ORIGINAL BOARD RECOMMENDATION (APRIL 2017)

Advisory Board on Toxic Substances and Worker Health Recommendations – Adopted at April 18-20, 2017 Meeting

Recommendation #2

Presumptions for Work-Related Asthma

1. DOL should use the generally accepted unifying term, work-related asthma (WRA) for claims evaluation and decision-making. Work-related asthma includes: a) occupational asthma (OA), or new onset asthma that is initiated by an occupational agent, and b) work-exacerbated asthma (WEA), which is established asthma that is worsened by workplace exposures. The recognition of both forms of work-related asthma should be communicated to claimants, their physicians and consulting IH's and CMC's.

2. Medical criteria for the diagnosis of asthma: The diagnosis of asthma by a treating or evaluating physician should be sufficient for the recognition that the claimant has asthma. Bronchodilator reversibility of FEV1 and/or a positive methacholine challenge test may be helpful but should not be required to accept the diagnosis of asthma, which is made by a health care provider.

3. Work-related asthma, whether OA or WEA, is defined as the presence of medically-diagnosed asthma that is associated with worsening of any one or more of the following in relation to work: asthma-related symptoms, asthma medication usage or asthma-related health care utilization temporally related to work, or change in peak expiratory flows associated with work. Such a history should be documented by a treating or evaluating health care provider, or addressed by a CMC if consulted in a claim evaluation.

4. The same criteria for WRA should be used in evaluating asthma claims whether the claim is made contemporaneous with the period of DOE employment or after the end of that period of employment. A specific triggering event causing onset of WRA may occur but is not typical or necessary. Inciting exposures such as dusts, fumes, heat or cold or others should be specifically identified when possible, but should not be required for the diagnosis of WRA.

Rationale

Work-related asthma induced or exacerbated by inhaled toxicants in the workplace is common in the United States, associated with up to 25% of adult asthma (Tarlo 2008; Henneberger, 2011). Occupational asthma in previously health workers is known to be caused by over 400 specific workplace agents with additional agents being reported annually (Friedman-Jimenez 2015). Dusts, gases, vapors, and fumes in general can worsen pre-existing asthma or asthma that otherwise has developed among workers (Henneberger, 2011).

Due to variation in diagnostic criteria, clinical management, and terminology, the chief professional organizations of pulmonary physicians in the United States, the American Thoracic Society and the American College of Chest Physicians, periodically issue consensus statements to promote clarity, uniformity, and quality in the recognition and care of workers with work-related asthma (Tarlo 2008; Henneberger, 2011). The criteria contained in the above recommendation reflect the most recent statements. Specifically, the American Thoracic Society wrote in 2011 that work-exacerbated asthmas is "pre-existing or concurrent asthma" in which "the exacerbation of asthma was temporally associated with work, based either on self-reports of symptoms or medication use relative to work, or on more objective indicators like work-related patterns of serial PEFR" and when "conditions exist at work that can exacerbate asthma" (Henneberger, 2011). Occupational asthma is asthma induced by airborne sensitizers or irritants at work (Tarlo 2008; Henneberger, 2011).

Asthma, which is marked by chronic airway inflammation, is defined by the "history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation" (Global Initiative for Asthma 2016). The diagnosis of asthma is complicated by the fact that the patient is often already on asthma medications when an evaluating, treating, or consulting physician first sees the patient. The disease is also variable, so that negative tests cannot rule out the disease when it is inactive. Objective pulmonary function tests may not provide typical patterns that reflect asthma, since physicians (and patients) are often reluctant to stop asthma treatment prior to testing. Therefore, the clinical history and presentation may effectively become the sole basis for diagnosis and represents a fully accepted method in clinical medicine.

