Office of Workers' Compensation Programs Washington, DC 20210



August 31, 2023

Dr. Steven Markowitz, Chair Advisory Board on Toxic Substances and Worker Health Queens College, Remsen Hall 65-30 Kissena Boulevard Flushing, NY 11367

Dear Dr. Markowitz:

Thank you for your letters dated July 3 and July 7, 2023, transmitting recommendations adopted by the Advisory Board on Toxic Substances and Worker Health (Advisory Board or Board) during its meeting on May 17-18, 2023. On behalf of Acting Secretary of Labor Julie A. Su, to whom you addressed your letters, the Office of Workers' Compensation Programs (OWCP) responds to the recommendations herein.

The Board adopted the following recommendation regarding Assessment of Validity of Contract Medical Consultant (CMC) Reports in the Examination for Claims:

The ABTSWH recommends that the EEOICP implement a mechanism to evaluate the validity and accuracy of the opinions and rationales that are expressed in the reports of the Contract Medical Consultants (CMC) in the claims evaluation process, with particular attention paid to the issue of causation of disease. This process may most usefully be applied to denied claims but may also be applied prospectively to a number of claims under evaluation. This mechanism should have sufficient independence of the current method of developing and obtaining CMC opinions in order to avoid actual or perception of conflict of interest.

Supporting its request, the Board provided the following rationale:

The Board recognizes that the EEOICP has in the past assessed aspects of the quality of the Contract Medical Consultant (CMC) reports that are obtained in the evaluation of claims in EEOICP. These aspects include timeliness of report, selection of appropriate medical specialties, responsiveness to questions posed by claims examiners, inclusion of welldeveloped rationales in the reports, and others. These are important attributes of the contract medical consulting process and can be assessed by non-medical personnel. However, the Board notes that the current evaluation process of the CMC reports does not directly assess whether the opinions expressed by physicians in these reports and the medical knowledge upon which they rely conform with generally accepted medical opinion. That is, the validity or accuracy of these reports is not assessed, either in the routine claims evaluation process or by way of a special audit of a sample of CMC reports on a periodic basis. As a general matter, physicians may face the same set of medical facts and may vary in their interpretation of those facts in making decisions, especially about disease causation. Such variation within a reasonable range of opinion is normal, expected, and tolerable. However, in its review of claims, the Board has noted that a minority of CMC reports are in gross error, even as they appear to meet quality criteria of timeliness, selection of appropriate medical specialty, responsiveness to questions posed by claims examiners, and inclusion of well-developed rationales in the reports. This is not surprising given the volume of claims and the challenges inherent in decision-making about complex diseases and their causes. In addition, occupational medicine is a very broad medical discipline with many niches. Not all such physicians have the combined clinical and epidemiological skill sets required to weigh in accurately about disease causation.

The EEOICP program needs to develop an enhanced capability, strategy, and protocol to ensure that CMC reports are valid and accurate and that the current CMC contractor receives needed feedback and takes corrective actions to obtain a very high level of quality of CMC reports. The Board stands ready to provide additional advice to the program in this process.

Regarding the recommendation, OWCP fully agrees with the Board that the medical opinions from CMC physicians are an integral component of the claim development process and must be of the highest quality and reliability given the weight they are given in the claims adjudication process. However, DOL finds the recommendation that additional oversight mechanisms are needed to be problematic.

Current adjudication procedures provide claims examiners (CE) with the necessary guidance to assess the weight of medical evidence in determining the validity and accuracy of medical opinions submitted by a CMC.

Additionally, other programmatic safeguards also already exist. In those situations, in which a CMC opinion lacks proper foundation or medical rationalizations, CEs are required to demand additional opinion evidence from the physician. Further, the program has clearly defined mechanisms for evaluating the accuracy and quality of CMC opinions. Finally, DOL employs dedicated staff whose sole responsibility is to perform quality assurance reviews of actions taken to adjudicate cases.

As these actions are already defined within the program processes and are carried forth within the existing due process procedures afforded all claimants to perfect their claim under the Act, additional review runs a risk of duplication of effort and delay in the claim adjudication process. When a claim is denied by the program, the decision provides a clear explanation to the claimant why the medical evidence of record was insufficient to establish the claim and provides the pathway that can be followed to perfect the opinion evidence. Nevertheless, since the mandate of the Board speaks specifically to providing guidance about the weighing of evidence under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the Department requests that the Board provide specific guidance or references to medical health science data that can be communicated to staff or CMCs about medical standards or epidemiological data that could serve to eliminate or reduce instances of "gross errors," as is mentioned by the Board in its recommendation rationale. This would work to improve the qualitative and probative value of medical opinions relied on by DOL to adjudicate claims.

The Board adopted the following recommendation regarding Improvements in Industrial Hygiene (IH) Assessment of Exposures in EEOICPA Claims:

The ABTSWH recommends that exposure assessments made by Industrial Hygienists (IH) be enhanced to specifically refer to the basic metrics of exposure science: (1) exposure intensity, (2) exposure route, (3) exposure frequency, and (4) exposure duration. These elements can have distinct value in determining causation. These metrics may further be divided by the facility and job under which they occurred for a claimant as relevant. We recommend that DOL adopt an IH exposure assessment form that puts the work of the IH in the context of these four basic metrics of exposure. The toxicants to be included on the form would be those determined relevant to the claimed medical conditions. An example form is provided with this recommendation.

