

DEPARTMENT OF JUSTICE (DOJ)

Statement of Regulatory Priorities

The highest priority of the Department is to protect America against acts of terrorism, both foreign and domestic, within the letter and spirit of the Constitution. Without ever relaxing in the fight against terrorism, the Department is also reinvigorating its traditional missions by embracing its historic role in fighting crime, protecting civil rights, preserving the environment, and ensuring fairness in the market place. The Department is working to ensure the fair and impartial administration of justice for all Americans, assist the agency's state and local partners, and defend the interests of the United States according to the law. In addition to using investigative, prosecutorial, and other law enforcement activities, the Department is also using the regulatory process to better carry out the Department's wide-ranging law enforcement missions.

The Department of Justice's regulatory priorities focus in particular on a major regulatory initiative in the area of civil rights. Specifically, the Department is planning to revise its regulations implementing titles II and III of the Americans With Disabilities Act (ADA). However, in addition to this specific initiative, several other components of the Department carry out important responsibilities through the regulatory process. Although their regulatory efforts are not singled out for specific attention in this regulatory plan, those components carry out key roles in implementing the Department's anti-terrorism and law enforcement priorities.

Civil Rights

In June 2008, the Department has published proposed rules to revise its regulations implementing titles II and III of the ADA to amend the ADA Standards for Accessible Design (28 CFR part 36, appendix A) to be consistent with the revised ADA accessibility guidelines published by the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) on July 23, 2004. During FY 2010, the Department expects to complete its work on these regulations and to further amend the Department's regulations to implement the ADA Amendments Act of 2008, which took effect on January 1, 2009.

Title II of the ADA prohibits discrimination on the basis of disability by public entities, and title III prohibits such discrimination by places of public

accommodation and requires accessible design and construction of places of public accommodation and commercial facilities. In implementing these provisions, the Department of Justice is required by statute to publish regulations that include design standards that are consistent with the guidelines developed by the Access Board. In 2004, the Access Board revised its Accessibility Guidelines to address issues such as unique State and local facilities (e.g., prisons, courthouses), recreation facilities, play areas, and building elements specifically designed for children's use that were not addressed in the initial guidelines, to promote greater consistency between the Federal accessibility requirements and the model codes, and to provide greater consistency between the ADA guidelines and the guidelines that implement the Architectural Barriers Act. Therefore, the Department proposed to adopt revised ADA Standards for Accessible Design that are consistent with the revised ADA Accessibility Guidelines.

The Department has also proposed to revise its regulations implementing title II and title III (28 CFR parts 35 and 36) to ensure that the requirements applicable to new construction and alterations under title II are consistent with those applicable under title III, to update the regulations to reflect the current state of law, and to ensure the Department's compliance with the Regulatory Flexibility Act, as amended.

The Department's proposed rules were the second step in a three-step process to adopt and interpret the Access Board's revised and amended guidelines. The first step of the rulemaking process was an advance notice of proposed rulemaking, published in the Federal Register on September 30, 2004, at 69 FR 58768, which the Department believes simplified and clarified the preparation of the proposed rule. In addition to giving notice of the proposed rule that will adopt revised ADA accessibility standards, the advance notice raised two sets of questions for public comment, and proposed a framework for the regulatory analysis that will accompany the proposed rule. The second step of the rulemaking process was the publication of proposed rules that would adopt revised ADA accessibility standards and that will supplement the standards with specifications for prisons, jails, court houses, legislative facilities, building elements designed for use by children, play areas, and

recreation facilities. The proposed rule also offered proposed answers to the interpretive questions raised in the advance notice and presented an initial regulatory assessment.

The final step in the process will be the publication of a final rule. Changes mandated by the ADA Amendments Act will be addressed in a separate rulemaking.

Other Department Initiatives

1. Prison Rape Elimination

The National Prison Rape Elimination Commission (NPREC) was created by Congress as a bipartisan panel as part of the Prison Rape Elimination Act of 2003 (PREA.) In June 2009, the NPREC issued its report consisting of findings, conclusions and recommendations to the President, Congress, the United States Attorney General, and other Federal and State officials. The Department is in the process of reviewing the Commission's recommendations, engaging stakeholders, and drafting regulations to adopt national standards for the detection, reduction, and punishment of prison rape, as provided for by the PREA.

