



ACHA ACHD Accreditation
User Manual

2022-2023

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Why Accreditation?

Importance of Accreditation

Congenital heart disease (CHD) is the most common birth defect, diagnosed in close to 1% of births (or 1 in 100) in the United States. Advances in medical and surgical care have resulted in better care delivery for children with CHDs and dramatically improved the survival rate of these patients. As of 2010, two thirds of the CHD population are 18 years of age or older and have moderate or complex forms of CHD. It is estimated that 20,000 “recruits” enter adulthood with a CHD each year, adding to the 1.3 million adults living with CHD in the United States.

The successes in treating pediatric patients with CHD has led to a growing, complex adult population which is now larger than the pediatric population. These adult patients do not have the same health care delivery systems in place afforded to both children with CHD and adults with acquired heart disease. Adult CHD (ACHD) patients fall victim to increased morbidity and increased early mortality. There is also a care gap for ACHD patients and a need for the standardization of care guidelines and criteria as well as quality measurement in ACHD care. There are currently no measurable standards within the ACHD program community. By establishing a concrete set of criteria, the **Adult Congenital Heart Association Adult Congenital Heart Disease Accreditation Program** (ACHA ACHD Accreditation Program) strives to provide continuity to the care of ACHD patients. This standardization will ease the transition from pediatric to adult CHD care and improve coordination among providers to help manage the comorbidities and reduce the mortality rates that are characteristic of patients with CHD.

The ACHA ACHD Accreditation Program is not intended to be punitive or to alienate those ACHD Programs that do not meet all the criteria required for Accreditation. This program is meant to be a transparent resource that every ACHD provider can use to elevate the overall care of ACHD patients. In order to improve ACHD care and quality, we must have a clear and effective collaborative approach. In a recent study conducted by Mylotte et. al a “referral to specialized ACHD care was independently associated with a significant mortality reduction.” In other words, they believed that their findings supported a specialized care model for ACHD patients.¹ ACHA ACHD Accreditation provides a clear roadmap for providers to improve their ACHD programs and removes some of the mystery and inconsistency that has characterized ACHD care in the past.

Background on ACHA and Accreditation

The Adult Congenital Heart Association (ACHA) was founded in 1998 as a national 501(c)3 organization with the mission **to improve and extend the lives of millions born with congenital heart disease, through education, advocacy, and research.** Currently, ACHA has a membership of more than 19,000 patients, family members and professionals and is the largest worldwide organization representing the ACHD community.

In 2008, when the petition for ACHD Board Certification was being submitted to the American Board of Internal Medicine (ABIM) and the American Board of Pediatrics (ABP), ACHA, serving as a patient

¹ Specialized adult congenital heart disease care: the impact of policy on mortality. Mylotte D, Pilote L, Ionescu-Iltu R, Abrahamowicz M, Khairy P, Therrien J, Mackie AS, Marelli A. *Circulation*. 2014 May 6;129(18):1804-12.

advocacy organization, convened a panel of members of ACHA leadership and ACHD professionals from the ACHA Medical Advisory Board (MAB) to discuss how ACHA could develop an agenda to improve the care for ACHD patients in the US. From this, a directive known as Vision 2020 sought to define and improve the ACHD workforce and develop an accreditation process to improve the quality of care delivered within ACHD clinics and programs throughout the US.

With this background, ACHA firmly recognized that the vision of ACHD Program Accreditation was aligned with the mission of ACHA and should be carried out under ACHA's organizational auspices. A Steering Committee was developed from the MAB consisting of experts in the field of ACHD from both small, medium, and large ACHD programs, ACHA leadership, and ACHD patients to promote a process of peer review and approval.

The Accreditation Steering Committee members were tasked with developing the ACHA ACHD Accreditation Program criteria. The committee members who are currently on, or emeritus from the ACHA MAB as well as patient representatives acted as the leads for specific topic areas and external experts in the field.

The Committee utilized all current data sources such as the Cystic Fibrosis Foundation program accreditation, Pulmonary Hypertension program accreditation, published ACHD accreditation criteria (from the United Kingdom), as well as personal experience as ACHD Medical Program Directors or experts in ACHD to derive a first draft set of criteria for each category listed.

Along with the development of specific program criteria, parallel processes with experts and working committees in database/registry, quality metrics, and health care policy have been developed as vital supportive services for the accreditation process. Please see a [full list of our current steering committee members](#) in the appendices.

Accreditation Process

For the purposes of this User Manual the term 'Applicant' will be used to refer to the ACHD program/center/site that is applying for accreditation.

Introduction

ACHA understands that this process is quite extensive, and it is the goal of the organization to make the process as easy, seamless, and fair as possible. Accreditation is valid for a 5-year period. In the last year of this cycle, ACHA will notify the applicant regarding the first steps for the re-accreditation process. For detailed information on the re-accreditation process, please see section titled [Reaccreditation Process](#).

Below, each step of the accreditation process is outlined in detail, but please reach out to the ACHA staff listed at the bottom of this section if any aspect of the process needs clarification.

Application Timeline Overview

ACHA accepts applications throughout the year. Applications are reviewed and site visits are scheduled based on the order in which applications are received. All applications and site visits are reviewed by the Steering Committee. The Steering Committee meets twice per year, once in the spring and fall, with ad hoc meetings scheduled as necessary. Prior to beginning an application, applicants must submit an

Accreditation Program Agreement (APA), Business Associate Agreement (BAA), and application fee. Once an applicant has completed and submitted each of these documents, ACHA will send a link to the application. Once provided with the application link, each applicant will have three months to submit their application.

For a time frame of the accreditation process, refer to the Application Timeline document on the [Accreditation Program Documents' Webpage](#). Please note the exact timing of the site visit and Steering Committee review may vary based on the number of applicants, availability of dates and submission date of the application.

Accreditation Program Agreement (APA), Business Associate Agreement (BAA) & Application Fee

The APA ([Appendix A](#)), BAA ([Appendix B](#)) and application fee ([Fee Schedule – Appendix C](#)) are due prior to beginning an application. ACHA requires each applicant to sign an APA and a BAA. Applicants may contact the ACHA Accreditation Program Manager for questions pertaining to these application requirements.

Additional information about the APA and BAA is provided below.

APA:

The APA outlines the terms and conditions of the accreditation process and ongoing maintenance of and adherence to criteria during the 5-year accreditation period. ***The APA cannot be modified in any way.***

Annual audit: By signing the APA, applicants acknowledge agree to complete a yearly audit. This audit will be conducted using the ACHA ACHD Clinic Directory. Applicants are required to submit updated information to the ACHA ACHD Clinic Directory on a yearly basis that will be reviewed by an ACHA Accreditation staff member. If there are any identified deficiencies, ACHA will follow up to obtain more information from the program. Programs are required to self-report changes to their program that occur outside of the yearly audit period in accordance with the APA

Criteria Maintenance Guidelines, which includes steps and timeline to resolve deficiencies and subsequent consequences should the deficiency not be resolved in the indicated time frame, is outlined in [Appendix D](#) of this User Manual.

BAA:

The BAA is an agreement to establish the relationship between ACHA and applicant for the purpose of accreditation covering the potential that ACHA may receive any individually identifiable health information that qualifies as Protected Health Information.

If necessary, ACHA's legal counsel will work with the applicant's legal team to facilitate the applicant's BAA approval process. Any time spent over 30 minutes by ACHA legal counsel to change the BAA in any way will be billed back to the applicant, above and beyond the application fee.

We strongly recommend using ACHA's version of the BAA as protected health information (PHI) is not collected during this process (either in the application or during the site visit). The BAA is a protection put in place in case the applicant inadvertently submits PHI in any part of the application or during the site visit. ACHA will follow the appropriate protocols to report the submission of PHI.

Fee:

The fee schedule for the ACHA Accreditation Application is outlined in [Appendix C](#) of this document.

Please send all application fees via check to:

Attn: Accreditation
Adult Congenital Heart Association
280 North Providence Road, Suite 6
Media, PA 19063

ACHA does not accept partial payments. If there are any questions about the application fee, please contact Cortney Faust, Accreditation Manager at cfaust@achaheart.org or Danielle Hile, Senior Director of Mission Delivery dhile@achaheart.org.