Supporting its request, the Board provided the following rationale:

Referral of a case for industrial hygiene review and evaluation of potential exposure is a critically important part of the claim adjudication process, with numerous stakeholders relying on this evaluation for their next decisions. These include the claims examiner, the treating physician, the contract medical consultant and the claimant. The importance of this report in subsequent decision-making, especially causation analysis, is fundamental. The basic metrics of an exposure assessment influence in distinct ways the different health effects associated with that exposure. These basic metrics are: 1. Type of exposure (direct, bystander, or area) 2. Route of exposure (inhalation, ingestion, skin absorption) 3. Intensity of exposure (concentration) 4. Frequency of exposure 5. Duration of exposure 6. Calendar timing of exposure (appropriate latency) 7. Use of personal protective equipment (PPE), engineering controls or other mitigating factors. Information about each of these elements of an exposure can contribute to the determination of causation for one condition differently from how that same exposure may contribute to another condition. Their value to this process may range from very relevant, to vague, to unknown. The accuracy of causation determinations by medical professionals can be harmed when all the aspects are fused together as a single metric as an exposure that may be of low relevance for one condition, could be of high relevance for another. For this reason, a singular assessment of relevance can obscure rather than aid the causation decision-making process.

Therefore, the Board recommends that the IH report explicitly state the sources of information used to make the determinations. In many cases, there is no documentation available, and this would be important information for the end user of the industrial hygiene report to have. Our recommendation is to implement a substantive change in the reporting of exposure assessments to better inform the determination of causation. Specifically, the exposure assessment and referenced summary report should include the key metrics describing the exposure as distinct categories for each relevant exposure. The Board proposes a new IH exposure assessment form (attached) including these metrics to help inform and guide this recommended change in process.

Regarding the recommendation, DOL agrees that the metrics of exposure science referenced by the Board are important factors that must be used to accurately inform a physician's opinion on the relationship between an employee's occupational exposure to a toxic substance and a claimed, diagnosed illness. From DOL's perspective, the current IH reporting methodology communicates much of the information the Board references. DOL has attached a recently completed report that was modified to reference fictious employee demographic information. From this example, the narrative content and a summary table provide data from the professional judgment of the IH about the nature of the employee's exposure to different toxic substances and refers to the basic components of exposure analysis. While IH reports are tailored to the unique circumstances of each claim, the example demonstrates the general approach that DOL takes profiling toxic substance exposures.

The report contains an accounting of the employee's work history, including a description of the duration of employment for each job worked. The report goes on to provide a narrative discussion of temporal considerations employed by the IH to judge the extent of exposure before and after the mid-1990s. It provides a discussion of each targeted toxic substance under review, and likely routes of exposure. The discussion also describes the likely mechanisms of exposure. For each toxic substance, the IH then provides a professional judgment about the likely intensity and frequency of exposure. Within the Conclusion section of the report, the IH summarizes the assignment of frequency and level to each targeted toxic substance within a table. This is done for each position with a likely significant exposure. DOL considers the existing methodology of communicating exposure data to be sufficient for a qualified physician to possess a comprehensive understanding of the basic metrics of exposure referenced by the Board.

Nevertheless, DOL agrees that adjustments are warranted to the IH reporting methodology that will serve to enhance the quality of IH profiles. A summary table does provide an efficient manner of communicating information. Currently, DOL does not include a summary table for cases that involve a limited number of toxic substances or for employees with a non-complicated work history. IH's also do not include a summary table for the assignment of exposure that is not deemed significant. DOL agrees to add a summary table for reports that involve the assignment of significant exposure to any toxic substance.

Regarding the table itself, DOL agrees to include the Board's proposal about the addition of a data field relating to the type of exposure (direct/bystander/area). This information will provide added contextual information that a physician may find useful in informing an opinion about causation.

Regarding the other table fields that the Board proposes, DOL has concerns with the scientific value of reporting such information. Moreover, DOL is concerned that providing summary data about certain topics may not communicate nuances that can be better explained in a narrative format. For example, reliable data is very rarely available about the proper use of Personal

Protective Equipment (PPE) by employees. Any reference to PPE use in current reports is generally discussed in general terms as having been available or potentially used by an employee. From DOL's perspective, it is more critical to describe documented violations of established PPE protocols, including lack of or improper PPE use during hazardous working conditions, and the IH reports contain this information when it is available. DOL does not believe it can reliably or accurately categorize PPE use in the manner described by the Board. DOL does not believe that providing a table for the sources of data, listing file page numbers for IH monitoring data, or comments adds value to the existing reporting methodology. IH reports refer to the sources of information reviewed within the narrative content. Any important commentary about the referral will also be discussed by the IH in the narrative and its inclusion in a table would be redundant. Finally, DOL does not agree that providing page numbers about IH monitoring data, or the lack thereof, is a necessary reporting requirement. The reviewing physician is expected to use the interpretation of exposure data, as interpreted by an IH, to render an opinion of causation. DOL does not consider it necessary to provide the physician with specific IH monitoring data that is outside of their purview to consider.

Based on the context of the Board's recommendation, DOL has undertaken action to engage with our CMC contractor to solicit information regarding improvements to how information is communicated in IH assessments. This is an opportunity for CMCs to provide input on whether any additional metrics in an IH report will aid them in making their determinations. DOL will share any feedback it receives with the Board to further advance our shared interest in ensuring the publication of accurate and understandable characterizations of toxic substance exposures.

On behalf of the Department, OWCP, the Division of Energy Employees Occupational Illness Compensation, and the communities we serve, I look forward to the Board's continued efforts.

Sincerely,

Digitally signed by CHRISTOPHER GODFREY Date: 2023.08.31 08:36:11 -04'00'

Christopher J. Godfrey Director, Office of Workers' Compensation Programs

Enclosure: Sample IH Memo