3300 Woodcreek Drive
Downers Grove, Illinois 60515
630-573-0600 / 630-963-8607 fax
Email: info@asge.org
Web site: www.asge.org

December 12, 2016

Doug Erickson, Chairman
Facility Guidelines Institute
1919 McKinney Avenue
Dallas, TX 75201

Dear Mr. Erickson:

On behalf of the American Society for Gastrointestinal Endoscopy (ASGE), a national medical society representing more than 14,000 physicians trained in the use of endoscopy for the diagnosis and treatment of gastrointestinal diseases and conditions, I want to thank the Health Guidelines Revision Committee for its drafting of the 2018 edition of the Facility Guidelines Institute (FGI) *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*, which are currently under consideration. We appreciate the opportunity to provide comment on the draft 2018 guidelines.

The Ambulatory Surgical Center (ASC) is a vital part of the gastroenterology practice, providing a safe, patient-friendly and cost effective environment for the provision of medical services. Gastroenterology procedures are the most frequently preformed procedures in single-specialty and multi-specialty ASCs. We estimate that nearly 50 percent of ASGE physician members care for patients in the ASC setting. The majority of ASCs in which gastroenterologists practice are single specialty centers. Of the more than 5,000 ASCs in the United States, 22 percent specialize in just gastrointestinal (GI) procedures.

Proper facility construction and function play a vital role in the quality, safety, and success of endoscopy centers. Well-designed endoscopy centers maximize efficiency, improve workflow, and enhance patient experience.

The purpose of the FGI Guidelines for Design and Construction of Health Care Facilities is to establish minimum standards in the construction and equipment for medical facilities. ASGE is concerned that some of the proposed amendments in the 2018 edition of the facility guidelines go beyond the minimum standards needed to provide quality and safe medical care in an outpatient endoscopy setting. We believe that some of the proposed amendments to the requirements for the core elements, outpatient surgery and gastrointestinal endoscopy sections represent model instead of minimum standards. If adopted, these standards would prove to be excessive and overly burdensome for most Ambulatory Endoscopy Centers (AECs), particularly smaller ones.

Our comments focus on the proposed amendments that will impact GI endoscopy centers.

CORE ELEMENTS

Section 3.1-3.6.5.3(2): Requirements for Handwashing Stations that Serve Multiple Patients

We believe that it is unreasoned to require "even distribution" of hand-washing stations when serving multiple patient care stations. Depending on the arrangement of the patient care stations, sinks could be spaced further away from all the patient care positions. We believe it is more appropriate to establish a maximum acceptable distance from the foot of any given patient care position rather than even distribution.

Section 3.1-3.6.10.1: Soiled Workroom or Soiled Holding Room Location

Requiring separation between the soiled work room and a clean work room seems contrary to the long-standing dual purpose of soiled work and decontamination in a majority of existing Outpatient Surgery Facilities (OSFs) where a one-way flow is used when reprocessing instruments. Since reprocessed instruments are first completely cleaned in soiled utility, then moved to clean utility for continued cleaning/sterilization, it is not clear what benefit results from physically carrying the instruments into a hallway then back into clean utility as opposed to using a door, pass-through, or washer/sanitizer directly between the areas. Additional movement of the instruments, often through semi-restricted passage ways, increase the risk of damage during handling and exposure to others in that hallway.

Section 3.1-5.1.3.2: Sterile Reprocessing Area

Decontamination Room

Requiring an instrument air outlet in the Decontamination room will not benefit facilities where limited types of instruments are reprocessed. In the absence of compelling evidence regarding the need or benefit of these instrument air outlets, this provision should not be considered a universal requirement in all decontamination rooms. This requirement should be specific to the type and kinds of instruments used in the facility.

An additional amendment requires a decontamination room to have a two-basin sink with a counter. In facilities reprocessing limited quantities of instruments, the two-basin sink in addition to a hand-washing station is not necessary. While we agree with the need of two sinks, one to facilitate reprocessing and one for handwashing, we do not see the benefit of requiring the dirty sink to be a more expensive two-basin sink that would further reduce the counter space which is required for the cleaning process.

This amendment would decrease the utility of the countertop surface provided without providing any additional benefits or increased quality control in the decontamination room. Therefore, we urge the Committee to remove this amendment.

Clean Workroom

Again, our society believes that the provision of an instrument air outlet should not be considered a universal requirement. The instrument air outlet should be specific to the setting and instruments to be cleaned.

Section 3.1-6.2.3.2: Seating Capacity

The requirement for seating capacity in a Waiting area should not be standardized. Waiting area capacity is an operational consideration which includes factors such as: on-time delivery of care, patient demographics, and/or the types of sedation/anesthesia used. The amount of seating needed is highly dependent upon the kinds of surgery performed and the length of procedures. We urge the Committee to remove this section from the guideline.