Likewise, objective pulmonary function testing that demonstrates airway reversibility in relation to workplace agents, though helpful, is not an absolute requirement for the diagnosis of work-related asthma (Tarlo 2008). Key to the diagnosis of work-related asthma is the temporal relation between workplace exposures and asthma activity, whether identified by symptoms, medication usage, or visits to health care providers. Any of these measures may suffice as demonstration of the work-elatedness of asthma. Notably, there are patients in whom even these measures are not definitive, as work-related asthma can have delayed symptoms that may not be easily related to exposures at work.

References

1. Friedman-Jimenez G, Harrison D, Luo H. Occupational asthma and work-exacerbated asthma. Semin Respir Crit Care Med. 2015 Jun;36(3):388-407.
2. Henneberger PK, Redlich CA, Callahan DB, Harber P, Lemiere C, Martin J, Tarlo SM, et al. An official American Thoracic Society Statement: work-exacerbated asthma. Am J Respir Crit Care Med. 2011; 184:368–378.
3. Jajosky RA, Harrison R, Reinisch F, Flattery J, Chan J, Tumpowsky C, Davis L, et al. Surveillance of work-related asthma in selected U.S. states using surveillance guidelines

for state health departments – California, Massachusetts, Michigan, and New Jersey, 1993–1995. MMWR. 1999; 48:1–20.
4. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2016. Available from: www.ginasthma.org.
5. Tarlo SM, Balmes J, Balkissoon R, Beach J, Beckett W, Bernstein D, Blanc PD, Brooks SM, Cowl CT, Daroowalla F, Harber P, Lemiere C, Liss GM, Pacheco KA, Redlich CA, Rowe B, Heitzer J. Diagnosis and management of work-related asthma: American College Of Chest Physicians Consensus Statement. Chest. 2008 Sep;134(3 Suppl):1S-41S.

DOL RESPONSE (NOVEMBER 2017)

Department of Labor Responses to Recommendations from the April 2017 Public Meeting of the Advisory Board on Toxic Substances and Worker Health

Response:

OWCP agrees with Recommendation #2-1, and it has already modified the Procedure Manual to incorporate these into the September 2017 revision (Exhibit 15-4).

OWCP also agrees that a diagnosis of asthma by a treating physician should be sufficient, without specific reference to the tests listed in Recommendation #2-2; however, the physician's opinion should include appropriate medical rationale, based on objective findings, to support the diagnosis, as is required for any other diagnoses claimed under the program.

For Recommendations #2-3 & #2-4, in its most recent update to Chapter 15 of the Procedure Manual, OWCP applies a policy regarding the assessment of work-related/occupational asthma that comports in part with these recommendations. OWCP policy requires evidence of a contemporaneous diagnosis of occupational asthma during covered Part E contractor employment or the well-rationalized opinion of a physician after a period of covered employment, as recommended in #2-3. The policy differs slightly from the recommendation in Recommendation #2-4, by requiring a triggering mechanism that occurred to cause, contribute to, or aggravate the condition. Legally, OWCP must require evidence that the toxic substance was the likely trigger for the condition because a condition can only be accepted as a compensable "covered illness" if "it is at least as likely as not that the exposure to such toxic substance was related to employment at a Department of Energy facility." 42 U.S.C. § 7385s-4(c)(1)(B). A mere temporal association, without identification of a toxic substance, would not satisfy the statutory requirement for eligibility. In addition, neither "heat" nor "cold" (as referenced in the Board's recommendation) can be defined as a "toxic substance" under this definition.

COMMENTS ON RECOMMENDATIONS (FEBRUARY 2018)

Advisory Board on Toxic Substances and Worker Health, Department of Labor

Revised Recommendations and Comments on Board's October 2016 and April 2017 Recommendations and the Department of Labor Responses

Issues for Consideration by the Future Advisory Board on Toxic Substances and Worker Health

ABTSWH responses to DOL's comments

The Board's April 2017 Recommendation on Presumptions for Work-Related Asthma (WRA) contained 4 parts. Each initial recommendation is provided bolded, followed by a summary of the DOL's response, and additional comments of the Advisory Board to the DOL to add further clarity or, where indicated, help the DOL implement the Recommendation.

