

ALI-ABA Audio Seminar

NEW Proposed Regulations for the ADA Amendments Act

October 21, 2009

Telephone Seminar/Audio Webcast

**Regulations To Implement the Equal Employment
Provisions of the Americans With Disabilities Act, as Amended**

(ii) § 820.30 of this chapter. Design controls.

(iii) § 820.50 of this chapter. Purchasing controls.

(iv) § 820.100 of this chapter. Corrective and preventive action.

(v) § 820.170 of this chapter. Installation.

(vi) § 820.200 of this chapter. Servicing.

(2) If the combination product includes a device constituent part and a drug constituent part, and the current good manufacturing practice operating system has been shown to comply with the QS regulation, the following provisions of the drug cGMPs must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the drug cGMPs need be made:

(i) § 211.84 of this chapter. Testing and approval or rejection of components, drug product containers, and closures.

(ii) § 211.103 of this chapter. Calculation of yield.

(iii) § 211.132 of this chapter. Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.

(iv) § 211.137 of this chapter. Expiration dating.

(v) § 211.165 of this chapter. Testing and release for distribution.

(vi) § 211.166 of this chapter. Stability testing.

(vii) § 211.167 of this chapter. Special testing requirements.

(viii) § 211.170 of this chapter. Reserve samples.

(3) In addition to being shown to comply with the other applicable current good manufacturing practice requirements listed under § 4.3, if the combination product includes a biological product constituent part, the current good manufacturing practice operation system must also be shown to implement and comply with all current good manufacturing practice requirements identified under § 4.3(c) that would apply to that biological product if that constituent part were not part of a combination product.

(4) In addition to being shown to comply with the other applicable current good manufacturing practice requirements listed under § 4.3, if the combination product includes an HCT/P, the current good manufacturing practice operation system must also be shown to implement and comply with all current good manufacturing practice requirements identified under § 4.3(d) that would apply to that HCT/P constituent part if that constituent part were not part of a combination product.

(c) During any period in which the manufacture of a constituent part to be included in a co-packaged or single-entity combination product occurs at a separate facility from the other type(s) of constituent part(s) to be included in that single-entity or co-packaged combination product, the current good manufacturing practice operating system for that constituent part must be demonstrated to comply with all current good manufacturing practice requirements applicable to that type of constituent part.

(d) When two or more types of constituent parts to be included in a single-entity or co-packaged combination product have arrived at the same facility, or the manufacture of these constituent parts is proceeding at the same facility, application of a current good manufacturing process operating system that complies with § 4.4(b) may begin, except with respect to any constituent part that remains or becomes subject to § 4.4(c).

(e) The current good manufacturing practice requirements set forth in this subpart and in parts 210, 211, 600 through 680, 820, and 1271 of this chapter, supplement, and do not supersede, each other unless the regulations explicitly provide otherwise. In the event of a conflict between regulations applicable under this subpart to combination products, including their constituent parts, the regulations most specifically applicable to the constituent part in question shall supersede the more general.

Subpart B [Reserved]

Dated: September 17, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1630

RIN 3046-AA85

Regulations To Implement the Equal Employment Provisions of the Americans With Disabilities Act, as Amended

AGENCY: Equal Employment Opportunity Commission (EEOC).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Equal Employment Opportunity Commission (the Commission or EEOC) proposes to revise its Americans with Disabilities

Act (ADA) regulations and accompanying interpretive guidance in order to implement the ADA Amendments Act of 2008. The Commission is responsible for enforcement of title I of the ADA, as amended, which prohibits employment discrimination on the basis of disability. Pursuant to the ADA Amendments Act of 2008, EEOC is expressly granted the authority to amend these regulations, and is expected to do so, in order to conform certain provisions contained in the regulations to the Amendments Act.

DATES: Written comments on this rulemaking must be submitted on or before November 23, 2009.

