



Criteria also available in tabular format on the PHCC website (www.PHCareCenters.org)

Full appendix of abbreviations available on Page 7

Pediatric Regional Clinical Program (RCP) Criteria

I. PR1. RCP Director

- Pediatric RCP *must* have a Center Director who has the following attributes:
 - **PR1.1** *Must* be Board Certified in Pediatric Pulmonary Medicine, Critical Care Medicine, Cardiology, or Neonatology
 - a. Documentation of specialty certification *must* be on file
 - **PR1.2** *Must* have a minimum of 2 years of experience treating pediatric PH and actively be managing a substantial cohort of PAH patients under the age of 18
 - a. One of the years may have been specialized fellowship training in pulmonary hypertension
 - **PR1.3** The Center's director *must* have ≥ 0.25 FTE dedicated to the PH program
 - a. *If using parental prostacyclins*, Director *must* have ≥ 0.5 FTE dedicated to PH program
 - **PR1.4** *Must* be an active participant in the PH community beyond the institution within the preceding 3 years, as exemplified by the following:
 - a. Membership on a PH-related Committee/Taskforce sponsored by at least a regional organization or society
 - b. Membership on an Organizing/Steering Committee for PH-related activities sponsored by at least a regional organization or society
 - c. Involvement in community outreach (patient support groups, schools, fundraising, etc.)
 - d. Participation in PH-related committee work
 - e. Presenting/Speaking on PH-related topics at scientific meetings
 - **PR1.5** *Must* be involved in PH-related education at Center within the preceding 3 years as exemplified by some of the following endeavors:
 - a. Overseeing the education of Center and hospital staff by program staff
 - b. Mentoring trainees at the PH Center, if applicable
 - **PR1.6** *Must* have attended at least one PH-focused meeting in the previous 3 years (e.g., PHA International Conference, regional CME meetings, post-graduate courses)
 - **PR1.7** *Must* be a member of Pulmonary Hypertension Clinicians and Researchers (PHCR)
 - **PR1.8** *Must* have completed 25 hours of CME related to PH over the past 3 years (attending and/or presenting)
 - **PR1.9** Transitional Directors: If the Center's Director leaves the Institution, the new

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Director *should* meet the criteria outlined in section PR1

- a. If the criteria are not met, these will be reviewed on a case-by-case basis taking into consideration years of experience and other program-related factors
- b. The Program may need to transition to “Program Under Review” status until criteria can be met

II. **PR2. RCP Clinical Coordinator**

- Pediatric RCP *must* have a designated coordinator who has the following attributes:
 - **PR2.1** *Must* be an RN, NP, PA, RRT, or Pharmacist
 - a. Coordinator *must* be employed by the Center, practice, or parent institution.
 - b. Coordinator’s position within the Center *must* be ≥ 0.25 FTE*
 - i. *If administering parenteral therapies*, the coordinator’s position within the Center *must* be ≥ 0.5 FTE*

*See Section PR3.1 (Program Staff and Support Services) for total requirement for coordinator support
 - **PR2.2** *Must* be proficient in the disease state and with all non-parenteral PH therapies
 - a. *Must* be knowledgeable about the approval, initiation, and maintenance of all PH therapies prescribed by the program
 - b. *If administering parenteral therapies*, Center staff *must* provide primary management of parenteral therapy
 - **PR2.3** *Must* be an active participant in the PH community beyond the institution within the preceding 3 years, as exemplified by the following:
 - a. Membership on a PH-related Committee/Taskforce sponsored by at least a regional organization or society
 - b. Membership on an Organizing/Steering Committee for PH-related activities sponsored at least a regional organization or society
 - c. Promotion of medical and general community disease awareness
 - d. Regular involvement in PH support group activities
 - e. Presenting/Speaking on PH-related topics at scientific meetings
 - **PR2.4** *Must* be involved in PH-related education at the Center within the preceding 3 years, as exemplified by some of the following endeavors:
 - a. Overseeing the education of Center and hospital staff
 - b. Educating allied health care practitioners
 - **PR2.5** *Should* have attended at least one PH-focused meeting in the previous 3 years (e.g., PHA International Conference/PHPN Symposium, regional CME meetings, post-graduate courses)
 - **PR2.6** *Must* be a member of the Pulmonary Hypertension Professionals Network (PHPN)
 - **PR2.7** *Must* have completed 12 hours of CME/CEU related to PH over the past 3 years