2. Federal Habeas Corpus Review Procedures in Capital Cases

Pursuant to the USA PATRIOT Improvement and Reauthorization Act of 2005, on December 11, 2008 the Department promulgated a final rule to implement certification procedures for states seeking to qualify for the expedited Federal habeas corpus review procedures in capital cases under chapter 154 of title 28 of the United States Code. On February 5, 2009, the Department published in the *Federal Register* a notice soliciting further public comment on all aspects of the December 2008 final rule. The Department is presently reviewing the comments it received in response to the February 2009 solicitation and will publish a summary and response as appropriate.

3. Criminal Law Enforcement

In large part, the Department's criminal law enforcement components do not rely on the rulemaking process to carry out their assigned missions. The Federal Bureau of Investigation (FBI), for example, is responsible for protecting and defending the United States against terrorist and foreign intelligence threats, upholding and enforcing the criminal laws of the United States, and providing leadership and criminal justice services to Federal, State, municipal, and international

agencies and partners. Only in very limited contexts does the FBI rely on rulemaking. For example, the FBI is currently updating its National Instant Criminal Background Check System regulations to allow criminal justice agencies to conduct background checks prior to the return of firearms.

The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) issues regulations to enforce the Federal laws relating to the manufacture and commerce of firearms and explosives. ATF's mission and regulations are designed to:

- Curb illegal traffic in, and criminal use of, firearms, and to assist State, local, and other Federal law enforcement agencies in reducing crime and violence;
- Facilitate investigations of violations of Federal explosives laws and arson-for-profit schemes;
- Regulate the firearms and explosives industries, including systems for licenses and permits;
- Assure the collection of all National Firearms Act (NFA) firearms taxes and obtain a high level of voluntary compliance with all laws governing the firearms industry; and
- Assist the States in their efforts to eliminate interstate trafficking in, and the sale and distribution of, cigarettes and alcohol in avoidance of Federal and State taxes.

ATF will continue, as a priority during fiscal year 2010, to seek modifications to its regulations governing commerce in firearms and explosives. ATF plans to issue final regulations implementing the provisions of the Safe Explosives Act, title XI, subtitle C, of Public Law 107-296, the Homeland Security Act of 2002 (enacted November 25, 2002).

Combating the proliferation of methamphetamine and preventing the diversion of prescription drugs for illicit purposes are among the Attorney General's top drug enforcement priorities. The Drug Enforcement Administration (DEA) is responsible for enforcing the Controlled Substances Act and its implementing regulations to prevent the diversion of controlled substances, while ensuring adequate supplies for legitimate medical, scientific, and industrial purposes. DEA accomplishes its objectives through coordination with State, local, and other Federal officials in drug enforcement activities, development and maintenance of drug intelligence systems, regulation of legitimate

controlled substances, and enforcement coordination and intelligence-gathering activities with foreign government agencies. DEA continues to develop and enhance regulatory controls relating to the diversion control requirements for controlled substances.

One of DEA's key regulatory initiatives is its Notice of Proposed Rulemaking "Electronic Prescriptions for Controlled Substances" [RIN 1117-AA61]. This regulation would provide practitioners with the option of writing prescriptions for controlled substances electronically and permit pharmacies to receive, dispense, and archive electronic prescriptions for controlled substances. This regulation would provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances.

In the past, drug traffickers have been able to easily obtain large quantities of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, and others used in the clandestine production of methamphetamine from both foreign and domestic sources. One of DEA's key regulatory initiatives has been implementation of the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which further regulates the importation, manufacture, and retail sale of ephedrine, pseudoephedrine, and phenylpropanolamine and drug products containing these three chemicals. CMEA imposes sales and purchase limits for over-the-counter ephedrine, pseudoephedrine, and phenylpropanolamine products at the retail level; provides for the establishment of aggregate and individual company import and manufacturing quotas; and limits importation to that which is necessary to provide for medical, scientific, and other legitimate purposes. CMEA also provides investigators with necessary identifying information regarding manufacturers and importers of these chemicals. Regulations pertaining to implementation of CMEA include, but are not limited to:

- "Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products" [RIN 1117-AB05]
- "Implementation of the Combat Methamphetamine Epidemic Act of 2005; Notice of Transfers Following

