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By email: rs@dir.ca.gov

Christine Hoffman
Zohra Ali
Senior Safety Engineers
Department of Industrial Relations
Division of Occupational Health and Safety
1515 Clay St., Suite 1901
Oakland, CA 94612

Re: Occupational Exposure to Surgical Smoke Plume

Dear Ms. Hoffman and Ms. Ali:

California hospitals are committed to providing safe environments for patients, workers, and those who operate and perform surgical procedures in hospital facilities. Minimizing surgical smoke exposure is a critical piece of ensuring patients and workers are healthy and safe.

On behalf of nearly 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments to the Division of Occupational Safety and Health (Cal/OSHA) discussion draft of possible regulatory language regarding AB 1007 (2023-2024: Occupational safety and health standards: plume).

General Comments

In 2018, CHA and member hospitals actively participated in Cal/OSHA advisory meetings to discuss whether Cal/OSHA should develop regulations on surgical smoke. Throughout the legislative process, CHA vigorously advocated against AB 1007 because it created an unworkable framework that proscribed a standard that was neither feasible nor practicable. Although AB 1007 was signed into law, we look forward to working with Cal/OSHA — in partnership with CHA and other interested parties — to craft science-based standards that protect workers and patients, are feasible to implement, reasonable in costs, and do not interfere with or hinder patient care.

As previously communicated to Cal/OSHA and the Legislature, most of CHA's member hospitals have already voluntarily adopted policies and technologies to mitigate exposure to surgical smoke. Regulatory requirements should align with national standards and guidance and allow for flexibility in how facilities

meet them. Engineering controls and ventilation protocols must be clinically appropriate and supported by scientific evidence and best practices.

Hospitals vary widely in terms of size, infrastructure, and financial resources, as do their operating rooms and ambulatory surgery center rooms where procedures may generate surgical smoke. Any regulatory proposal should not mandate a single technological solution but instead allow facilities to implement comparable and effective alternatives.

The draft proposal's financial and operational impacts on California hospitals should also be considered, as they face and will continue to face significant operational and financial challenges. Any new mandates must be scientifically based and consistent with industry standards and plume evacuation best practices.

Upgrading or installing systems in affected areas would also require time for planning, procurement, training, and — when necessary — the Department of Health Care Access and Information (HCAI) approval. The final standards should provide a minimum of 12 months for full implementation so that hospitals have enough time to implement the requirements.

Definitions

As written, the definition of “Plume” in Section (b)(11) includes reference to “mechanical tools [used] during surgical, diagnostic or therapeutic procedure” without any language describing the intended mechanical tools. Energy-based devices, such as electrosurgical and electrocautery devices, generate plume. Therefore, the definition of “Plume” should be amended as follows:

“Plume” means airborne contaminants generated from the use of energy-based devices, *such as* electrosurgical devices *or* electrocautery devices, ~~or mechanical tools used~~ during surgical, diagnostic, or therapeutic procedures.

The definition of “plume evacuation system” (PES) in Section (b)(11) continues to be problematic for hospitals. As CHA communicated to the Legislature, there is no existing plume system that can capture or remove plume entirely. Although the proposed definition leaves room for controls, equipment, and technological feasibility, it is unclear what entity will determine what is technologically feasible. We look forward to discussing this issue in greater detail during the advisory committee meetings with the objective to refine the PES definition into a workable standard that provides sufficient flexibility for all hospitals and ambulatory surgical centers.

The draft proposal also includes the use of high efficiency particulate air (HEPA) filters and also “Ultra-low particulate air (ULPA) filter(s).” Currently, operating rooms and ambulatory surgical settings utilize HEPA filters to evacuate surgical smoke — considered the “gold standard” in the industry. However, the draft proposal would also require the use of ULPA filters without reference to the necessity or circumstances. We look forward to receiving additional information and the scientific basis for including ULPAs, as well as information on what additional protections an ULPA provides that a HEPA filter cannot and why the combined use of engineering controls and a HEPA filter cannot achieve the same results.

Written Exposure Control Plan

We acknowledge that the Written Exposure Control Plan (“Plan”) requirements contained in Section (c) are like those in other safety orders. However, we have concerns about the proposed language and

advocate for a risk-assessment based approach that is unique to each facility and the potential hazards presented.

Although we do not object to employee involvement, we question the degree to which an authorized representative has the subject matter expertise necessary to actively involve themselves in “all elements” of the exposure control plan as contemplated under (c)(2)(F).

Concerning review of the Plan, hospitals conduct initial risk assessments to determine where plume is present so they can properly evacuate as close to the source as possible. Similarly, hospitals conduct risk assessments when new equipment enters the work environment. However, Section (c) (2[3]) requires review, evaluation, and an update of the Plan annually, as well as when either one of the following occurs:

- “(B) When new processes, procedures, and equipment are introduced into the workplace, and
- (C) Whenever a new or previously unrecognized hazard is identified.”

We have no objection to reviewing and updating the Plan to account for changes to processes, procedures or equipment *related to the evacuation of plume*. However, a comprehensive review is not necessary every time a change occurs or when a new hazard is identified that is unrelated to plume. Each facility should have the flexibility to develop a Plan that is based on its own risk assessment findings rather than a generalized standard as proposed here.

Control Measures

Engineering controls are a vital component to workplace safety standards as they aim to isolate or reduce hazards at their source and before they reach workers, provided they make sense and are attainable. Identifying the appropriate control strategy depends on many factors, including the fact that not all surgical smoke is the same.

