

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 63 Protection from Surgical Smoke

SPONSOR(S): Woodson and others

TIED BILLS: **IDEN./SIM. BILLS:** SB 410

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Innovation	14 Y, 0 N	Guzzo	Calamas
2) Health Care Appropriations Subcommittee	14 Y, 0 N	Smith	Clark
3) Health & Human Services Committee	20 Y, 0 N	Guzzo	Calamas

SUMMARY ANALYSIS

Surgical smoke is the gaseous by-product produced when tissue is dissected or cauterized by heat generating devices such as lasers, electrosurgical units, ultrasonic devices, and high-speed burrs, drills and saws. Surgical smoke contains chemicals, blood and tissue particles, bacteria, and viruses, and has been proven to exhibit potential risks for surgeons, nurses, anesthesiologists, and technicians in the operating room due to long term exposure.

The bill requires hospitals and ambulatory surgical centers to adopt and implement policies by January 1, 2025, that require the use of a smoke evacuation system during any surgical procedure that is likely to generate surgical smoke. Smoke evacuation systems must effectively capture, filter, and eliminate surgical smoke at the site of origin before the smoke makes contact with the eyes or respiratory tract of occupants in the room.

The bill has no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Surgical Smoke

Surgical smoke is the gaseous by-product produced when tissue is dissected or cauterized by heat generating devices such as lasers, electrosurgical units, ultrasonic devices, and high-speed burrs, drills and saws.¹ During a surgical procedure, the heat generated from one of these devices causes the target cell membranes to rupture, and subsequently generates and releases a plume of smoke into the operating room.² Surgical smoke contains chemicals, blood and tissue particles, bacteria, and viruses, and has been proven to exhibit potential risks for surgeons, nurses, anesthesiologists, and technicians in the operating room due to long term exposure.³

Potential known health effects from the exposure to surgical smoke include eye, nose, and throat irritation; headache; cough; nasal congestion; and asthma and asthma-like symptoms, but little is known about the health effects from chronic exposure to surgical smoke.⁴ Other risks include the transmission of viruses through surgical smoke; for example, transmission of Human Papillomavirus (HPV) through surgical smoke from lasers has been documented,⁵ and some researchers have suggested that surgical smoke may act as a vector for cancerous cells that may be inhaled.⁶

Surgical Smoke Evacuation Systems

Smoke evacuators are devices which contain a suction unit (i.e. a vacuum), filter, hose, and inlet nozzle. They are designed, as recommended by the Center for Disease Control, to capture air from where the nozzle is targeted and filter the air through a HEPA filter.⁷ These systems may be stationary, with permanent construction requirements, or handheld portable systems with disposable filters, hand pieces, and hoses. While costs for these products range greatly, with installation of a stationary system costing as much as \$120,000,⁸ the more common handheld systems have recurring costs associated with disposable parts of roughly \$19 per surgery, and total recurring costs including filter replacement between \$8,000 and \$10,000 annually depending on frequency of use.⁹

¹ Liu Y, Song Y, Hu X, Yan L, Zhu X. Awareness of surgical smoke hazards and enhancement of surgical smoke prevention among the gynecologists. *Journal of Cancer* (June 2, 2019) available at <https://www.jcancer.org/v10p2788.htm> (last visited January 21, 2024).

² *Id.*

³ *Id.*

⁴ Steege AL, Boiano JM, Sw eeeney MH. NIOSH health and safety practices survey of healthcare workers: training and awareness of employer safety procedures. *American Journal of Industrial Medicine* (February 18, 2014) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504242/> (last visited January 21, 2024).

⁵ *Id.*

⁶ United States Department of Labor, Occupational Safety and Health Administration, *Surgical Suite >> Smoke Plume*, available at <https://www.osha.gov/etools/hospitals/surgical-suite/smoke-plume>, (last visited January 21, 2024).

⁷ Centers for Disease Control, *Control of Smoke from Laser/Electrical Surgical Procedures*, available at <https://www.cdc.gov/niosh/docs/hazardcontrol/hc11.html> (last visited January 21, 2024).

⁸ Relias Media, *Consider Overall Cost, Ease when Choosing Evacuators*, available at <https://www.reliasmedia.com/articles/61664-consider-overall-cost-ease-when-choosing-evacuators> (last visited January 21, 2024).

⁹ See Relias Media, *OR Teams Often Exposed to Toxic Chemicals in Surgical Smoke*, Mar. 1, 2021, available at <https://www.reliasmedia.com/articles/147530-or-teams-often-exposed-to-toxic-chemicals-in-surgical-smoke#:~:text=The%20estimated%20cost%20of%20using,for%20the%20standard%20electrosurgical%20pencil>. (last visited January 21, 2024), Ohio Legislative Service Commission, *SB 161 Fiscal Note & Local Impact Statement*, available at <https://www.legislature.ohio.gov/download?key=17773&format=pdf> (last visited January 21, 2024); Kreuger, Steven, et al., *The Effect of a Surgical Smoke Evacuation System on Surgical Site Infections of the Spine*, available at <https://www.oatext.com/pdf/CMD-3-132.pdf> (last visited January 21, 2024).