The OWCP indicated that changes in response to Recommendation #2 have already been incorporated into the most recent revision of the Procedure Manual (Procedure Manual 1.1; Appendix 1, 9/2017; sections related to WRA). Relevant sections of the Procedure Manual were also reviewed to assess how the recommended changes were incorporated.

Recommendation #2-1

DOL should use the generally accepted unifying term, work-related asthma (WRA) for claims evaluation and decision-making. Work-related asthma includes: a) occupational asthma (OA), or new onset asthma that is initiated by an occupational agent, and b) work-exacerbated asthma (WEA), which is established asthma that is worsened by workplace exposures. The recognition of both forms of work-related asthma should be communicated to claimants, their physicians and consulting IH's and CMC's.

The Advisory Board appreciates that OWCP agrees with this recommendation and has implemented it in the most recent Revision of the Procedure Manual (Procedure Manual 1.1; Appendix 1, page)

Recommendation #2-2

Medical criteria for the diagnosis of asthma: The diagnosis of asthma by a treating or evaluating physician should be sufficient for the recognition that the claimant has asthma. Bronchodilator reversibility of FEV1 and/or a positive methacholine challenge test may be helpful but should not be required to accept the diagnosis of asthma, which is made by a health care provider.

The Advisory Board appreciates that OWCP agrees that *"a diagnosis of asthma by a treating physician should be sufficient, without specific reference to the tests listed" (spirometry,*

methacholine challenge test). The Advisory Board agrees with OWCP that "the physician's opinion should include appropriate medical rationale, based on objective findings, to support the diagnosis."

The Advisory Board also appreciates that OWCP has attempted to implement this recommendation in the most recent Revision of the Procedure Manual (Version 1.1).

However, a review of the relevant sections of the Procedure Manual that describe the criteria for the diagnosis of asthma reveals sections that are confusing, do not appear to incorporate the above recommendation, and do not reflect current clinical practice. For example,

Procedure Manual 1.1, Appendix 1 (9/2017), page 524 states that:

"The criteria for accepting a Part E claim for asthma are:

a. The employee has a period of covered Part E contractor or subcontractor employment.

b. A qualified physician has diagnosed the employee with asthma. A medical diagnosis for asthma should be made when the physician is able to identify the presence of intermittent respiratory and physiologic evidence of reversible or variable airways obstruction including positive methacholine challenge test or post-bronchodilator reversibility. However, a physician can also rely on other clinical information to substantiate his or her diagnosis of asthma. ***For example, spirometry for measurement of FEV1 and FVC is the most reliable method for assessing airway obstruction.*** *The response to inhaled bronchodilator administration has been used as a measure of airway hyperresponsiveness. A 12% improvement in FEV1 of at least 200 mL after inhaled bronchodilator is how the American Thoracic Society defines a significant improvement indicative of hyperresponsive airways."*

This wording adds unnecessary confusion, especially the "For example" section. As noted in the Advisory Board's recommendation above the diagnosis of asthma by a treating or evaluating physician should be sufficient to recognize that a claimant has asthma for multiple reasons. Asthma is a condition that is episodic and variable over time. Spirometry testing is generally not performed during symptomatic exacerbations and can be normal when patients are not having exacerbations. Bronchodilator testing can be falsely negative, especially if performed after a patient has been started on standard asthma treatment such as inhaled steroids or long acting beta-agonists. Methacholine challenge testing can also have false negatives (and positives), entails risk of inducing an asthma attack, and is not widely available, especially in many outpatient office settings. Thus asthma is commonly diagnosed and treated without documentation of a positive bronchodilator response or methacholine challenge testing. The diagnosis is usually based on the patient's history, clinical presentation, specific symptoms, triggers, physical exam findings and response to treatment.