The fee, BAA and APA must be submitted prior to beginning an application. Via email, applicants must send signed copies of the APA and BAA to Cortney Faust, Accreditation Manager, at cfaust@achaheart.org. Applicants will need to send the name and contact information for the program representative who will be completing the application and communicating with ACHA staff during all phases of the accreditation process. Once the fee, BAA and APA have been received, applicants will be emailed a link and instructions to begin their application.

All Applicants that cannot move forward with the application process for any reason will lose access to their online application. These programs will remain in the ACHA ACHD Clinic Directory and are welcome to submit their application in the next round of applications. Applicants who resume the accreditation process in a new calendar year will be required to submit payment for any difference between rates in effect at the time of resumption of the process and the rate originally paid. Refer to [Appendix C](#).

Online Application

Accessing Application and Timeline for Completing Application

Each applicant will have three months to complete their online application on OpenWater, ACHA's application hosting system.

Applicants may preview a PDF version of the application on the ACHA accreditation website: <https://www.achaheart.org/for-professionals/accreditation-program-documents/>.

Applicants will be sent the application link once the APA, BAA, and fee have been submitted to ACHA. If a program applicant cannot complete the application, or the applicant submits an incomplete²

² Missing several key components of the application.

application, ACHA cannot guarantee that a site visit will be scheduled in time for the applicant to be reviewed by the next official Accreditation Steering Committee meeting.

Application Review

ACHA Administrative Review

After an applicant has completed their online application, an ACHA staff member will complete an initial administrative review. This review consists of examining the application for basic errors and/or omissions such as personnel, lack of policies, or unclear documentation. ACHA will ensure that all documents are uploaded correctly and note any sections that are missing documentation. After the administrative review, applicants will be made aware of any missing pieces that prevent them from moving forward to having a site visit. Applicants will be given time to resubmit that information with no negative effects to their overall potential accreditation. If the applicant has completed all components of the application, they will be notified that their application is ready for formal review. Once approved for formal review, no further action is needed from the applicant at that time.

Primary and Secondary Application Review

The formal primary application review process will be conducted by both an ACHA accreditation staff member and the site visitor (medical reviewer) who is an ACHA Cardiologist who serves on the ACHA Accreditation Steering Committee.

A second medical reviewer from the Accreditation Steering Committee will review the program's application as well. This secondary reviewer will not attend the site visit.

The ACHA accreditation staff member and medical reviewers will compare the application responses to the ACHA ACHA Accreditation Program Criteria. A checklist will be provided to reviewers to ensure an objective review.

The goal is to review each application as extensively as possible to ensure that all perspectives are being considered and that no key components of the program are overlooked.

Site Visit

Once the administrative review is complete, ACHA will notify the applicant about any missing criteria or documentation that is preventing their program from moving forward with the site visit.

Due to the ongoing COVID-19 pandemic, all site visits will be virtual until further notice. We will work to schedule the site visit date after we have completed the administrative review.

The timing of the site visit may depend on the number of applicants for that round. Site visits are scheduled based on the order in which applications are received so that the first sites to submit their application receive the first selection of available site visit dates.

Site Visit Preparation

The virtual site visit will be conducted by an ACHA accreditation staff member and a member of the ACHA Accreditation Steering Committee. The ACHA accreditation staff member, Accreditation Steering Committee member, and applicant will mutually agree on a date for the site visit. Usually, the

Accreditation Steering Committee member who reviews the application in detail during the formal review process will also perform the site visit.

The site visit will occur over a one-day period. All applicants must draft the itinerary for the day using the Site Visit Itinerary template as a guide. Review this itinerary on the ACHA Accreditation Program Documents Webpage at <https://www.achaheart.org/for-professionals/accreditation-program-documents/> for specific instructions about scheduling the day.

Applicants are required to submit a copy of the agenda at least **two weeks prior to the scheduled site visit date** for review and any modifications if necessary. Applicants that do not submit their site visit itinerary within this time frame may have their site visit rescheduled for a later date.

Site Visit Details

During the site visit, the ACHA accreditation staff member and Accreditation Steering Committee member will visit and assess key components of the applicant's ACHD program and meet with essential program personnel. The goal of the site visit is to obtain a sense of the applicant's ACHD program beyond the written documentation provided in the application. Applicants will be asked about their collaborative relationships with pediatric and adult IM (respectively) counterparts and will be required to provide detailed explanations of these relationships during the site visit. Accreditation site visitors will need to meet with the pediatric and adult providers separately as well as the program directors and chiefs separately from the providers they oversee. Below is the list of the ACHD team members that will need to meet with the Accreditation site visitors during the site visit³:

- ACHD Medical Program Director
- ACHD Administrative Contacts
- ACHD Providers including Cardiologists, APN, PA, RN listed as working with the ACHD Program
- Social Worker(s) and Psychologist(s)
- ACHD CT Surgical Director
- CT Surgical Director (pediatric and adult if applicable)
- ACHD Cardiac Cath Interventionalist
- Director, Cardiac Cath (pediatric and adult if applicable)
- ACHD Electrophysiologist
- Director of EP (pediatric and adult if applicable)
- ACHD Cardiologist responsible for Cardiac MRI and CT
- ACHD Cardiologist responsible for Echocardiography
- Chief of Pediatric Cardiology
- Chief of Cardiology (adult)
- Director of Heart Failure/Transplant and/or HF physician collaborating with the ACHD program
- Maternal Fetal Medicine
- Pulmonary Hypertension
- ACHD Fellow (if applicable)

³ Additional key members of the ACHD program may be asked to attend the site visit meeting.

- A physical tour of the ACHD Program is not necessary.

ACHA understands that providers and other program staff at each ACHD Program are extremely busy and that their schedules are subject to unexpected changes. If the site visitors are unable to meet with one of the above personnel during the site visit, a conference call or a video conference call will need to be scheduled within a reasonable timeframe⁴ after the site visit. Failure to meet with one of the above individuals could delay the application process and/or will be included in the decision report as a deficiency as determined at the Accreditation Steering Committee Meeting.

ACHA Accreditation Steering Committee Meeting

Meeting Process

The ACHA Accreditation Steering Committee Meetings will occur twice per year, with ad hoc meetings as necessary, in conjunction with the timing of the ACC Conference (typically in March) and the AHA Conference (typically in November).

During each meeting, members of the Accreditation Steering Committee will review each application in detail, going line by line through the ACHA ACHD Accreditation Program criteria. The ACHA Accreditation staff member and Accreditation Steering Committee member who attended the site visit will share their findings from the application review and site visit and the committee will discuss each program extensively. At the end of this discussion, the committee will vote on an accreditation status decision based on a rating system approved by the Accreditation Steering Committee. An applicant will either be given a status of Pending Accreditation with Minor Deficiencies or Pending Accreditation with Deficiencies. No applicant will receive a status of Accredited following the first review. A two-thirds majority rule is required for a decision to pass about an applicant's final accreditation status.

Approximately six to eight weeks after the Accreditation Steering Committee meeting, ACHA will send out a **Decision Report** informing each applicant of their accreditation decision (Pending Accreditation with Minor Deficiencies or Pending Accreditation with Deficiencies). ACHA will also inform the applicant if a second site visit is needed. **Please note that applicants are responsible for all costs associated with the second site visit.** This report also lists the applicant's strengths, deficiencies, and challenges for each section of the criteria. Please note that every applicant that has gone through the process has had deficiencies to correct.

Accredited Programs

Once an applicant corrects all deficiencies outlined in their decision report, ACHA will send the program director a formal accreditation letter.

Program Contact Information: All applicants must maintain updated contact information with ACHA throughout the accreditation cycle including, but not limited to: Program Director, Program Admin/Coordinator, and PR/Marketing representative (requested at time program is notified of accreditation as Comprehensive Care Center).

⁴ No more than two months after the site visit.

