

## BUSINESS ASSOCIATE ADDENDUM CHECKLIST

Contract Provision	Reg. Cite	Requirement	Related provisions, comments
	164.504(e)(2)(i)	Establish permitted and required uses and disclosures of PHI by BA	Final rule – must generally state purposes, reasons for use/disclosure and types of persons to whom info can be disclosed
	164.504(e)(2)(i)	May <u>not</u> authorize BA to use or further disclose info in a manner that would violate requirements of subpart if done by CE <b>except:</b> ↓	Must include “minimum necessary” language, either within this clause, or as a separate clause. <i>BA shall use/disclose PHI only in the minimum amount and to the minimum number of individuals necessary to achieve the purpose of the services being rendered to or on behalf of CE.</i>
	164.504(e)(2)(i)(A)	May permit BA to use or disclose PHI for “proper management & administration of BA as permitted by <b>(e)(4)</b>	
	164.504(e)(4)(i)(A) and (B)	<u>May permit BA to use PHI</u> – in its capacity as a BA if necessary for the proper management & administration of BA <b>or</b> to carry out the legal responsibilities of BA.	
	164.504(e)(4)(ii)	<u>May permit BA to disclose PHI</u> – in its capacity as a BA for same purposes, <b>but only if disclosure is</b> →	
	164.504(e)(4)(ii)(A)	Required by law <b>or</b> ↓	
	164.504(e)(4)(ii)(B)(1)	BA obtains reasonable assurances from person to whom info is disclosed that info will be held confidentially and used or further disclosed only as required by law or	

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		for purpose for which it was disclosed to the person <b>AND</b> →	
	164.504(e)(4)(ii)(B)(2)	The person to whom the information was disclosed notifies BA of any instance of which it is aware in which the confidentiality of the information has been breached.	
	164.504(e)(2)(i)(B)	BA may provide data aggregation services relating to the health care operations of the covered entity.	
	164.504(e)(2)(ii)(A)	BA will not use or further disclose the information other than as permitted or required by the contract or as required by law.	
	164.504(e)(2)(ii)(B)	BA will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract.	
	164.504(e)(2)(ii)(C)	BA will report to the CE any use or disclosure of the information not provided for by its contract of which it becomes aware.	Negotiate time and manner of reporting with BA – in writing, to whom, time frame, etc.
	164.504(e)(2)(ii)D	BA will ensure that any agents, including a subcontractor, to whom it provides PHI received from, or created or received by the BA on behalf of, the CE agrees to the same restrictions and conditions that apply to the BA with respect to such information.	May want BA to list subcontractors and agents in exhibit.
	164.504(e)(2)(ii)E	<u>Access</u> : BA will make available PHI in accordance with <b>164.524</b> .	Not necessary if BA does not have PHI in a designated record set.

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	164.504(e)(2)(ii)F	<u>Amendment</u> : BA will make available PHI for amendment and incorporate any amendments to PHI in accordance with <b>164.526</b> .	Not necessary if BA does not have PHI in a designated record set.
	164.504(e)(2)(ii)G	<u>Accounting</u> : BA will document disclosures of PHI as would be required for CE to respond to a request for an accounting.	
	164.504(e)(2)(ii)G	<u>Accounting</u> : BA will make available PHI to provide an accounting of disclosures in accordance with <b>164.528</b> .	
	164.504(e)(2)(ii)H	BA will make internal practices, etc. available to the Secretary.	
	164.504(e)(2)(ii)I	<u>Termination</u> : BA will – if feasible – return or destroy all PHI received from, or created or received by the BA on behalf of the CE. BA will retain no copies of such information. If return or destruction of such information is not feasible, BA will extend the protections of the K to the information and limit further uses and disclosures to those purposes that make the return or the destruction of the information infeasible.	
	164.504(e)(2)(iii)	Authorize termination by CE if CE determines that the BA has violated a material term of the contract.	
Not required by Privacy Rule		<u>Mitigation</u>	Not required by law, but included in sample language in August final rule.

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	Not required by Privacy Rule	<u>Insurance</u>	If main contract has insurance clause, may not be necessary in addendum.
	Not required by Privacy Rule	<u>Inspection</u> Allow CE to inspect BA’s systems, books, records if CE becomes aware of a breach	CE is not required to monitor BA’s activities for Privacy Rule purposes.
	Not required by Privacy Rule	<u>Indemnification</u>	If main contract has indemnification clause, may not be necessary in addendum.
	Not required by Privacy Rule	<u>Interpretation/ambiguity</u> – broadly as necessary to implement and comply with the Privacy Rule and applicable state laws. Any ambiguity shall be resolved in favor of a meaning that complies and is consistent with the Privacy Rule.	
	Not required by Privacy Rule	<u>Amendment to comply with law</u> - Modification of K to be in compliance with Privacy Rule	
	Not required by Privacy Rule	<u>Assistance in litigation or administrative proceedings</u>	If main contract has this type of clause, may not be necessary in addendum.
	Not required by Privacy Rule	<u>Conflict with contract</u> – addendum controls as it relates to PHI	