Documentation of specific asthma symptoms (e.g. wheeze, cough), symptom triggers, and physical exam findings (e.g. wheezing) are objective findings that are used to identify the

presence of reversible airflow obstruction, and would be better examples of *"other clinical information to substantiate his or her diagnosis of asthma"* than those provided (spirometry, bronchodilator and methacholine challenge testing).

Suggested alternate wording (major changes are underlined) to the current Procedure Manual 1.1 (pages 524-5) is as follows:

> *"A medical diagnosis for asthma should be made when the physician is able to identify the presence of intermittent respiratory and physiologic evidence of reversible or variable airways obstruction including post-bronchodilator reversibility on spirometry or a positive methacholine challenge test. <u>However, a physician can also rely on other clinical information to substantiate his or her diagnosis of asthma, such as the findings from a detailed medical history and physical examination. Documentation of recurrent symptoms of airflow obstruction or airway hyper-responsiveness, such as episodic cough, chest tightness or shortness of breath, or symptomatic improvement following treatment for asthma (e.g. inhaled bronchodilator or steroids) supports a diagnosis of asthma. Physical examination findings such as wheezing on lung examination, nasal swelling and drainage, or use of chest muscles to breath also support a diagnosis of asthma.</u>*
> *The response to inhaled bronchodilator administration has also been used as a measure of airway hyperresponsiveness. A 12% improvement in FEV1 of at least 200 mL after inhaled bronchodilator is how the American Thoracic Society defines a significant improvement indicative of hyperresponsive airways. <u>However, a negative bronchodilator test does not rule out a diagnosis of asthma, especially if the patient is on medical treatment for asthma."</u>*

Recommendation #2-3. Work-related asthma, whether OA or WEA, is defined as the presence of medically-diagnosed asthma that is associated with worsening of any one or more of the following in relation to work: asthma-related symptoms, asthma medication usage or asthma-related health care utilization temporally related to work, or change in peak expiratory flows associated with work. Such a history should be documented by a treating or evaluating health care provider, or addressed by a CMC if consulted in a claim evaluation.

The Advisory Board appreciates that OWCP agrees with this recommendation. The Advisory Board recognizes that implementation of the recommendation by the DOL will likely be challenging, as it will require education of claims examiners and treating and consulting physicians about WRA, including causative substances and diagnostic criteria.

Recommendation #2-4. The same criteria for WRA should be used in evaluating asthma claims whether the claim is made contemporaneous with the period of DOE employment or after the end of that period of employment. A specific triggering event causing onset of WRA may occur but is not typical or necessary. Inciting exposures such as dusts, fumes, heat or cold or others should be specifically identified when possible, but should not be required for the diagnosis of WRA.

OWCP's response to this recommendation notes that *"The policy (=updated Procedure Manual) differs slightly from Recommendation #2-4 by requiring a triggering mechanism that occurred to cause, contribute to, or aggravate the condition. Legally, OWCP must require evidence that the toxic substance was the likely trigger for the condition because a condition can only be accepted as a compensable "covered illness" if "it is at least as likely as not that the exposure to such toxic substance was related to employment at a Department of Energy facility. A mere temporal association, without identification of a toxic substance, would not satisfy the statutory requirement for eligibility. In addition, neither "heat" nor "cold" can be defined as a "toxic substance" under this definition."*

The Advisory Board understands that under Part E of the EEOICPA, an illness can only be accepted as a compensable covered illness if *"exposure to **a toxic substance** at a covered DOE facility was "at least as likely as not" a significant factor in aggravating, contributing to or causing the illness."* The Advisory Board also acknowledges that heat and cold should not be considered causative exposures for work-related asthma.

However, a review of the updated Procedure Manual 1.1 (see below) indicates that OWCP's current criteria for WRA differ more than "slightly" from the Advisory Board's recommendation and are not consistent with current knowledge and clinical practice regarding WRA. The primary area of discrepancy relates to the criteria regarding the physician's documentation of the exposure that likely caused the claimant's WRA.

