State, Federal

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RIN: 0938-AE47

HHS—HCFA

44. 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 1961(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 19861(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 Comment Period End	08/19/95	60 FR 48417
Final Action Effective	11/01/95	
NPRM	01/00/96	
Final Action	09/00/96	

Small Entities Affected:

Undetermined

Government Levels Affected:

Undetermined

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HHS—HCFA

45. MEDICARE PROGRAM: REVISIONS TO PAYMENT POLICIES AND ADJUSTMENTS TO THE RELATIVE VALUE UNITS (RVUS) UNDER THE PHYSICIAN FEE SCHEDULE FOR CALENDAR YEAR 1996 (BPD-827-FC)

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 1395w-4

CFR Citation:

42 CFR 400; 42 CFR 405; 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, 1996.

Abstract:

This final rule with comment period revises various payment policies for specific physician services and the relative value units (RVUs) for certain existing procedure codes, effective January 1, 1996. It also establishes

interim RVUs for new and revised procedure codes. 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 document will announce the RVUs upon which Medicare payment for physician services will be based in 1996, including interim RVUs for procedure codes that are new or revised for 1996. 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 3 full years of experience with the physician fee schedule, we have reevaluated several payment policies related to it. Proposed revisions to these policies were announced in a notice of proposed rulemaking on July 26, 1995. This final rule will respond to the public comments received on those proposals and announces the final policy decisions. Thus, it will discuss changes in payment for the services of teaching physicians, limiting payment for interpretation of electrocardiograms and x-rays taken in the emergency room, making budget neutrality adjustments on the conversion factor rather than the RVUs, and changes in the calculation of the multiple volume performance standard (MVPS). It will also announce final decisions regarding the extension of the site-of-service payment differential to ambulatory surgical centers, prohibition of separate payment for the transportation of diagnostic equipment to a patient, expansion of the definition of "diagnostic" mammography, and a variety of bundled services.

This document also discusses the process for periodic review and adjustment of all RVUs. 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.

Alternatives:

An alternative to this notice would be to continue to base payments on 1995 RVUs. This would continue inappropriate payments for certain services and would not allow a national basis for paying for new services. 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 notice will be implemented in a budget-neutral manner. Thus, 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	07/26/95	60 FR 38400
Final Rule With Comment Period	12/00/95	

Small Entities Affected:

None

Government Levels Affected:

None

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RIN: 0938-AG96

HHS—HCFA

46. • CRITERIA AND PROCEDURES FOR EXTENDING COVERAGE TO CERTAIN DEVICES AND RELATED SERVICES (BPD-841-FC)

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 1395y(a)(1)(A)

CFR Citation:

42 CFR 405; 42 CFR 411

Legal Deadline:

None

Abstract:

This final rule establishes in regulations that certain medical devices with an investigational device exemption (IDE) approved by the Food and Drug Administration (FDA) may be covered under Medicare. Specifically, it sets forth the process by which the FDA will assist HCFA in identifying nonexperimental investigational devices that may be potentially covered under Medicare. It is intended to provide Medicare beneficiaries with greater access to advances in medical technology.

Statement of Need:

In his National Performance Review, Vice President Gore directed the health agencies of the Department of Health and Human Services (HHS) to review their policies and processes to determine which requirements could be reduced or eliminated without lowering health and safety standards. In accordance with this directive, FDA reviewed its current regulatory approval processes and HCFA reviewed its Medicare coverage policies for medical devices that have not received full FDA approval.

The Medicare program has historically interpreted the statutory terms “reasonable and necessary” to mean that a service or medical device must be safe and effective, medically necessary and appropriate, and not experimental, in order to qualify for reimbursement. For Medicare coverage proposes, the term *experimental* has been used synonymously with the term *investigational*. Therefore, an approved investigational device exemption (IDE) application served as an indication that the device was not “reasonable and necessary” within the meaning of the Medicare program. Under this policy, Medicare coverage was denied for devices that require, but have yet to receive, 510(k) clearance and those that have received an IDE but have not received premarket approval (PMA).

There is increasing recognition that there are devices which are refinements of existing technologies or replications of existing technologies by other manufacturers. Many of these devices are placed within the IDE category as a means of gathering the scientific information necessary for FDA to establish the safety and effectiveness of

the particular device, even though there is scientific evidence that the type of device can be safe and effective. Arguably, these devices could be viewed as “reasonable and necessary” by Medicare and recognized for payment if it were possible to identify them in the FDA’s process.

Accordingly, FDA and HCFA are developing a revised policy to meet the needs of Medicare beneficiaries. The purpose of this effort is to determine if it is feasible to expand Medicare coverage to include certain medical devices that have not yet received FDA marketing approval/clearance without compromising the safety of medical care provided to Medicare beneficiaries. The intent is to devise ways to assure Medicare beneficiaries greater access to advances in proven medical technology, to encourage clinical researchers to conduct high-quality studies, and to clarify Medicare coverage of reasonable and necessary medical services during clinical trials for investigational devices.

Anticipated Costs and Benefits:

In most instances, payment for devices covered as a result of this regulation will be held to the level of the most similar approved device. However, it is possible that some beneficiaries may be better suited to the newly covered device, resulting in some additional claims. Program costs associated with any new claims are estimated at \$7 million for fiscal year 1996, rising to \$9 million in fiscal year 2000.

Risks:

The anticipated policy will make more effective medical devices available sooner without exosing clients to additional risks.

Timetable:

Action	Date	FR Cite
Final Rule With Comment Period	08/19/95	60 FR 48417
Comment Period End	10/20/95	
Effective Date	11/01/95	
Final Action	09/00/96	

Small Entities Affected:

None

Government Levels Affected:

None

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HHS—Administration for Children and Families (ACF)

PROPOSED RULE STAGE

47. QUALITY STANDARDS FOR HEAD START PROGRAMS

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 9801

CFR Citation:

45 CFR 1301; 45 CFR 1304; 45 CFR 1309

Legal Deadline:

NPRM, Statutory, May 18, 1995.

Legal deadline only pertains to performance standards.

Abstract:

The NPRM will establish performance standards with respect to services provided to children 0 to 5 years old by Head Start Programs, including health, education, parent involvement, nutritional, social, and transitional services, administrative and financial management standards and standards relating to the condition and location of facilities used to carry out Head Start activities.

Statement of Need:

This regulation responds to the Administration's commitment to re-engineer the Head Start program in terms of quality improvement and capacity expansion and incorporates the Head Start Amendments of 1994 provision authorizing a new program of comprehensive, developmental services for low-income families with infants and toddlers. The statute requires the Department of Health and Human Services to publish performance standards governing the projects to be funded under this authority.

Summary of the Legal Basis:

Section 112, Title I (the Head Start Act Amendments of 1994) of the Human Resource Amendments of 1994.

Alternatives:

These rules are required by statutory mandate. To the extent that there is flexibility in regulating specific provisions, all reasonable alternatives

were considered by the Administration for Children, Youth and Families prior to the promulgation.

Anticipated Costs and Benefits:

Any costs associated with this regulation are the result of legislation and therefore are reflected in the President's budget.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/95	

Small Entities Affected:

Governmental Jurisdictions, Organizations

Government Levels Affected:

Local, Tribal

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