Importation or Exportation" [RIN 1117-AB06]

- "Elimination of Exemptions for Chemical Mixtures Containing the List I Chemicals Ephedrine and/or Pseudoephedrine" [RIN 1117-AB11]
- "Registration Requirements for Importers and Manufacturers of Prescription Drug Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine" [RIN 1117-AB09]
- "Removal of Thresholds for the List I Chemicals Pseudoephedrine and Phenylpropanolamine" [RIN 1117-AB10]

The Federal Bureau of Prisons issues regulations to enforce the Federal laws relating to its mission: To protect society by confining offenders in the controlled environments of prisons and community-based facilities that are safe, humane, cost-efficient, and appropriately secure, and that provide work and other self-improvement opportunities to assist offenders in becoming law-abiding citizens. During the next 12 months, in addition to other regulatory objectives aimed at accomplishing its mission, the Bureau will continue its ongoing efforts to: streamline regulations, eliminating unnecessary language and improving readability; improve disciplinary procedures through a revision of the subpart relating to the disciplinary process; reduce the introduction of contraband through various means, such as clarifying drug and alcohol surveillance testing programs and protect the public from continuing criminal activity committed within prison; and enhance the Bureau's ability to more closely monitor the communications of high-risk inmates.

4. Immigration Matters

On March 1, 2003, pursuant to the Homeland Security Act of 2002 (HSA), the responsibility for immigration enforcement and for providing immigration-related services and benefits such as naturalization and work authorization was transferred from the Justice Department's Immigration and Naturalization Service (INS) to the Department of Homeland Security (DHS). However, the immigration judges and the Board of Immigration Appeals in the Executive Office for Immigration Review (EOIR) remain part of the Department of Justice; the immigration judges adjudicate approximately 300,000 cases each year to determine whether the aliens should be ordered

removed or should be granted some form of relief from removal, and the Board has jurisdiction over appeals from those decisions, as well as other matters. Accordingly, the Attorney General has a continuing role in the conduct of removal hearings, the granting of relief from removal, and the detention or release of aliens pending completion of removal proceedings. The Attorney General also is responsible for civil litigation and criminal prosecutions relating to the immigration laws.

In several pending rulemaking actions, the Department is working to revise and update the regulations relating to removal proceedings in order to improve the efficiency and effectiveness of the hearings in resolving issues relating to removal of aliens and the granting of relief from removal.

On June 3, 2009, the Attorney General announced his intention to initiate a new rulemaking proceeding for regulations to govern claims of ineffective assistance of counsel in immigration proceedings. The Department is currently drafting regulations to further this goal. The Department is also drafting regulations pursuant to the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 to take into account the specialized needs of unaccompanied alien children in removal proceedings.

DOJ—Civil Rights Division (CRT)

FINAL RULE STAGE

89. NONDISCRIMINATION ON THE BASIS OF DISABILITY IN PUBLIC ACCOMMODATIONS AND COMMERCIAL FACILITIES (SECTION 610 REVIEW)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

5 USC 301; 28 USC 509; 28 USC 510; 42 USC 12186(b)

CFR Citation:

28 CFR 36

Legal Deadline:

None

Abstract:

In 1991, the Department of Justice published regulations to implement title III of the Americans With

Disabilities Act of 1990 (ADA). Those regulations include the ADA Standards for Accessible Design, which establish requirements for the design and construction of accessible facilities that are consistent with the ADA Accessibility Guidelines (ADAAG) published by the U.S. Architectural and Transportation Barriers Compliance Board (Access Board). In the time since the regulations became effective, the Department of Justice and the Access Board have each gathered a great deal of information regarding the implementation of the Standards. The Access Board began the process of revising ADAAG a number of years ago. It published new ADAAG in final form on July 23, 2004, after having published guidelines in proposed form in November 1999 and in draft final form in April 2002. In order to maintain consistency between ADAAG and the ADA Standards, the Department is reviewing its title III regulations and expects to propose, in one or more stages, to adopt revised ADA Standards consistent with the final revised ADAAG and to make related revisions to the Department's title III regulations. In addition to maintaining consistency between ADAAG and the Standards, the purpose of this review and these revisions is to more closely coordinate with voluntary standards; to clarify areas which, through inquiries and comments to the Department's technical assistance phone lines, have been shown to cause confusion; to reflect evolving technologies in areas affected by the Standards; and to comply with section 610 of the Regulatory Flexibility Act, which requires agencies once every 10 years to review rules that have a significant economic impact upon a substantial number of small entities.

