STATE OF MARYLAND

Andrew N. Pollak, M.D.
CHAIRMAN

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

2020 SESSION
POSITION PAPER

BILL NO: **SB 728**
COMMITTEE: **Finance**
POSITION: **SUPPORT with Amendment**

TITLE: Health Facilities - Freestanding Ambulatory Care Facilities - Administration of Anesthesia

BILL ANALYSIS: Senate Bill 728 (SB 728), as proposed, requires the development of regulations by the Secretary of the Maryland Department of Health (MDH) requiring a freestanding ambulatory care facilities[1] (a provider type that includes freestanding ambulatory surgery facilities (referred to as FASFs)) to ensure that a health care practitioner administering anesthesia for a surgical procedure has access to all medical resources necessary to adequately and safely care for the patient, as determined by the practitioner in consultation with the health care provider performing the procedure. This requirement is an addition to an existing list of standards that the Secretary must develop related to quality of care and patient safety, including procedures for credentialing practitioners and evaluating practitioner performance; standards for the qualifications of health care practitioners and support staff; the procedures to be followed in an emergency; as well as protocols for postoperative recovery and patient discharge.

POSITION AND RATIONALE:
The Maryland Health Care Commission (the "Commission") supports the passage of SB 728 with consensus amendment reflecting a compromise between the Commission and the Maryland Society of Anesthesiologists. The Commission understands that anesthesiologists are concerned

[1] COMAR 10.05.01 defines Freestanding ambulatory care facility as (a) Freestanding surgical facility; (b) Freestanding endoscopy facility;(c) Freestanding facility utilizing major medical equipment;(d) Freestanding birthing center; and (e) Freestanding kidney dialysis center.

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that current regulatory limits on certain types of sedation for surgical procedures conducted in non-sterile procedure rooms rather than sterile operating rooms in FASFs may raise concerns with respect to patient safety. The Commission agrees that patient safety is of upmost importance at a time when the types of procedures that are conducted in FASFs, rather than hospitals, and in procedure rooms, rather than operating rooms, is changing rapidly.

The Commission's authority to regulate surgery rests in the Certificate of Need (CON) statute, Health General § 19–120. An "ambulatory surgical facility" as defined in CON law, is an FASF with three or more sterile operating rooms. Only this type of FASF is required to seek a CON from the Commission before opening, relocating, or adding operating rooms. In order to administer the CON law under this statutory definition, the Commission distinguishes between an "ambulatory surgical facility," that is subject to CON regulation and an FASF that is not subject to CON regulation, because it functions with two or fewer sterile operating rooms. The Commission refers, in its State Health Plan regulations, to FASFs with no more than two operating rooms, i.e., FASFs not subject to CON regulation, as "physician outpatient surgery centers." A physician outpatient surgery center must obtain a "coverage determination" from the Commission when opening, relocating, or when changing its physical facilities. These determinations require submission of information about the proposed FASF or the changes being made at the facility. The Commission's oversight of FASFs generally ends once the facility is established or, in the case of unregulated FASFs, proposed changes at an existing facility are reviewed and determined to not require further review or approval. The Office of Health Care Quality (OHCQ), a division of the Maryland Department of Health (MDH), licenses FASFs for ongoing operations regardless of operating room capacity and monitors quality of care and patient safety in these facilities.

SB 728 amends Health General § 19–3B–03, a provision of Maryland law detailing OHCQ's authority over FASFs and specifying policies that must be addressed in regulation of freestanding facilities. Existing MDH regulations (COMAR 10.05.05) do not restrict administration by a qualified anesthetist of any type or level of anesthesia to any patient in any setting or in any room in which a procedure is performed; in other words, OHCQ's regulations related to the licensure of FASFs do not limit the ability of a qualified anesthetist to adequately and safely care for patients. However, the Maryland Health Care Commission has regulations, in the State Health Plan, that limit the type and level of anesthesia that can be provided in non-sterile "procedure rooms" (COMAR 10.24.11). Procedure rooms are distinct from operating rooms in COMAR 10.24.11, the Commission's State Health Plan regulations for general surgical facilities, which apply to both hospitals and FASFs. MDH does not have authority to change the Commission's regulations, as the Commission is independent from MDH. The Commission does not regulate the type of anesthesia or the depth of sedation provided in a sterile operating room in a FASF. The regulations in the State Health Plan set the standards for the Commission's review of Certificate of Need applications and related regulatory activities.

