




HYBRID ENTITY Resources

Resources for Understanding, Evaluating and Becoming a Hybrid Entity

1. The U.S. Department of Health and Human Services, Office for Civil Rights (OCR), hosts a comprehensive website regarding the HIPAA Privacy Rule that includes many useful guidance documents, tools and training materials regarding HIPAA privacy and security regulations. The website is at <http://www.hhs.gov/ocr/privacy>.
 - For a “Summary of the HIPAA Privacy Rule” that provides information on who is covered, what it means to be a hybrid entity and what information is protected, go to <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>.
 - For FAQs regarding becoming a hybrid entity, go to:
 - “Are state, county or local health departments required to comply with the HIPAA Privacy Rule?” This FAQ explains how a health department can become a hybrid entity. <https://www.hhs.gov/hipaa/for-professionals/faq/358/are-state-county-or-local-health-departments-required-to-comply-with-hipaa/index.html>.
 - “When does a covered entity have discretion to determine whether a research component of the entity is part of their covered functions, and therefore, subject to the HIPAA Privacy Rule?” <https://www.hhs.gov/hipaa/for-professionals/faq/315/when-does-a-covered-entity-have-discretion-to-determine-covered-functions/index.html>.
 - “Can a postsecondary institution be a “hybrid entity” under the HIPAA Privacy Rule?” <https://www.hhs.gov/hipaa/for-professionals/faq/522/can-a-postsecondary-institution-be-a-hybrid-entity-under-hipaa/index.html>.
2. The Electronic Code of Federal Regulations provides the current and complete HIPAA Privacy Rule text. This rule defines the hybrid entity classification and sets forth the organizational requirements, including the standards and implementation specifications. [45 CFR §§ 164.103 and 164.105](#).
3. The following are tools for evaluating whether your health department is covered by HIPAA:
 - To determine if your health department is a covered entity:
 - Go to the Center for Medicare and Medicaid Services website at <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/Downloads/CoveredEntitiesChart20160617.pdf>.
 - To determine if your health department is a business associate, there are several sources that offer guidance:

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- Go to “Business Associate Decision Tree” at http://www.hollandhart.com/pdf/Business_Associate_Decision_Tree.pdf.
 - Go to “Decision Support Tool: Flowchart - Are You a Business Associate?” at <http://www.healthinfoweb.org/article/flowchart-ba>.
 - Go to “Decision Tree: When is a Business Associate Agreement (BAA) Required?” at https://www.slu.edu/Documents/provost/irb/Business_Associate_Agreement_Decision_Points.pdf.
4. In 2005, the Association of State and Territorial Health Officials published a report reflecting how state public health departments classify themselves under HIPAA. Association of State and Territorial Health Officials. (2005). *HIPAA Privacy Rule Implementation in State Public Health Agencies — Successes, Challenges, and Future Needs*. Retrieved from <https://biotech.law.lsu.edu/cdc/astho/HIPAA5FINAL.pdf>.
5. The following are resources exploring HIPAA coverage options, including becoming a hybrid entity:
- Bernstein, J. (2013). Implications for Covered Entity Public Health Agencies under the HIPAA Omnibus Rule. *ABA Health eSource*, 9, 9. Retrieved from https://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1305_bernstein.html.
 - Cynergistek. (2016). *Designating Hybrid Entity Status Under HIPAA in a University Setting: It is not as simple as it might seem*. Retrieved from <https://cynergistek.com/hybrid-entity-status-hipaa-university-setting/>.
 - Clearwater Compliance. (2014). *The Importance of Designating Covered Functions v. Non-Covered Functions Under HIPAA*. Retrieved from <https://clearwatercompliance.com/hipaa-compliance-guides/the-importance-of-designating-covered-functions-v-non-covered-functions-under-hipaa/>.
 - National Institutes of Health. *HIPAA Privacy Rule: To Whom Does the Privacy Rule Apply and Whom Will It Affect?* Retrieved from https://privacyruleandresearch.nih.gov/pr_06.asp.
 - Public Health Data Standards Consortium. (2008, December). *Health Information Privacy in State Public Health Agencies: A Review of Past, Present and Future Privacy-Related Issues and Priorities Affecting Public Health Practice*. Retrieved from http://www.phdsc.org/privacy_security/pdfs/PHDSC%20Best%20Priv%20Pract%20Proj%20-%20FULL%20REPORT%20-%20FINAL%20-%20201-15-09.pdf.
 - State Government – Government Information Value Exchange for States (GIVES). (2002). *Tactical Implementation for HIPAA Compliance – State Governments: A White Paper Describing the Unique State Government Implementation Issues and Options for Addressing Those Issues*. Retrieved from http://www.wvdhhr.org/hipaa/tech/State_Gov_White_Paper_HIPAA_Implementation_v3.htm
 - Centers for Disease Control and Prevention. (2003, April 11). *MMWR: HIPAA Privacy Rule and Public Health, Guidance from CDC and the U.S. Department of Health and Human Services*. (CDC Guidance). Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>.
6. The following are resources for municipalities, counties and local health departments regarding becoming a hybrid entity:
- Wall, A. (2015). Should a Local Government Be a HIPAA Hybrid Entity? *UNC School of Government: Coates Cannons: NC Local Government Law*. Retrieved from <https://canons.sog.unc.edu/should-a-local-government-be-a-hipaa-hybrid-entity/>.
 - Bakewell, C.M. (2012). Municipalities as Hybrid Entities under HIPAA. *The Missouri Municipal Review*, 24. Retrieved from http://c.ymcdn.com/sites/www.mocities.com/resource/resmgr/september_2012_review/munichybridentitiesunderhipa.pdf?hhSearchTerms=%22hipaa%22.
 - Fellows, M. (2003). THE HIPAA “PRIVACY RULE.” *League of California Cities*. Retrieved from <https://www.cacities.org/uploadedfiles/leagueinternet/b1/b1e39976-4976-414c-96c6-ed57a04623ac.pdf>.

