State of California
Department of Industrial Relations
Division of Occupational Safety and Health

Memorandum

Date: July 3, 2018

To: Marley Hart, Executive Officer

Occupational Safety and Health Standards Board
2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833

From: Juliann Sum, Chief
Division of Occupational Safety and Health

Re: Evaluation of Petition 569 from M.H. Schaffer, DMD, to Amend Title 8 Section 5193

1.0 INTRODUCTION

On February 20, 2018, the Division of Occupational Safety and Health (Cal/OSHA) received a petition from M.H. Schaffer, DMD (petitioner). Then on March 1, 2018, Cal/OSHA received copies of several email communications between Occupational Safety and Health Standards Board (Board) staff and the petitioner. The petitioner proposes to amend California Code of Regulations title 8, section 5193, Bloodborne Pathogens, to include an additional requirement to protect employees from hazards posed by contaminated sharps.

Labor Code section 142.2 permits interested persons to propose new or revised standards concerning occupational safety and health, and requires the Board to consider such proposals and render a decision no later than six months following receipt. Further, as required by Labor Code Section 147, any proposed occupational safety or health standard received by the Board from a source other than Cal/OSHA must be referred to Cal/OSHA for evaluation, and Cal/OSHA has 60 days after receipt to submit a report on the proposal.

2.0 REGULATORY CHANGES REQUESTED BY THE PETITIONER

The petitioner proposes to amend the exceptions to California Code of Regulations, title 8, subsections 5193(d)(3)(A)1.-3. (set forth in subsection (d)(3)(A)4.) that allow an employer to forgo the use of engineered sharps injury protection. "Engineered sharps injury protection" is a physical attribute built into a needle or a non-needle sharp that reduces the risk of a needle stick or a cut from a sharp. Engineered sharps injury protection typically functions by shielding or covering the needle or other sharp after usage.

The petitioner requests that the Board amend section 5193 to expressly require the use of a "non-integral" safety device (i.e., a mechanism that is separate from and not build into the sharp) immediately after using a sharp. The petitioner proposes that this new requirement apply whenever

engineered sharps injury protection cannot be used. The petitioner has not provided any suggested regulatory language.

3.0 HAZARDS ASSOCIATED WITH EXPOSURE TO CONTAMINATED SHARPS

Bloodborne pathogens include, but are not limited to, human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Bloodborne pathogens can exist in an infected individual's blood, other bodily fluids, or other potentially infectious material.[1] Transmission can occur when foreign blood or other potentially infectious material enters an employee's body through the employee's mucous membranes, non-intact skin, or skin that is pierced, cut, or abraded by contaminated sharps. Sharps injuries are a significant cause of bloodborne pathogen transmission in the workplace. The risk of infection from a percutaneous injury with infected blood is 0.3% for HIV, 6-30% for HBV, and 1.8% for HCV.[2] Depending on the pathogen and the circumstances, disease resulting from infection can be incurable, debilitating, and life-threatening.

4.0 LABOR CODE AND TITLE 8 REGULATIONS

4.1 Labor Code

Labor Code section 144.7 requires the Board to adopt a standard that includes sharps injury prevention technology (needleless systems, engineered sharp injury protection, and other engineering controls).[3] Subsection (b)(2) provides for exceptions where the technology does not promote employee or patient safety or interferes with a medical procedure.

Labor Code § 144.7. Regulation revising bloodborne pathogen standard

*****

(b) The board shall adopt a standard, as described in subdivision (a), to be developed by the Division of Occupational Safety and Health. The standard shall include, but not be limited to, the following:

(1) A revised definition of "engineering controls" that includes sharps injury prevention technology including, but not limited to, needleless systems and needles with engineered sharps injury protection, which shall be defined in the standard.

(2) A requirement that sharps injury prevention technology specified in paragraph (1) be included as engineering or work practice controls, except in cases where the employer or other appropriate party can demonstrate circumstances in which the technology does not promote employee or patient safety or interferes with a medical procedure. Those circumstances shall be specified in the standard, and shall include, but not be limited to, circumstances where the technology is

---

[1] For a complete list of bodily fluids and materials that are considered to contain bloodborne pathogens, see the definition of "other potentially infectious materials" in section 5193.

[2] CDC, Exposure to Blood, What Healthcare Personnel Need to Know, July 2003. Https://www.cdc.gov/HAI/pdfs/bbp/Exp_to_Blood.pdf

[3] http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=144.7.&lawCode=LAB

medically contraindicated or not more effective than alternative measures used by the employer to prevent exposure incidents.
*****

4.2 Title 8 section 5193, bloodborne pathogens

Title 8 section 5193 applies to all workplaces where employees can be reasonably anticipated to have contact with blood or other potentially infectious materials. To protect employees from punctures and cuts from needles and other sharps, section 5193 contains several subsections that require engineering controls, including engineered sharps injury protection.