ADDRESSES: Written comments should be submitted to Stephen Llewellyn, Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street, NE., Suite 4NW08R, Room 6NE03F, Washington, DC 20507. As a convenience to commenters, the Executive Secretariat will accept comments transmitted by facsimile ("FAX") machine. The telephone number of the FAX receiver is (202) 663-4114. (This is not a toll-free number.) Only comments of six or fewer pages will be accepted via FAX transmittal to ensure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663-4070 (voice) or (202) 663-4074 (TTY). (These are not toll-free telephone numbers.) You may also submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments. Copies of comments submitted by the public will be available for review at the Commission's library, 131 M Street, NE., Suite 4NW08R, Washington, DC 20507, between the hours of 9:30 a.m. and 5 p.m. or can be reviewed at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Christopher Kuczynski, Assistant Legal Counsel, or Jeanne Goldberg, Senior Attorney Advisor, Office of Legal Counsel, U.S. Equal Employment Opportunity Commission at (202) 663-4638 (voice) or (202) 663-7026 (TTY). These are not toll-free-telephone numbers. This document is also available in the following formats: large print, Braille, audio tape, and electronic file on computer disk. Requests for this document in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663-4191 (voice) or (202) 663-

4494 (TTY) or to the Publications Information Center at 1-800-669-3362.

SUPPLEMENTARY INFORMATION: The ADA Amendments Act of 2008 (“the Amendments Act”) was signed into law by President George W. Bush on September 25, 2008, with a statutory effective date of January 1, 2009.

Pursuant to the 2008 amendments, the definition of disability under the ADA, 42 U.S.C. 12101, *et seq.*, shall be construed in favor of broad coverage to the maximum extent permitted by the terms of the ADA as amended, and the determination of whether an individual has a disability should not demand extensive analysis. The Amendments Act makes important changes to the definition of the term “disability” by rejecting the holdings in several Supreme Court decisions and portions of EEOC’s ADA regulations. The effect of these changes is to make it easier for an individual seeking protection under the ADA to establish that he or she has a disability within the meaning of the ADA. Statement of the Managers to Accompany S. 3406, The Americans with Disabilities Act Amendments Act of 2008 (hereinafter 2008 Senate Managers’ Statement); Committee on Education and Labor Report together with Minority Views (to accompany H.R. 3195), H.R. Rep. No. 110-730 part 1, 110th Cong., 2d Sess. (June 23, 2008) (hereinafter 2008 House Comm. on Educ. and Labor Report); Committee on the Judiciary Report together with Additional Views (to accompany H.R. 3195), H.R. Rep. No. 110-730 part 2, 110th Cong., 2d Sess. (June 23, 2008) (hereinafter 2008 House Judiciary Committee Report).

The Amendments Act retains the ADA’s basic definition of “disability” as an impairment that substantially limits one or more major life activities, a record of such an impairment, or being regarded as having such an impairment. However, it changes the way that these statutory terms should be interpreted in several ways, therefore necessitating revision of the existing regulations and interpretive guidance contained in the accompanying “Appendix to Part 1630—Interpretive Guidance on Title I of the Americans with Disabilities Act,” which are published at 29 CFR part 1630.

Consistent with the provisions of the Amendments Act and Congress’s expressed expectation therein, the proposed rule:

- Provides that the definition of “disability” shall be interpreted broadly;
- Revises that portion of the regulations defining the term “substantially

limits” as directed in the Amendments Act by providing that a limitation need not “significantly” or “severely” restrict a major life activity in order to meet the standard, and by deleting reference to the terms “condition, manner, or duration” under which a major life activity is performed, in order to effectuate Congress’s clear instruction that “substantially limits” is not to be misconstrued to require the “level of limitation, and the intensity of focus” applied by the Supreme Court in *Toyota Motor Mfg., Ky v. Williams*, 534 U.S. 134 (2002) (2008 Senate Managers’ Statement at 6);