PR/Marketing: All materials regarding the promotion of an applicant's accreditation must be reviewed and approved by ACHA. Accreditation is valid for a 5-year period. (see Program Promotion, Marketing and Communications section below for more details)

Clinic Directory Listing: ACHA will also list the ACHD program as an accredited center on the website as well as each individual Clinic Directory listing, <https://www.achaheart.org/your-heart/programs/accreditation/>. It is ACHA's hope that these accredited centers will eventually be a part of a network of ACHD programs that will participate in a unifying database, multicenter research, quality initiatives, and benchmarking projects.

Reaccreditation: One year prior to the program's 5-year accreditation date, information regarding the reaccreditation process will be sent to the ACHD Program Director and/or designated contacts on file with ACHA.

Pending Accreditation/Not Accredited Programs

If the Accreditation Steering Committee determines that the applicant is Pending Accreditation, they will be informed of exactly what documents or pieces of the criteria they are missing that are preventing accreditation in the decision report. Applicants that are determined to be Pending Accreditation with Minor Deficiencies will have six (6) months after notification to correct these deficiencies. If a decision of Pending Accreditation with Deficiencies is made, the Applicant will have up to one (1) year to correct these deficiencies. This includes completing a second site visit if necessary.

No applicant will be determined as Not Accredited during the first review. Applicants with many deficiencies will be determined as Pending Accreditation with Deficiencies and given one (1) year to improve the deficiencies in their application.

Please send all documentation to address deficiencies via email to Courtney Faust at cfaust@achaheart.org and Danielle Hile at dhile@achaheart.org. All deficiency documentation should be sent at one time (instead of individually submitted over time). This practice reduces the likelihood of any documentation being overlooked.

ACHA will review all documentation submitted to correct minor deficiencies. For major deficiencies, ACHA will need to review the documentation with the entire Steering Committee during one of the bi-annual meetings (Spring and Fall). If the Accreditation Steering Committee determines that these deficiencies have been corrected, the applicant will be accredited. If the applicant has improved, but still has not met all the criteria and documentation requirements for accreditation, they will repeat the above resubmission process (additional fees may apply). If the applicant has not improved or has deteriorated since their initial re-review, they will receive a decision of Not Accredited and have the option to reapply. Any applicant that is determined to be Not Accredited at the Accreditation Steering Committee Meeting and chooses to reapply will be responsible for re-submitting their application fee. No discounts will be offered for these applicants.

Please note that Not Accredited is **NOT** a default status. It is a determination that will be made after the entire accreditation application process (i.e., completion of online application, application review, site visit, Accreditation Steering Committee Meeting first and second review, if applicable) has been

completed. If an applicant chooses not to apply or must discontinue the process at any point during the application process, they will not receive a Not Accredited status.

Applicants that receive a final decision of 'Not Accredited' will remain listed on the ACHA Clinic Directory with no reference to the decision (in other words, there will be no notation regarding the application results). ACHA will not list any applicants as Not Accredited in the Clinic Directory.

Only accredited centers will be listed in the Clinic Directory with the notation 'ACHA ACHD Accredited Center'.

Program Promotion, Marketing and Communications

Applicants are required to work with the ACHA Communications team for promotion of the Accreditation status. During the process of applying for the ACHA ACHD Accreditation Program, applicants may only announce that they are "Currently Applying for the ACHA ACHD Accreditation Program". Such announcements can occur only after the applicant has been provided access to the online application by ACHA which happens when the APA and BAA are signed and submitted, and the accreditation fee has been paid in full.

Once an applicant is approved and is designated as an ACHA ACHD Accredited Program, they will be notified by ACHA as to when they can publicly announce their ACHA ACHD Accreditation status in collaboration with ACHA's Communications team. Applicants must provide their hospital or institution's marketing/PR team's contact information once they receive their official accreditation letter from ACHA. Please review the below rules of press announcements.

- All press materials announcing ACHA ACHD Accreditation must be reviewed by ACHA before distribution. Each applicant should allow at least five business days for review.
- All press releases announcing the applicant's ACHA ACHD Accreditation must include the following overview of the Accreditation Program linking to ACHA's website:
 - The Adult Congenital Heart Association (ACHA) in conjunction with leading adult congenital heart disease (ACHD) providers across the country developed criteria for ACHD Accreditation. Those with congenital heart disease (CHD) need specialized care and testing that can only effectively be provided by ACHD specialists. Through the ACHA ACHD Accreditation Program we enable those with CHD to receive quality care regardless of where they may live. As care within the CHD world has been evolving within the past 25 years, we are moving forward to ensure that quality care and access is available to all patients, and when they are unable to be seen locally within an ACHD center, they are able to work with accredited providers to close the gap in care. For more information about ACHA or the Accreditation Program, please visit us at www.achaheart.org.
- All applicants can use the following accredited title below when referring to the ACHD Program's accreditation:
 - ACHA ACHD Accredited Comprehensive Care Center
- Accreditation logo can only be placed on materials that directly relate to CHD/ACHD and must be approved by ACHA.
 - If placed on website, ACHA asks that it be hyperlinked to the website at www.achaheart.org.

Any premature promotion of any Accredited ACHD Program, ACHD Facility and/or Hospital or Hospital System may result in losing status within the ACHA Clinic Directory for one (1) year or more, in addition to removal of the Program's ACHA ACHD Accreditation status online and in ACHA promotional materials.

Reaccreditation Process

For the purposes of this User Manual the term 'Applicant' will be used to refer to the ACHD program/center/site that is applying for accreditation or reaccreditation.

Introduction

ACHA ACHD Accreditation as a Comprehensive Care Center is valid for five (5) years from the date of initial accreditation. Accredited centers will be invited to apply for reaccreditation and will be notified one (1) year in advance of their reaccreditation date via email and accompanying letter on ACHA letterhead.

The process for reaccreditation consists of an updated and signed BAA, signed APA, fee submission, completed online application and site visit. Please note that in 2019, there was an addition of new criteria for cardiac anesthesia and reproductive services. The full criteria are outlined in detail on the Program Documents page on the ACHA website: <https://www.achaheart.org/professionals/accreditation-program-documents/>.

Below, each step of the reaccreditation process is outlined in detail. Please reach out to the ACHA staff listed at the bottom of this section if any aspect of the process needs clarification.

Application Timeline

Program Directors will be notified via email of their upcoming reaccreditation date twice: initially, one year in advance and a second time six months in advance. Applicants will be notified of their reaccreditation at the beginning of the quarter within which their initial accreditation date falls. For example, if an applicant's accreditation date is 2/15/2019, the applicant should receive their one-year advance notification in January 2023.

When an applicant receives the six-month notification, a link to the reaccreditation application will be provided. ACHA will work on a quarterly schedule for reaccreditation. Applicants may begin the reaccreditation process following their six-month notification but must allow at least three full months to complete the process (submission of BAA, APA, fee and application, application review, scheduling/completion of site visit and reaccreditation determination). Applicants should submit their application as close to three months prior to their accreditation date as possible. However, if an applicant completes the reaccreditation process in the quarter within which their initial accreditation date falls, there will be no removal of accredited status internally or on the ACHA website. For example, if an applicant's reaccreditation date is 11/20/2024, the applicant may become reaccredited anytime during Quarter 4 (October – December) without penalty.

Application Fee, Business Associate Agreement & Program Agreement

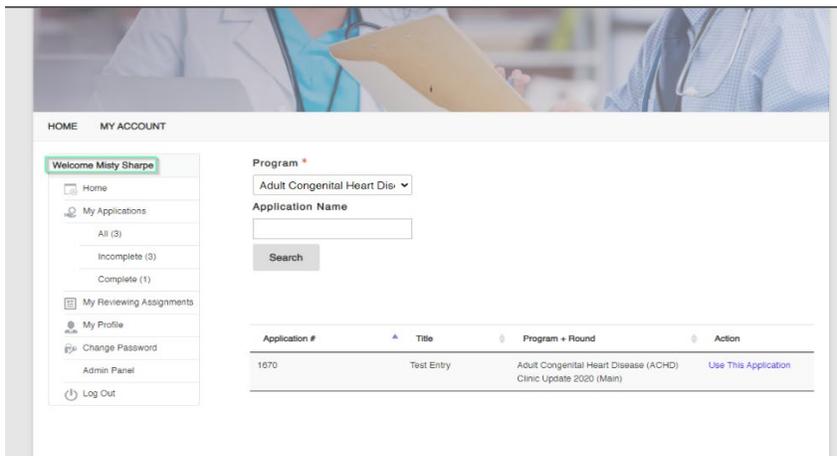
Programs seeking reaccreditation will be required to submit a signed Accreditation Program Agreement (APA), updated Business Associate Agreement (BAA) and reaccreditation fee. Please refer to pages 5-6 of the User Manual for details on these requirements. A copy of the APA and BAA are included at the end of this User Manual as [Appendix A](#) and [Appendix B](#), respectively. The fee schedule and Criteria Maintenance Guidelines are listed as [Appendix C](#) and [Appendix D](#), respectively, at the end of this User Manual.