III. PR3. Program Staff and Support Services

Please refer to the application instructions and/or document checklist for a comprehensive list of required letters of support from support services

- **PR3.1** Outpatient coordinator and support staff *must* be commensurate with the Center’s total volume and complexity of patients
 - a. The Center must have adequate support to manage patients on parenteral therapies if provided by the Center
 - b. Coordinator FTE requirement can be satisfied by more than one person, but one individual *must* be the Center’s designated “Lead Coordinator” and fulfill all criteria in Section PR2
- **PR3.2** The Center *should* be actively managing a minimum of 25 PH patients with at least 10 patients classified as Group I PAH based on current diagnostic criteria
 - a. The accreditation application will contain instructions for creating a Group I and IV PH and Group III PH patient roster that will be reviewed during the accreditation visit
 - i. All patients included on the patient rosters *should* have been seen and actively managed in the preceding 4 years for initial accreditation and in the preceding 3 years for reaccreditation
- **PR3.3** *Must* have proficiency and experience with all non-parental PAH therapies
 - a. *Experience administering parenteral prostacyclin therapy is NOT required of a pediatric RCP*
- **PR3.4** *Must* follow available diagnosis and treatment consensus guidelines, when possible, for example:
 - a. V/Q scan or alternative perfusion imaging techniques (such as dual energy CT, MRI perfusion, etc.) to exclude CTEPH, if clinically suspected
 - b. RHC to confirm PH diagnosis
 - c. Acute vasodilator testing in guideline recommended subgroups of PH patients (or document valid reason for not performing in each case)
 - d. Risk assessment performed and documented at regular intervals
- **PR3.5** When appropriate, the Center collaborates and co-manages patients with a regional pediatric CCC for advanced medical therapies, advanced surgical interventions, and investigational protocols
 - a. Use of any prostacyclins *should* be in accordance with the Collaborative Care letter of support agreement by a pediatric CCC
 - b. Centers that manage parenteral prostacyclins *must* have support services equivalent to that of a pediatric CCC
 - c. De-identified list of patients, which includes the PH diagnosis, route of parenteral agent administered (IV or SQ), the period of infusion, and the most recent dose of medications will be requested and reviewed in accreditation application
- Pediatric RCP *must* have the resources/consultants outlined in criteria 3.6 – 3.15 available:
 - **PR3.6** PH provider on call 24/7 (may include PH physician, nurse or PA)
 - a. Members of the PH Program *must* be directly involved daily with care of the

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Center's inpatients

- i. If in-person involvement of the PH team is not available, patients *should* be seen in-person by the pulmonary or cardiology service
 - ii. PH team *must* be available for consultation daily
- **PR3.7** Pediatric Rheumatology consultants
 - **PR3.8** Pediatric Pulmonary consultants
 - **PR3.9** Pediatric Anesthesia with extensive PH experience
 - **PR3.10** Pulmonary/Cardiac Transplant Service through an established referral process via CCC collaboration
 - **PR3.11** Congenital Heart Disease Specialist
 - **PR3.12** Pediatric Surgery consultants
 - **PR3.13** Neonatal/Pediatric Critical Care Services for the management of infants and children with all forms of PH (includes PPHN, BPD, CLD, CDH)
 - **PR3.14** *If providing parenteral therapies, must* have experienced central line placement and repair personnel with PH experience (e.g., pediatric surgery, interventional cardiology, interventional radiology)
 - a. *Must* have written protocol for transition of parenteral prostacyclin therapy to a new central line
 - **PR3.15** Palliative Care Service. Should have both inpatient and outpatient services
- Pediatric RCP *should* have the resources/consultants outlined in criteria 3.16 – 3.17 available:
- **PR3.16** Social Work
 - a. *SW should* be designated to the PH program and be a consistent resource for the Center staff but does NOT have to be exclusively assigned to the program
 - b. The institution *must* provide resources for financial assistance and assistance in obtaining insurance for patients who are uninsured or underinsured
 - **PR3.17** Dietary/Nutrition Services
 - a. Dietitian does not have to be dedicated to the PH Program

IV. PR4. Facility

Please refer to the application instructions and/or document checklist for a comprehensive list of required letters of support from facilities

