20001. The materials may also be ordered via the AASHTO bookstore located at the following URL: *http://www.aashto.org/aashto/home.nsf/FrontPage.*

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DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 2

RIN 1290–AA23

Requirements for DOL Agencies' Assessment of Occupational Health Risks

AGENCY: Office of the Secretary; Office of the Assistant Secretary for Policy.
ACTION: Proposed rule; withdrawal.

SUMMARY: The Department of Labor (''Department'' or ''DOL'') is withdrawing its proposed rule governing DOL agencies' assessment of occupational health risks. The proposed rule sought to compile Department procedures related to risk assessment into a single regulation and included new requirements aimed at establishing consistent procedures intended to promote greater public input and awareness of the Department's health rulemakings.

DATES: This withdrawal is effective on August 31, 2009.

FOR FURTHER INFORMATION CONTACT: Kathleen Franks, Office of Regulatory and Programmatic Policy, Office of the Assistant Secretary for Policy, U.S. Department of Labor, (202) 693–5959. This is not a toll-free number. Individuals with hearing or speech impairments may access the number above via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On August 29, 2008, the Department published in the **Federal Register** (73 FR 50909 Aug. 29, 2008) a notice of proposed rulemaking (NPRM) to codify DOL's internal risk assessment procedures for health standard rulemakings that address workplace exposure to toxic substances and hazardous chemicals. The NPRM stated that it summarized and would codify DOL agencies' existing risk assessment paradigm and requested public comment on two specific procedural requirements: A new requirement that DOL agencies issue an Advance Notice of Proposed Rulemaking (ANPRM) as a first step whenever developing a health standard that would regulate workplace exposure to toxic substances or hazardous chemicals; and a requirement that DOL agencies electronically post all documents relied upon to develop such health standards within fourteen days of each regulatory step. Because the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) are the only two agencies within the Department that issue health standards related to toxic substances and hazardous chemicals, it was anticipated that the proposed rule would affect only those agencies.

The Department accepted public comment on the NPRM for a period of 30 days. While some interested parties, including members of Congress, urged DOL to extend the public comment period and requested that the Department hold public hearings on the proposal, the Department declined these requests due to its desire to adhere to the originally published timeframe for completion of this rulemaking.

The Department received comments in response to the NPRM from a variety of sources, including members of Congress, private citizens, labor unions, worker advocacy organizations, industry associations, employer groups, and risk assessment experts. The majority of the commenters were opposed to the rulemaking.[1]

II. Reasons for Withdrawal of Proposed Rule

After careful review of the comments and upon reconsideration of the issues involved in this rulemaking, the Department has decided to withdraw the proposed rule. As described below, the two proposed requirements are unnecessary. Moreover, given the nature of the issues, the Department believes that it is more useful to continue describing its internal risk assessment policies through guidance rather than through promulgation of a regulation.

Proposed ANPRM Requirement. The proposal would have required DOL agencies to issue an ANPRM in every rulemaking for a health standard involving toxic substances or hazardous chemicals, apart from emergency temporary standards. Many commenters were opposed to this new requirement. *See, e.g.*, Exs. 7.1; 16.1; 42.1; and 48.1.[2] Some commenters, including members of Congress and Senators, employer groups, and worker advocacy organizations claimed that an ANPRM is not always useful and that imposing an ANPRM requirement in a health standard rulemaking when it was not necessary would unduly delay the rulemaking. *See, e.g.*, Exs. 32.1; 37.1; and 42.1. They argued that this in turn could harm workers by unnecessarily delaying the introduction of the health protections required by the standard. Labor unions and worker advocacy organizations also claimed that requiring an unnecessary ANPRM would divert agency resources from other rulemaking efforts. *See, e.g.*, Exs. 45.1 and 48.1.

The current policy of both OSHA and MSHA is to publish an ANPRM only if the agency believes it will be beneficial to the rulemaking. This decision is made on a case-by-case basis. In light of the comments to the proposal and after reconsideration of the proposed ANPRM requirement, the Department has determined that OSHA and MSHA should continue to follow their current ANPRM policy.