Section 5193 does not expressly require the use of non-integral safety devices for contaminated sharps that are exempted from engineered sharps injury protection requirements.

4.2.1 Title 8 subsection 5193(d)(2)(a), engineering and work practice controls - general requirements

Subsection 5193(d)(2)(A) requires engineering and work practice controls whenever they eliminate or minimize employee exposure to blood and other potentially infectious material. This subsection does not require a specific type of engineering control. Engineering controls include needleless systems, engineered sharps injury protection, non-integrated safety devices, one-handed capping devices, and sharps disposal containers.

§ 5193. Bloodborne Pathogens.
*****
(b) Definitions.
*****
"Engineering Controls" means controls (e.g., sharps disposal containers, needleless systems and sharps with engineered sharps injury protection) that isolate or remove the bloodborne pathogens hazard from the workplace.
*****
(d) Methods of Compliance.
*****
(2) Engineering and Work Practice Controls -General Requirements.
(A) Engineering and work practice controls shall be used to eliminate or minimize employee exposure.
*****

4.2.2 Title 8 subsection 5193(d)(3)(a), engineering and work practice controls - specific requirements

Subsection 5193(d)(3)(A) is a prescriptive standard that requires the use of needleless systems or medical devices with engineered sharps injury protection. Safety devices that must be added to a sharp or that would otherwise be physically separate from the sharp do not meet the definition of engineered sharps injury protection and therefore do not meet the requirements of subsection 5193(d)(3)(A).

There are four exceptions to the requirement to use needleless systems or engineered sharp injury protection, which are based on market availability, patient safety, safety performance, and absence of safety data. The exceptions are contained in subsection 5193(d)(3)(A)4.

§ 5193. Bloodborne Pathogens.

*****

(b) Definitions.

*****

"Engineered Sharps Injury Protection" means either:

(1) A physical attribute built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, which effectively reduces the risk of an exposure incident by a mechanism such as barrier creation, blunting, encapsulation, withdrawal or other effective mechanisms; or

(2) A physical attribute built into any other type of needle device, or into a non-needle sharp, which effectively reduces the risk of an exposure incident.

*****

(d) Methods of Compliance.

*****

(3) Engineering and Work Practice Controls -Specific Requirements.

(A) Needleless Systems, Needle Devices and non-Needle Sharps.

1. Needleless Systems. Needleless systems shall be used for:
   a. Withdrawal of body fluids after initial venous or arterial access is established;
   b. Administration of medications or fluids; and
   c. Any other procedure involving the potential for an exposure incident for which a needleless system is available as an alternative to the use of needle devices. *****
2. Needle Devices. If needleless systems are not used, needles with engineered sharps injury protection shall be used for:
   a. Withdrawal of body fluids;
   b. Accessing a vein or artery;
   c. Administration of medications or fluids; and
   d. Any other procedure involving the potential for an exposure incident for which a needle device with engineered sharps injury protection is available.
3. Non-Needle Sharps. If sharps other than needle devices are used, these items shall include engineered sharps injury protection.
4. Exceptions. The following exceptions apply to the engineering controls required by subsections (d)(3)(A)1.-3.:
   a. Market Availability. The engineering control is not required if it is not available in the marketplace.
   b. Patient Safety. The engineering control is not required if a licensed healthcare professional directly involved in a patient's care determines, in the reasonable exercise of clinical judgement, that use of the engineering control will jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the

patient. The determination shall be documented according to the procedure required by (c)(1)(B)7.

c. Safety Performance. The engineering control is not required if the employer can demonstrate by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer.

d. Availability of Safety Performance Information. The engineering control is not required if the employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining by means of objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents occurring in the employer's workplace.

*****

4.2.3 Title 8 subsection 5193(d)(3)(C), requirements for handling contaminated sharps; and 5193(d)(3(D), sharps containers for contaminated sharps

Subsections 5193(d)(3)(C) and 5193(d)(3)(D) require that contaminated sharps be promptly placed in sharps containers. Such containers must be located as close as feasible to the sharps user. Additionally, the containers must be rigid, puncture resistant, closable and sealable. Subsections 5193(d)(3)(B)6. and 5193(d)(3)(B)7. prohibit employees from opening or accessing the contents of a sharps container.

