



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

Full appendix of abbreviations available on Page 7

Pediatric Center of Comprehensive Care (CCC) Criteria

I. PC1. CCC Director

- Pediatric CCC *must* have a Center Director who has the following attributes:
 - **PC1.1** *Must* be Board Certified in Pediatric Pulmonary Medicine, Critical Care Medicine, Cardiology, or Neonatology
 - a. Documentation of specialty certification *must* be on file
 - **PC1.2** *Must* have a minimum of 4 years of experience treating pediatric PH and be *actively* 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
 - **PC1.3** Director's efforts towards PH program *should* be ≥ 0.50 FTE. This can be satisfied by more than one person (i.e., Co-Directors)
 - a. If the Center has Co-Directors, each *must* individually fulfill the Director criteria
 - **PC1.4** *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
 - **PC1.5** *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 Center, if applicable
 - **PC1.6** *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)
 - **PC1.7** *Must* be a member of Pulmonary Hypertension Clinicians and Researchers (PHCR)
 - **PC1.8** *Must* have completed 25 hours of CME related to PH over the past 3 years (attending and/or presenting)
 - **PC1.9** Transitional Directors: If the Center's Director leaves the Institution, the new

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Director *should* meet the criteria outlined in section PC1

- 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. PC2. CCC Clinical Coordinator

- Pediatric CCC *must* have a designated coordinator who has the following attributes:
 - **PC2.1** *Must* be an RN, NP, PA, RRT, or Pharmacist
 - a. Coordinator *must* be employed by the Center, practice, or parent institution
 - b. Lead coordinator’s position within the Center *should* equal ≥ 0.5 FTE*
* See section PC3.2-3.3 (Program Staff and Support Services) for total requirement for coordinator support
 - **PC2.2** *Must* be proficient in the disease state and with all PH therapies (oral, inhaled, IV/SQ) and delivery devices
 - a. *Must* be knowledgeable about the approval, initiation, and maintenance of all PH therapies
 - b. Reliance of the Center on Specialty Pharmacy personnel to manage parenteral therapies in their PAH patients is not acceptable
 - **PC2.3** *Must* be an active participant in 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. 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
 - **PC2.4** *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
 - b. Educating Allied Health Care Practitioners
 - **PC2.5** *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)
 - **PC2.6** *Must* be a member of the Pulmonary Hypertension Professionals Network (PHPN)
 - **PC2.7** *Must* have completed 12 hours of CME/CEU related to PH over the past 3 years

III. PC3. 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

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- **PC3.1** Physicians' combined effort towards PH program, including clinical care, clinical research, and administrative duties, *must* total ≥ 0.75 FTE
- **PC3.2** PH Coordinators' total FTE requirement *must* be ≥ 1.0 . This can be satisfied by more than one person, but one individual *must* be the Center's designated "Lead Coordinator" and fulfill all remaining criteria in Section PC2
- **PC3.3** Outpatient coordinator and support staff *must* be commensurate with the Center's volume of complexity patients
- **PC3.4** The Center *should* be actively managing a minimum of 75 PH patients with at least 50 patients classified as Group I PAH and at least 20 patients classified as Group 3 PH (e.g., BPD, CDH) 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 roster *should* have been seen and actively managed in the prior 4 years for initial accreditation and in the prior 3 years for reaccreditation
 - b. If a Center's census falls slightly below this range a number of other factors will be taken into consideration. The ultimate accreditation decision will rely on the Center's overall application. Factors that may be taken into consideration include:
 - i. Duration of Center's existence
 - ii. Tenure of Director at the Center
 - iii. Number and proximity of additional PH Centers near the candidate Center
 - iv. Regional population and Center's catchment area
- **PC3.5** The Center *must* have proficiency and experience with inpatient and outpatient use of all PH therapies: oral, inhaled, and parenteral (SQ and IV)
- **PC3.6** The Center *should* have managed at least 16 different PAH patients on outpatient parenteral prostacyclin infusion over the preceding 4 years, of which at least half are IV prostacyclin infusion
 - a. 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 the accreditation visit
- **PC3.7** The Center *must* follow available diagnosis and treatment consensus guidelines when possible, for example:
 - a. V/Q scans 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. Parenteral prostacyclins for WHO FC IV patients, "high-risk" profile, or those who have progressive symptoms despite proper utilization of oral and/or inhaled therapies (or document valid reason for not using)

