



ACHA ACHD Accreditation User Manual

2021

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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 advocacy organization, convened a panel of members of ACHA leadership and ACHD professionals from

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.

their 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

Introduction

Programs can apply as a Comprehensive Care Center.

The process of becoming accredited consists of an online application and an in-person site visit. At ACHA, we understand that this process is quite extensive, and it is our goal to make the process as easy, seamless, and as fair as possible. Accreditation is valid for a 5-year period. The program will be encouraged to reapply at this time.

Below, we have outlined each step of the accreditation process 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.

ACHA Application Announcement

ACHA will announce the opening of the accreditation process and all pertinent information related to accreditation via an email to stakeholders and Program Directors. This information will also be made available on the ACHA website: <https://www.achaheart.org/provider-support/accreditation-program/accreditation-program-documents/>. Please monitor this page for any real-time accreditation updates.

Application Timeline

When the application period opens, each site will have at least two to three full months to submit their application. All dates are subject to change, and notifications will be posted on the accreditation portion of the ACHA website: <https://www.achaheart.org/provider-support/accreditation-program/accreditation-program-documents/>.

The application cycle will have two deadlines, one in the spring and one in the fall, which will determine when sites have their site visits and are reviewed by the Steering Committee. We have two Steering Committee meetings per year. One around the time of the ACC meeting in March and the other at the AHA meeting in November.

For exact dates, please refer to the Application Timeline document on our Accreditation Program Documents' Webpage (<https://www.achaheart.org/provider-support/accreditation-program/accreditation-program-documents/>). Please note the exact timing of the site visit may vary based on the number of applicants and availability of dates.

Application Fee and Business Associate Agreement

The application fee for the ACHA Accreditation Application and process is \$14,500. ACHA will also need each program to sign a Business Associate Agreement (BAA). We will send the BAA to the appropriate contact at each program, but we have also attached a copy of the [BAA template](#) to the appendices of this document. Our legal team can work with the program's legal team to have the individual BAA's approved. But any time spent above 45 minutes for our legal team to change the BAA in any way will be billed back to the ACHA Program, above and beyond the \$14,500 application fee. We strongly recommend using ACHA's BAA as we do not collect any PHI during this process (either in the application or during the site visit). The BAA is a protection put in place in case we were to encounter any PHI accidentally in the application or during the site visit.

The \$14,500 application fee and final signed BAA are due by the application due date.

We will need the fee and BAA submitted by the due date of the application cycle (refer to timeline document)². If a program needs additional time to process their application fee, our legal team can work with the program to establish an extended due date. It is our goal to make this process as inclusive as possible. If the program does not meet the updated due date established during these negotiations, they will not be eligible for this round of the application process. All programs that cannot move forward with the application process for any reason, will not be listed as "Not Accredited" in any ACHA material. They simply will lose access to their online application. These programs are welcome to submit their application in the next round of applications for the same fee³.

² Programs who may need additional time to process the application fee should contact ACHA to develop a payment plan and gain access to the online application site.

³ Only one application fee will be collected per year. If the program's application is still incomplete after a full year of opportunities to submit their application, they may be subject to an additional application fee.

Please send all application fees via check to:

Attn: Accreditation

Adult Congenital Heart Association

280 North Providence Road, Suite 6

Media, PA 19063

We do not accept partial payments. If you have any questions about the application fee, please contact Misty Sharpe, Accreditation Manager at msharpe@achaheart.org or Danielle Hile, Senior Director of Mission Delivery dhile@achaheart.org.

Online Application

Accessing Application and Timeline for Completing Application

Each program will have around two to three months to complete their online application on OpenWater, our application hosting system. Information about how to access the online application is available on the ACHA accreditation website: <https://www.achaheart.org/provider-support/accreditation-program/accreditation-program-documents/>. If a program cannot complete the application, or the program submits an incomplete⁴ application, we cannot guarantee that a site visit will be scheduled in time for the program to be reviewed by the next official Accreditation Steering Committee meeting.