Surgical Smoke Regulation

Hospitals and ambulatory surgical centers (ASCs) must comply with the 2021 National Fire Protection Association (NFPA) 101 Life Safety Code.¹⁰ The 2021 version does not require the use of surgical smoke evacuation systems, but the 2024 version does. However, in Florida, the 2021 version will be enforceable until 2027, when the State Fire Marshal adopts the 2024 version.¹¹ The 2024 version requires facilities to capture surgical smoke using either a dedicated exhaust system (may share an established system for waste gas removal), a connection and return or exhaust duct after air cleaning through high efficiency particulate air (HEPA) and gas phase filtration, or a point of use smoke evacuator for air cleaning and return to the space. As a result, Florida will have no regulatory requirement to use surgical smoke evacuation systems in hospitals and ASCs until 2027.

The Occupational Safety and Health Administration (OSHA) recognizes potential risk factors and remedial measures, but it has not adopted regulations on protection from surgical smoke. OSHA's recognized controls and work practices for surgical smoke include:¹²

- Using portable local smoke evacuators and room suction systems with in-line filters.
- Keeping the smoke evacuator or room suction hose nozzle inlet within two inches of the surgical site to effectively capture airborne contaminants.
- Having a smoke evacuator available for every operating room where plume is generated.
- Evacuating all smoke, no matter how much is generated.
- Keeping the smoke evacuator "ON" (activated) at all times when airborne particles are produced during all surgical or other procedures.
- Considering all tubing, filters, and absorbers as infectious waste and dispose of them appropriately.
- Using new tubing before each procedure and replace the smoke evacuator filter as recommended by the manufacturer.
- Inspecting smoke evacuator systems regularly to ensure proper functioning.

Additionally, the Joint Commission, an accrediting organization for hospitals and ASCs, recommends the following actions to protect patients and staff from the dangers of surgical smoke:

- Implement standard procedures for the removal of surgical smoke and plume through the use of engineering controls, such as smoke evacuators and high filtration masks.
- Use specific insufflators for patients undergoing laparoscopic procedures.
- During laser procedures, use standard precautions to prevent exposure to the aerosolized blood, blood by-products and pathogens contained in surgical smoke plumes.
- Establish, review, and make available policies and procedures for surgical smoke safety and control.
- Provide surgical team members with initial and ongoing education and competency verification on surgical smoke safety, including the organization's policies and procedures.
- Conduct periodic training exercises to assess surgical smoke precautions and consistent evacuation for the surgical suite or procedural area."¹³

As of August 2023, 11 states have adopted legislation to require the use of surgical smoke evacuation systems in certain health care facilities. Of those 11 states, 8 states require surgical smoke evacuation systems to be used in hospitals and ASCs for procedures that generate surgical smoke, and 3 states require them to be used in all health care facilities for procedures that produce surgical smoke.¹⁴

¹⁰ Rule 69A-3.012, F.A.C., and s. 633.206(1)(b), F.S.

¹¹ S. 633.202(1), F.S., requires the State Fire Marshal to adopt a new version of the fire prevention code every third year. The 2021 version becomes effective December 31, 2024, so the 2024 version will not become effective until December 31, 2027.

¹² *Id.*

¹³ The Joint Commission, *Quick Safety Issue 56: Alleviating the Dangers of Surgical Smoke*, available at <https://www.jointcommission.org/resources/news-and-multimedia/new-sletters/new-sletters/quick-safety/quick-safety-issue-56/quick-safety-issue-56/> (last visited January 21, 2024).

¹⁴ Staff of the Select Committee on Health Innovation conducted a 50-state analysis on laws relating to surgical smoke evacuation.

Effect of the Bill

The bill requires hospitals and ASCs to adopt and implement policies by January 1, 2025, that require the use of a smoke evacuation system during any surgical procedure that is likely to generate surgical smoke. Smoke evacuation systems must effectively capture, filter, and eliminate surgical smoke at the site of origin before the smoke makes contact with the eyes or respiratory tract of occupants in the room.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Creates s. 395.1013, F.S., relating to smoke evacuation systems required.

Section 2: Provides an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will have a negative fiscal impact on hospitals and ASCs who do not currently use surgical smoke evacuation systems during procedures that generate surgical smoke. Such hospitals and ASCs could incur costs of up to \$10,000 per surgical suite annually.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None. The bill does not appear to affect local or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill does not necessitate rule-making for implementation.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

None.