Reaccreditation Application

The reaccreditation application is slightly different from the initial accreditation application. Applicants will be asked to provide updates on the progress of the Patient Family Advisory Council and Quality Assessment/Quality Improvement (QA/QI) meetings. This is an opportunity to highlight any significant achievements over the past five years.

Applicants will be required to provide updated CVs, certifications, and policies with their reaccreditation application. If there are no major changes to the policies submitted during the applicant’s initial accreditation application, applicants must indicate they have reviewed their policies internally by including updated signatures and dates.

If a program applicant has an updated Clinic Directory listing, they will have the option to transfer information to the reaccreditation application. Once logged in to OpenWater using the reaccreditation application link, the applicant’s Clinic Directory application will be listed at the bottom of the home page. Click “Use this application” to begin the reaccreditation application. Please see the below screenshot for reference.



Application Review

ACHA Administrative Review

After an applicant has completed their online application, an ACHA staff member will complete an initial administrative review. This review consists of examining the application for basic errors, changes in personnel or omissions in personnel or policies. After administrative review, applicants will be made aware of any missing pieces that prevent them from moving forward to having a site visit. Applicants will

be given time to resubmit that information with no negative effects to their potential reaccreditation. If an applicant has completed all components of the application, they will be notified their application is ready for formal review.

Formal Application Review

As with initial accreditation, the formal review process will be conducted by an ACHA accreditation staff member and the site visitor who is an ACHD Cardiologist serving on the ACHA Accreditation Steering Committee. This review will determine the type of site visit required based on changes to the program since the applicant's initial accreditation date. Following formal review, applicants will be contacted to begin scheduling a site visit.

Site Visit

Reaccreditation site visits will be conducted virtually, in-person or a combination of the two depending on programmatic changes. ***This is subject to change based on the ongoing COVID-19 pandemic.***

Site visits will range from a half day (4 hours) to a full day (8 hours). Depending on the changes within an ACHD program, a site visit may be conducted solely by an ACHA accreditation staff member or an ACHA accreditation staff member and medical provider from the Steering Committee. ACHA accreditation program staff will notify the applicant of the type of site visit required and provide a list of personnel that should be scheduled during the site visit.

Applicants will require a full day site visit if there are major program changes. Examples include, but are not limited to:

- Change in ACHD Medical Program Director
- Significant turnover of ACHD cardiologists
- Major change in leadership personnel
- Change in hospital structure (i.e., mergers with other institutions)

All determinations for site visits are at the discretion of ACHA and the Steering Committee.

Reaccreditation Promotion, Marketing and Communications

Promotion of an applicant's reaccreditation will follow the same guidelines as outlined on page 11 of this User Manual.

Questions or Concerns

ACHA understands that the accreditation process is time consuming. The goal of accreditation is not to be exclusionary or punitive, but to help standardize and improve care for ACHD patients. ACHA aims to foster a collaborative environment in which ACHD programs and providers can assist and learn from each other by sharing best practices. ACHA understands that there is not one way to successfully provide care to the ACHD population. Through the ACHA ACHD Accreditation Program, ACHA hopes to demonstrate the varied ways that programs can successfully incorporate all the accreditation criteria into their program and raise the overall quality of ACHD care.

If there are any questions or concerns about the accreditation process, please do not hesitate to contact the ACHA staff members listed below. ACHA is here to help through this process!

Cortney Faust

Accreditation Manager – ACHA
Email: cfaust@achaheart.org

Danielle Hile

Senior Director of Mission Delivery – ACHA
Email: dhile@achaheart.org

ACHA ACHD Accreditation Steering Committee Members

Chair: Curt J. Daniels, MD

Director, Columbus Adult Congenital Heart Disease and Pulmonary Hypertension Program Nationwide Children's Hospital/OSU, Columbus, OH

Jamil Aboulhosn, MD

Director, Ahmanson/UCLA ACHD Center, University of California, Los Angeles, Los Angeles, CA

Craig Broberg, MD, MCR

Director, Adult Congenital Heart Disease Clinic, Oregon Health and Science University, Portland, OR

Michael G. Earing, MD

Director, Chicago Adult Congenital Heart Disease Alliance, University of Chicago, Advocate Children's and Christ/Lutheran General Hospitals, Chicago, IL

Sue Fernandes, LP.D, PA-C

Program Director, Adult Congenital Heart Program at Stanford Lucile Packard Children's Hospital and Stanford Hospital and Clinic, Stanford, CA

Joe Kay, MD

Director, Colorado's Adult & Teen Congenital Heart Program (CATCH), Aurora, CO

Michael J. Landzberg, MD

Boston Adult Congenital Heart Program (BACH) and Pulmonary Hypertension Service (PHT); Children's Hospital Boston/Brigham and Women's Hospital; Boston, MA

Arwa Saidi, MB, BCh

Director Adult Congenital Heart Disease Program, University of Florida, Gainesville, FL

Karen Stout, MD

Director, Adult Congenital Heart Disease Program University of Washington & Seattle Children's Hospital, Seattle, WA

Jeremy Nicolarsen, MD

Director, Adult Congenital Heart Disease Program, Providence Sacred Medical Center & Children's Hospital, Spokane, WA

Richard Krasuski, MD

Director, Adult Congenital Heart Disease Program, Duke University Medical Center, Durham, NC

Danielle Hile

Senior Director of Mission Delivery, ACHA

Cortney Faust

Accreditation Manager, ACHA

Mark Roeder

President & CEO, ACHA

A Guide to the ACHA ACHD Accreditation Application Policies/Procedures Documentation

Introduction

ACHA understands that the ACHA ACHD Accreditation application process can seem daunting, especially from an administrative perspective. In an effort to reduce the administrative burden and overall stress of the process, a list of template documents has been compiled for most of the criteria that require an uploaded policies/procedures document. These templates are available on the Accreditation Program Documents Webpage: <https://www.achaheart.org/for-professionals/accreditation-program-documents/>. ACHA hopes these templates will ease the difficulty of the process and assist in the standardization and overall improvement of ACHD care.

This section, “A Guide to the ACHA ACHD Accreditation Application Policies/Procedures Documentation” will explain the template documents and provide general advice for compiling the applicant’s ACHD policies and procedures.

Compiling Policies and Procedures Documentation

ACHA has template documents to help streamline the application process. The template documents are meant to serve as a guide, especially for the applicants that do not already have written policies and procedures. If an applicant already has a template and/or policy and procedure document in place that satisfies the ACHA ACHD Accreditation Program criteria, they are more than welcome, and encouraged, to use that documentation for the application. ACHA does ask that these pre-existing templates are reviewed to ensure that they contain all key information specific to that piece of criteria. As long as the relevant information is in the document, the exact text and format can vary.

If the applicant does not have pre-established written policies and procedures for the criteria, please use the template documents as a reference point. Again, the format and text of the document can vary as long as the relevant information for each criterion is included. ACHA aims to identify and establish a standard process of care for ACHD patients, but it is not a goal to make “cookie-cutter” ACHD programs. ACHA recognizes there are many ways these criteria can be successfully implemented into an ACHD program.

The policies and procedures are official documents and should contain the applicant’s official logo and/or letterhead, the date the policy is effective, if it is ACHD program policy or hospital policy, and any required signatures. The templates will indicate which documents require signatures and what personnel signatures are required for those documents. If the document does not require a signature, “N/A” will be listed under the “Required Signatures” section. ACHA wants to emphasize that these documents do not need to be long and verbose. A half-page to one page for each will be enough⁵.