The first step in adopting revised Standards was an advance notice of proposed rulemaking that was published in the Federal Register on September 30, 2004, at 69 FR 58768, issued under both title II and title III. The Department believes that the advance notice simplified and clarified the preparation of the proposed rule. In addition to giving notice that the proposed rule will adopt revised ADA accessibility standards, the advance notice raised questions for public comment and proposed a framework for the regulatory analysis that accompanied the proposed rule.

The adoption of revised ADAAG will also serve to address changes to the ADA Standards previously proposed in RIN 1190-AA26, RIN 1190-AA38, RIN

1190-AA47, and RIN 1190-AA50, all of which have now been withdrawn from the Unified Agenda. These changes include technical specifications for facilities designed for use by children, accessibility standards for State and local government facilities, play areas, and recreation facilities, all of which had previously been published by the Access Board.

The timetable set forth below refers to the notice of proposed rulemaking that the Department issued as the second step of the above described title III rulemaking. This notice proposed to adopt revised ADA Standards for Accessible Design consistent with the minimum guidelines of the revised ADAAG, and initiated the review of the regulation in accordance with the requirements of section 610 of the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

Statement of Need:

Section 504 of the ADA requires the Access Board to issue supplemental minimum guidelines and requirements for accessible design of buildings and facilities subject to the ADA, including title III. Section 306(c) of the ADA requires the Attorney General to promulgate regulations implementing title III that are consistent with the Access Board's ADA guidelines. Because this rule will adopt standards that are consistent with the minimum guidelines issued by the Access Board, this rule is required by statute. Similarly, the Department's review of its title III regulation is being undertaken to comply with the requirements of the Regulatory Flexibility Act, as amended by SBREFA.

Summary of Legal Basis:

The summary of the legal basis of authority for this regulation is set forth above under Legal Authority and Statement of Need.

Alternatives:

The Department is required by the ADA to issue this regulation. Pursuant to SBREFA, the Department's title III regulation will consider whether alternatives to the currently published requirements are appropriate.

Anticipated Cost and Benefits:

The Access Board has analyzed the effect of applying its proposed amendments to ADAAG to entities covered by titles II and III of the ADA and has determined that they constitute

a significant regulatory action for purposes of Executive Order 12866. The Access Board's determination will apply as well to the revised ADA standards published by the Department.

As part of its revised ADAAG, the Access Board made available in summary form an updated regulatory assessment to accompany the final revised ADAAG. The Department prepared an initial Regulatory Impact Analysis (RIA), pursuant to E.O. 12866, of the combined economic impact of changes contained in this proposed rule and in the companion NPRM to amend the Department's title II regulation (RIN 1190-AA46). The RIA incorporates the elements required for the Initial Regulatory Flexibility Analysis (IRFA) required by the Regulatory Flexibility Act, as amended. A summary of this RIA was published in the Federal Register at 73 FR 37009, 37042 (June 30, 2008). The full analysis is available for public review on www.regulations.gov and on the Department's ADA Home Page, www.ada.gov. A revised RIA will be made available to the public when the final rules are published.

The preliminary RIA indicates that the proposed rules will have a net positive public benefit, i.e., the benefits will exceed the costs over the life of the rule. This concept is expressed as the discounted net present value (NPV). The RIA projects that the NPV will be between \$7.5 billion (at a 7% discount rate) and \$ 31.1 billion (at a 3% discount rate). The RIA also concludes that the combined effect of the proposed rules would not have a significant economic impact on a substantial number of small entities.

Section 4(2) of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1503(2), excludes from coverage under that Act any proposed or final Federal regulation that "establishes or enforces any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability." Accordingly, this rulemaking is not subject to the provisions of the Unfunded Mandates Reform Act.

Risks:

Without the proposed changes to the Department's title III regulation, the ADA Standards will fail to be consistent with the ADAAG.

