



Erica Pan, MD, MPH
Director and State Public Health Officer

Gavin Newsom
Governor

Aug 10, 2026

Maggie Barsoum
Rady Children's Hospital Orange County
1201 W La Veta Ave
Orange, CA 92868

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

APPROVAL OF PROGRAM FLEXIBILITY FOR FLEX-15260

Dear Maggie Barsoum,

This letter is in response to the request submitted by **Rady Children's Hospital Orange County** for program flexibility for California Code of Regulations T22 DIV5 CH1 ART6-70438.1(b).

The alternative means of compliance with T22 DIV5 CH1 ART6-70438.1(b) include

The proposed alternate method is to permit the use of the cardiac catheterization laboratory for the performance of cardiac catheterization procedures in accordance with established clinical protocols. The procedures are listed below:

1. Cardiac catheterization right; Percutaneous stent placement, right ventricular conduit.
2. Cardiac catheterization left; Percutaneous stent placement, pulmonary artery.



3. Cardiac catheterization, right and left; Percutaneous stent placement, pulmonary vein.
4. Coronary angiography; Percutaneous stent placement, aorta.
5. Pericardiocentesis; Percutaneous stent placement, ductus arteriosus.
6. Endomyocardial biopsy; Embolization of other vascular structure.
7. Transcatheter closure of patent ductus arteriosus.
8. Pulmonary vasodilator testing.
9. Transcatheter closure of atrial septal defect.
10. Drug study with hemodynamic or electrophysiology recording.
11. Transcatheter closure of Fontan fenestration.
12. Umbilical vein catheterization.
13. Percutaneous replacement of pulmonary valve.
14. Umbilical artery catheterization.
15. Atrial septostomy.
16. Central venous catheterization with Fluoroscopy.
17. Transcatheter closure of ventricular septal defect; hybrid Stage I palliation for Hypoplastic left heart syndrome.
18. Hybrid periventricular closure of ventricular septal defect.
19. Percutaneous balloon pulmonary valvuloplasty.
20. Hybrid access for catheterization procedure.
21. Percutaneous balloon aortic valvuloplasty.

22. Fluoroscopy of mechanical heart valve.
23. Percutaneous balloon tricuspid valvuloplasty.
24. Insertion of peripherally inserted central venous catheter (PICC).
25. Percutaneous balloon mitral valvuloplasty.
26. Transthoracic echocardiogram.
27. Percutaneous stent placement, systemic vein.
28. Electrophysiology study, with mapping.
29. Catheter radiofrequency ablation.
30. Catheter cryoablation.
31. Transvenous lead placement, permanent pacemaker.
32. Extraction of transvenous pacemaker lead.
33. Insertion of temporary transvenous pacemaker.
34. Revision/relocation of pacer or implantable event recorder pocket.
35. Insertion of pacemaker pulse generator.
36. Removal of pacemaker pulse generator.
37. Insertion of Automatic Implantable Cardioverter Defibrillator (AICD).
38. Replacement AICD pulse generator.
39. AICD testing.
40. Implantation of loop recorder.
41. Removal of loop recorder.
42. Cardioversion.

Your request for program flexibility of **T22 DIV5 CH1 ART6-70438.1(b)** is approved under the following conditions:

1. Facility must maintain Cardiac Catheterization Laboratory Services in the hospital quality assurance program.
2. The facility must maintain a set of admission/screening criteria (developed from a "Clinical Risk Assessment" as described in the HCAI Advisory Guide Series A10) to determine if the current condition of each patient is appropriate for performing each procedure in the CCL. This criteria must be consistent with professional standards such as the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions.
3. The facility must maintain compliance with Title 22 section 70438.1(c) and the Title 22 sections listed in the section, including: Title 22 sections 70433(a), (b), (c)(1), (e), (i), (j), 70435a) and 70437(a).
4. Facility shall continue to comply with adverse events and unusual occurrence reporting requirements specified in HSC section 1279.1 and Title 22 CCR section 70737(a).
5. Facility shall perform the alternative concept in accordance with recognized professional standards, such as Society for Cardiovascular Angiography and Interventions (SCAI).
6. Facility must follow hospital policies and procedures related to radiological service, surgical service, cardiovascular surgery service and cardiac catheterization laboratory service as well as infection prevention and control.
7. Facility must maintain adequate space in each CCL room to accommodate staff, equipment, supplies and to maintain unobstructed pathways of ingress and egress for patient, staff, and equipment and to meet patient care needs.
8. Facility must assign responsibility and tasks to staff within the scope of licensure, experience, and competence. The physician who performs the

procedures must be adequately trained with an adequate annual volume of each of the above procedures to maintain competency.

9. Facility shall continue to provide necessary care in accordance with patient needs and make all reasonable efforts to act in the best interest of patients.
10. Facility must maintain cardiovascular surgery service on the hospital license.

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 Aug 10, 2026 until Aug 09, 2029.

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,



Danielle Boles, Program Manager
Centralized Program Flex Unit