- **PR4.1** *Must* have written protocols for managing inhaled prostacyclins
- **PR4.2** On-site ability to deliver inhaled Nitric Oxide
- **PR4.3** *If providing parenteral therapies, must* have inpatient pediatric wards and ICU facilities, including NICU and PICU (within the affiliated hospital), with staff who are specially trained in managing PAH and chronic prostacyclin infusions
 - a. *Must* have written protocols for managing parenteral prostacyclins
 - b. *Must* have formal ongoing training in the management of PH for all staff involved in the care of PH patients (e.g., nursing, respiratory therapy, pharmacy), which must be documented

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- c. *Must* have a protocol for immediate notification of PH team for patients who present to the Emergency Department
- **PR4.4** *Must* have a cardiac catheterization laboratory
 - a. *Must* have experience with acute vasodilator testing using guideline recommended vasodilator agents
 - b. Either the PH Program Director or a designated physician *should* be involved* in the catheterization procedures
 - * involved = performs or presides over RHC and must personally review tracings.
 - c. *Must* have a written protocol for performing RHCs for PH patients, including for all provocative challenges
 - d. There *should* be systematic communication between the ordering provider and the proceduralist to discuss the need for any provocative testing for each case
- **PR4.5** *Must* have an echocardiography laboratory with experience in PH
 - a. The echocardiography laboratory *should* have accreditation by the Intersocietal Accreditation Commission
- **PR4.6** *Must* have a Pulmonary Function Laboratory
- **PR4.7** *Must* be able to perform Exercise Testing (e.g. 6 Minute Walk, CPET, or submaximal exercise test [SHAPE])
 - a. For the 6 Minute Walk Test, the protocol *must* conform to ATS recommendations for its performance
- **PR4.8** *If providing parenteral therapies, must* have a pharmacy with immediate access to parenteral prostacyclin
 - a. Pharmacy staff *must* be proficient with preparation of prostacyclin infusions
- **PR4.9** The pharmacy *must* have a process for obtaining non-formulary PH medications when needed
- **PR4.10** *Must* have a Pediatric Radiology department with expertise in PH
- **PR4.11** *Must* have a multi-disciplinary group for diagnosis and management of patients with CTEPH or an established referral process
 - a. Patients undergoing PTE or BPA will be reviewed during accreditation chart review
- **PR4.12** *Must* have system in place to assure patient confidentiality
- **PR4.13** *Should* accept patients insured by governmental insurance
- **PR4.14** *Should* have the ability to transfer patients via an expedited route
- **PR4.15** *Must* have Institutional support for the PH Program

V. **PR5. Research** (*not mandatory for Pediatric RCP accreditation*)

- If Pediatric RCP is conducting research, the Center *should* have the following resources available as outlined in criteria 5.1-5.4:
 - **PR5.1** If the Program does not offer a study for a particular PH group, referral to another Center conducting an appropriate trial *should* be considered

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- **PR5.2** *Must* have knowledgeable research staff (i.e. study coordinator) with participation in at least one phase 2 or 3 clinical investigation and/or non-industry investigation in the past 3 years
 - a. Program research staff (physicians and coordinators) *must* meet IRB requirements to conduct research
- **PR5.3** *Should* have access to an Investigational Drug Service that stores, prepares, and dispenses investigational medications
- **PR5.4** *Must* have institutional IRB or the ability to use outside (central) IRB

End of PEDIATRIC RCP Criteria

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Appendix:

Abbreviations:

BPD – bronchopulmonary dysplasia
CCC – Comprehensive Care Center
CDH – congenital diaphragmatic hernia
CEU – continuing education unit
CLD – chronic lung disease
CME – continuing medical education
CTEPH – chronic thromboembolic pulmonary hypertension
FTE – full time employment
IRB – institutional review board
IV – intravenous
NP – nurse practitioner
PA – physician assistant
PAH – pulmonary arterial hypertension
PH – pulmonary hypertension
PHA – Pulmonary Hypertension Association
PHCC – Pulmonary Hypertension Care Center
PHCR – Pulmonary Hypertension Clinicians and Researchers
PHPN – Pulmonary Hypertension Professionals Network
PPHN – persistent pulmonary hypertension in the newborn
PTE – pulmonary thromboendarterectomy
RCP – Regional Clinical Program
RN – registered nurse
RHC – right heart catheterization
RRT – registered respiratory therapist
SQ – subcutaneous
SW – social work