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2020 SESSION
POSITION PAPER

BILL NO: **HB 935**
COMMITTEE: **Health and Government Operations**
POSITION: **SUPPORT with Amendment**

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

BILL ANALYSIS: House Bill 935 (HB 935), as proposed, requires the development of regulations by the Secretary of the Maryland Department of Health (MDH) requiring a freestanding ambulatory care facility (FACF)[1] (a provider type that includes freestanding ambulatory surgery facilities (FASF)) 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 (Commission) understands that Anesthesiologists are concerned that current regulatory limits on certain types of sedation for surgical procedures conducted in procedure rooms (not operating rooms) in FASFs may interfere with patient safety. The Commission agrees with the Anesthesiologists that patient safety is of upmost importance at a time when the types of procedures that are conducted in FASFs (as opposed to hospitals) and in

[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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procedure rooms (rather than operating rooms) is changing rapidly. The Commission believes that this complex issue would be best addressed through a regulatory change. If the General Assembly believes a statutory change is needed, we have provided a suggested amendment.

The Commission's authority to regulate surgery rests in the CON statute, Health General § 19–120. Ambulatory Surgery Facilities, a type of FASF, are required to seek a Certificate of Need from the Commission before opening a facility with three or more operating rooms or when adding one or more operating rooms in an existing facility. The Commission distinguishes between an "ambulatory surgical facility," that is subject to CON regulation and a freestanding ambulatory surgical facility that is not subject to CON regulation. Ambulatory Surgery Facilities with three or more operating rooms are subject to CON regulation.[2] Ambulatory Surgery. The Commission refers to Ambulatory Surgery Facilities with no more than two operating rooms, as "physician outpatient surgery centers" or "POSCs."[3] A POSC must obtain a "coverage determination" from the Commission when opening or when changing operating room capacity. "Coverage determinations" are less burdensome than applications for a Certificate of Need. The Commission's oversight of Ambulatory Surgery Centers of any size ends once the facility (if new) or new operating room are licensed and operating. The Office of Health Care Quality (OHCQ), a component of the MDH, licenses FASFs for ongoing operations regardless of operating room capacity.

HB 935 amends Health General § 19–3B–03, a provision of Maryland law related to the Office of Health Care Quality's authority over FASFs and directs the Secretary of MDH to make regulatory changes. 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. The Commission has regulations, under 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 applies to hospitals and FASF. The Secretary of MDH does not have authority to change these 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.

Because the Commission's regulatory responsibilities differ depending on the number of operating rooms in an FASF,[4] it is important that the Commission be able to distinguish between

[2] Health General §19-114(b) defines an "ambulatory surgery facility as a facility with three or more operating rooms.
[3] COMAR 10.24.11
[4] 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

sterile operating rooms and non-sterile procedure rooms.[5] 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.

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".[6] On-going innovations in surgery and anesthesia have resulted in changing practice patterns; increasingly

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adding approximately 400 additional operating rooms with only a "determination of coverage" from the Commission, not a Certificate of Need.

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

[6] 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

procedures that may require moderate or deep sedation are likely to be scheduled in procedure room, and anesthesiologists want the flexibility to provide all appropriate supports to patients, including deeper sedation and increased airway support, when necessary for patient safety and comfort. HB 935 is an attempt to obtain that flexibility.

The Commission asks the Committee to consider the importance of ensuring that a clear definitional boundary between operating rooms and procedure rooms remains as they respond to the anesthesiologists' sincere and rational concern that they have the capability to intervene when necessary if a deeper level of sedation than was originally planned for is necessary in a procedure room. The Commission is also concerned about whether this change in law may invite less scrupulous providers to use procedure rooms for an expanding range of procedures for which the operating room is a safer setting (operating rooms have a reduced risk of surgical site infections because of the design, air handling, and ventilation standards that apply to operating rooms).

The Facility Guide Institute (FGI), the national nonprofit organization that develops guidelines for designing and building hospitals and other health care facilities, recommends that procedure rooms in which anesthetics[7] are delivered be approximately 25 percent larger than procedure rooms in which anesthetics would not be delivered. Of the almost 500 procedure rooms now in operation in FACFs in Maryland, the Commission has limited information on how many of these procedure rooms conform to the size recommendations of FGI or are otherwise equipped to support safely more advanced surgical procedures, which until now have been performed in operating rooms. The Commission believes that FGI guidelines should be followed. This means that anesthetics should not be delivered in procedure rooms that are too small to safety accommodate the equipment needed to deliver that anesthetic. The flexibilities contained in HB 935 should not be allowed to override the FGI guidelines.

The Commission supports the development of regulations that allow for the evolution of surgical practice. As written, House Bill 935 is overly broad. If the Committee moves forward with this bill, the Commission recommends the following amendment:

[7] 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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AMENDMENT TO HOUSE BILL 935
(First Reading File Bill)

On Page 2, strike beginning with "**A**" in line 12, down through "**PROCEDURE**" in line 16, and substitute "**NON-STERILE PROCEDURE ROOMS IN A HOSPITAL OR FREESTANDING AMBULATORY SURGICAL FACILITY ARE ONLY USED FOR PERFORMANCE OF PROCEDURES THAT CAN BE SAFELY PERFORMED IN SUCH ROOMS, BASED ON THE TYPE OF NON-STERILE PROCEDURE ROOM, THE TYPE OF SURGICAL PROCEDURE, AND THE TYPE OF ANESTHETIC AGENT AND THE DEPTH OF SEDATION REQUIRED FOR SAFE PERFORMANCE OF THE SURGICAL PROCEDURE**".

This amendment ensures that health care providers have the flexibility necessary to ensure patient safety while maintaining some controls over what procedures are appropriate for different procedure rooms to ensure high quality outcomes and patient safety.

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