§ 5193. Bloodborne Pathogens.

*****

(d) Methods of Compliance.

*****

(3) Engineering and Work Practice Controls -Specific Requirements.

*****

(B) Prohibited Practices.

*****

6. The contents of sharps containers shall not be accessed unless properly reprocessed or decontaminated.

7. Sharps containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of sharps injury.

*****

(C) Requirements for Handling Contaminated Sharps.

*****

2. Immediately or as soon as possible after use, contaminated sharps shall be placed in containers meeting the requirements of subsection (d)(3)(D) as applicable.

3. At all time during the use of sharps, containers for contaminated sharps shall be:

a. Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
b. Maintained upright throughout use, where feasible; and
c. Replaced as necessary to avoid overfilling.

(D) Sharps Containers for Contaminated Sharps.

1. All sharps containers for contaminated sharps shall be:
   a. Rigid;
   b. Puncture resistant;
   c. Leakproof on the sides and bottom;
   d. Portable, if portability is necessary to ensure easy access by the user as required by subsection (d)(3)(C)3.a.; and
   e. Labeled in accordance with subsection (g)(1)(A)(2).
2. If discarded sharps are not to be reused, the sharps container shall also be closeable and sealable so that when sealed, the container is leak resistant and incapable of being reopened without great difficulty.

*****

4.2.4 Title 8 subsection 5193(c)(1), exposure control plan

Section 5193 requires employers to have a written "Exposure Control Plan." This plan must include procedures for ensuring that the most suitable engineering controls for protecting employees are selected and used and include procedures to document the determinations that engineered sharps injury protection should not be used due to patient safety concerns.

§ 5193. Bloodborne Pathogens.

*****

(c) Exposure Response, Prevention and Control.

(1) Exposure Control Plan.

(A) Each employer having an employee(s) with occupational exposure as defined by subsection (b) of this section shall establish, implement and maintain an effective Exposure Control Plan which is designed to eliminate or minimize employee exposure and which is also consistent with Section 3203.

*****

(B) The Exposure Control Plan shall be in writing and shall contain at least the following elements:

*****

6. An effective procedure for identifying currently available engineering controls, and selecting such controls, where appropriate, for the procedures performed by employees in their respective work areas or departments;
7. An effective procedure for documenting patient safety determinations made pursuant to Exception 2. of subsection (d)(3)(A); and
8. An effective procedure for obtaining the active involvement of employees in reviewing and updating the exposure control plan with respect to the procedures performed by employees in their respective work areas or departments.

*****

5.0 FEDERAL OSHA REGULATION

Code of Federal Regulations, title 29, section 1910.1030, Bloodborne Pathogens (29 CFR 1910.1030), is the corresponding federal OSHA regulation to California Code of Regulations, title 8, section 5193.[4] The California and federal bloodborne pathogen standards are similar in some respects, but differ in several significant areas.

29 CFR 1910.1030 does not expressly require the use of needleless systems or engineered sharps injury protection, but federal OSHA enforcement procedures require such engineering controls be used where the controls will reduce employee exposure, either by removing, eliminating or isolating the hazard.[5] Federal OSHA enforces the use of needleless systems and engineered sharps injury protection through the general engineering and work practice controls requirement in 29 CFR 1910.1030(d)(2)(i) (which is identical to title 8 subsection 5193(d)(2)(A)). Federal OSHA also recognizes that engineered sharps injury protection is not always feasible, such as when such controls compromise patient safety or procedural integrity.[6]

Similar to the California regulation, the federal regulation does not expressly require that non-integral sharps protectors be used when a worker is finished using a contaminated sharp that lacks engineered sharps injury protection.

Unlike the California regulation, the federal regulation does not contain requirements to:

1. Identify currently available engineering controls.
2. Document determinations that engineered sharps injury protection should not be used due to patient safety, or
3. Involve employees in reviewing and updating the exposure control plan.

```
§ 1910.1030 Bloodborne pathogens.
   *****
   1910.1030(b) Definitions.
   *****
   Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing
   needles, safer medical devices, such as sharps with engineered sharps injury
   protections and needleless systems) that isolate or remove the bloodborne pathogens
   hazard from the workplace.
   *****
   Sharps with engineered sharps injury protections means a nonneedle sharp or a needle
   device used for withdrawing body fluids, accessing a vein or artery, or administering
```

[4] Title 29 Code of Federal Regulations, section 1910.1030 https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

[5] OSHA Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens. Revised 3/1/17. Page 19. https://www.osha.gov/sites/default/files/enforcement/directives/CPL_02-02-069.pdf

[6] Federal OSHA 12/15/00 letter to Bard Peripheral Technologies https://www.osha.gov/laws-regs/standardinterpretations/2000-12-15 "If the use of an engineering control, in this case a sharp with engineered sharp injury protection (SESIP), compromises patient safety or procedural integrity, it would not be considered feasible."