The Department believes that an ANPRM can be a valuable part of the rulemaking process in the right circumstances, but that an inflexible requirement would not fit the varied circumstances in which rulemakings are conducted and could cause unnecessary delays. When an agency lacks important information needed to develop an effective proposed rule, an ANPRM provides one means of attempting to obtain that information. However, there are times when an agency has sufficient information to issue a successful proposed rule without taking that step. Avoiding an ANPRM in these situations allows the agency to more effectively use its rulemaking resources. There are also many other ways in which OSHA and MSHA can obtain needed information without using an ANPRM, such as holding stakeholder meetings, conducting surveys, consulting advisory committees, doing site visits, issuing Requests for Information, conducting peer reviews, and, in the case of OSHA, obtaining small entity (including small business) input through procedures required by the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 609(b)). By allowing the agency to decide whether or not to use an ANPRM for a rulemaking, the agency retains flexibility to choose the information gathering methods that it has determined will best fit each individual situation.

Proposed Electronic Posting Requirement. The proposal would have required the Department to make

[1] Comments are available for review at *http://www.regulations.gov*. Reference Docket Number: DOL–2008–0002.

[2] ''Ex.'' Refers to exhibits included in the rulemaking docket, which can be referenced using the URL provided in Footnote 1, supra.

available, on *http://www.regulations.gov* or *http://www.dol.gov*, ''all relevant documents related to a rulemaking addressing occupational exposure to toxic substances and hazardous chemicals no later than fourteen days after the conclusion of the relevant rulemaking step that relied upon or utilized those documents.'' 73 FR at 50914. Commenters such as some industry associations and employer groups, who addressed this issue generally supported the electronic posting requirement and its goal of transparency in rulemaking. *See, e.g.*, Exs. 11.1; 25.1; 32.1; and 38.1. Several commenters, including labor unions, other employer groups, and industry associations however, pointed out that the Department is already required to, and does, make rulemaking information available online. *See, e.g.*, Exs. 17.1; 32.1; and 35.1. Indeed, the E-Government Act of 2002 requires all federal agencies to maintain a publicly accessible website containing electronic dockets for rulemakings. Public Law No. 107–347, Title II, 201 to 216 (codified as 44 U.S.C. 3501 note), at 206(d)(1). All public comments, as well as ''other materials that by agency rule or practice are included in the rulemaking docket'' are required to be made available to the public via the electronic docket. Public Law No. 107–347, Title II, at 206(d)(2)(A), (B). To implement the E-Government Act and provide the public with a single government-wide access point for rulemaking information and submissions, federal agencies were required to consolidate all electronic rulemaking dockets on *http://www.regulations.gov*. Office of Management and Budget (OMB), Implementation Guidance for the E-Government Act of 2002, M–03–18 (Aug. 1, 2003), available at *http://www.whitehouse.gov/omb/memoranda/m03-18.pdf*. The E-Government Act built on previous efforts to use information technology to provide citizens with easier access to government information and participation. *See, e.g.*, OMB, Redundant Information Systems Relating to On-Line Rulemaking Initiative, M–02–08 (May 6, 2002), *available at http://www.whitehouse.gov/omb/memoranda/m02-08.pdf*.

Pursuant to the E-Government Act, it is the practice of both OSHA and MSHA to post, in a timely manner, information relevant to agency rulemakings on *http://www.regulations.gov*. This includes the posting of all scientific studies that are relied upon in the rulemaking. The Department has determined, therefore, that the proposed electronic posting requirement is duplicative of E-Government Act requirements and is not needed.

