AACVPR LEGAL FAQS FOR THE PARTICIPATION AGREEMENT

Please provide this document to anyone who will be reviewing the Participation Agreement; specifically legal counsel.

Explanation

We understand that organizations may have their legal counsel review the Participation Agreement (“Agreement”) for the pulmonary and/or cardiac rehabilitation registries (“Registries”). Please note that any revisions you request must be reviewed and approved by AACVPR’s legal counsel. This document provides answers to frequently asked questions and notes any areas in the Agreement that are required by AACVPR and therefore cannot be subject to revisions. We find that it is helpful for your counsel to understand the Registries and why AACVPR must require certain provisions in the Agreement.

The AACVPR Registries are quality assurance databases. The primary goal of a Registry is to promulgate data useful for quality assessment and improvement, provide benchmarks, and improve overall care provided to patients in outpatient cardiac and pulmonary rehabilitation programs.

HIPAA and the Business Associate and Data Use Agreement

Q: What data elements will my organization submit to the Registry?

A: The data submitted into the Registries at the individual program level may include some patient identifiers (last name, date of birth, zip code, and medical record number). However, these fields are not required in order to create a registry record. Visit the AACVPR Web site for the Cardiac and Pulmonary data elements:

Cardiac Rehabilitation Registry Selected Data Elements

Pulmonary Rehabilitation Registry Selected Data Elements

Therefore, the data available to the individual program on their own data is not be “de-identified”, nor is it a “limited data set” as those terms are defined under HIPAA. However, once the data is in the Registries, AACVPR creates a “limited data set” to create the benchmarking reports for quality improvement (health care operations under HIPAA). In addition, AACVPR aggregates and de-identifies the data in order to prepare the quality improvement benchmarking reports for all participants in the Registries. Such reports are de-identified. Any requests for the registry data for research purposes must go through a separate review and approval process by the Research Committee.
Q: Does AACVPR sign a HIPAA business associate agreement?

A: Yes, the Participation Agreement includes a HIPAA business associate and data use agreement.

Q: Will AACVPR sign our organization’s business associate agreement?

A: No. For several reasons, AACVPR requires that the business associate (BAA) and data use agreement contained within the Participation Agreement be used by the parties. The BAA is specifically tailored to the Registries and specifies how AACVPR can and cannot use and disclose PHI related to these specific Registries. Second, the Participation Agreement also includes a HIPAA Data Use Agreement, which is required to participate in the Registries. Finally, the Participation Agreement has other provisions related to the BAA and Data Use Agreement and therefore would require further revisions throughout the Agreement. For these reasons, AACVPR must insist on the BAA and Data Use Agreements that are included within the Participation Agreement. If you feel it is appropriate, you can make revisions to the BAA section of the Participation Agreement and AACVPR legal counsel will review such revisions and decide whether to accept such revisions.

Q: Does AACVPR’s business associate agreement include the provisions required by HITECH and the Omnibus Rule issued January 25, 2013?

A: Yes.

Q: Why does AACVPR’s business associate and data use agreement state that AACVPR will use a limited data set for research?

A: As a professional organization, AACVPR strives to support programs and professionals in the provision of high quality of care. AACVPR also recognizes the need for research that adds to the body of scientific knowledge that leads to improving the quality of care and patient outcomes that is disseminated within an appropriate framework. Thus, processes are in place to address research requests that require either de-identified or a limited data set for “research” as that term is defined under HIPAA. These terms must be included in the business associate and data use agreement in order for your institution to participate in the Registries. AACVPR is a multidisciplinary professional association comprised of health professionals who serve in the field of cardiac and pulmonary rehabilitation. AACVPR’s mission is to reduce morbidity, mortality and disability from cardiovascular and pulmonary disease through research and other related activities. Central to AACVPR’s core mission is improvement in quality of life for patients and their families.

Q: Does AACVPR sell our data?

A: No. AACVPR does not sell any data, including de-identified data.
Q: In addition to the HIPAA business associate agreement, our facility has a separate list of required security measures. Will AACVPR agree to that?

A: In the business associate agreement AACVPR has explicitly agreed that it will comply with all applicable HIPAA requirements, including the HIPAA Security Rule, which imposes numerous security measures for electronic protected health information. Some hospitals ask vendors to agree to the hospital’s own security measures or other specific measures. AACVPR cannot agree to those specific measures because AACVPR contracts with hundreds of hospitals for the Registries and could not agree to multiple different types of specific security measures, some of which may not be consistent.

**Multiple Participants for One Participation Agreement**

Q: Our hospital is a part of a hospital system. We would like to enter into one Agreement with AACVPR that will cover all hospitals within the system, can we do that?

A: No, for various reasons, AACVPR needs each hospital/facility to enter into its own Participation Agreement. However, you can use the same template agreement approved by both parties.

**The Format for Submitting the Data/Data Reliability Standards**

Q: Section 1.1 requires us to submit the data to the Registries in accordance with data reliability standards and in a format required by AACVPR. What are the standards and what is the required format?