Application Review

ACHA Administrative Review

After a program 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. We will ensure that all the documents are uploaded correctly and note any sections that are missing documentation. After the administrative review, programs will be made aware of any missing pieces that are preventing them from moving forward to having a site visit. They will be given time to resubmit that information with no negative effects to their overall potential accreditation. If the program 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 program at this 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 who is an ACHD Cardiologist who serves on the ACHA Accreditation Steering Committee. The ACHA accreditation staff member and reviewers will compare the application responses to the ACHA ACHD Accreditation Program Criteria. A checklist will be provided to reviewers to ensure an objective review.

A second reviewer from the Accreditation Steering Committee, will review the program's application as well. This secondary reviewer will not attend the site visit. Our goal is to review each application as

⁴ Missing several key components of the application.

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 program about any missing criteria or documentation that is preventing their program from moving forward with the site visit. ACHA staff will work with the program to schedule an in-person site visit if appropriate. We will work to schedule the site visit date before we have completed the administrative review. Due to the number of providers we need to meet with and busy schedules of site visitors, we want to ensure we get the best dates for the program and the site visitors. Please know we will not confirm the site visit (i.e. book flights and hotels) until this administrative review is complete and we can confirm that we can move forward with the site visit. The timing of the site visit may depend on the number of applicants for that round. We typically schedule the site visits so that the first sites to submit their application for that round get the first selection of site visit dates.

Site Visit Preparation

The in-person 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 prospective accreditation program 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 sites must draft the itinerary for the day using our site visit itinerary template as a guide.

Review this itinerary at the ACHA Accreditation Program Documents Webpage at <https://www.achaheart.org/provider-support/accreditation-program/accreditation-program-documents/> for specific instructions about scheduling the day.

Please provide us with a copy of the agenda at least **two weeks prior to the scheduled site visit date** so that we can review and make any modifications if necessary.

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 ACHD program and meet with essential program personnel. The goal of the site visit is to obtain a sense of the ACHD program beyond the written documentation provided in the application. Programs will be asked about their collaborative relationships with their pediatric and adult IM (respectively) counterparts and will be required to provide detailed explanations of these relationships during the site visit with the key staff members. We ask 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 we will need to meet with during the site visit⁵:

- 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)

⁵ Additional key members of the ACHD program may be asked to attend the site visit meeting.

- 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)
- We **do not** need a physical tour of the ACHD Program

We understand that providers and other program staff are extremely busy and that their schedules are subject to unexpected changes. If we are unable to meet with one of the above personnel during the site visit, we will need to schedule a conference call or a video conference call within a reasonable timeframe⁶ after the in-person site visit. Failure to meet with one of the above individuals either in person or via telecommunication could delay the application process and/or prevent the program from receiving accreditation at the Accreditation Steering Committee Meeting.

ACHA Accreditation Steering Committee Meeting

Meeting Process

The ACHA Accreditation Steering Committee Meetings will occur twice per year, unless additional meetings are 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 program 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. A program will either be given a status of Accredited; Pending Accreditation with Minor Deficiencies; or Pending Accreditation with Deficiencies. No program will receive a decision of “Not Accredited” during the first review. A two-thirds majority rule is required for a decision to pass about a program’s final accreditation status.

Approximately six to eight weeks after the Accreditation Steering Committee meeting, ACHA will send out a **Decision Report** informing each center of their accreditation decision (Accredited, Pending Accreditation with Minor Deficiencies, and Pending Accreditation with Deficiencies). We will also inform the site if a second site visit is needed. **Please note that sites are responsible for all costs (i.e. travel**

⁶ No more than two months after the site visit.

expenses of site visitors) associated with the second site visit. This report also lists the program's strengths, deficiencies, and challenges for each section of the criteria. Please note that every program that has gone through the process has had at least a few deficiencies to correct.

Accredited Programs

Once a program corrects any and all deficiencies outlined in their decision report, ACHA will send the program director their formal accreditation letter. We also ask that centers send us their PR/Marketing contact. Please know that all materials regarding the promotion of a program's accreditation must be reviewed and approved by ACHA. Accreditation is valid for a 5-year period. The program will be encouraged to reapply at this time.