Section 3.1-7.2.2.3: Doors and Hardware

This section requires a non-standard 34-inch minimum clearance at doors. In the absence of compelling evidence that traditional 36-inch doors reduce occupant health or safety, the requirement should be amended to permit the most common door in the outpatient setting, 36 inches. A 36-inch door is fully compliant with National Fire Protection Association (NFPA) and the Americans with Disabilities (ADA) Act of 1990.

Similarly, the requirement for a 45.5-inch clear door opening for gurney transport is also excessive in most outpatient facility situations. A 44-inch wide door leaf (with an approximately 41-inch opening) has long been the acceptable minimum standard. Most outpatient gurneys are 30 to 32 inches wide. Even with side rails and attachments, gurneys are rarely greater than 36 inches wide. Requiring a 48-inch door is the largest door width allowed by NFPA codes. A 44-inch door should not be required unless special circumstances necessitate a greater door width.

Lastly, the requirement for 83.5-inch clear opening height (84-inch door) at any door in any outpatient facility is excessive as a minimum standard. In a majority of circumstances, a standard 80-inch high door (79.5 inch clear) is entirely adequate and appropriate.

We urge the Committee to eliminate these expensive non-standardize measurement requirements for doors in OSFs.

OUTPATIENT SURGERY FACILITIES

Section 3.7-3.4.1.1: Operating Room

Area

ASGE strongly opposes the significant increase in the proposed area from 250 to 400 square feet for an ASC operating room. The proposed square footage significantly exceeds the minimum clear area requirement for a great number of outpatient surgical procedures and will unnecessarily increase the cost of new facilities.

The justification for this "minimum" area requirement is significantly flawed. It assumes that all surgical procedures are of the same complexity, require the same equipment and/or accessories, or have the same number of personnel present. This justification also further assumes that all OSF procedures require a sterile field or an anesthesia cart, which is inaccurate. Moreover, the "circulator pathway" requirement assumes multiple personnel will be walking in opposite directions for the full perimeter of the surgical table – which is highly unlikely in an outpatient facility.

Given that there is no evidence that supports that an OR of this size is the only safe size in which to provide all outpatient surgical procedures, we urge the Committee to reconsider increasing the square footage required for an operating room.

Clearances

We are equally concerned about the minimum clearances that are proposed for around the operating table, gurney, or procedural chair. In most instances, the arrangement of equipment and work areas in an ASC operating room is determined by clinical need and physician preference. We strongly believe that fixed dimensions cannot be applied universally across all operating rooms and adherence to this amendment would be difficult to maintain. We request that the Committee provide justification for the need of this proposed requirement universally.

Operating Room for Surgical Procedures that Require Additional Personnel and/or Large Equipment

The proposed requirement outlined in A3.7-3.4.1.2 should be removed from the guideline. The mention of surgical specialties where a larger room would be required is arbitrary, and the phrase "some procedures" lacks clear definition to meet adherence of this amendment. While there are procedures from a variety of specialties that could benefit from more space, it is misleading to imply that an entire specialty should be taxed. We believe section 3.7-3.4.1.2 (1) is a more realistic and appropriate explanation that highlights potential need for larger ORs based clinical needs and/or risk.

Section 3.7-3.5.2: Support Areas In or Directly Accessible to Pre- and Postoperative Patient Care Area(s)

Nurse Station

This section is amended to require that the Nurse Station have a direct sightline to the patient in areas where Phase I services are provided. Due to the use of privacy curtains for these services, putting the Nurse Station in direct sightline does not provide any increased visibility of the patient. Without removing the privacy curtains, we believe that this requirement is not meaningful and does not increase the safety or the quality of care provided to the patient.

Section 3.7-3.5.2.9: Support Areas for Patients and Visitors

Patient Toilet Room

This section indicates that facilities with a one-room OR are not required to have a dedicated patient toilet in the staff controlled area. As written, this section would require patients to use

public toilets while under the effects of pre- or post-procedure sedation or anesthesia. This amendment as proposed is not in the best interest of the patient.

Section 3.7-3.6.1: Support Areas in the Semi-Restricted Area

Nurse Station

Section 3.7-3.6.1.1 states that "a nurse or control station(s) shall be located at the point of primary ingress, and access through all other entries shall be controlled." This amendment is ambiguous and does not clearly state what areas the ingress or access leads to. ASGE does not believe there is any evidence to support that the only acceptable location for a control station is immediately adjacent to ingress doors. In all instances the point of ingress may not be the best location for a nurse or control station, therefore, we request that this section be deleted.

