Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	051808	05/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ampla Health	355 Samuel Drive, Yuba City, 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)
J0044	PHYSICAL PLANT AND ENVIRONMENT CFR(s): 491.6(b)(3) The clinic . . . has a preventive maintenance program to ensure that: 491.6(b)(3) The premises are clean and orderly. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure supply storage, and instrument processing areas were clean, and orderly when: 1. Clean and dirty instrument processing areas were not clearly separated, and defined. 2. Manufacturers' instructions for use (IFUs) were not available for staff reference in the instrument processing area. 3. Disposable peel-open pouches used for sterilization of reusable instruments were expired, and being used past the manufacturer's beyond use date. 4. Sharp instruments were packaged for sterilization without tip protectors to prevent tips from penetrating through the peel-open pouches, and affecting the integrity of the package. 5. Unsterile unpackaged wooden tongue depressors (used for patient examinations) were being stored in clear glass canisters in each of the patient exam rooms. These failures had the potential for the sterile integrity of reusable instruments processed by the facility to be compromised, and tongue depressors to be contaminated during the removal from canisters, resulting in patient infections, and other negative clinical outcomes.

Findings:

The facility's policy and procedure titled, "Cleaning, Autoclaving & Sterilizing Procedure," dated 3/23/17, was reviewed, and indicated that the facility would ensure critical elements, and methods of decontamination, disinfection, and sterilization were incorporated into practice and procedures.

1. During a concurrent observation, and interview, on 5/13/21 at 9:55 am, with the Nursing Supervisor (NS), the facility's reusable instrument reprocessing area was observed. A table top steam autoclave (used to sterilize reusable instruments) was observed to the left of the dirty instrument washing sink. A defined barrier between clean and dirty instrument processing areas was not evident. The NS confirmed the proximity of the autoclave to the dirty sink was not ideal, and could result in contamination of the sterilizer, and any clean or sterile items on the adjacent counter-top with contaminated droplets when washing instruments in the sink.

The Centers for Disease Control and Prevention (CDC), "Sterilizing Practices Guideline for Disinfection and Sterilization in Healthcare Facilities, dated 2008, was reviewed, and indicated that the central processing area(s) should be divided into at least three areas; decontamination, packaging, and sterilization and storage.

2. During a concurrent observation, and interview, on 5/13/21 at 10:10 am, with the NS, the instructions for reprocessing of reusable instruments were noted not to be posted, or available to staff in the instrument reprocessing area. The NS was asked to provide the manufacturer's instructions for use (IFUs) for reprocessing the facility's reusable instruments. The NS stated the facility primarily purchased instruments from one manufacturer, but did not have the IFUs for staff to reference when reprocessing the instruments.

The Centers for Disease Control and Prevention (CDC) "Sterilizing Practices Guideline for Disinfection and Sterilization in Healthcare Facilities, dated 2008, was reviewed, and indicated that instruments should be prepared, and sterilized according to device manufacturer's instructions.

3. During a concurrent observation, and interview, on 5/13/21 at 10:00 am, with the NS, three boxes of peel-open pouches used for packaging and sterilizing reusable instruments were observed. All three boxes had manufacturer expiration dates that were past the manufacturer beyond use date. The boxes contained three sizes of peel-open pouches:

7 1/2 inches (") x 13", expired 8/23/20.

5 1/2 x 10", expired 8/2017.

3 1/2" x 9", expired 11/22/20.

The NS confirmed the peel-open pouches were expired, and should be removed from use.

4. During a concurrent observation, and interview, on 5/13/21 at 10:10 am, with the NS, the storage of sterile reusable instrument in peel-open pouches was observed. Two of the four peel-open pouches observed contained sharp tipped scissors. Tips of

	the scissors were not protected to prevent penetration through the sterilization pouch. The NS confirmed the tips of the scissors could poke through the peel-open pouch, resulting in contamination of the scissors. The facility's policy and procedure titled, "Cleaning, Autoclaving & Sterilizing Procedure," dated 3/23/17, was reviewed, and indicated that instruments that have sharp points or other parts which might puncture the wrapping will have 2x2 or 4x4 folded over the pointed, or sharp areas. 5. During a concurrent tour of the facility and interview, on 5/13/21 from 9:05 am to 10:32 am, with the Site Administrator (SA) and the NS, the facility's 18 patient exam rooms were observed. Unsterile disposable wooden tongue depressors were observed in clear glass canisters with silver colored lids on the countertops. When questioned about the aseptic removal of a tongue depressor from a canister without touching, and cross-contaminating other tongue depressors, both the SA, and the NS confirmed the practice to be a possible infection control issue. The SA stated the practice would be corrected by purchasing individually packaged tongue depressors to be placed in each room instead.