Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	55C0001059	02/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Fort Sutter Surgery Center, A Ca Limited Partnership	2801 K Street, Suite 525, Sacramento, CA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	**Summary Statement of Deficiencies** (Each deficiency should be preceded by full regulatory or LSC identifying information)
Q0241	SANITARY ENVIRONMENT CFR(s): 416.51(a) The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation, interview and document review, the Ambulatory Surgery Center (ASC) failed to maintain a sanitary environment when 1) A physician did not wear adequate surgical attire during a procedure, and 2) Air exchange measurements were unavailable for two surgical procedure rooms and other clinical areas. These failures potentially placed patients at risk for the development of surgery-related infections. Findings: 1. During an 11:57 a.m., 1/10/19 colonoscopy (test in which a tube with a camera is guided inside the large intestine to look for cancer or pre-cancerous conditions) performed on Patient 2, Medical Doctor 2 (MD 2) was observed without a mask for the duration of the approximately 30 minute-long procedure. The assisting Registered Nurse was noted to be wearing a mask.

In an 11:02 a.m., 2/1/10 interview, MD 2 stated that he chose not to wear a mask during the procedure. He denied any potential risk to Patient 2 from his not wearing a mask and noted that colonoscopy was not a procedure performed under sterile conditions.

Review of the ASC's 1/18/19 "Dress Code and Work Practices in the Clinical Setting" policy reflected, "The use of personal protective equipment (PPE) provided by the surgery center is required by all clinical staff as appropriate...Protective eyewear, masks or face shields...must be worn whenever staff is at risk for exposure to infectious materials as appropriate...."

Review of the 1/22/19 "Medical Staff Rules and Regulations indicated, "All practitioners must be familiar with and support the facility regarding the requirement for the ASC to maintain an ongoing infection control program...The...program must include documentation that the facility has...implemented nationally recognized infection control guidelines...The facility must provide a...sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice...Surgical masks...must be worn whenever splashes, spray, spatter, or droplets of blood, body fluids, or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated...."

PPE is required by the Bloodborne Pathogens Standard if exposure to blood and other potentially infectious materials (OPIM) is anticipated and where occupational exposure remains, after institution of engineering and work practice controls [29 CFR 1910.1030(d)(2)(i)].

During a 3:10 p.m., 1/29/19 interview, the designated Infection Preventionist, Nurse Manager 2 (NM 2), stated the ASC adhered to standards for infection prevention set by The Association of periOperative Registered Nurses (AORN) and the Association for Professionals in Infection Control and Epidemiology (APIC).

2019 AORN Guidelines' "Surgical Attire Recommendation I" reflects, "Clean surgical attire should be worn in the semi-restricted and restricted areas of the perioperative setting...The collective body of evidence supports wearing clean surgical attire in the perioperative setting to reduce the number of microorganisms in the environment..."

APIC's 2018 guidelines state, "Personnel should wear a clean surgical mask that covers the mouth and nose and is secured in a manner to prevent venting ...when preparing, performing or assisting with surgery and other invasive procedures... Surgical masks worn in the perioperative setting serve two purposes. First, they help

protect the patient and environment from microbial contamination by organisms carried in the provider's mouth or nose. Second, they provide protection for the wearer from exposure to...potentially infectious materials...."

The United States Department of Labor Occupational Health and Safety Administration's Bloodborne Pathogens Standard states that "PPE [personal protective equipment such as masks] is required...if exposure to blood and/or other potentially infectious materials (OPIM) is anticipated and where occupational exposure remains, after institution of engineering and work practice controls [29 CFR 1910.1030(d)(2)(i)]."

Review of Section 8.01 of the ASC's 4/26/17 "Governing Body Bylaws" reflected, "... the Governing Body will take all reasonable steps and develop policies to ensure that it and the Facility comply with all applicable federal, state and local laws and regulations, including...all applicable occupational health and safety regulations for health care workers, such as the Occupational Safety and Health Administration (OSHA) rules on Occupational Exposure to Bloodborne Pathogens."

2. Review of a 9/28/18 air handler testing report reflected, "The following is a list of rooms tested for...room airchanges [sic] per hour...ORs [Operating Rooms] - 1 thru OR - 5, G.I rooms 1 & 2 [gastrointestinal, rooms in which procedures involving the digestive tract were completed], Procedure rooms 1 & 2 [areas used for pain management procedures], Clean storage, and Sterile supply."

The report included no detail for air changes per hour (ACH) for the two pain procedure rooms. In addition, there was no documentation indicating ACHs were measured in the surgical instrument decontamination area, the gastrointestinal instrument reprocessing area and the Post-Anesthesia Care Unit (PACU, the after-surgery recovery area).

At 9:25 a.m., 2/1/19, the Administrator stated he would contact the company which performed the testing to obtain additional detail. No further information was provided during the survey.

2019 AORN Guidelines "Design and Maintenance Recommendation XII" states, "The health care organization should create and implement a systematic process for monitoring and maintaining structural surfaces and HVAC [heating/ventilation/air conditioning] system performance...Heating, ventilation, and air conditioning systems control room air quality...The HVAC system reduces the amount of environmental contaminants (eg, microbial-laden skin squames [flakes of dead skin tissue], dust, lint) in the surgical suite by carrying airborne contaminants away from the sterile field...."

	"Design and Maintenance Recommendation II.e.1 Table 3" reflected minimum air changes per hour standards for the following areas not documented as evaluated in the testing report: [pain] procedure rooms, sterile processing decontamination room, endoscope [gastrointestinal procedure instrument] cleaning room, and the PACU. Review of the ASC's 1/18 "IC [Infection Control] - Air Exchanges, Temperature and Humidity Settings in the Operating Room/Procedure Room" policy indicated, "An effective ventilation system is in place to minimize airborne microbial contamination... Operating [and surgical procedure] Room air exchanges will be at least 15 per hour. This will be measured and documented at least annually...." Additionally, review of the 4/26/17 "Indoor Air Quality" policy reflected, "[The ASC] will take adequate and reasonable measures to ensure that the facility's indoor air quality is safe...for its...patients...The air handling system will be maintained and operated in a manner that promotes a safe and health [sic] environment...A preventive maintenance program and documentation has been established, [sic] that will ensure that all HVAC systems are well maintained...Air balance must be operated correctly and efficiently...."