Timetable:

Action	Date	FR Cite
ANPRM	09/30/04	69 FR 58768

Action	Date	FR Cite
ANPRM Comment Period End	01/28/05	
ANPRM Comment Period Extended	01/19/05	70 FR 2992
ANPRM Comment Period End	05/31/05	
NPRM	06/17/08	73 FR 34508
NPRM Comment Period End	08/18/08	
NPRM Correction	06/30/08	73 FR 37009
Final Action	03/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Additional Information:

RIN 1190-AA44, which will effect changes to 28 CFR 36 (the Department's regulation implementing title III of the ADA), is related to another rulemaking of the Civil Rights Division, RIN 1190-AA46, which will effect changes to 28 CFR 35 (the Department's regulation implementing title II of the ADA).

Agency Contact:

John L. Wodatch
Chief, Disability Rights Section
Department of Justice
Civil Rights Division
950 Pennsylvania Avenue NW
Washington, DC 20030
Phone: 800 514-0301
TDD Phone: 800 514-0383
Fax: 202 307-1198

RIN: 1190-AA44

DOJ—CRT

90. NONDISCRIMINATION ON THE BASIS OF DISABILITY IN STATE AND LOCAL GOVERNMENT SERVICES (SECTION 610 REVIEW)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

5 USC 301; 28 USC 509 to 510; 42 USC 12134; PL 101-336

CFR Citation:

28 CFR 35

Legal Deadline:

None

Abstract:

On July 26, 1991, the Department published its final rule implementing title II of the Americans With Disabilities Act (ADA). On November 16, 1999, the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) issued its first comprehensive review of the ADA Accessibility Guidelines (ADAAG), which form the basis of the Department's ADA Standards for Accessible Design. The Access Board published an Availability of Draft Final Guidelines on April 2, 2002, and published the ADA Accessibility Guidelines in final form on July 23, 2004. The ADA (section 204(c)) requires the Department's standards to be consistent with the Access Board's guidelines. In order to maintain consistency between ADAAG and the Standards, the Department is reviewing its title II regulations and expects to propose, in one or more stages, to adopt revised standards consistent with new ADAAG. The Department will also, in one or more stages, review its title II regulations for purposes of section 610 of the Regulatory Flexibility Act and make related changes to its title II regulations.

In addition to the statutory requirement for the rule, the social and economic realities faced by Americans with disabilities dictate the need for the rule. Individuals with disabilities cannot participate in the social and economic activities of the Nation without being able to access the programs and services of State and local governments. Further, amending the Department's ADA regulations will improve the format and usability of the ADA Standards for Accessible Design; harmonize the differences between the ADA Standards and national consensus standards and model codes; update the ADA Standards to reflect technological developments that meet the needs of persons with disabilities; and coordinate future ADA Standards revisions with national standards and model code organizations. As a result, the overarching goal of improving access for persons with disabilities so that they can benefit from the goods, services, and activities provided to the public by covered entities will be met.

The first part of the rulemaking process was an advance notice of proposed rulemaking, published in the Federal Register on September 30, 2004, at 69 FR 58768, issued under both title II and title III. The Department believes the advance notice simplified and clarified the preparation of the proposed rule to

follow. In addition to giving notice of the proposed rule that will adopt revised ADA accessibility standards, the advance notice raised questions for public comment and proposed a framework for the regulatory analysis that accompanied the proposed rule.

The adoption of revised ADA Standards consistent with revised ADAAG will also serve to address changes to the ADA Standards previously proposed under RIN 1190-AA26, RIN 1190-AA38, RIN 1190-AA47, and RIN 1190-AA50, all of which have now been withdrawn from the Unified Agenda. These changes include technical specifications for facilities designed for use by children, accessibility standards for State and local government facilities, play areas, and recreation facilities, all of which had previously been published by the Access Board.

The timetable set forth below refers to the notice of proposed rulemaking that the Department issued as the second step of the above-described title III rulemaking. This notice also proposed to eliminate the Uniform Federal Accessibility Standards (UFAS) as an alternative to the ADA Standards for Accessible Design.