Section (d)(1)(A)(1) presents a concern as it requires *continuous* operation of the PES whenever plume is present. Additional clarity is needed for the term “continually” on whether it refers to the entire medical procedure or only when a plume generating device is in use.

Similarly, Section (d)(A)(3)(ii) requires the use of an ULPA filter *and* a gas phase filter. The need to have both filters in operating and/or surgical rooms is questionable, particularly when the procedure itself does not warrant such devices. For example, removing a skin tag — a common procedure performed in a clinical setting — may generate plume, but the level it would generate does not warrant an ULPA filter and gas phase filter. Moreover, many impacted facilities may not have the space to accommodate the equipment and would require significant retrofitting of existing space — a costly and avoidable change when other alternatives exist that would achieve the same purpose.

With respect to Section (d)(1)(B), “General Ventilation,” although at least 20 air changes per hour is consistent with current operating room standards, extending the requirement to ambulatory surgical centers or standard procedure rooms in addition to the PES may present significant challenges. For some facilities, compliance could require costly retrofitting, and for those facilities that lease space, retrofitting may be difficult if not prohibited by the lease terms. Based on CHA’s 2018 data, costs to satisfy this provision would be significant. For example, one hospital reported an approximately \$300,000 cost per location to change out the air handlers to achieve the minimum 20 exchanges per hour in hospital

licensed ambulatory surgery centers. Adjusted for inflation, this figure would amount to nearly \$400,000 today.

In its 2024 edition of the NFPA 99, Health Care Facilities Code, the National Fire Protection Association (NFPA) recently adopted a requirement to capture surgical smoke at the source in operating rooms nationwide. The NFPA is a highly regarded organization and a source for building code standards, including those adopted by HCAI. To ensure consistency in *all* standards, Cal/OSHA should consider NFPA standards when discussing plume evacuation systems and ventilation protocols.

Regarding Section (d)(2), “Administrative Controls,” we agree they should be used to minimize employee exposure, but a “greatest extent feasible” standard should not be included for the same reasons commented previously.

The requirement for hospitals and surgical centers to provide and *ensure* appropriate use of eye protection and respirators under Sections(d)(2) and (d)(3) also presents concerns. AB 1007 does not mandate eye protection, and there is no guidance on what “appropriate” eye protection means. Based on CHA findings, only certain specialty goggles are designed to keep smoke away, but they also present other challenges, including discomfort and decreased visibility. The potential risks to a worker’s ability to perform a procedure and the patient’s health and safety is outweighed by any benefit — which remains unclear — to wearing goggles. Moreover, facilities cannot “ensure” that workers — particularly physicians and surgeons who are not employees — are wearing eye protection unless workers are hired to patrol the operating and surgical rooms for compliance, which is neither realistic nor sensible.

Similarly, the requirement to have respirators when engineering or administrative controls “do not prevent plume from contacting the respiratory track” presents additional concerns. It is impossible for a facility to know if plume comes into contact with a respiratory track. As with eye protection, workers disfavor respirators because they are uncomfortable, extremely taxing on the lungs, and interfere with patient care. Pursuant to Cal. Code Regs. Tit. 8, § 5144, all users must first undergo a medical exam, fit test, and training before use. The practical effect is, hospitals and surgical centers would either require all workers to receive respiratory clearance or risk surgery cancellations — neither of which is a preferred or realistic choice, and one that can be avoided by removing the requirement.

Training

Appropriate training is a critical component of any employee health and safety program. Although employees should receive training on the proper use of PES, the proposed requirements are overly prescriptive. The current language requires the training be “applicable to each employee’s assignment” – in other words, individualized training, which is neither feasible nor cost effective when you consider the various “assignments” workers may receive on any given day. Any required training should be general in scope but specific to the PES utilized and the methods used.

Health care workers already spend a considerable number of working hours completing mandated training — hours that could be devoted to patient care — while hospitals spend an increasing amount of time and resources delivering and tracking the time. Cal/OSHA should provide language that allows flexibility in the delivery of the training and leave open the opportunity for training in a classroom, online, or through any other effective interactive format. Cal/OSHA should also develop a model training program for facilities to adopt and implement (should they desire).

Recordkeeping

Section (f)(2)(A) includes unnecessary training recordkeeping requirements. Training records are kept to document who received and completed the training and when. The names and qualifications of people who delivered the training are unnecessary. Concerning records demonstrating that a PES conforms to these safety standards as required under Section (f)(3)(A), clarification is needed as to what kind of record would demonstrate conformity.

Additional Concerns

California hospitals are facing threats on multiple fronts, with sweeping cuts to Medi-Cal coming from the federal level and the state Office of Health Care Affordability capping hospitals' spending on care well below the basic rate of inflation. Today, 53% of California hospitals are struggling to keep their doors open, losing money every day caring for patients. Therefore, Cal/OSHA should consider costs when developing workplace safety standards that impact California hospitals to ensure that the regulations are both effective in protecting workers and financially sustainable for health care facilities to implement.

Under the "corporate practice of medicine" doctrine, most California hospitals cannot employ physicians or surgeons. As such, hospitals do not have the authority to dictate what equipment a surgeon or physician uses, and hospitals should not be mandated to ensure compliance by non-employees.

CHA looks forward to continued discussions to ensure that the final standards consider the various possible exposure scenarios and provide a risk-based approach to protecting the workplace safety of workers and patients.

Sincerely,



Erika Frank

V.P., Legal Counsel