A better understanding of what is meant by the phrase *"a toxic substance"* and also what is known about the causes of WRA provides greater clarity and should resolve this discrepancy. The U.S. National Institute of Health (NIH) (and others) define a toxic substance as:

> *"**A toxic substance** is simply a material which has toxic properties. It may be a discrete toxic chemical or **a mixture of toxic chemicals**. For example, lead chromate, asbestos, and gasoline are all toxic substances. More specifically:*
>
> - *Lead chromate is a discrete toxic chemical.*
> - *Asbestos is a toxic material that does not consist of an exact chemical composition but **a variety of fibers and minerals**.*
> - *Gasoline is also **a toxic substance** rather than a toxic chemical in that it contains **a mixture of many chemicals**. Toxic substances may not always have a constant composition. For example, "the composition of gasoline varies with octane level, manufacturer, time of season, and other factors." https://toxtutor.nlm.nih.gov/01-002.html*

There are numerous other examples of well-known toxic substances that are mixtures of many chemicals, particles or fumes, such as cigarette smoke, coal dust, diesel exhaust, degreasing solvents, combustion products or dust from the World Trade Center attacks. These exposures are well recognized to be toxic, even though they are not a single specific toxic chemical or a mixture of chemicals with unvarying composition. Stating that EEOICPA Part E requires identification of a specific exposure or exposure event in order to consider a condition to be compensable is a misunderstanding of the EEOICPA statutory requirement. Rather EEOICPA

requires identification of work exposure(s) that on an at least as likely as not basis were a significant factor in aggravating, contributing to or causing the illness.

Multiple different potentially toxic substances can cause or exacerbate WRA, including various irritants, allergens, dusts, fumes, vapors and gases. This is acknowledged in the current Procedure Manual page 524: "*The CE does not apply a toxic substance exposure assessment to a claim for work-related asthma, including the application of the SEM or IH referral process, because any dust, vapor, gas or fume has the potential to affect asthma."*

Most cases of WRA result from repeated inhalational exposures over months to years, rather than a specific exposure incident. In the great majority of cases of WRA diagnosed in the US, a single specific causative agent or specific exposure event is not identified, nor a triggering mechanism, even when patients are evaluated by occupational lung specialists. Commonly identified exposures that contribute to WRA include dusts, fumes, chemicals, cleaning products, and pyrolysis products.(1-5) Also of note, the mechanisms by which most exposures cause or exacerbate asthma remain poorly defined.

The criteria to diagnose WRA that are described in newly revised Procedure Manual 1.1, Appendix 1, pages 524-5 (noted below), differ more than slightly from Recommendation #2-4, are not reflective of current knowledge and practice regarding WRA, and contain internal inconsistencies:

> *"**Asthma**: Work-related asthma includes: a) occupational asthma; or new onset asthma that is initiated by an occupational agent, and b) work-exacerbated asthma, which is established asthma that is worsened by work place exposures. The CE does not apply a toxic substance exposure assessment to a claim for work-related asthma, including the application of the SEM or IH referral process, because any dust, vapor, gas or fume has the potential to affect asthma. Given the scope of potential occupational triggers that can affect asthma, the CE relies exclusively on the assessment of the medical evidence by a qualified physician to arrive at a determination of compensability. The criteria for accepting a Part E claim for asthma are:*
>
> a. *The employee has a period of covered Part E contractor or subcontractor employment.*
> b. *A qualified physician has diagnosed the employee with asthma ..... (see above).*
> c. *Once having established covered Part E contractor or subcontractor employment and a diagnosis of asthma, the following criteria are available to demonstrate that the employee has work related asthma (as defined above):*
>   i. *A qualified physician, who during a period contemporaneous with the period of covered Part E employment, diagnosed the employee with work-related asthma or;*
>   ii. *After a period of covered employment, a qualified physician conducts an examination of either the patient or available medical records and he or she concludes that the evidence supports that the employee had asthma and that an occupational exposure to a toxic substance was at least as*