- Expands the definition of “major life activities” through two non-exhaustive lists:
 - The first list includes activities such as caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, sitting, reaching, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, interacting with others, and working, some of which the EEOC previously identified in regulations and sub-regulatory guidance, and some of which Congress additionally included in the Amendments Act;
 - The second list includes major bodily functions, such as functions of the immune system, special sense organs, and skin; normal cell growth; and digestive, genitourinary, bowel, bladder, neurological, brain, respiratory, circulatory, cardiovascular, endocrine, hemic, lymphatic, musculoskeletal, and reproductive functions, many of which were included by Congress in the Amendments Act, and some of which have been added by the Commission as further illustrative examples;
- Provides that mitigating measures other than “ordinary eyeglasses or contact lenses” shall not be considered in assessing whether an individual has a “disability”;
- Provides that an impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active;
- Provides that the definition of “regarded as” is changed so that it no longer requires a showing that the employer perceived the individual to be substantially limited in a major life activity, and instead provides that an applicant or employee who is subjected to an action prohibited by the ADA (*e.g.*, failure to hire, denial of promotion, or termination) because of an actual or perceived impairment

will meet the “regarded as” definition of disability, unless the impairment is both transitory and minor;

- The proposed rule provides that actions based on an impairment include actions based on symptoms of an impairment, and the Commission invites public comment on this point;
- Provides that individuals covered only under the “regarded as” prong are not entitled to reasonable accommodation; and,
- Provides that qualification standards, employment tests, or other selection criteria based on an individual’s uncorrected vision shall not be used unless shown to be job-related for the position in question and consistent with business necessity.

To effectuate these changes, the proposed rule revises the following sections of 29 CFR part 1630 and the accompanying provisions of the accompanying Appendix:

- § 1630.1 (adds subsections (3) and (4));
- § 1630.2(g)(3) (adds cross-reference to 1630.2(l));
- § 1630.2 (h) (replaces the term “mental retardation” with the term “intellectual disability”);
- § 1630.2(i) (revises definition of “major life activities” and provides examples)
- § 1630.2(j) (revises definition of “substantially limits” and provides examples)
- § 1630.2(k) (provides examples of “record of” a disability)
- § 1630.2(l) (revises definition of “regarded as” having a disability and provides examples)
- § 1630.2(m) (revises terminology)
- § 1630.2(o) (adds subsection (4) stating that reasonable accommodations are not available to individuals who are only “regarded as” individuals with disabilities)
- § 1630.4 (renumbers section and adds subsection (b) regarding “claims of no disability”)
- § 1630.9 (revises terminology in subsection (c) and adds subsection (e) stating that an individual covered only under the “regarded as” definition of disability is not entitled to reasonable accommodation)
- § 1630.10 (revises to add provision on qualification standards and tests related to uncorrected vision)
- § 1630.16(a) (revises terminology).

These regulatory revisions are explained in the revised Part 1630 Appendix containing the interpretive guidance which would be issued and published in the Code of Federal Regulations with the final rule. The Commission originally issued the

interpretive guidance concurrent with the issuance of the original Part 1630 ADA regulations in order to ensure that individuals with disabilities understand their rights under these regulations and to facilitate and encourage compliance by covered entities. The Appendix addresses the major provisions of the regulations and explains the major concepts. The Appendix as revised would continue to represent the Commission's interpretation of the issues discussed, and the Commission will be guided by it when resolving charges of employment discrimination under the ADA.

Regulatory Procedures

Executive Order 12866

The rule has been drafted and reviewed in accordance with Executive Order 12866, 58 FR 51735 (Sept. 30, 1993), section 1(b), Principles of Regulation. It is considered to be a "significant regulatory action" pursuant to section 3(f)(4) of Executive Order 12866 in that it arises out of the Commission's legal mandate to enforce the ADA, and therefore was circulated to the Office of Management and Budget for review. These revisions are necessary to bring the Commission's regulations into compliance with the ADA Amendments Act of 2008, which became effective January 1, 2009, and explicitly invalidated certain provisions of the regulations. The proposed revisions to the title I regulations and Appendix are intended to add to the predictability and consistency between judicial interpretations and executive enforcement of the ADA as now amended by Congress.

