



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

Full appendix of abbreviations available on Page 7

Adult Center of Comprehensive Care (CCC) Criteria

I. AC1. CCC Director

- Adult CCC *must* have a Center Director who has the following attributes:
 - **AC1.1** *Must* have completed Fellowship in Pulmonary Medicine or Cardiology
 - a. *Must* be Board Certified in Pulmonary Medicine or Cardiology
 - b. Documentation of specialty certification *must* be on file
 - **AC1.2** *Must* have a minimum of 2 years of experience treating PH after fellowship
 - **AC1.3** Director's efforts towards PH program *should* be ≥ 0.50 FTE. This total 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
 - **AC1.4** *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
 - **AC1.5** *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 by program staff
 - b. Mentoring trainees at the Center, if applicable
 - **AC1.6** *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)
 - **AC1.7** *Must* be a member of Pulmonary Hypertension Clinicians and Researchers (PHCR)
 - **AC1.8** *Must* have completed 25 hours of CME related to PH over the past 3 years (attending and/or presenting)
 - **AC1.9** *Should* have an Associate Center Director
 - a. *Should* be Board Certified in Pulmonary Medicine or Cardiology
 - b. *Should* spend at least 0.10 FTE working with PH Center in a clinical capacity
 - c. *Should* demonstrate involvement with program's management, clinical care, and

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research

- d. *Should* have a minimum of 1 year of experience treating PH after fellowship
**Lack of an Associate Director can jeopardize the maintenance of Center accreditation in the event the Director leaves the Center*
- **AC1.10** Transitional Directors: If the Center’s Director leaves the Institution, the new Director *should* meet the criteria outlined in section AC1
 - 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. **AC2. CCC Clinical Coordinator**

- Adult CCC *must* have a designated coordinator who has the following attributes:
 - **AC2.1** *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 AC3.2-3.3 (Program Staff and Support Services) for total requirements for coordinator support*
 - **AC2.2** *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
 - **AC2.3** *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 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
 - **AC2.4** *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
 - **AC2.5** *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)
 - **AC2.6** *Must* be a member of the Pulmonary Hypertension Professionals Network (PHPN)
 - **AC2.7** *Must* have completed 12 hours of CME/CEU related to PH over the past 3 years

III. AC3. 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

- **AC3.1** Physicians' combined effort towards PH program, including clinical care, clinical research, and administrative duties, *must* be ≥ 0.75 FTE
- **AC3.2** 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 AC2
- **AC3.3** Outpatient coordinator and support staff *must* be commensurate with the Center's volume and complexity of patients
- **AC3.4** The Center *should* be actively managing a minimum of 75 patients with either a Group I or Group IV PH diagnosis based on current diagnostic criteria
 - a. The accreditation application will contain instructions for creating a Group I and IV 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 over the preceding 3 years
 - 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
- **AC3.5** The Center *must* have proficiency and experience with inpatient and outpatient use of all PH therapies: oral, inhaled, and parenteral (SQ and IV)
- **AC3.6** The Center *must* have managed at least 20 different PAH patients on parenteral prostacyclin infusion over the preceding 3 years
 - a. De-identified list of patients with the PAH diagnosis, route of parenteral agent administered (IV or SQ), and date of initiation will be requested and reviewed in the accreditation visit
- **AC3.7** The Center *must* follow available diagnosis and treatment consensus guidelines when possible, for example:
 - a. VQ scan or alternative perfusion imaging techniques (such as dual energy CT, MRI perfusion, etc.) to exclude CTEPH
 - 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 in each case)
 - e. Risk assessment performed and documented at regular intervals

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- Adult CCC *must* have the resources/consultants outlined in criteria 3.8 – 3.16 available:
 - **AC3.8** PH provider on-call 24/7
 - 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
 - **AC3.9** Rheumatology consultants
 - **AC3.10** Cardiology consultants for pulmonary-based programs. Pulmonary consultants for cardiology-based programs
 - **AC3.11** Cardiac Anesthesia
 - **AC3.12** Pulmonary Transplant Service or established referral process
 - **AC3.13** Congenital Heart Disease Specialist or established referral process. Specialist should be board certified or board eligible in congenital heart disease
 - **AC3.14** 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
 - **AC3.15** Central line placement and repair service
 - a. Can be performed by Surgery or Interventional Radiology Services
 - b. *Must* have written protocol for transition of parenteral prostacyclin therapy to a new central line
 - **AC3.16** Palliative Care Service. Should have both inpatient and outpatient services available
- Adult CCC *should* have the resources/consultants outlined in criteria 3.17 – 3.19 available:
 - **AC3.17** 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
 - **AC3.18** Dietary/Nutrition Services
 - a. Dietitian does not have to be dedicated to the PH Program
 - **AC3.19** Pulmonary and/or Cardiac rehabilitation
 - a. *Must* actively consider referral to pulmonary or cardiac rehab

IV. AC4. Facility

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

- **AC4.1** *Must* have inpatient wards and ICU facilities (within 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

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- 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
- **AC4.2** *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 *must* 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 provocative testing for each case
- **AC4.3** *Must* have an echocardiography laboratory with experience in PH
 - a. The echocardiography laboratory *should* have accreditation by the Intersocietal Accreditation Commission
- **AC4.4** *Must* have a Pulmonary Function Laboratory
- **AC4.5** *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.
- **AC4.6** *Must* have a pharmacy with immediate access to parenteral prostacyclins
 - a. Pharmacy staff *must* be proficient with preparation of prostacyclin infusions
- **AC4.7** The pharmacy *must* have a process for obtaining non-formulary PH medications when needed
- **AC4.8** *Must* have a Radiology department with expertise in PH, specifically:
 - a. Thoracic Radiology
 - b. Nuclear Medicine (for performance and interpretation of V/Q Scans)
- **AC4.9** *Must* have system in place to assure patient confidentiality
- **AC4.10** *Should* accept patients insured by governmental insurance
- **AC4.11** *Should* have the ability to accept transfer of referred patients via an expedited route
 - a. Assistance to nearby RCPs, including case discussions and/or the acceptance of patients in need of advanced PH therapies, *should* be provided when requested
- **AC4.12** *Must* have Institutional support for the PH Program

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V. **AC5. Research**

- Adult 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
 - **AC5.1** Program *must* have actively participated in at least 3 separate IRB-approved PH clinical investigations within the previous 3 years, at least one of which must be a phase 2 or 3 study
 - 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. One of the three IRB-approved investigations may be a multi-center registry
 - d. Active participation *requires* enrollment of at least one patient in at least two clinical investigations, other than a registry
 - 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
 - **AC5.2** *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
 - **AC5.3** *Should* have access to an Investigational Drug Service that stores, prepares, and dispenses investigational medications
 - **AC5.4** *Must* have institutional IRB or the ability to use outside (central) IRB
 - **AC5.5** Institution *must* have published at least one PH-related publication within the last 5 years in a peer-reviewed journal

END of ADULT CCC Criteria

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Appendix:

Abbreviations:

CCC – Comprehensive Care Center
CEU – continuing education unit
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
RCP – Regional Clinical Program
RN – registered nurse
RHC – right heart catheterization
RRT – registered respiratory therapist
SQ – subcutaneous
SW – social work