



TOMÁS J. ARAGÓN, M.D., Dr.P.H.  
State Public Health Officer & Director

State of California—Health and Human Services Agency  
**California Department of Public Health**



GAVIN NEWSOM  
Governor

Jul 01, 2024

Cheryl Zuniga  
Children's Hospital of Orange County  
1201 W La Veta Ave  
Orange, CA 92868

**FACILITY: Children's Hospital of Orange County, LICENSE # 060000011**

**APPROVAL OF PROGRAM FLEXIBILITY FOR FLEX-9645**

Dear Cheryl Zuniga,

This letter is in response to the request submitted by **Children's Hospital of Orange County** for program flexibility for California Code of Regulations T22 DIV5 CH1 ART3-70223(g).

The alternative means of compliance with T22 DIV5 CH1 ART3-70223(g) include

CHOC hospital is requesting program flexibility for the exemption of anatomical parts, tissues and foreign objects from the Pathologist's examination and review. The hospital has exceptions for submitting specimens to pathology that has been approved by the clinical & medical staff, pathologists, and governing board. The exceptions were selected based upon current professional protocols, guidelines, and standards. The surgeon may choose to submit any of the specimens that have been outlined on the exemption request if clinical presentation indicates further studies.

Your request for program flexibility of **T22 DIV5 CH1 ART3-70223(g)** is approved under the following conditions:



- Hospital will ensure that pathology specimen-related policy(s) and procedure(s) will be written and updated jointly by the medical/clinical staff and pathologist(s) and approved by the Medical Executive Committee and governing body.
- Hospital will ensure that the policies and procedures are consistent with the most current version of professional standards, such as College of American Pathologists protocols & guidelines, Association of Surgical Technologists (AST) standards of practice, and The Joint Commission (TJC) standards (QSA 13.01.01 EP2).
- Hospital will adhere to the Safe Medical Devices Act (SMDA) of 1990 and U.S. Food and Drug Administration (FDA) regulations.
- Hospital will ensure that the pathology exemptions are exercised at the discretion of the surgeon or physician; the surgeon or physician having examined the specimen and having concluded that further examination would not contribute to quality and safety in patient care.
- Hospital will have an alternative procedure for documenting the removal and disposition of any specimens or devices not submitted to pathology for examination.
- Hospital will ensure that any specimen not submitted for pathology will be adequately described in the patient's health record to include, at a minimum, the location & laterality of the specimen, size, color, and shape of the tissue.
- Hospital will act in the best interest of the patient when evaluating whether to send a specimen to pathology.
- Hospital will ensure that all staff, including surgeons, physicians, and others who obtain, process, and send specimens to pathology are trained/notified on these policies and procedures.
- Hospital will maintain a record of the date, training content/notification message, and staff trained/notified. This record will be available to the California Department of Public Health upon request.

Either this letter or a true copy thereof shall be posted immediately adjacent to the facility's license.

This approval shall remain in effect from Jul 01, 2024 until Jun 30, 2027.

**NOTE:** The Department may revoke the program flexibility if the licensee does not comply with the conditions set forth in the approval or if the department determines the proposed alternative does not adequately meet the intent of the regulations.

If you have any questions, please contact Centralized Program Flex Unit at (916) 323-5053 or by email at [CentralizedProgramFlex@cdph.ca.gov](mailto:CentralizedProgramFlex@cdph.ca.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Banks', written over a horizontal line.

Sevrine A. Banks, Program Manager  
Centralized Program Flex Unit