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- Reno, J. and Lauber, J. (2005). HIPAA's Privacy and Security Rules and their Effect on Local Governments. *Municipal Lawyer*, 46(2), 6. Retrieved from http://www.laubermunicipallaw.com/assets/hippa_s-privacy-and-security-rules.pdf.
7. The following are resources for evaluating legal status of health departments:
- Egler, P. (2001). What Gives Cities and Counties the Authority to Create Charters, Ordinances, and Codes? *Perspectives Teaching Legal Research and Writing*, 9, 145. Retrieved from <https://info.legalsolutions.thomsonreuters.com/pdf/perspec/2001-spring/spring-2001-10.pdf>.
 - Internal Revenue Service. (2017, August 17). *Government Entities and Their Federal Tax Obligations: What are Government Entities and Their Federal Tax Obligations?* Retrieved from <https://www.irs.gov/government-entities/federal-state-local-governments/government-entities-and-their-federal-tax-obligations>.
 - Social Security Administration. *State and Local Government Employers – Information: How To Determine An Entity's Legal Status*. Retrieved from https://www.ssa.gov/section218training/advanced_course_9.htm.
 - Public Health Accreditation Board. *Who is eligible?* Retrieved from <http://www.phaboard.org/accreditation-overview/who-is-eligible/>.
 - Public Health Law Center at William Mitchell College of Law. (2015, April). *State & Local Public Health: An Overview of Regulatory Authority*. Retrieved from http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-fs-state-local-reg-authority-publichealth-2015_0.pdf.
 - Association of State and Territorial Health Officials. (2017, November). *ASTHO Profile of State & Territorial Public Health*, vol. 4. Retrieved from <http://www.astho.org/Profile/Volume-Four/2016-ASTHO-Profile-of-State-and-Territorial-Public-Health/>.
 - National Health Policy Forum. (2010, August 18). *Governmental Public Health: An overview of State and Local Public Health Agencies*. Retrieved from https://www.nhpf.org/library/background-papers/BP77_GovPublicHealth_08-18-2010.pdf.
8. OCR took HIPAA enforcement action against University of Massachusetts Amherst – a hybrid entity - for failure to properly become a hybrid entity and identify all covered entity components, failure to implement technical security controls and other violations.
- Office of Civil Rights' enforcement action against UMass, available at <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/umass>.
 - A variety of resources analyzing the UMass enforcement action are available:
 - Go to <http://www.hallrender.com/2016/12/05/ocr-settlement-announced-hybrid-entity-hipaa-breach-2/>
 - Go to <https://www.hitechanswers.net/mixing-hipaa-hybrid-entities/>.
 - Go to <https://www.bakerdonelson.com/ocr-examines-hybrid-entity-designation-in-latest-hipaa-settlement>.
 - Go to <https://www.huntonprivacyblog.com/2016/11/30/hhs-announces-hipaa-settlement-with-umass/>.
9. The following are sample hybrid entity policies and procedures:
- Statement on the Designation of the Montana Department of Public Health and Human Services as a Hybrid Entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), available at <https://dphhs.mt.gov/Portals/85/qad/documents/ProgramCompliance/HIPAA/HybridEntityDesignationStatement.pdf>.
 - State of Oklahoma, OMES DESIGNATION AS A HYBRID ENTITY UNDER HIPAA, available at <https://ok.gov/OSF/documents/HybridEntityHIPAA.pdf>.
 - University of North Carolina at Chapel Hill, STATEMENT ON ITS DESIGNATION AS A HYBRID ENTITY UNDER HIPAA, available at <http://privacy.unc.edu/files/2014/09/Hybrid-Entity.pdf>.
 - Washington and Lee University, Statement on Designation as a Hybrid Entity under HIPAA, available at <https://www.wlu.edu/general-counsel/code-of-policies/confidentiality-and-information-security/hipaa-hybrid-entity-designation>.

- New Jersey Institute of Technology, HIPAA – Hybrid Entity Policy; Designation of NJIT as a Hybrid Entity, available at <https://www.njit.edu/policies/sites/policies/files/lcms/pdf/HIPAA-Hybrid-Entity-Policy.pdf>

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