

ACGME HIPAA FAQs – February, 2010

Introduction

HITECH¹ was adopted as part of the American Recovery and Reinvestment Act of 2009 and imposes certain requirements on business associates. ACGME is requiring a HITECH amendment ("ACGME HITECH Amendment") to the current ACGME Business Associate Agreement ("ACGME BAA")² in order to facilitate compliance with HITECH for itself and for the covered entities with which ACGME has business associate agreements.

The following FAQs are meant to provide information about the ACGME HITECH Amendment.

1. Why is ACGME requiring an ACGME HITECH Amendment to its BAA?

Despite the absence of clarifying regulations, ACGME believes that compliance with HITECH requires amendment of the ACGME BAA.³ Therefore, as part of its HITECH compliance, ACGME is requiring that covered entities with which ACGME has BAAs execute an ACGME HITECH Amendment.

The ACGME HITECH Amendment, which is posted on the ACGME website, amends the ACGME BAA, and includes new provisions that address HITECH.

2. What institutions are required to enter into an ACGME HITECH Amendment to the ACGME BAA?

Current Sponsoring Institutions. For some time, ACGME has required each sponsoring institution that is a covered entity to execute and submit to ACGME the ACGME BAA made available on the ACGME website.⁴ ACGME now also requires each sponsoring institution that is a covered entity to execute an ACGME HITECH Amendment.

¹ Health Information Technology for Economic and Clinical Health Act. On February 17, 2009, the stimulus law, the American Recovery and Reinvestment Act of 2009 ("ARRA") was enacted. HITECH is Title XIII of ARRA. HITECH imposes new federal security breach notice requirements and adds numerous new privacy and data security restrictions for covered entities and their business associates under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

² The current ACGME BAA on the web is titled "ACGME Amended BAA 2007."

³ See, 42 USC §§17931(a) & 17934(a).

⁴ ACGME has also required each sponsoring institution, regardless of whether it is a covered entity, to execute a Representation which states, in part,

Sponsoring Institution has taken, and will continue to take, that action necessary, consistent with law, to ensure that ACGME has access to information necessary to perform its accreditation function, which information is in the control of the Sponsoring Institution, participating institutions, and clinical sites.

ACGME HITECH Amendment

A sponsoring institution that executes an ACGME HITECH Amendment will be required to submit the executed ACGME HITECH Amendment to ACGME no later than December 31, 2010. Please return to:

HIPAA Compliance Office
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, Illinois 60654

New Sponsoring Institutions. ACGME requires each institution that is a covered entity, and that is applying for initial accreditation as a sponsoring institution, to submit to ACGME with its application for initial accreditation an executed ACGME BAA and an executed ACGME HITECH Amendment.

Clinical Sites. Many sponsoring institutions that are covered entities maintain a single BAA with ACGME, and their clinical sites do not have separate BAAs with ACGME. For these institutions, clinical sites disclose PHI to ACGME as a business associate of the sponsoring institution, per the BAA between ACGME and the sponsoring institution. *See* 45 CFR §160.103 (definition of business associate). ACGME urges clinical sites to consider that it is likely that a BAA with ACGME is unnecessary.

Sponsoring institutions that are not covered entities do not maintain BAAs with ACGME. Nevertheless, these sponsoring institutions, like all sponsoring institutions, are required to ensure that ACGME has accreditation access to program related information in the control of the sponsoring institution and clinical sites, subject to the confidentiality and other provisions of ACGME policies and procedures.⁵

Sponsoring institutions should work with clinical sites to determine whether clinical sites require a BAA with ACGME in order for ACGME to access PHI as part of its accreditation function. If a determination is made that the information can be provided to ACGME without the use of a BAA between ACGME and a clinical site, then ACGME does not require an ACGME BAA or an ACGME HITECH Amendment with the clinical site(s).

However, if a clinical site decides that it needs a BAA with ACGME, ACGME requires each clinical site to execute an ACGME BAA and an ACGME HITECH Amendment.

For some time, ACGME has required each sponsoring institution to maintain ACGME BAAs that clinical sites have executed, and to make them available at institutional and single program site visits. In addition, each sponsoring institution is now required to maintain a copy of each ACGME HITECH Amendment executed by a clinical site. Sponsoring institutions will be site surveyed for copies of ACGME HITECH Amendments executed by clinical sites at institutional site visits and at single program site visits beginning January 1, 2011.