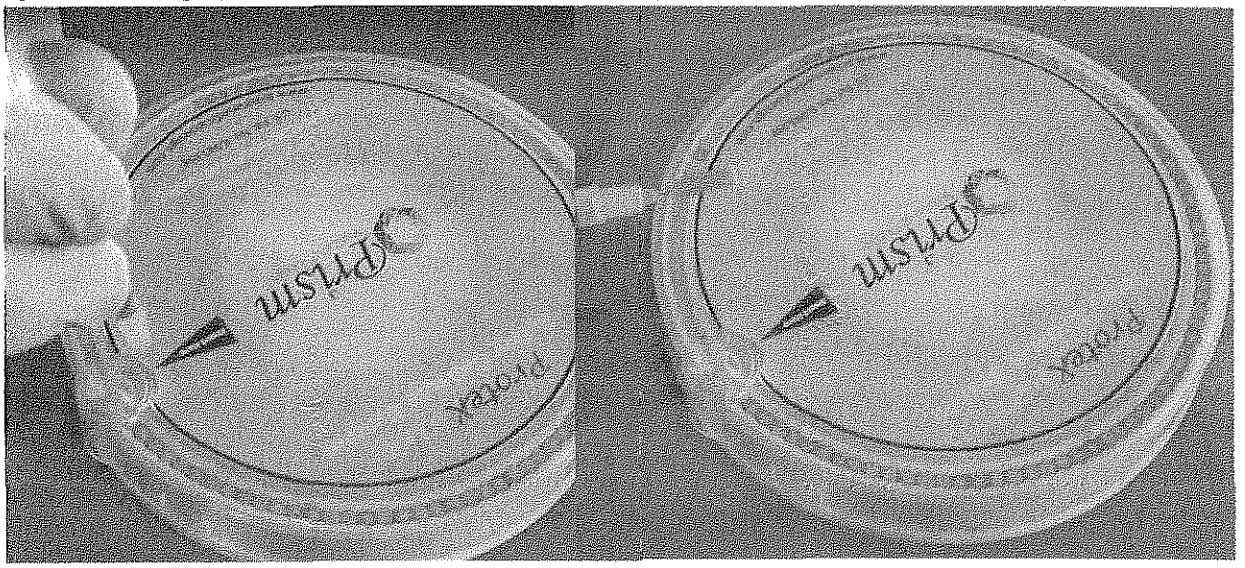
```
medications or other fluids, with a built-in safety feature or mechanism that
effectively reduces the risk of an exposure incident.
*****
1910.1030(d) Methods of Compliance -
*****
   (d)(2) Engineering and Work Practice Controls.
      (d)(2)(i) Engineering and work practice controls shall be used to eliminate or
      minimize employee exposure.
      *****
```

6.0 PETITIONER'S NON-INTEGRAL SAFETY DEVICE AND BASIS FOR A REVISED REGULATION

6.1 Petitioner's non-integral safety device

The petitioner owns a business that patented and markets a non-integral safety device. The petition describes it as a "sharps-end capture device" that secures a protective cover onto a needle tip after the needle end is inserted into a dispenser. The petitioner asserts that his device renders a needle safe for handling. The petitioner also states that the device is one of multiple non-integral safety devices that are commercially available from various manufacturers.

Figure 1: Photographs of petitioner's "sharps-end capture" non-integral needle safety device



6.2 Petitioner's basis for a revised regulation

The petitioner notes that healthcare workers sometimes handle contaminated sharps that lack engineered sharps injury protection, such as in the following situations:

1. A particular sharp with "engineered sharps injury protection" is not commercially available.
2. The "engineered sharps injury protection" costs too much.
3. The "engineered sharps injury protection" endangers the patient.

4. The "engineered sharps injury protection" cannot be engaged because the medical procedure requires a bent needle.

The petitioner believes that some employers may incorrectly determine that a medical device equipped with engineered sharps injury protection will jeopardize patient safety.

The petitioner also believes that non-integral safety devices are needed to protect employees from exposure to discarded sharps that have been placed in sharps containers.

According to the petitioner, when engineered sharps injury protection is not used, specific alternative protection for employees is needed and should be expressly required by section 5193. The petitioner states that the appropriate alternative to using engineered sharps injury protection is the use of non-integral safety devices that encompass a wide range of devices, including the petitioner's sharps-end capture device.