Section 3.7-3.10.2: Patient Toilet Room

Location

Section 3.7-3.10.2.2 (c) states that the patient toilet room(s) shall be directly accessible to pre- and post-operative patient care areas(s). We request clarification on how a patient toilet would be "directly accessible" from both pre-op and post-op areas. Providing separate doors to these areas can be problematic as it relates to patient privacy and the ability of staff to remain aware of a patient's disposition. Several AECs have a linear flow from pre-op to the procedure room and out the other side to recovery. This design eliminates the availability of a patient toilet room to be "directly accessible", as the OR or procedure room is between the two areas.

ENDOSCOPY

Section 3.9-3: Diagnostic and Treatment Areas

General Purpose Examination Room

We are unclear of the role the General Purpose Examination Room referenced in section 3.1 would provide in an AEC. Most endoscopy patients have a comprehensive examination within 30 days of the procedure date. When an examination is required, for the procedure or anesthesia, it is typically conducted at the bedside. There is no need for a General Purpose Examination Room in a GI Endoscopy facility. Usage of such a room would mandate a change in the traffic flow of patient care and create a patient flow bottleneck without adding benefit to the process or patient experience.

Section 3.9-3.7: Support Areas for Staff

Toilet Facilities

This section requires that toilet facilities be directly accessible to the staff lounge. We believe that the requirement for a toilet to open directly in the staff lounge (immediately accessible) is

insensitive, as staff privacy and dignity may be challenged due to the location of the toilet facilities.

Section 3.9-5.1.2: Decontamination Area

As stated above in our comments regarding Section 3.1-5.1.3.2, ASGE does not believe a two-basin sink in addition to a hand washing station in the decontamination area should be universally required. As it relates to endoscopy equipment reprocessing, we are concerned that a two-basin sink may not allow sufficient bowl size for manual processes during our reprocessing process. Additionally, in stances where automatic scope reprocessing equipment and/or specialty sink equipment is utilized, the need for the sinks described is significantly reduced.

This section's requirement for an instrument air "outlet" in the decontamination area implies that there is a requirement for a central instrument air system per NFPA 99. The most common resource for compressed air is the use of portable cylinders. Requiring a central instrument air system increases the complexity and, therefore, the expense of an ASC without adding a measured benefit to the decontamination process.

Section 3.9-5.1.3: Clean Work Area

As previously stated, the requirement for an instrument air "outlet" in the clean work area implies that there is a requirement for a central instrument air system per NFPA 99. The most common resource for compressed air is the use of portable cylinders. Requiring a central instrument air system increases the complexity and, therefore, the expense of an ASC without adding a measured benefit to the process.

TABLES

Table 3.1-1 Electrical Receptacles for Patient Care Areas

Upon review, most of the requirements in this table are inconsistent with the NFPA 99 requirements. Most importantly, we believe that 36 receptacles in an OR is extensive and does not take into consider the size of the room or complexity of surgery to be performed. Additionally, post anesthesia recovery space is considered a critical area. Such a requirement forced on endoscopic ASCs, which prep and recover patients in a stretcher bay separated by curtains, would require the majority of front wall space on which to place 36 electric receptacles of which an overwhelming majority would never be used.

Table 3.1-2: Locations for Nurse Call Devices

This section is unclear and should be omitted until clarification is provided as to the meaning of each device type, along with the appropriate review period.

Table 3.1-3: Station Outlets for Oxygen, Vacuum, and Medical Air, and Instrument Air Systems in Outpatient Facilities

Instrument air is rarely provided in freestanding outpatient facilities. It is unreasonably expensive to provide instrument air from a central piped source. We request that the table be revised to allow the instrument air location column head to permit portable equipment in lieu of piped.

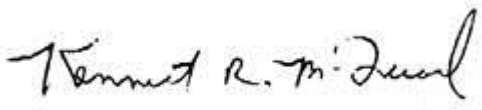
Table 3.1-5: Waiting Area Seating

The listed minimum ratios of patients per care position or treatment room are as likely to be low as they are to be high. The requirement for seating capacity in a Waiting area is more of an operational consideration verses universal or numerically quantifiable one. We request that this table be placed in the appendix or be deleted entirely.

CONCLUSION

ASGE believes that ASCs play a vital role in the health care system by providing efficient, cost-effective facilities that provide high-quality care to patients at economical costs. They have been doing so at remarkably high levels of safety while meeting current design and construction standards. Adoption of these proposed guidelines will place unwarranted financial burdens and overly burdensome compliance provisions on new ASCs in states that implement the guidelines. ASGE appreciates the opportunity to provide comments, and hopes that you consider the recommendations of our experienced physician endoscopists and practice administrators who are committed to assuring a safe high quality environment for GI endoscopy. Should you have any questions or seek additional information, please contact Lakitia Mayo, ASGE Senior Director of Health Policy, Quality and Practice Operations at lmayo@asge.org or (630) 570-5641.

Sincerely,



Kenneth R. McQuaid, MD, FASGE
President
American Society for Gastrointestinal Endoscopy