ACHA also asks that no specific personnel are referenced in the policies and procedures documents. Even if “Dr. Smith,” the ACHD cardiologist, is typically involved in each process, the role of the personnel (i.e., the ACHD cardiologist) should be stated (i.e., the cardiologist is involved in this process). This

⁵ Some documents will need to be longer depending on the depth of information required.

practice will reduce the overall number of required updates needed if physicians or other staff leave the institution or change roles.

ACHA did not provide templates for documents such as “On-Call Schedules” or “Meeting Schedules,” because these documents are already in place for most institutions and guidance is not needed in creating them. Please ensure that the call schedules demonstrate 24/7 coverage of the individuals listed in the application (either the ACHD cardiologists or the providers that work with the ACHD team for that section of the application).

Uploading Documents

When uploading the policies and procedures documents, the documents must be saved with the specific criteria number at the beginning of the title (i.e., B2 - Letter from Division Chief). This naming convention should be used for any document uploaded to the “additional files” section as well. **Please upload all documents as PDFs NOT word documents.**

If uploading an example of a policy and procedure or a document typically found in a patient’s chart, any sensitive patient information that could reveal his/her identity or other identifying factors must be removed. This is a key requirement when signing the Business Associate Agreement. ACHA will be extremely careful with each applicant’s documentation and ensure that it is protected. Any sites that upload multiple (more than one) documents with patient information may lose their opportunity to become accredited.

Uploading documents to the “additional files” section is not required. ACHA provided this section for applicants to include extra information about their ACHD Program. Please note that the lack of additional files uploaded will not negatively affect an applicant’s chance of becoming an ACHA ACHD Accredited Program.

Conclusion

ACHA understands that compiling and/or writing these policies and procedures might seem tedious and redundant at times. The goal of this process is to standardize and improve the quality of care for ACHD patients through this Accreditation Program and the development of professional and consistent ACHD program policies is an important step in achieving this objective.

Additional Questions or Comments

If there are any additional questions or comments about the template documentation or the Accreditation application process in general, ACHA is here to help. Please do not hesitate to contact the ACHA Accreditation staff listed below:

Cortney Faust
Accreditation Manager – ACHA
cfaust@achaheart.org

Danielle Hile
Senior Director of Mission Delivery – ACHA
dhile@achaheart.org

Appendices

Appendix A – Accreditation Program Agreement

ADULT CONGENITAL HEART ASSOCIATION **ACCREDITATION PROGRAM AGREEMENT**

ACCREDITATION BY THE ADULT CONGENITAL HEART ASSOCIATION IS GRANTED IN FIVE-YEAR TIME PERIODS. THE FOLLOWING AGREEMENT MUST BE COUNTER SIGNED, DATED, AND RETURNED TO THE ADULT CONGENITAL HEART ASSOCIATION BEFORE THE ACCREDITATION APPLICATION PROCESS MAY BEGIN OR ACCREDITATION MAY BE GRANTED. ACCREDITATION WILL NOT BE GRANTED WITHOUT THIS AGREEMENT EXECUTED BY THE APPLICANT.

This Agreement is made and entered into this ____ day of ____, 202_ by and between The Adult Congenital Heart Association, a Pennsylvania nonprofit corporation with its principal place of business at 280 North Providence Rd, Suite 6, Media, PA 19063 (“ACHA”) and _____, a _____ entity with its principal place of business at _____ (“Applicant”).

WHEREAS, Applicant will submit an application as provided through ACHA’s website to seek accreditation or reaccreditation by ACHA.

WHEREAS, as part of the application process Applicant must demonstrate to ACHA it meets each of the ACHA ACHD Program criteria as set forth on ACHA’s website;

WHEREAS, Applicant and ACHA have executed the Business Associate Agreement in Exhibit A, which, if Accreditation is granted shall continue in full force and effect for the entire period of Accreditation, and any subsequent periods of Accreditation;

WHEREAS, the parties wish to set forth their understanding with respect to the accreditation application and review process and the term of the agency’s accreditation;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the parties agree as follows:

1. Review of Applicant’s Congenital Heart Program. This Agreement governs the Applicant’s application for Accreditation, and, if Accreditation is granted by ACHA, Applicant’s Accreditation period. ACHA shall, in accordance with ACHA’s application process then in effect in the User Manual, available on ACHA’s website, review and consider Applicant’s application for accreditation or reaccreditation. ACHA shall determine, in its sole discretion, whether Applicant meets the ACHA ACHD Accreditation Program Criteria. Applicant shall submit its application online through ACHA’s website

within three (3) months of executing this Agreement; failure to do so may result in a rejection of the application, or additional standards or procedural requirements, as determined by ACHA in its sole discretion. Applicant understands that it must follow the procedures and meet the ACHA ACHD Accreditation Program Criteria, as determined by ACHA in its sole discretion. Applicant understands that ACHA may, in its sole discretion, alter the processes and criteria in the User Manual in reviewing Applicant's application; ACHA will advise Applicant of any such changes in writing.

2. Term of Accreditation. If ACHA decides to grant accreditation to Applicant, it will grant Applicant accreditation for five (5) years.
3. Application Fee. In consideration for ACHA's initial review and processing of Applicant's application for accreditation throughout the accreditation cycle, as well as for any ongoing review during the Accreditation period (if Accreditation is granted by ACHA) Applicant shall pay ACHA an accreditation fee as set forth in Schedule B, Fee Schedule. All fees shall be paid within thirty (30) days of returning this executed Accreditation Program Agreement to ACHA. Applicant may then submit to ACHA its application for Accreditation. Once the application is submitted, the fee is nonrefundable.

ACHA DOES NOT ACCEPT PAYMENT FOR ACCREDITATION. ACCREDITATION IS GRANTED SOLELY ON ACHA'S EVALUATION OF WHETHER APPLICANT MEETS ACHA'S ACCREDITATION REQUIREMENTS. ACHA CANNOT GUARANTEE THAT ACCREDITATION WILL BE GRANTED AFTER APPLICATION IS MADE AND FEES ARE PAID. FEES PAID UNDER THIS AGREEMENT ARE NOT FOR OBTAINING ACCREDITATION BUT FOR ACHA'S UNDERTAKING THE ACCREDITATION APPLICATION AND REVIEW PROCESS.

4. Communications. The Applicant shall designate a contact person for each accreditation cycle, advising ACHA's Accreditation Manager of such person's identity and contact information. Applicant shall timely cooperate with ACHA to schedule site visit(s) as are required by ACHA, in its sole determination, during the application process and during the accreditation period, if any.
5. Accreditation Probation or Revocation. Accreditation may be revoked by ACHA pursuant to ACHA's procedures for revocation of accreditation if the Applicant fails to satisfy any of the ACHA ACHD Accreditation Program Criteria or ACHA's compliance requirements during the term of its accreditation ("Deficiency"). Applicant's failure to meet ACHA's compliance requirements shall result in probation of accreditation or revocation of accreditation, at ACHA's discretion. Upon the occurrence of any Deficiency Applicant

shall take all steps required as set forth in ACHA's Criteria Maintenance Guidelines (as amended from time to time) within the timeline set forth therein. If Applicant fails to correct any Deficiency within the required timeframe, then Applicant's accreditation will be revoked. Applicant agrees that, immediately upon notice of revocation of accreditation, that Applicant will immediately cease publishing, advertising or claiming accreditation and remove all references thereto, and any use of ACHA's name, marks or claimed affiliation, including from Applicant's website(s) and materials provided to patients. If Applicant corrects any Deficiencies after the required timeframe, then it may request reinstatement of its accreditation, which ACHA may grant within its sole discretion. Applicant agrees that failure to comply with this Paragraph 5 shall give rise to a right by ACHA to file for temporary and/or permanent injunctive relief, without bond or the necessity of proving actual damages. Should ACHA prevail in an action for injunctive relief, ACHA shall be awarded, as an element of damages, its attorneys' fees and costs in prosecuting same.