7.0 ANALYSIS OF THE PROPOSAL

The petitioner seeks to add a prescriptive requirement to section 5193 mandating that non-integral safety devices be used where needleless systems or medical devices with engineered sharps injury protection are not used. However, a prescriptive requirement for non-integral" safety devices is not necessary for the following reasons:

1. Using a non-integral safety device will increase risks to employees who can promptly dispose of sharps in a sharps container that is within easy reach.
2. Non-integral safety devices are not needed to protect employees from the contents of sharps containers.
3. Non-integral safety devices, where they would reduce risks to employees, are already required by section 5193.

7.1 Using a non-integral safety device will increase risks to employees who can promptly dispose of sharps in a sharps container that is within easy reach

Employee handling of unprotected contaminated sharps should be eliminated where possible or minimized in situations where sharps must be used. The best method to reduce exposure, when sharps are used, is to activate the engineered sharps injury protection as soon as an employee has finished using a sharp.

When engineered sharps injury protection cannot be used on a disposable sharp, exposure is best minimized by immediately disposing of the sharp in a sharps container located next to the employee.

To require employees to use a non-integral safety device prior to disposing of the sharp introduces additional handling of a contaminated sharp and increases the likelihood that an employee is cut or stuck with the sharp. Additionally, adding extra steps for disposing of sharps unnecessarily complicates the process.

7.2 Non-integral safety devices are not needed to protect employees from the contents of

sharps containers

The petitioner contends that "non-integral" safety devices are needed to protect employees from the contents of sharp containers. However, existing requirements already ensure that employees are not exposed to such contents.

Section 5193 includes the following requirements to protect employees from exposure to the contents of sharps containers that contain contaminated needles or other sharps:

1. Non-reusable sharps disposal containers must be puncture resistant, leakproof, and incapable of being reopened without great difficulty (subsection 5193(d)(3)(D)).
2. The storage or processing of contaminated sharps must not require employees to reach into sharps containers (subsection 5193(d)(3)(B)3.).
3. Sharps containers must not be opened, emptied, or cleaned manually or in any other manner that would expose employees to the risk of sharps injury (subsection 5193(d)(3)(B)7.).
4. The contents of sharps containers must not be accessed unless properly reprocessed or decontaminated (subsection 5193(d)(3)(B)6.).
5. Sharp containers must be closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping (subsection 5193(d)(3)(E)2.a.).

7.3 Non-integral safety devices, where they would reduce risks to employees, are already required by section 5193

Subsection 5193(d)(2)(A) requires employers to use engineering and work practice controls to eliminate or minimize exposure to bloodborne pathogens. Unlike subsection 5193(d)(3)(A), subsection 5193(d)(2)(A) has no exceptions.

Engineering controls include, but are not limited to, non-integral safety devices such as a needle destruction devices, needle-end or sharps-end capture devices, one-handed recapping devices, and other controls that isolate bloodborne pathogens. Engineering controls also include the use of sharps containers.

Situations where non-integral safety devices can reduce risks to employees include the following:

- Sharps containers cannot be located near the sharps user
- Sharps must be detached from a medical device

8.0 CONCLUSION

The use of non-integral safety devices are already required by section 5193(d)(2)(A) where they would improve employee safety and engineered sharps injury protection cannot be used. It is therefore unnecessary to amend section 5193. To add a prescriptive requirement to mandate a specific type of engineering control other than needleless systems and engineered sharps injury protection may create greater risks to employees. The existing performance language of the regulation ensures greater safety of employees because the most appropriate and safest engineering control can be determined for every situation.

However, it would be helpful to make a non-substantive change to section 5193 to inform employers and employees that where the exceptions to using needleless systems and engineered sharps injury protection apply, other engineering controls are still required. Cal/OSHA recommends that the Board grant petition 569 to the extent that the following be added to section 5193:

§ 5193. Bloodborne Pathogens.
*****
(d) Methods of Compliance
*****
(3) Engineering and Work Practice Controls -Specific Requirements.
*****
(A) Needleless Systems, Needle Devices and non-Needle Sharps.
*****
4. Exceptions. The following exceptions apply to the engineering controls required by subsections (d)(3)(A)1.-3.:
"Note: These exceptions do not apply to subsection (d)(2)(A), which contains general requirements to use engineering and work practice controls, including engineering controls other than needleless systems and engineered sharps injury protection."

*****

cc: Kevin Graulich
Chris Kirkham
Eric Berg