likely as not a significant factor in causing, contributing to or aggravating the condition. ***The qualified physician must provide a well-rationalized explanation with specific information on the mechanism for causing, contributing to, or aggravating the conditions. The strongest justification for acceptance in this type of claims is when the physician can identify the asthmatic incident(s) that occurred while the employee worked at the covered work site and the most likely toxic substance trigger. A physician's opinion that does not provide a clear basis for diagnosing asthma at the time of covered employment or the physician provides a vague or generalized opinion regarding the relationship between asthma and occupational toxic substance exposure will require additional development including the CE's request for the physician to offer further support of the claim.*** *If the CE is unable to obtain the necessary medical evidence from the treating physician to substantiate the claim for work-related asthma, the CE will need to seek an opinion from a CMC. If a CMC referral is required, the CE will need to provide the CMC with the relevant medical evidence from the claim file and provide a detailed description of the employee's covered employment which must include each covered worksite, dates of covered employment, labor categories, and details about the jobs performed."*

The above criteria for WRA would more accurately reflect the medical literature and current practice if the sections that are bolded were eliminated.

Also of note, the updated Procedure Manual refers to Exhibit 18-1; Matrix for Confirming Sufficient Evidence of Non-cancerous Covered Illnesses; Asthma, Occupational (page 568) for further guidance. This Table (page 568; dated 9/2017) summarizes the criteria to diagnose Asthma and WRA. It does not reflect the Procedure Manual text, contains inaccurate medical information, and requires revision.

The Advisory Board, which has substantial expertise in WRA, is willing to provide the DOL additional guidance on updating the Procedure Manual and implementation of the WRA Presumption.

Additional References:

1. Jajosky RA, Harrison R, Reinisch F, Flattery J, Chan J, Tumpowsky C, Davis L, Reilly MJ, Rosenman KD, Kalinowski D, Stanbury M, Schill DP, Wood J. Surveillance of work-related asthma in selected U.S. states using surveillance guidelines for state health departments--California, Massachusetts, Michigan, and New Jersey, 1993-1995. MMWR CDC Surveill Summ 1999; 48: 1-20.

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4. Talini D, Ciberti A, Bartoli D, Del Guerra P, Iaia TE, Lemmi M, Innocenti A, Di Pede F, Latorre M, Carrozzi L, Paggiaro P. Work-related asthma in a sample of subjects with established asthma. Respir Med 2017; 130: 85-91.

5. Anderson NJ, Fan ZJ, Reeb-Whitaker C, Bonauto DK, Rauser E. Distribution of asthma by occupation: Washington State behavioral risk factor surveillance system data, 2006-2009. J Asthma 2014; 51: 1035-1042.

DOL Responses to Advisory Board on Toxic Substances and Worker Health
February 16, 2018 Clarifications to Recommendations

5. Comments on Recommendation: Presumption for Work-Related Asthma. The Advisory Board recommends language changes to procedural guidance relating to the existing presumption for occupational asthma. As part of this recommendation, the Board has offered an alternative definition of the term, "toxic substance."

The DEEOIC implemented several updates to program procedure derived from input from the Board on work-related asthma. The focus of the agreed-to changes centered on clarifying the terminology of work-related asthma. Additional input from the Board, which the DEEOIC has not yet applied procedurally, relates to advice regarding clinical interpretation of medical evidence and wording changes regarding a physician's assessment of toxic substance linkage to work-related asthma. The DEEOIC agrees to make additional changes given the Board's input on these two topics, as long as it does not overly restrict the physician's ability to make his/her own medical assessment.

With regard to the Board's definitional guidance regarding the phrase "a toxic substance," the Department of Labor has defined what is meant by the statutory term "toxic substance" through rulemaking, which provides the basis for these definitions. This has the force and effect of law and it cannot consider how other entities define that term for purposes other than the adjudication of claims under Part E of EEOICPA.