6. Warranty by Applicant. Applicant warrants that all information provided to ACHA, including, without limitation, any document furnished in connection with this Agreement or the application process, is accurate and any changes to such information will be immediately reported to ACHA. Furthermore, if ACHA grants accreditation, Applicant warrants that any changes to the information provided during the application process, or any changes to Applicant's compliance with ACHA's accreditation requirements, will be immediately reported to ACHA.
7. Continuing Obligations. Applicant agrees that it will timely and completely respond to annual reviews ("Check-In Reviews") initiated by ACHA within six (6) weeks of receipt of same, including providing requested documents and required signatures. Applicant will report to ACHA any changes to its compliance with ACHA's accreditation requirements within thirty (30) days of such changes. Applicant will provide an annual reporting of providers in place, with attesting signatures of site officials required by ACHA, within four (4) weeks of such reporting. Applicant will cooperate with ACHA to permit any site visits requested by ACHA during the accreditation period. During the Accreditation Period, Applicant will prominently display ACHA's Accreditation plaque in Applicant's congenital heart program offices and will prominently display ACHA's Accreditation badge on its congenital heart program website pages.
8. Confidentiality. Neither Applicant nor ACHA shall during the term of this Agreement or thereafter, without the other party's prior written consent, disclose to others, use or allow others to use any proprietary or confidential information of the other. The parties shall ensure that their employees, collaborators, agents, managers, and other appointees will maintain absolute confidentiality about information, knowledge, data, etc. exchanged between

parties. The parties agree that this Agreement, and any nonpublic communications by ACHA to Applicant are considered ACHA's confidential information.

9. Independent Contractors. ACHA and Applicant agree that the relationship created by this Agreement is an independent contractor relationship and nothing contained in this Agreement shall be construed to place any of the parties in the relationship of principal and agent, master and servant, partners or joint venturers.
10. Assignment. The rights and obligations arising under this Agreement may not be assigned by either party without the express written consent of the other party.
11. Waiver. This Agreement and any rights hereunder shall not be waived in any manner except by an instrument in writing signed by each of the Parties. The failure of a Party to enforce any of the provisions of this Agreement at any time shall in no way be construed to be a waiver of such provision, nor affect the validity of this Agreement or such provision, or limit the right of the Party thereafter to enforce this Agreement or such provision.
12. Governing Law. This Agreement shall be governed by the laws of the state in which the Applicant's facility is situated, without giving effect to its principles of conflicts of law. The Parties hereby consent to the exclusive jurisdiction of the state and federal courts located in or with jurisdiction over the County in which Applicant's facility is situated to resolve any disputes arising hereunder. The Parties waive any objection to such forum based on lack of personal jurisdiction, forum non-conveniens or otherwise. The Parties agree that, due to the complexity of the issues involved, that each Party waives its right to a jury trial for any matter, claim or lawsuit arising out of this Agreement.
13. Severability. The illegality or partial illegality of any provision of this Agreement shall not affect the validity of this Agreement or any other provision hereof. If any provision of this Agreement is held to be unenforceable for any reason, it shall be adjusted, rather than voided, in order to achieve the intent of the Parties to this Agreement to the extent possible. In any event, all other provisions of this Agreement shall be deemed valid and enforceable to the full extent possible.
14. Counterparts. This Agreement may be executed in one or more counterparts, including in electronic or facsimile versions, each of which shall, for all purposes, be deemed to be an original and all of which shall constitute the same instrument.
15. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be duly given to either party, (a) upon delivery to the address of such party specified below if delivered in person or by courier; (b) delivery into the United States Mail by certified or registered mail, return receipt requested, postage prepaid;



or (c) upon dispatch if transmitted by telecopy or other means of facsimile, to the following addresses or telecopy numbers:

If to ACHA: By email only: accreditation@achaheart.org

If to the Applicant:

The parties may change the foregoing addresses and facsimile numbers through written notice to the other party as provided herein.

- 16. Complete Agreement. This Agreement together with Exhibits A, B and C which are incorporated herein by reference, sets forth the complete understanding of the parties with respect to the subject matter hereof, supersedes any prior, oral or written understandings and may not be altered, modified or amended except by a written instrument signed by both parties.
- 17. Indemnification. The healthcare organization/hospital shall remain exclusively responsible, indemnify and hold harmless ACHA from and against any claim, damage or liability arising out of or resulting from the execution of this Agreement.
- 18. Warranty of Authority. Applicant makes the following representations to ACHA, on which ACHA is entitled to rely in executing this Agreement: (i) Applicant is duly organized and existing under the laws of the state in which its Adult Congenital Heart Program is situated, and is qualified to do business in such state and has the power to enter into this Agreement and the transactions contemplated hereby and to perform its obligations hereunder; (ii) by proper resolution the signatory hereto has been duly authorized to execute and deliver this Agreement, which shall be and is binding on Applicant; and (iii) the execution, delivery, and performance of this Agreement and the consummation of the transactions herein contemplated shall not conflict with or result in a violation or breach of, or default under Applicant’s formational or governing documents (including, but not limited to articles of incorporation, certificate of formation, bylaws, charter or partnership or operating agreements, as amended), or any indenture, mortgage, note, security agreement, or other agreement or instrument to which Applicant is a party or by which it is bound.

IN WITNESS WHEREOF, intending to be legally bound, the parties have caused the Agreement to be executed on the day and year first above written.

Adult Congenital Heart Association

[Applicant]

By: _____
[NAME] [TITLE]

By: _____
[NAME] [TITLE]
[PROGRAM OR CENTER NAME]

Date: _____

Date: _____

Appendix B – Business Associate Agreement

Business Associate Agreement

This Business Associate Agreement (“Addendum”) is entered into this _____ day of _____, 20____, and is made part of the Application submitted by _____ (“Applicant”) to the Adult Congenital Heart Association’s (“ACHA”) Adult Congenital Heart Disease Program Accreditation process and/or pilot site program. Applicant and ACHA are collectively referred to as “Parties.”

WHEREAS, the Application and the Addendum establish the relationship between the Parties for the purpose of accreditation;

WHEREAS, Applicant is a Covered Entity pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the regulations promulgated thereunder by the U.S. Department of Health and Human Services codified at 45 C.F.R. parts 160 and 164 (Standards for Privacy of Individually Identifiable Health Information or “Privacy Rule” and the Security Standards for the Protection of Electronic Health Information or “Security Rule”); and the security provisions of the American Recovery and Reinvestment Act of 2009 (the “HITECH Act”), and the regulations promulgated thereunder;

WHEREAS, in the course of accreditation, ACHA may access or receive individually identifiable health information from Applicant that qualifies as Protected Health Information (“PHI”);

WHEREAS, in receiving or accessing such PHI, ACHA would become a “Business Associate” of the Applicant as defined by HIPAA;

WHEREAS, Applicant as a Covered Entity is required to enter into this Agreement to obtain satisfactory assurances that ACHA, as a Business Associate, will appropriately safeguard all PHI received by ACHA on behalf of Applicant.

In consideration of the mutual promises in this Addendum, the Parties agree as follows:

I. DEFINITIONS

- 1.01 Addendum. “Addendum” means this Business Associate Agreement.
- 1.02 Protected Health Information (“PHI”). “Protected Health Information” or “PHI” shall have the same meaning as the term “Protected Health Information” in 45 C.F.R. §160.103, limited to that subset of PHI held by ACHA that is received by Applicant on behalf Applicant. PHI as stated herein will include PHI in electronic form unless specifically stated otherwise.
- 1.03 Capitalized terms used but not otherwise defined in this Addendum shall have the same meaning as set forth in 45 C.F.R. parts 160 and 164.

