Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	051117	12/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
County Of Stanislaus	401 East Paradise Road, Ste E, Modesto, 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)
J0152	PATIENT HEALTH RECORDS CFR(s): 491.10(a)(3)(i)-(iv) 491.10(a) Records system. (3) For each patient receiving health care services, the clinic . . .. maintains a record that includes, as applicable: (i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient; (ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings; (iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress; (iv) Signatures of the physician or other health care professional. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure an informed consent was completed prior to conducting a scheduled procedure for one of two sampled Patients (Patient 1), when facility did not obtained an informed consent (is a document in which a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure) which was signed by the physician or Patient 1 that would educate Patient 1 of potential risk and benefits of the procedure. This Failure resulted in Patient 1 not consenting to procedure, not being informed of risks, benefits or potential side effects and received a second degree burn (affects first and second layer of the skin) on right upper arm. Findings: During an interview on 8/16/23 at 2:00 p.m. with Patient 1, Patient 1 stated the facility was treating him for wart removal with application of liquid nitrogen (cold liquid used

to freeze and remove diseased skin) which resulted in pain, bruising, and blistering of the area. Patient 1 stated prior to and after the procedure the risks and benefits or potential side effects were not explained, and he did not sign a consent form. Patient 1 stated he felt, the liquid nitrogen was left on his wart site too long causing damage to the surrounding skin. Patient 1 stated he proceeded to go to the Urgent care for further treatment following the procedure. Patient 1 stated he was diagnosed with second degree burn to surrounding skin of the wart site during the Urgent Care visit.

During a review of Patient 1's "California Urgent Care Transcription", dated 7/29/23, the Transcription indicated, "...Patient 1... Diagnosis: Burn of second degree of right upper arm... Burn of first degree (burn that affects the outer layer of the skin) of right forearm...cellulitis (bacterial infection of the skin) of right upper limb...viral wart..."

During a review of Patient 1's "Late Entry-Procedure Note", dated 7/28/23, the Procedure Note indicated, "...The patient complains of redness, irritation, tenderness and swelling ... indication: inflamed lesion ... consent signed: no ...Comment: consent signed on 7/14/23 ...Procedure #1: wart destruction ... Technique: liquid N2 (Nitrogen)..."

During concurrent interview and record review on 8/17/23 at 9:45 a.m. with Registered Nurse Manager (RNM), "Office Visit" dated 7/28/23, was reviewed. The "Office Visit" indicated, Patient 1 was treated for wart to the right elbow with use of liquid nitrogen. RNM stated, the process for the use of liquid nitrogen for treatment of a wart included the completion of an informed consent for every visit requiring the use for this treatment. RNM stated the process was for the informed consent to be reviewed with the Patient by a medical assistant, then the Medical Provider will inform the Patient of the risk and complications associated with the use of liquid nitrogen.

During an interview on 8/17/23 at 11:35 a.m. with Medical Assistant (MA), MA stated the process of using liquid nitrogen for treatment included obtaining an informed consent from the patient prior to the procedure. MA stated the process was for the Physician to educate the patient of risks and complications because the procedure cannot be done unless there was a consent.

During an interview on 8/17/23 at 11:53 a.m. with Registered Nurse (RN), RN stated the MA and physician would obtain informed consent prior to any procedure requiring a consent. Procedures were completed after the consent was signed by the patient and the Physician.

During concurrent interview and record review on 8/17/23 t 12:20 p.m. with Nurse Practitioner (NP), the facility's policy and procedure (P&P) titled, "Consent Clinic Procedures-No Sedation" dated 11/05, and facility's policy titled, "Informed Consent" undated were reviewed. The P&P indicated, "...the medical staff shall be responsible for determining those procedures that in nature are requiring written consent ..." The P&P for informed consent indicated, " ... a separate consent is required for all procedures ..." NP stated she did not know that a consent form was needed for every procedure and that she was unaware that it was written in the facility P&P. NP stated if the patient was going to the facility for a follow up appointment for the treatment involving use of liquid nitrogen, another consent form was not needed since the patient signed a consent in their prior office visit.

During an interview on 8/18/23 at 11:45 a.m. with Physician Assistant (PA), PA

	stated she was the preceptor for the NP and asked her to perform a procedure with the use of liquid Nitrogen for Patient 1 on 7/28/23. PA stated NP was made aware after the procedure was completed that no consent form was obtained. PA stated the possible side effects of liquid Nitrogen use included possible bruising and blistering of surrounding skin to application site, and Patient 1 would have been aware of those side effects if education was provided during the consent process. PA stated NP needed to be trained on obtaining informed consent as she was new and was not aware a consent was needed prior to a follow up procedure. During a review of facility policy and procedure (P&P) titled, "NP/PA Procedure and Minor Surgery and competency Documentation for Advance Practice Nurse (APN) and Physician Assistant (PA)" dated 5/3/2018, indicated, "...Policy...b. Patients sign appropriate consents before procedures are performed...c. Patients are given verbal/or written aftercare information.....d. All other applicable standardized procedures relative to procedures outlined in this policy and procedure are followed during patient management..."