ACHA will also list the program as an accredited center on our website, <https://www.achaheart.org/provider-support/accreditation-program/>. 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.

Pending Accreditation/Not Accredited Programs

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

No program will be voted as Not Accredited during the first review of the program. Programs with a large amount of 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 Misty Sharpe at msharpe@achaheart.org and Danielle Hile at dhile@achaheart.org. We ask that programs send documentation in groups as opposed to individual documents. This practice reduces the likelihood of any documentation being missed. Please allow us to review all documentation submitted to correct minor deficiencies. For the major deficiencies, we will need to review the documentation with the entire Steering Committee during one of our bi-annual meetings (March/April and November). If the Accreditation Steering Committee determines that these deficiencies have been corrected, the program will be accredited. If the program has improved, but still not met all the criteria and documentation requirements for accreditation, they will repeat the above resubmission process (additional fees may apply). If the program has not improved or has deteriorated since their initial re-review, they will receive a status of Not Accredited and have the option to reapply. Any program 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 programs.

ACHA will work with each program individually to ensure that they will be able to move forward through the accreditation process.

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, and Accreditation Steering Committee Meeting and a review) has been completed. If a program chooses not to apply or must discontinue the process at any point during the application process, they will not receive a Not Accredited status. We will not list any programs as Not Accredited. Only programs that are accredited will be listed on the ACHA website. We do not list Not Accredited programs or any status other than accredited.

Program Promotion, Marketing and Communications

ACHD Programs are required to work with ACHA with regard to promotion/publicity of the Accreditation status. During the process of applying for the ACHA ACHD Accreditation Program sites may only announce that they are “Currently Applying for the ACHA ACHD Accreditation Program” once their full fee has been paid and they have gained access to the online application form.

Once a program 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 marketing team. Programs 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 site should allow at least five business days for review.
- All press releases announcing the institution’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 despite 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 institutions can use the following accredited title below when referring to your institution’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 our 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.

Questions or Concerns

ACHA understands that the accreditation process is time consuming. Please rest assured that the goal of accreditation is not to be exclusionary or punitive, but to help standardize and improve care for ACHD

patients. We aim to foster a collaborative environment in which ACHD programs and providers can assist and learn from each other by sharing best practices. We understand 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. We are here to help through this process!

Misty Sharpe

Accreditation Manager – ACHA

Email: msharpe@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

Wisconsin Adult Congenital Heart Disease Program (WAtCH) at Children's Hospital of Wisconsin, Milwaukee, WI

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, MD, 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

Updated 7/8/2021

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

Introduction

We understand 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, we have compiled a list of template documents for most of the criteria that require an uploaded policies/procedures document. These templates are available at our Accreditation Program Documents Webpage: <https://www.achaheart.org/provider-support/accreditation-program/accreditation-program-documents/>. We hope 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 institution’s ACHD policies and procedures.

Compiling Policies and Procedures Documentation

We have template documents to help streamline the application process. The template documents are meant to serve as a guide, especially for the ACHD programs that do not already have written policies and procedures. If an institution 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. We do ask that these pre-existing templates are reviewed to ensure that they contain all of the 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 institution 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 criteria is included. We aim to identify and establish a standard process of care for ACHD patients, but it is not our goal to make “cookie-cutter” ACHD programs. We know 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 institution’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. We want to emphasize that these documents do not need to be long and verbose. A half-page to one page for each will be enough⁷.

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

⁷ Some documents will need to be longer depending on the depth of information required.

We 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 our 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 PDF’s 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. We will be extremely careful with each institution’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. We provided this section for sites to include extra information about their ACHD Program. Please note that the lack of additional files uploaded will not negatively affect a program’s chance of becoming an ACHA ACHD Accredited Program.

Conclusion

We understand that compiling and/or writing these policies and procedures might seem tedious and redundant at times. It is our goal 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, we are here to help. Please do not hesitate to contact the ACHA Accreditation staff listed below:

Misty Sharpe
Accreditation Manager – ACHA
msharpe@achaheart.org

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

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