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Because the Commission's regulatory responsibilities differ depending on the number of operating rooms in an FASF,[2] it is necessary for the Commission to distinguish between sterile operating rooms and non-sterile procedure rooms.[3] COMAR 10.24.11 defines the two types of rooms as follows:

> *"Operating room" or "OR" means a sterile room in the surgical suite that meets the requirements of a restricted area and is designated and equipped for performing surgical operations or other invasive procedures that require an aseptic field. Any form of anesthesia may be administered in an OR."*
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> *"Procedure room" means a non-sterile room in which minor surgical procedures are performed under only topical, local, regional anesthesia, or minimal intravenous sedation. A deeper level of intravenous sedation in a procedure room is only appropriate for a minor procedure, such as an endoscopy, that is minimally invasive. Minimal intravenous sedation is a drug-induced state during which a patient responds normally to verbal commands, and the patient's airway reflexes, ventilator functions, and cardiovascular functions are unaffected. Spinal and epidural routes are appropriate only if those methods are used exclusively for closed pain management procedures and not in preparation for open surgical procedures. A procedure room shall be accessed only from a semi-restricted corridor or an unrestricted corridor."*

To regulate surgical facilities, including hospitals and FASFs, on an equitable basis, the Commission requires that surgical facility designs clearly separate sterile operating rooms and non-sterile procedure rooms. This is why the definition of "procedure room" in COMAR 10.24.11 states that, "a procedure room shall be accessed only from a semi-restricted corridor or an unrestricted corridor." Additionally, the State Health Plan contains "Design Requirements" for facilities specifying that procedure rooms cannot be "accessed directly from a restricted area of the facility," must be "equipped and ventilated separately from any sterile operating room(s)," and must "be used exclusively for minor procedures in which patients are given only analgesic agents that are appropriate for a procedure room." Facilities cannot place operating rooms and procedure rooms on the same corridor of a facility because grouping rooms together in the same "surgical suite" does not allow the Commission to make a consistent, material distinction between a sterile operating room and a non-sterile procedure room.

[2] The definition in Health General § 19-114(b) leads to the requirement for a Certificate of Need for ambulatory surgery facilities with three or more operating rooms. This provision of law was amended in 2019 through Senate Bill 940 (Chapter 474, 2019). This change in law means that the 320 FASFs in Maryland have the potential for adding approximately 400 additional operating rooms with only a "determination of coverage" from the Commission, not a Certificate of Need.

[3] The Commission's State Health Plan regulations do not limit the number of non-sterile procedure rooms for a FASF of any size.

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As noted above, the Commission's current regulatory definition of a procedure room describes a room used for "minor surgical procedures" that require only "minimal sedation".[4] Innovations in surgery and anesthesia have resulted in changing practice patterns over time. Increasingly, procedures that may require levels of sedation that go beyond minimal sedation are being scheduled in procedure rooms. Because of this, anesthesiologists want the flexibility to provide all appropriate support to patients, including deeper sedation levels and the potential airway support that may be needed for these deeper levels of sedation, when necessary for patient safety and comfort. SB 728, as drafted, mandates that flexibility.

The Commission asks that, as Committee members consider this bill, the members take into account the importance of ensuring that a clear definitional boundary between operating rooms and procedure rooms can be maintained in the CON regulations. The Commission is also concerned about whether this change in law may encourage expanded use of non-sterile procedure rooms for a greater range of procedures for which the operating room is a safer setting. (The sterile operating room environment reduces the risk of surgical site infections because of the size, design, and air handling/ventilation standards applicable to operating rooms).

The Facility Guidelines Institute (FGI), the national organization that develops guidelines for designing and building hospitals and other health care facilities, recommends that procedure rooms in which an anesthesia machine[5] is used be approximately 25 percent larger than procedure rooms in which deeper levels of sedation are not used. The Commission believes that the FGI guidelines should be followed in Maryland regulation of health care facilities. This means that non-sterile procedure rooms should not be put on a par with sterile operating rooms with respect to deeper levels of sedation if such rooms are not appropriate for such use and that FASFs should limit the routine use of deep sedation and general anesthesia in non-sterile procedure rooms to situations in which patient safety requires these levels of anesthesia. The Commission has some information on the approximately 500 non-sterile procedure rooms now in operation in Maryland FASFs because of its CON authority and its activity in reviewing requests for determinations of coverage. We know that most such rooms are relatively small and do not incorporate special air handling systems. The Commission supports the evolution of FASF operations to allow for a wider range of surgical procedures to be performed in appropriately designed and equipped non-sterile procedure rooms and to allow for such evolution to occur in a safe manner.

[4] The American Society of Anesthesiologists characterize this level of sedation as one in which the patient's airway, spontaneous ventilation, and cardiovascular function is "unaffected", a characterization that was included in the Commission's regulations. https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia

[5] Anesthetists propose to use anesthesia machines to deliver deeper sedation in procedure rooms. This portable device integrates monitoring devices and includes systems for blending a precision mixture of respiratory and anesthetic gases (anesthesia machine and vaporizers), dispensing those gases to the patient (anesthesia breathing system), delivering positive pressure ventilation (anesthesia ventilator), and systems for removing waste gases. A new anesthesia machine may cost in excess of $100,000.

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Therefore, the Commission supports the development of regulations that allow for the evolution of surgical practice and provide health care providers with the flexibility necessary to ensure patient safety, while maintaining a definitional line between procedure rooms and operating rooms. The Commission has worked closely with the Maryland Society of Anesthesiologists to develop a consensus amendment. The parties to this negotiation expect to finalize this amendment promptly and will provide it to the Committee at that time. The Commission recommends that the Committee support this bill with amendment.

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