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State Public Health Officer & Director

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



GAVIN NEWSOM
Governor

Jan 24, 2024

Daniel Price
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-7646

Dear Daniel Price,

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 ART6-70435(b)(2), T22 DIV5 CH1 ART6-70435(b).

The alternative means of compliance with T22 DIV5 CH1 ART6-70435(b)(2), T22 DIV5 CH1 ART6-70435(b) include

Both the Registered Nurse (RNFA) and Physician Assistant shall have training and experience in the performance of second surgical assistance in cardiac surgery.

Your request for program flexibility of **T22 DIV5 CH1 ART6-70435(b)(2), T22 DIV5 CH1 ART6-70435(b)** is approved under the following conditions:

- Hospital and providers shall follow the cardiovascular surgery standards of care, standards of practice and accepted guidelines for the health and safety of the patient.

Center for Health Care Quality
Centralized Program Flex Unit (CPFU)
P.O. Box 997377 MS 3405 Sacramento, CA 95899-7377
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- Hospital is required to have a 3-team cardiovascular (CV) surgical team in the Operating Room (OR).
- Hospital must ensure the primary surgeon and first assist must be independent and fully qualified surgeons. The third member may be a Physician Assistant (PA) Nurse Practitioner (NP) or Registered Nurse First Assist (RNFA) who is qualified, trained and experienced in CV procedures. A PA, NP or RNFA cannot be the first assist for CV operative procedures.
- Hospital must ensure that, at a minimum, one surgeon will be certified or eligible for certification by the American Board of Thoracic Surgery or the American Board of Surgery with training and experience in cardiovascular surgery and shall be present during the operative case.
- Hospital is required to adopt standards, and policy and procedures for special cardiovascular services to implement this process regarding the cardiovascular surgery team, cardiovascular surgical staff requirements, and cardiovascular procedures that reflect the current standard of care and guidelines from Society of Thoracic Surgeons, American College of Surgeons, and American College of Cardiology. These policies shall include the following:
 1. There are bylaw regulations approved by the Medical Staff Committee and Governing Board for credentialing qualified PA, NP or RNFA.
 2. There are delineated privileges and duties that the PA, NP or RNFA shall perform with roles and qualifications clearly defined.
 3. Annual review on all qualified non-surgeon used in this capacity will include letters of competency from the supervising physician and routine chart reviews will be conducted.
 4. The PA, NP or RNFA substituting for the third surgeon must meet the requirements found in Section 70706 et al and 70706 1(b), Title 22, California Code of Regulations (CCR). *The hospital must maintain evidence of the PA, NP or RNFA competency to function as the three CV team member/second assist. *The hospital must continue to follow the requirements outlined in 70435(b)(1).
 5. Policies are developed by the person responsible for the cardiovascular surgery service in consultation with other appropriate health professionals. These policies must describe the medical and surgical criteria which determines the qualifications of the PA, NP or RNFA who replaces the third surgeon, including assessing clinical competence and specific privileges while acting as the third surgeon. The governing body shall approve policies; the medical staff and administration shall approve procedures.



- Hospital will ensure that while in the operating room, the PA, NP or RNFA shall perform or assist in those specific privileges or procedures approved by the credentialing process only under the direct supervision of the primary surgeon.
- Hospital will ensure as part of the hospital's on-going quality assurance program, a methodology for periodic evaluation of the effectiveness of this alternate method shall be developed. There shall be provisions for recommendations to be made to the administration and medical staff and any follow-up action.
- Hospital will maintain a plan for orientation of personnel as deemed appropriate to hospital policies and procedures, professional standards, and statutory and regulatory requirements.

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 Jan 24, 2024 until Jan 23, 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.

Sincerely,



Sevrine A. Banks, Program Manager
Centralized Program Flex Unit