Statement of Need:

Section 504 of the ADA requires the Access Board to issue supplemental minimum guidelines and requirements for accessible design of buildings and facilities subject to the ADA, including title II. Section 204(c) of the ADA requires the Attorney General to promulgate regulations implementing title II that are consistent with the Access Board's ADA guidelines. Because this rule will adopt standards that are consistent with the minimum guidelines issued by the Access Board, this rule is required by statute. Similarly, the Department's review of its title II regulations is being undertaken to comply with the requirements of the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Summary of Legal Basis:

The summary of the legal basis of authority for this regulation is set forth above under Legal Authority and Statement of Need.

Alternatives:

The Department is required by the ADA to issue this regulation as described in the Statement of Need above. Pursuant to SBREFA, the Department's title II regulation will consider whether

alternatives to the currently published requirements are appropriate.

Anticipated Cost and Benefits:

The Administration is deeply committed to ensuring that the goals of the ADA are met. Promulgating this amendment to the Department's ADA regulations will ensure that entities subject to the ADA will have one comprehensive design standard to follow. Currently, entities subject to title II of the ADA (State and local governments) have a choice between following the Department's ADA Standards for title III, which were adopted for places of public accommodation and commercial facilities and which do not contain standards for common State and local government buildings (such as courthouses and prisons), or the Uniform Federal Accessibility Standards (UFAS). By developing one comprehensive standard, the Department will eliminate the confusion that arises when governments try to mesh two different standards. As a result, the overarching goal of improving access to persons with disabilities will be better served.

The Access Board has analyzed the effect of applying its proposed amendments to ADAAG to entities covered by titles II and III of the ADA and has determined that they constitute a significant regulatory action for purposes of Executive Order 12866. The Access Board's determination will apply as well to the revised ADA Standards published by the Department.

As part of its revised ADAAG, the Access Board made available in summary form an updated regulatory assessment to accompany the final revised ADAAG. The Department prepared an initial Regulatory Impact Analysis (RIA), pursuant to E.O. 12866, of the combined economic impact of changes contained in this proposed rule and in the companion NPRM to amend the Department's title III regulation (RIN 1190-AA44). The RIA incorporates the elements required for the Initial Regulatory Flexibility Analysis (IRFA) required by the Regulatory Flexibility Act, as amended. A summary of this RIA was published in the Federal Register at 73 FR 36964, 36996 (June 30, 2008). The full analysis is available for public review on www.regulations.gov and on the Department's ADA Home Page, www.ada.gov. A revised RIA will be made available to the public when the final rules are published.

The preliminary RIA indicates that the proposed rules will have a net positive public benefit; i.e., the benefits will exceed the costs over the life of the rule. This concept is expressed as the discounted net present value (NPV). The RIA projects that the NPV will be between \$ 7.5 billion (at a 7% discount rate) and \$ 31.1 billion (at a 3% discount rate). The RIA also concludes that the combined effect of the proposed rules would not have a significant economic impact on a substantial number of small entities.

The Access Board has made every effort to lessen the impact of its proposed guidelines on State and local governments but recognizes that the guidelines will have some federalism effects. These effects are discussed in the Access Board's regulatory assessment, which also applies to the Department's proposed rule. Section 4(2) of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1503(2), excludes from coverage under that Act any proposed or final Federal regulation that "establishes or enforces any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability." Accordingly, this rulemaking is not subject to the provisions of the Unfunded Mandates Reform Act.

Risks:

Without this amendment to the Department's ADA regulations, regulated entities will be subject to confusion and delay as they attempt to sort out the requirements of conflicting design standards. This amendment should eliminate the costs and risks associated with that process.

Timetable:

Action	Date	FR Cite
ANPRM	09/30/04	69 FR 58768
ANPRM Comment Period End	01/28/05	
ANPRM Comment Period Extended	01/19/05	70 FR 2992
ANPRM Comment Period End	05/31/05	
NPRM	06/17/08	73 FR 34466
NPRM Comment Period End	08/18/08	
NPRM Correction	06/30/08	73 FR 36964
Final Action	03/00/10	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

RIN 1190-AA46, which will effect changes to 28 CFR 35 (the Department’s regulation implementing title II of the ADA), is related to another rulemaking of the Civil Rights Division, RIN 1190-AA44, which will effect changes to 28 CFR 36 (the Department’s regulation implementing title III of the ADA). By adopting revised ADAAG, this rulemaking will, among other things, address changes to the ADA Standards previously proposed in RINs 1190-AA26, 1190-AA36, and 1190-AA38, which have been withdrawn and merged into this rulemaking. These changes include accessibility standards for State and local government facilities that had been previously published by the Access Board (RIN 1190-AA26) and the timing for the compliance of State and local governments with the curb-cut requirements of the title II regulation (RIN 1190-AA36). In order to consolidate regulatory actions implementing title II of the ADA, on February 15, 2000, RINs 1190-AA26 and 1190-AA38 were merged into this rulemaking and on March 5, 2002, RIN 1190-AA36 was merged into this rulemaking.