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- e. Risk assessment performed and documented at regular intervals
- Pediatric CCC *must* have the resources/consultants outlined in criteria 3.8 – 3.19 available:
 - **PC3.8** PH provider on call 24/7 (may be PH physician, nurse or PA)
 - a. Members of the PH Program *must* be directly involved daily with care of the 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
 - **PC3.9** Pediatric Rheumatology consultants
 - **PC3.10** Pediatric Pulmonary consultants
 - **PC3.11** Pediatric Anesthesia with extensive PH experience
 - **PC3.12** Pulmonary/Cardiac Transplant Service or established referral process
 - **PC3.13** Congenital Heart Disease Specialist
 - **PC3.14** Congenital Heart Surgeon
 - **PC3.15** Pediatric Surgery consultants
 - **PC3.16** 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
 - **PC3.17** Neonatal/Pediatric Critical Care Services for the management of infants and children with all forms of PH (includes PPHN, BPD, CLD, CDH)
 - **PC3.18** 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
 - **PC3.19** Palliative Care Service. Should have both inpatient and outpatient services
- Pediatric CCC *should* have the resources/consultants outlined in criteria 3.20 – 3.22 available:
 - **PC3.20** 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
 - **PC3.21** Dietary/Nutrition Services
 - a. Dietitian does not have to be dedicated to the PH Program
 - **PC3.22** Pediatric exercise test specialist (Either exercise physiologist or physician experienced in performing cardiopulmonary exercise testing in children)

IV. PC4. Facility

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

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- **PC4.1** *Must* have inpatient pediatric wards and ICU facilities, including NICU and PICU (within the affiliated hospital), with staff who are specially trained in managing PH and chronic prostacyclin infusions
 - a. *Must* have written protocols for managing inhaled and 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
 - c. *Must* have a protocol for immediate notification of PH team for patients who present to the Emergency Department
 - d. *Must* have the ability to deliver inhaled nitric oxide on-site
- **PC4.2** *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
- **PC4.3** *Must* have an echocardiography laboratory with experience in PH
 - a. The echocardiography laboratory *should* have accreditation by the Intersocietal Accreditation Commission
- **PC4.4** *Must* have a Pulmonary Function Laboratory
- **PC4.5** *Must* be able to perform Exercise Testing (e.g. 6 Minute Walk, CPET or submaximal exercise test [SHAPE]; must provide manual of procedures and report document)
 - a. For the 6 Minute Walk Test, the protocol *must* conform to ATS recommendations for its performance
- **PC4.6** *Must* have a pharmacy with immediate access to parenteral prostacyclins
 - a. Pharmacy staff *must* be proficient with preparation of prostacyclin infusions
- **PC4.7** The pharmacy *must* have a process for obtaining non-formulary PH medications when needed
- **PC4.8** *Must* have a Pediatric Radiology department with expertise in PH
- **PC4.9** *Must* have system in place to assure patient confidentiality
- **PC4.10** *Should* accept patients insured by governmental insurance
- **PC4.11** *Should* have the ability to accept transfer of referred patients via an expedited route
- **PC4.12** *Must* have Institutional support for the PH Program

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V. PC5. Research

- Pediatric CCC's demonstrate a strong commitment to clinical research, as a part of the larger PH community's efforts to improve outcomes and find a cure
 - **PC5.1** Program *must* have actively participated in at least 1 IRB-approved phase 2 or 3 PH clinical investigation within previous 3 years
 - a. May include sponsored research or institutional initiated single or multi-center studies
 - b. May include therapeutic or non-therapeutic investigations (e.g. pharmacologic, non-pharmacologic, genetic, epidemiologic, or mechanistic studies)
 - c. Active participation *should* have enrollment of at least 1 patient in 1 study
 - d. Requirement cannot be satisfied by observational registries
 - e. Program research staff *must* meet IRB requirements to conduct research
 - f. If the Program does not offer a study for a particular PH group, referral to another center conducting an appropriate trial *should* be considered
 - **PC5.2** *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 5 years
 - **PC5.3** *Should* have access to an Investigational Drug Service that stores, prepares, and dispenses investigational medications
 - **PC5.4** *Must* have institutional IRB or the ability to use outside (central) IRB
 - **PC5.5** Institution *must* have published at least one PH-related publication within the last 5 years in a peer-reviewed journal

END of PEDIATRIC CCC 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
RCP – Regional Clinical Program
RN – registered nurse
RHC – right heart catheterization
RRT – registered respiratory therapist
SQ – subcutaneous
SW – social work