II. ACHA’S OBLIGATIONS

- 2.01 Ownership. ACHA agrees and acknowledges that any PHI that ACHA receives in connection with the services rendered pursuant to the Application, is confidential and shall remain the exclusive property of Applicant.
- 2.02 Use and Disclosure of Protected Health Information. ACHA will not use or disclose PHI in any manner that would violate the Privacy Rule at Subpart E 45 C.F.R §164 if done by Applicant except as required by law and as specified below:
 - A. Use and disclosure in a manner compliant with the Privacy Rule Subpart E of 45 C.F.R. Part 164 that is necessary to perform the services set forth in the Application;
 - B. Use of PHI for ACHA’s proper management and administration and to fulfill of legal responsibilities ACHA;
 - C. Disclosure of PHI for ACHA’s proper management and administration or to carry out its legal responsibilities, provided that the disclosures are required by law, or ACHA has i) obtained from the third party written assurance that the PHI will remain confidential and will be used or disclosed only as required by law or for the purposes for which it was disclosed, and ii) the third party agrees to notify ACHA of any instances of which it is aware in which the confidentiality of the PHI has been breached;
 - D. Use or disclosure of PHI to provide Data Aggregation services in relation to Health Care Operations of Applicant that have authorized ACHA to perform Data Aggregation services;
 - E. De-identify PHI on behalf of the Applicant pursuant to 45 C.F.R. §164.502(d) for use in research, quality improvement or other purposes consistent with ACHA’s charitable mission;

F. ACHA agrees to make uses, disclosures and requests for PHI consistent with Applicant's minimum necessary policies.

2.03 Applicant's Obligations: To the extent that ACHA carries out any obligations of Applicant under the Privacy Rule, ACHA will comply with the requirements of the Privacy Rule that apply to Applicant in carrying out those obligations.

2.04 Prohibited Use & Disclosure of Protected Health Information: ACHA will not use or further disclose PHI other than as permitted by this Business Associate Agreement or as required by law.

2.05 Safeguards. ACHA agrees to use reasonable and appropriate safeguards to prevent use or disclosure of PHI other than as permitted by this Agreement or as required by law. ACHA agrees to implement appropriate administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of any PHI in accordance with Subpart C of 45 C.F.R. 164 and comply with all provisions of the Security Rule at 45 C.F.R. §§164.308, 164.310, 164.312 and 164.316.

2.06 Reporting and Breach Notification. ACHA shall report to Applicant any use or disclosure of PHI not provided for in the Agreement, any Security Incident involving electronic PHI, and any Breach of Unsecured PHI as required at 45 C.F.R. §164.410. Such report shall be provided promptly and without unreasonable delay, but no later than fifteen (15) days after ACHA first learns of the unauthorized use or disclosure, Security Incident or Breach.

A. The parties agree that this section satisfies any notices necessary by ACHA to Applicant of the occurrence of unsuccessful Security Incidents for which no additional notice to Applicant shall be required. For purposes of this Agreement, such unsuccessful Security Incidents include, without limitation, activity such as pings and other broadcast attacks on ACHA's firewall, port scans, unsuccessful log-on attempts, denial of service and any combination of the above, so long as no such incident results in unauthorized access, use or disclosure of Electronic PHI.

2.07 Access, Amendment and Accounting of Disclosures. With respect to all PHI in ACHA's possession, ACHA agrees to the following:

A. Access to PHI. To the extent that ACHA possesses an applicable Designated Record Set, that is not otherwise in possession of Applicant, and within fifteen (15) business days of receipt of a written request by Applicant for Individual to access such PHI, ACHA shall make available such PHI, to the extent required for Applicant's compliance with its obligations under 45 C.F.R. §164.524.

- B. Amendment of PHI. To the extent that ACHA possesses an applicable Designated Record Set, and within fifteen (15) business days of receipt of a written request from Applicant or Individual, ACHA shall make any amendment(s) to such PHI as directed or agreed to pursuant to 45 C.F.R. §164.526 or take other measures as necessary to satisfy ACHA's obligations under 45 C.F.R. §164.526.
- C. Availability of Compliance Records. ACHA shall make its internal practices, books and records available to the Secretary of the U.S. Department of Health and Human Services for purposes of determining compliance with the HIPAA Rules.
- D. Accounting. Within fifteen (15) business days of receipt of a written request from Applicant, ACHA shall make available to Applicant disclosures of PHI as would be required for Applicant to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. §164.528.

2.08 Subcontractors. ACHA agrees to ensure that any subcontractor, to whom it provides or transmits PHI received from Applicant, or created or received by ACHA on behalf of Applicant agrees to the same restrictions and conditions that apply through this Agreement to ACHA with respect to such information.

2.09 Marketing and Sale. ACHA will not engage in communication that might be deemed to be "Marketing" under the HITECH Act. ACHA will not engage in the sale of PHI.

III. APPLICANT'S OBLIGATIONS

3.01 Notice of Privacy Practices. Applicant shall provide to ACHA any notice of privacy practices produced in accordance with 45 C.F.R. § 164.520 and any changes to that notice.

3.02 Restrictions on Use and Disclosure. Applicant agrees to notify ACHA in writing, of any restriction on the use or disclosure of PHI agreed to by Applicant in accordance with 45 C.F.R. §164.522 to the extent that the restriction affects ACHA's use or disclosure of PHI. Should the restrictions materially affect ACHA's ability to perform accreditation services or increase ACHA's costs of performance, Applicant authorizes ACHA to terminate the application and accreditation maintenance relationship.

3.03 Individual Authorization Revocation. Applicant agrees to inform ACHA of any change to, or revocation of, an Individual's Authorization to use or disclose PHI to the extent that such change may affect ACHA's use or disclosure of PHI, within a reasonable period of time after Applicant becomes aware of such change.

3.04 Permissible Requests. Applicant shall not request ACHA to use or disclose PHI in any manner that would not be permissible under the Privacy Rule at Subpart E of 45 C.F.R. Part 164 if done by Applicant.

3.05 Notice of Security Incidents. Applicant shall report to ACHA in writing any Security Incident relating to any PHI reviewed or held by ACHA of which it becomes aware.

IV. TERMINATION

4.01 This Addendum shall commence on the Effective Date.

4.02 Either Party may terminate this Addendum by providing written notice to the other Party.

4.03 This Addendum shall automatically terminate upon the termination date of the Accreditation process as set forth in the Application, including application, provisional accreditation, accreditation monitoring and accreditation maintenance.

4.04 Upon termination of this Addendum for any reason, except as provided in paragraph (B) of this section, ACHA agrees:

A. to return to Applicant or to destroy all PHI received from Applicant or otherwise through the performance of services for Applicant, that is in the possession or control of ACHA or its agents.

B. in the case of PHI which is not feasible to “return or destroy,” to extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as ACHA maintains such PHI. ACHA further agrees to comply with other applicable state or federal law, which may require a specific period of retention, redaction, or other treatment of such PHI.

V. MISCELLANEOUS

5.01 Survival. The rights and obligations under Section II of this Addendum, shall survive the termination of this Addendum.

5.02 Choice of Law and Jurisdiction. The Parties agree that the law of Pennsylvania shall govern this Addendum and that any dispute arising under this Addendum shall be resolved in a court of competent jurisdiction located in Pennsylvania.

5.03 Mutual Indemnification.

A. Each party shall indemnify, defend and hold harmless the other from and against any and all claims, liabilities, losses, damages expenses and costs (including reasonable attorney’s fees), that arise in connection with this Addendum or any negligent or wrongful acts or omissions related to this Addendum, caused in whole or in part by either party’s failure to comply with this Addendum, to the extent that party’s failure caused or contributed to the other’s liability for such claims, penalties, damages or other amounts payable.

B. Each party shall indemnify the other, and pay, or reimburse, the other for all reasonable costs of notification of individuals, including legal fees and other costs associated with



determination of notification duty, drafting the notification letter, mailing the notification letter and staffing the call center, that arise from its own acts, omissions or negligence.

