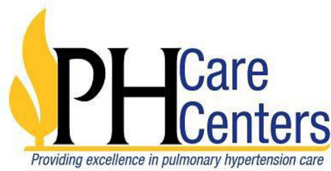

Criteria also available in tabular format on the PHCC website (www.PHCareCenters.org)

Full appendix of abbreviations available on Page 7

Adult Regional Clinical Program (RCP) Criteria

I. AR1. RCP Director

- Adult RCP *must* have a Center Director who has the following attributes:
  - **AR1.1** *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
  - **AR1.2** *Must* have a minimum of 2 years of experience treating PH after Fellowship
  - **AR1.3** The Program's director *must* have ≥ 0.25 FTE dedicated to the PH program
    a. *If using parental prostacyclins,* Director *must* have FTE commensurate with volume of parenteral prostacyclin patients
  - **AR1.4** *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
  - **AR1.5** *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
  - **AR1.6** *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, etc.)
  - **AR1.7** *Must* be a member of Pulmonary Hypertension Clinicians and Researchers (PHCR)
  - **AR1.8** *Must* have completed 25 hours of CME in PH over the past 3 years (attending and/or presenting)
  - **AR1.9** Transitional Directors: If the Center's Director leaves the Institution, the new Director *should* meet the criteria outlined in section AR1

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. AR2. RCP Clinical Coordinator

- Adult RCP *must* have a designated coordinator who has the following attributes:
  - **AR2.1** *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 *should* at a minimum be ≥ 0.25 FTE*
      i. *If administering parenteral therapies*, the coordinator's position within the Center *must* be commensurate with parenteral therapy patient volume

      *See Section AR3.1 (Program Staff and Support Services) for total requirement for coordinator support
  - **AR2.2** *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
  - **AR2.3** *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 meeting
  - **AR2.4** *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
  - **AR2.5** *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)
  - **AR2.6** *Must* be a member of the Pulmonary Hypertension Professionals Network (PHPN)
  - **AR2.7** *Must* have completed 12 hours of CME/CEU related to PH over the past 3 years

III. R3. 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

- **AR3.1** Outpatient coordinator and support staff *must* be commensurate with the Center's total volume and complexity of patients
    a. Coordinator FTE requirement can be satisfied by more than one person, but one individual must be the Center's designated "Lead Coordinator" and fulfill the criteria in section AR2
- **AR3.2** The Center *should* be actively managing a minimum of 25 patients with 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
- **AR3.3** The Center *must* have proficiency with non-parenteral PH therapies
    a. *Experience administering parenteral prostacyclin therapy is NOT required of an RCP*
        i. *If the Center is prescribing parenteral prostacyclin therapy*, staff *must* demonstrate adequate proficiency with initiation and maintenance of therapies
- **AR3.4** 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)
    d. Parenteral prostacyclins for patients in WHO FC IV, "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)
        i. If parenteral prostacyclin therapy is not available at the RCP, timely transfer to CCC should be pursued (or document reason for not transferring)
    e. Risk assessment performed and documented at regular intervals
- **AR3.5** *When appropriate*, Center collaborates and co-manages patients with a regional center that provides the scope of medical therapies at the level of a CCC
    a. *Must* demonstrate collaborative management with a regional CCC (or regional program able to provide services comparable to a CCC) when the need for more advanced care that cannot be provided at the RCP arises (e.g., administering parenteral prostacyclins, evaluation and management of congenital heart disease, consideration for thromboendarterectomy or transplantation, etc.)

   b. RCPs are encouraged to refer patients to regional CCCs (or comparable regional referral centers) for consideration in investigational protocols that are unavailable at the RCP
   c. Regional CCC (or comparable regional referral center) *must* provide a Letter of Support to affirm that this type of collaboration is occurring

- Adult RCP *must* have the following resources/consultants outlined in criteria 3.6-3.14 available:
  - **AR3.6** 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
  - **AR3.7** Rheumatology consultants
  - **AR3.8** Cardiology consultants for pulmonary-based programs. Pulmonary consultants for cardiology-based programs
  - **AR3.9** Cardiac Anesthesia or institution to refer
  - **AR3.10** Pulmonary Transplant Service or established referral process
  - **AR3.11** Congenital Heart Disease Specialist or established referral process. Specialist should be board certified or board eligible in congenital heart disease
  - **AR3.12** 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
  - **AR3.13** *If prescribing parenteral prostacyclins infusions,* central line placement and repair services
    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
  - **AR3.14** Palliative Care Service. Should have both inpatient and outpatient services
- Adult RCP *should* have the resources/consultants outlined in criteria 3.15-3.17 available*:*
  - **AR3.15** Social Work
    a. SW *should* be designated to the PH Program and be a consistent resource for 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
  - **AR3.16** Dietary/Nutrition Services
    a. Dietitian does not have to be dedicated to the PH program
  - **AR3.17** Pulmonary and/or Cardiac rehabilitation
    a. *Must* actively consider referral to pulmonary or cardiac rehab

IV. R4. Facilities

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

- **AR4.1** *Must* have ICU facilities (within affiliated hospital)
- **AR4.2** *Must* have written protocols for managing inhaled prostacyclins
- **AR4.3** *If providing prostacyclin infusions*, *must* have inpatient wards and ICU facilities with staff who are specially trained in managing PH 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
    c. *Must* have a protocol for immediate notification of PH team for patients who present to the Emergency Department
- **AR4.4** *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 *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 any provocative testing for each case
- **AR4.5** *Must* have an echocardiography laboratory with experience in PH
    a. The echocardiography laboratory *should* have accreditation by the Intersocietal Accreditation Commission
- **AR4.6** *Mus*t have a Pulmonary Function Laboratory
- **AR4.7** *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
- **AR4.8** *If providing prostacyclin infusions*, *must* have a pharmacy with immediate access to parenteral prostacyclins
    a. Pharmacy staff *must* be proficient with preparation of prostacyclin infusions
- **AR4.9** The pharmacy *must* have a process for obtaining non-formulary PH medications when needed
- **AR4.10** *Must* have a Radiology department, which should have expertise in PH, specifically:
    a. Thoracic Radiology
    b. Nuclear Medicine (for performance and interpretation of V/Q Scans)

- **AR4.11** *Must* have a system in place to assure patient confidentiality
- **AR4.12** *Should* accept patients insured by governmental insurance
- **AR4.13** *Should* have the ability to accept transfer of referred patients via an expedited route
- **AR4.14** *Must* have Institutional support for the PH Program

V. AR5. Research *(not mandatory for RCP accreditation)*

- If Adult RCP is conducting research, the Center *should* have the following resources available as outlined in criteria 5.1-5.4:
  - **AR5.1** If the Center does not offer a study for a particular PH group, referral to another Center conducting an appropriate trial *should* be considered
  - **AR5.2** *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
  - **AR5.3** *Should* have access to an Investigational Drug Service that stores, prepares, and dispenses investigational medications
  - **AR5.4** *Must* have institutional IRB or the ability to use outside (central) IRB

END of RCP CRITERIA

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