Other Requirements. The proposed regulatory text also stated that agency risk assessments must, when the data are available, use industry-by-industry evidence relating to working life exposures. Proposed 29 CFR 2.9(c)(3), 73 FR at 50915. Of the commenters that discussed the ''industry-by-industry'' language, the majority, including members of Congress and Senators, risk assessment experts, worker advocacy organizations, and labor unions viewed it as a departure from the Department's existing longstanding practice of using a 45-year working life assumption for selecting exposure limits for health standards. *See, e.g.*, Exs. 18.1; 23; 28.1; 42.1; and 48.1. Some employer groups and industry associations, however, expressed support for using industry-specific data to develop working life assumptions. *See, e.g.*, Exs. 27.1; 31.1; and 35.1.

Section 6(b)(5) of the Occupational Safety and Health Act requires the agency to regulate in a manner that ''most adequately assures * * * that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard * * * for the period of his working life.'' 29 U.S.C. 655(b)(5). The Mine Act has nearly identical language, except that it refers to miners rather than employees. 30 U.S.C. 811(a)(6)(A). To implement these provisions, it has been the Department's longstanding practice to use a general 45-year working life assumption. This practice is not based on empirical data that most employees are exposed to the hazard for 45 years. Rather, it is based on the statutory directive that ''no employee'' suffer material impairment ''even if'' such employee is exposed for the period of his or her working life. The Department's practice of using a 45-year working life has won judicial approval. *See, e.g., Building and Constr. Trades Dep't, AFL–CIO* v. *Brock*, 838 F.2d 1258, 1264–65 (D.C. Cir. 1987) (explaining that the assumption of a 45-year working life ''appear[ed] to conform to the intent of Congress''); for examples of DOL standards using a 45-year working life, see Asbestos, 51 FR 22612, 22648 (June 20, 1986); Bloodborne Pathogens, 56 FR 64004, 64031 (Dec. 6, 1991); Diesel Particulate Matter Exposure of Underground Coal Miners, 66 FR 5526, 5663–64 (Jan. 19, 2001); Hexavalent Chromium, 71 FR 10100, 10224 (Feb. 28, 2006).

OSHA and MSHA have not conducted separate industry-by-industry analyses of working life for their risk assessments. The Department has consistently rejected the claim that it must conduct a separate risk assessment for each industry regulated by a standard. *Public Citizen Health Research Group* v. *U.S. Dep't of Labor*, 557 F.3d 165, 186–188 (3d Cir. 2009); *American Dental Ass'n* v. *Martin*, 984 F. 2d 823, 827 (7th Cir. 1993); *UAW* v. *OSHA*, 37 F.3d 665, 670 (D.C. Cir. 1994); Control of Hazardous Energy Sources (Lockout/Tagout), OSHA Supplemental Statement of Reasons, 58 FR 16612–02, 16620–16621 (Mar. 30, 1993).

Guidance versus Regulation. The Department received a small number of comments, from risk assessment experts, policy groups, and labor unions that questioned the need for a regulation when it was possible to issue internal guidance instead. All of these commenters argued that the risk assessment rulemaking was unnecessary because the Department already has risk assessment guidance and because guidance rather than regulation is the more appropriate format for such internal Department procedures. *See, e.g.*, Exs. 26.1; 32.1; 46.1; and 48.1. Upon reconsideration of this issue, the Department has concluded that a risk assessment rulemaking is not necessary. The Department believes that guidance, as opposed to regulation, is a more suitable vehicle for its internal risk assessment procedures and allows the Department more flexibility to quickly adapt and improve its risk assessment procedures in the future. Compared to changes to internal guidance, changes to a regulation would take far more time and require a lengthy notice and comment rulemaking.

Other Issues. There were a number of other issues addressed in public comments to the proposed rule. These issues included: (1) Whether the rule was a ''significant regulatory action'' under Executive Order 12866, thus requiring a cost/benefit analysis before promulgating the rule; (2) whether the rule was substantive or procedural and, if substantive, whether proper rulemaking procedures were followed; (3) whether the rule was appropriately issued under 5 U.S.C. 301; and (4) whether the Assistant Secretary for Policy had a proper delegation of authority to issue the rule. The Department notes that these and other issues raised by commenters, while important, are no longer relevant given the Department's decision to terminate the rulemaking.