ADULT CONGENITAL HEART ASSOCIATION

Signature

Name

Title

Date

Adult Congenital Heart Association
280 North Providence Road, Suite 6
Media, PA 19063
Address

APPLICANT NAME

Signature

Name

Title

Date

Address

Address

Appendix C – Fee Schedule

Application Year	Fee
Reaccreditation 2022 – 2024	\$14,500
Reaccreditation 2025 - 2030	\$15,500
Initial Accreditation 2022 - 2023	\$15,500
Initial Accreditation 2024-2025	\$16,500
Initial Accreditation 2026-2027	\$17,500
Initial Accreditation 2028-2029	\$18,500
Initial Accreditation 2030 - 2031	\$19,500

Appendix D – Criteria Maintenance Guidelines

Criteria	What constitutes a deficiency	Center's Responsibility to Report Deficiency to ACHA*	Probation Conditions				Time to resolve deficiency from date of plan submission	Consequences if deficiency not resolved within given time frame
			None	If plan submitted within 6 weeks, probation until deficiency resolved	If plan NOT submitted within 6 weeks, automatic suspension	Automatic Suspension with or without plan		
2 ACHD Cardiologists	Less than 2 ACHD Board Certified/Board Eligible Cardiologists	Written plan for recruitment of a new cardiologist and plan for providing care to and 24/7 coverage for ACHD patients		X	X		12 months	Suspension of accredited status until resolved
	Less than 1 ACHD Board Certified/Board Eligible Cardiologists	Written policy for recruitment of two new cardiologists				X	6 months	Suspension of accredited status until resolved
ACHD Medical Program Director	Medical Program Director that is NOT ACHD Board Certified with additional ACHD Board Certified cardiologist(s) providing patient care	Written plan for ACHD Board Certified/Eligible cardiologist to assume Medical Program Director role		X	X		12 months	Suspension of accredited status until resolved
	Medical Program Director that is NOT ACHD Board Certified and no other ACHD Board Certified cardiologist(s) providing patient care	Written plan for recruitment of ACHD Board Certified Medical Program Director and at least one ACHD Board Certified/Eligible cardiologist				X	6 months	Suspension of accredited status until resolved
Advanced Practice Nurse/Physician Assistant	Less than 1 APP/PA or not 1.0 FTE dedicated to ACHD	Written plan to cover the work of the APP and recruitment plan to fill position		X	X		12 months	Suspension of accredited status until resolved
Registered Nurse	Less than 1 RN or not 1.0 FTE dedicated to ACHD	Written plan to cover the work of the RN and recruitment plan to fill position		X	X		12 months	Suspension of accredited status until resolved
Cardiothoracic Surgery/Cardiothoracic Intensive Care Unit	One CHD surgeon and no current plan in place for 24/7 coverage for ACHD surgeries	Written plan for recruitment of CHD surgeon and plan to provide 24/7 surgical coverage		X			12 months	*Suspension of accredited status for programs with no CHD surgeons until resolved
	Less than 1 CHD surgeon	Written plan for recruitment of two CHD surgeons				X	12 months	Suspension of accredited status until resolved
Heart Failure, Heart Transplant, Heart/Lung Transplantation	Less than 1 HF/Transplant Cardiologist or lack of collaboration with Accredited Transplant Center	Written plan for recruitment of new provider and plan for HF/Transplant evaluation coverage/collaboration with ACHA ACHD Accredited Comprehensive Care Center		X	X		12 months	Suspension of accredited status until resolved
Interventional Cardiac Catheterization	Less than 1 ACHD Interventionalist	Written plan for recruitment of new provider with CHD experience and plan for coverage of ACHD interventional needs		X	X		12 months	Suspension of accredited status until resolved
Interventional Electrophysiology	Less than 1 Electrophysiologist	Written plan for recruitment of new provider with CHD experience and plan for coverage of ACHD electrophysiology needs		X	X		12 months	Suspension of accredited status until resolved
Inpatient Services	Change in hospital structure, such as a merger with another institution, that impacts patient care (i.e. physician privileges, access to EMR system, transfer between facilities)	Report hospital structure change; submit documentation/letter demonstrating the merging institutions' support of the ACHD program; Updated policies for Outpatient/Inpatient Services must be submitted within 6 months or once merger is finalized		X	X		6 months	Suspension of accredited status until resolved

Criteria	What constitutes a deficiency	Center's Responsibility to Report Deficiency to ACHA*	Probation Conditions				Time to resolve deficiency from date of plan submission	Consequences if deficiency not resolved within given time frame
			None	If plan submitted within 6 weeks, probation until deficiency resolved	If plan NOT submitted within 6 weeks, automatic suspension	Automatic Suspension with or without plan		
Outpatient Services	Change in hospital structure, such as a merger with another institution, that impacts patient care (i.e. physician privileges, access to EMR system, transfer between facilities)	Report hospital structure change; submit documentation/letter demonstrating the merging institutions' support of the ACHD program; Updated policies for Outpatient/Inpatient Services must be submitted within 6 months or once merger is finalized		X	X		6 months	Suspension of accredited status until resolved
Transitional Services	Change in hospital structure, such as a merger with another institution, that impacts patient care (i.e. physician privileges, access to EMR system, transfer between facilities)	Report hospital structure change; submit plan demonstrating the ability of the program to continue the same care for all ACHD patients		X	X		6 months	Suspension of accredited status until resolved
Patient-Centered Care	Patient-Family Advisory Council (PFAC) is not present at 2.5 year mark into initial accreditation	Report deficiency and provide plan to implement the PFAC	X				6 months	Continued education about the need for a PFAC. While a program's accredited status will not be suspended for absence of a PFAC, it will not be re-accredited without a PFAC in place.
Echocardiography	Less than 1 ACHD Echocardiographer or Sonographer	Report deficiency and submit plan to recruit echocardiographer or sonographer experienced in CHD		X	X		6 months for sonographer and QI meeting 12 months for echocardiographer	Suspension of accredited status until resolved
	Quality Improvement (QI) meetings not in place between echocardiography and ACHD at 2.5 year mark into initial accreditation	Submit plan to implement quality improvement meetings	X				6 months	Continued education about the need for dedicated QI meetings; program will not be re-accredited without QI meetings in place.
Cardiac Magnetic Resonance Imaging	Less than 1 ACHD Advanced Imager	Report deficiency and submit plan to recruit advanced imager experienced in CHD		X	X		12 months	Suspension of accredited status until resolved
	Quality Improvement (QI) meetings not in place between echocardiography and ACHD at 2.5 year mark into initial accreditation	Submit plan to implement quality improvement meetings	X				6 months	Continued education about the need for dedicated QI meetings; program will not be re-accredited without QI meetings in place.
Cardiac Computed Tomography	Less than 1 ACHD Advanced Imager	Report deficiency and submit plan to recruit advanced imager experienced in CHD		X	X		12 months	Suspension of accredited status until resolved
	Quality Improvement meetings not in place between CT and ACHD at 2.5 year mark into initial accreditation	Submit plan to implement quality improvement meetings	X				6 months	Continued education about the need for dedicated QI meetings; program will not be re-accredited without QI meetings in place.
Pulmonary Arterial Hypertension	Less than 1 Pulmonary Hypertension consultant	Report deficiency and submit plan to recruit pulmonary hypertension consultant		X	X		12 months	Suspension of accredited status until resolved
	Quality Improvement meetings not in place between Pulmonary Hypertension and ACHD at 2.5 year mark into initial accreditation	Submit plan to implement quality improvement meetings	X				6 months	Continued education about the need for dedicated QI meetings; program will not be re-accredited without QI meetings in place.

Criteria	What constitutes a deficiency	Center's Responsibility to Report Deficiency to ACHA*	Probation Conditions				Time to resolve deficiency from date of plan submission	Consequences if deficiency not resolved within given time frame
			None	If plan submitted within 6 weeks, probation until deficiency resolved	If plan NOT submitted within 6 weeks, automatic suspension	Automatic Suspension with or without plan		
Reproductive Services	Absence of collaborative conference	Provide plan to implement collaborative conference between ACHD and MFM		X	X		6 months	Suspension of accredited status until resolved
Cardiac Anesthesia	Less than 1 Cardiac Anesthesiologist	Report deficiency and submit plan to recruit cardiac anesthesiologist with experience in CHD and coverage for anesthesia needs		X	X		6 months	Suspension of accredited status until resolved
Psychology and Social Work	Less than 1 social worker that is 0.5 FTE dedicated to ACHD at 2.5 year mark into initial accreditation	Report deficiency and submit plan to recruit social worker		X	X		6 months	Suspension of accredited status until resolved