⁵ See Footnote No. 4.

3. Must the ACGME HITECH Amendment be executed by the DIO?

It is up to the covered entity to determine who is authorized to bind the covered entity to the ACGME BAA and the ACGME HITECH Amendment. Some sponsoring institutions require the CEO, some the DIO, the Privacy Officer, or others. ACGME does not mandate who the signatory must be.

4. My sponsoring institution is a covered entity, but it does not think that it and/or its clinical sites submit PHI to ACGME. Therefore, it does not believe that a BAA with ACGME is necessary. How should my organization proceed?

ACGME encounters PHI orally and in documents in various contexts in the performance of its accreditation function: (1) during site visits following submission of accreditation applications and reapplications (sometimes); (2) during site visits to investigate issues raised by complaints about residency programs (sometimes); (3) in the Resident Case Log System; (4) in complaints relating to residency programs (rarely); and (5) in information sent by programs to ACGME responding to complaints (rarely).

If the lack of a BAA or an ACGME HITECH Amendment from a sponsoring institution or a clinical site impedes ACGME in its ability to perform its accreditation function, relating to a site visit or otherwise, the RRC or IRC, as appropriate, will consider the extent and nature of the impediment, and will determine the course of action to take, up to and including adverse accreditation action, just as it would if there were an impediment for reasons unrelated to HIPAA compliance.

5. Is PHI submitted to ACGME electronically?

Yes. Most of the information transmitted to the Resident Case Log System is not PHI, but there is some. As of July 1, 2009, over 90% of the ACGME multi-program sponsoring institutions will sponsor at least one program that is required to submit case data to the System. In addition, complaints and responses to complaints submitted in part by email on rare occasion contain some small amounts of PHI.

6. In its role as a sponsoring institution, my organization is not a covered entity. Does my organization need to sign a BAA with ACGME?

No. However, all sponsoring institutions must execute (once) and comply with a Representation posted on the ACGME website.⁶

7. Will ACGME need access to ACGME/sponsoring institution and ACGME/clinical site BAAs during every site visit for every program?

No. For some time, during institutional and single program site visits, ACGME has asked to verify the maintenance of (1) an executed Representation; (2) an executed

⁶ See Footnote No. 4.

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ACGME BAA with the sponsoring institution (if the sponsoring institution is a covered entity); and (3) any ACGME/clinical site BAAs. This verification will continue.

During institutional and single program site visits after December 31, 2010, ACGME will ask to verify the maintenance of (4) an executed ACGME HITECH Amendment with the sponsoring institution (if the sponsoring institution is a covered entity); and (5) any executed clinical site ACGME HITECH Amendments.

Verification of these (1-5) will only be needed during non-institutional and non-single program site visits if requested information is not provided and HIPAA is the reason given for not providing it.

8. What will happen if, because of HIPAA, ACGME is refused access to information that it deems necessary to perform its accreditation function during a site visit or otherwise?

ACGME has always required sponsoring institutions to ensure that ACGME has accreditation access to program related information in the control of the sponsoring institution and clinical sites, subject to the confidentiality and other provisions of ACGME policies and procedures. HIPAA introduced new requirements, the satisfaction of which may be necessary to accomplish this.

If this ability to access information needed to appropriately perform the accreditation function is impeded for any reason during a site visit or otherwise, the RRC or IRC, as appropriate, will consider the extent and nature of the impediment, and will determine the course of action to take, up to and including adverse accreditation action, just as it would if there were an impediment for reasons unrelated to HIPAA compliance.

9. Must a covered entity use the ACGME BAA and the ACGME HITECH Amendment, or can it use its own?

As ACGME maintains a large number of ACGME BAAs, and the language and form of the ACGME BAA have been accepted and recognized as sufficient for HIPAA-compliance by institutions across the country, ACGME requires that the "covered entity" use the ACGME BAA and the ACGME HITECH Amendment.

10. I have more questions. Whom should I contact?

Please email questions to hipaa@acgme.org. Responses will be sent as soon as possible.