Agency Contact:

John L. Wodatch
Chief, Disability Rights Section
Department of Justice
Civil Rights Division
950 Pennsylvania Avenue NW
Washington, DC 20030
Phone: 800 514-0301
TDD Phone: 800 514-0383
Fax: 202 307-1198

RIN: 1190-AA46

DOJ—Drug Enforcement Administration (DEA)

FINAL RULE STAGE

91. ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

21 USC 802; 21 USC 821; 21 USC 827; 21 USC 829; 21 USC 871(b)

CFR Citation:

21 CFR 1300; 21 CFR 1306; 21 CFR 1311

Legal Deadline:

None

Abstract:

DEA is revising its regulations to establish the criteria that will allow DEA-registered practitioners to sign and transmit controlled substances prescriptions electronically. The regulations will also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations would not mandate the use of electronic prescriptions, but would establish the requirements that must be met by any registrant that wishes to issue or receive electronic prescriptions for controlled substances. The regulations would establish requirements that practitioners must meet when issuing electronic prescriptions, including requirements for the software applications used to issue those prescriptions; registrants would have to use only those software applications that meet the security requirements if they intend to sign, transmit, or process electronic prescriptions for controlled substances. The regulations would not apply to software used to create a prescription that is then printed and manually signed. These revised regulations would be in addition to, not a replacement of, the existing rules.

Statement of Need:

These regulations are needed to give pharmacies, hospitals, and practitioners the ability to use modern technology for controlled substance prescriptions, while maintaining the closed system of distribution of controlled substances dispensing. The regulations are required to ensure, to the extent possible, that non-registrants cannot gain access to electronic prescription software applications to issue illegal prescriptions and that legitimate prescriptions, once written, cannot be altered or repudiated.

Summary of Legal Basis:

The Controlled Substances Act (21 U.S.C. 871(b) provides that the Attorney General, DEA by delegation, may promulgate and enforce any rules, regulations, and procedures deemed necessary for the efficient execution of the Attorney General’s functions,

including general enforcement of the Controlled Substances Act. Specific legal authority for this regulation is provided above.

Alternatives:

DEA solicited comments on all aspects of its Notice of Proposed Rulemaking regarding this matter, and also sought specific information on a number of issues and topics. All comments received have been considered. DEA has addressed comments in its Final Rule.

Anticipated Cost and Benefits:

The estimated annualized cost of the Final Rule is \$34 million (7 percent net present value), which covers the costs for practitioners, pharmacies, and application providers.

Electronic prescriptions provide potential benefits in terms of reduced processing time, reduced callbacks, and fewer medication errors. These benefits of electronic prescriptions are not directly attributable to this rule except to the extent the rule facilitates implementation of electronic prescribing of controlled substances. Pharmacies will directly benefit from the rule as they will not be required to maintain paper copies of electronic prescriptions. Electronic prescriptions for controlled substances will also provide benefits as certain types of forgery or alteration of prescriptions may be less likely to occur.

Risks:

Were DEA not to promulgate these regulations, prescribing practitioners would not be permitted to sign and transmit electronic controlled substances prescriptions. Pharmacies would not be permitted to receive, dispense, and archive these electronic prescriptions.

Timetable:

Action	Date	FR Cite
ANPRM	03/05/01	66 FR 13274
NPRM	06/27/08	73 FR 36722
NPRM Comment Period End	09/25/08	
Final Rule	03/00/10	
Final Action Effective	05/00/10	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Additional Information:

DEA-218

URL For Public Comments:

www.dea.diversion.usdoj.gov

Agency Contact:

Mark W. Caverly
Chief, Liaison and Policy Section
Department of Justice
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152
Phone: 202 307-7297
Email: dea.diversion.policy@usdoj.gov

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