A: If submitting data through the web-based interface, it will be validated programmatically for the correct data type and whether it is within expected range before being saved to the database. If the user is submitting data through an advanced programming interface (API), the developer of the link between the user’s application and the registry database will be required to ensure that the uploaded data meets the data definitions as defined in the API document supplied by AACVPR and Cissec, Inc, and will have their API tested prior to submitting patient records. All users are expected to ensure that the data they submit is accurate.

**License to AACVPR to Use the Data**

Q: Why does our organization need to grant AACVPR a non-exclusive, irrevocable, perpetual license to use our data (Section 1.2)?

A: You will continue to own the data that you submit to the Registries. However, because these Registries are used for ongoing benchmarking reports and research, the data will always remain in the Registries. Therefore, each participant must grant AACVPR a non-exclusive, irrevocable, perpetual license to use your data. This is required to participate in the Registries and cannot be modified.
**Audits**

Q: Why would AACVPR charge me a fee for additional audits (Section 1.6)?

A: In order to obtain valid, complete and accurate data, AACVPR must have the ability to conduct audits of participants. AACVPR conducts the initial audit at its own expense. If the audit reveals that the participant is not submitting complete and accurate data, AACVPR will provide a correction period then will require the additional audit. This additional audit will be conducted at the participant’s expense. The fee for the audit will be determined by AACVPR but it will cover AACVPR’s expenses. Again, it is not AACVPR’s goal to make a profit from an additional audit, but to simply cover its costs. Therefore, this language must remain. We also note that this is a very rare occurrence.

**Publishing Guidelines**

Q: Section 4.2 states that I must comply with all publication guidelines established by AACVPR. Can you provide a copy of the guidelines?

A: The Research-Registry Sub-committee is currently developing policies and procedures for publications and presentations for use of the registry data that goes beyond using their own data for internal, quality improvement purposes. Aggregated registry data used for external purposes (e.g., promotional, educational, presentations, and publications) cannot be used without review and consent of AACVPR.

**Automatic Renewal of the Agreement**

Q: Does AACVPR agree to a limited term and not have automatic renewal (Section 6.1)?

A: No, AACVPR requires automatic renewal. The fees for these Registries are very reasonable – the highest possible is $225 for an 18 month renewal. AACVPR keeps the fees low by keeping administrative costs down. A significant administrative cost is tracking expiration of Agreements and entering into new agreements. Therefore, AACVPR cannot agree to revise this term.

**Refund of Fees**

Q: Why doesn’t AACVPR ever refund fees (Section 6.2)?

A: The fees for these Registries are very reasonable – the highest possible annual fee is $225 for an 18 month renewal. AACVPR keeps the fees low by keeping administrative costs down. In addition, AACVPR allows a participant to terminate from the Registries at any time and for any reason. As a result, AACVPR does not agree to refund fees under any circumstance, even if AACVPR is found to be in breach of the Agreement.
**Assignment**

Q: Our facility would like the ability to assign this Agreement without AACVPR’s consent to affiliated entities or upon sale or merger; does AAVPR allow this (Section 9.3)?

A: Because AACVPR tracks data and participation by each participant, AACVPR cannot agree to any revisions to this section. AACVPR must provide approval before an Agreement can be assigned to another entity.

**Exclusion**

Q: Our facility requires a representation and warranty that AACVPR, its employees, officers, and directors have not been excluded by any federal or state health care programs. Can AACVPR agree to this?

A: AACVPR cannot agree. The law that prohibits an entity from contracting with an excluded vendor only applies when the vendor provides goods or services that are reimbursed by federal health care programs. In operating the Registries, AACVPR does not provide goods or services reimbursed by federal health care programs. In addition, AACVPR is not a Medicare/Medicaid provider. As a result, AACVPR does not check the exclusion list and cannot make a representation and warranty that AACVPR, its employees, officers, and directors have not been excluded by any federal or state health care programs.

**Insurance**

Q: Our facility has a standard provision that requires certain types and amounts of insurance. Can AACVPR agree to this?

A: In AACVPR’s experience most hospitals have boilerplate insurance requirements that are very specific. AACVPR contracts with hundreds of hospitals that participate in the Registries and each typically request a different type and amount of insurance. As a practical matter, AACVPR cannot agree to all of the different requirements for specific types and amounts of insurance. Therefore, as a rule AACVPR cannot agree to any provision which requires a specific type or amount of insurance.

**Compliance with a Participant’s Compliance Plan**

Q: Our hospital has a standard contract provision that requires vendors to obtain, review and comply with our hospital’s compliance plan. Will AACVPR agree to this?

A: Unfortunately, no. AACVPR contracts with hundreds of hospitals. It is not feasible or within the fees charged for the Registries for AACVPR to obtain, review and track all of the requirements in such compliance plans. In addition, most of the hospital compliance plans relate to vendors who are in some way involved in patient care, or billing for patient care. AACVPR is not involved in these activities, directly or indirectly.