Preliminary Regulatory Impact Analysis

The following preliminary review of existing research highlights the costs and benefits of providing reasonable accommodation under the ADA and suggests that the effect on the economy of the changes to EEOC's regulation as a result of the ADA Amendments Act will very likely be below the \$100 million threshold for "economically significant" regulations. Focusing on the costs of reasonable accommodations required by the regulations implementing the ADA Amendments, this preliminary review considers estimates of the cost of accommodation, the prevalence of accommodation already in the workplace, the number of additional accommodation requests that the ADA Amendments Act would need to generate to reach the \$100 million threshold for a economically significant regulatory impact, and the reported benefits to employers of providing

reasonable accommodations. Since the existing research measuring the relevant costs and benefits is limited, however, the Commission seeks public comment on this issue in order to determine whether further regulatory impact analysis will be required.

Preliminary Discussion of Assumptions

Although this review is based on data regarding how many people will benefit from the changes in the ADA and what the anticipated costs will be, it is important to take note of the following unique factors bearing on any inquiry into the increased costs imposed by the ADA Amendments Act and EEOC's proposed rule:

- The fact that prior to the Amendments Act many plaintiffs lost reasonable accommodation cases in litigation based on coverage does not mean employers denied the underlying accommodation requests because they concluded that individuals did not meet the definition of "disability." Many pre-Amendments Act court decisions, including those cited by Congress in the legislative history of the Amendments Act, held that someone was not an individual with a disability in cases where the employer's denial of accommodation had nothing to do with coverage. Rather, coverage was raised as a legal defense after-the-fact against the asserted violation of the ADA. This suggests that costs associated with the Amendments and implementing regulations are not newly imposed and in many instances have already been expended under the ADA.
- It is incorrect to assume that cancer, epilepsy, diabetes, or other impairments addressed in section 1630.2(j)(5) of the NPRM were not covered, in absolute terms, under the prior definition, but now are. Many people with the types of impairments identified in section (j)(5) that will consistently meet the new definition of disability were already covered under EEOC's prior interpretation of the law and by those employers who voluntarily complied with it.
- Many of the individuals actually brought within the new definition of "disability" are likely to have less severe limitations needing less extensive accommodations. Moreover, those brought within the new "regarded as" definition of "disability" are not entitled to accommodation at all.
- Of those newly covered under the amended definition who do both request and need accommodation, employers will sometimes provide whatever is requested based on

existing employer policies and procedures (e.g., use of accrued annual or sick leave or employer unpaid leave policy, employer short- or long-term disability benefits, employer flexible schedule options guaranteed by a CBA, voluntary transfer programs, "early return to work" programs, etc.), or under another statute (e.g., FMLA, workers' compensation, etc.).

- Moreover, of those individuals with disabilities who do request accommodation, not all will be entitled to it under the ADA because, for example, they do not need the accommodation requested, there is no reasonable accommodation that can be provided absent undue hardship, or they would not be "qualified" or would pose a "direct threat to safety, even with an accommodation."
- EEOC fully expects to issue a new or revised small business handbook as part of revisions made to all of our ADA publications, which include dozens of enforcement guidances and technical assistance documents, some of which are specifically geared toward small business (e.g., "The ADA: A Primer for Small Business," <http://www.eeoc.gov/ada/adahandbook.html>).
- An emphasis on the anticipated "difference" in compliance costs between smaller and larger entities may overlook some offsets to costs incurred by smaller entities. For example, EEOC makes available even more free outreach and training materials than it does paid trainings. Moreover, smaller entities are less likely to have detailed reasonable accommodation procedures containing information relating to the definition of disability that must be revised or deleted.
- The under-utilization of tax incentives available to encourage employers to provide reasonable accommodation, the lag time in receipt of the offsets, and the fact that the offsets are only partial, do not necessarily support greater costs, since the incentives typically apply to accommodations that would relate to more severe disabilities covered prior to the ADA Amendments Act.

Reasonable Accommodation

We note at the outset that extensive data on the costs of providing reasonable accommodations for applicants and employees with disabilities does not exist, and that much of the data that has been collected was obtained through either limited sample surveys or surveys that collected very little information.