Withdrawal. For the reasons discussed above, the Department is withdrawing its risk assessment

rulemaking, effective on August 31, 2009.

Authority and Signature.

Megan Uzzell,

Acting Assistant Secretary for Policy.

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DoD–2008–HA–0090; RIN 0720–AB23]

TRICARE; Off-Label Uses of Devices; Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Proposed rule.

SUMMARY: The Department of Defense is publishing this proposed rule to revise the definition of ''unlabeled or off-label drug'' to ''off-label use of a drug or device.'' This revision is consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act. Additionally, this rule removes the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed in TRICARE regulations. As it is determined that reliable evidence demonstrates that previously unproven drugs, devices, and medical treatments or procedures have proven medical effectiveness, TRICARE has removed them from the list and authorized medically necessary care. This revision removing the partial list is necessary as the list will never be completely current, and is only a partial list of examples. The removal of this partial list does not change or eliminate any benefits that are currently available under the TRICARE program.

DATES: Written comments received at the address indicated below by October 30, 2009 will be accepted.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by either of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: René L. Morrell, TRICARE Management Activity, Medical Benefits and Reimbursement Branch, telephone (303) 676–3618.

SUPPLEMENTARY INFORMATION: This proposed rule revises the definition of ''unlabeled or off-label drug'' to ''off-label use of a drug or device.'' This revision is consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*). Additionally, this proposed rule removes the partial list of examples of unproven drugs, devices, and medical treatments or procedures proscribed under § 199.4(g)(15).

Off-Label Uses of Devices

On January 6, 1997, the Office of the Secretary of Defense published a final rule in the **Federal Register** (62 FR 627–631) clarifying the TRICARE exclusion of unproven drugs, devices, and medical treatments or procedures and adding the TRICARE definition of unlabeled or off-label drugs. This rule also added the provision for coverage of unlabeled or off-label uses of drugs that are Food and Drug Administration (FDA) approved drugs that are prescribed or administered by a health care practitioner and are used for indications or treatments not included in the approved labeling. We are now modifying the definition of ''unlabeled or off-label drug'' to ''off-label use of a drug or device'' to be consistent with the regulatory framework under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) However, this proposed rule does not present new agency policy. Rather, it corrects an error and omission from the current rule. Coverage is limited to those indications for which there is reliable evidence, as defined in section 199.2, sufficient to establish that the off-label use is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. In addition, the off-label use must be reviewed for medical necessity.

Partial List of Examples of Unproven Drugs, Devices, and Medical Treatments or Procedures

By law, TRICARE can only cost-share medically necessary supplies and services. Any drug, device, and medical treatment or procedure, the safety and efficacy of which have not been established, as described in § 199.4(g)(15), is unproven and cannot be cost-shared by TRICARE except as authorized under § 199.4(e)(26). The current regulation and program policy provide a partial list of examples of unproven drugs, devices, and medical treatments or procedures that are excluded from benefits. The intent of this partial list was to provide information on specific examples of emerging drugs, devices, and medical treatments or procedures determined to be unproven by TRICARE based on review of current reliable evidence. Due to the rapid and extensive changes in medical technology it is not feasible to maintain this list in the regulation. Removal of this partial list of examples does not change the exclusion of unproven drugs, devices, and medical treatments or procedures. Removal of the partial list of examples does not change the process TRICARE follows in determining for purposes of benefit coverage when a drug, device, and medical treatment or procedure has moved from the status of unproven to proven medical effectiveness. The intent of this revision is to ensure that benefit determinations are made based on current reliable evidence rather than relying on outdated regulatory and policy provisions.

Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review''

Section 801 of Title 5, U.S.C., and Executive Order (E.O.) 12866 require certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts. It has been certified that this rule is not an economically significant rule, however, it is a regulatory action which has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866.

Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.