The Network for Public Health Law

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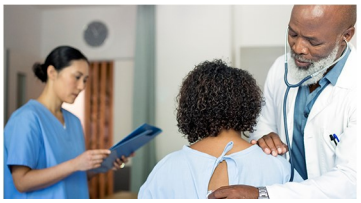
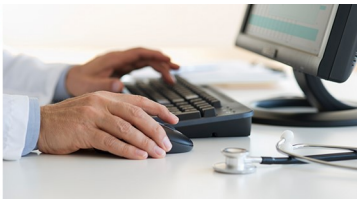

DE-IDENTIFICATION – SUMMARY OF SELECTED FEDERAL STATUTES

Table of Statutes

De-Identification: As Described by Federal Statutes

Most laws either do not apply to de-identified information or permit disclosure of de-identified information. While de-identified information can usually be freely disclosed, how laws define whether information is sufficiently de-identified vary. This table sets out legal provisions that apply to disclosure of de-identified information under selected federal laws and provides definitions, criteria or standards that are relevant to determinations of whether information is de-identified. Some of these laws apply to the federal government's data de-identification and other laws apply to any data holder. This table does not cover exceptions under the various laws that might allow disclosure of identifiable information for specific purposes, such as public health activities or research. Some of these laws are not explicit in stating that de-identified information might be disclosed. At the same time, they may not explicitly prohibit disclosure of de-identified information. If a request for information is filed under an applicable Freedom of Information law, privacy provisions must be read in conjunction with that law. With regard to health information held by a federal agency, two exemptions to the Federal Freedom of Information Act might apply:

> Exemption 3 – Information that is specifically exempted from disclosure by another statute. The statute must (i) require that the matter be withheld from the public in such a manner as to leave no discretion on the issue; or (ii) establish particular criteria for withholding or refer to particular types of matters to be withheld. If enacted after the date of enactment of the OPEN FOIA Act of 2009, the statute must specifically cite to the paragraph in the FOIA that establishes exemptions. 5 U.S.C. § 552(b)(3).
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> Exemption 6 – Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. 5 U.S.C. § 552(b)(6).

LAW	PROVISION(S) THAT ALLOW DISCLOSURE OF DE-IDENTIFIED INFORMATION	CRITERIA OR STANDARD FOR DETERMINING WHETHER INFORMATION IS IDENTIFIABLE
Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, implemented by the HIPAA Privacy Rule, 45 CFR Part 160 and Part 164.	The HIPAA Privacy Rule applies to "protected health information" or "PHI." The Privacy Rule does not apply to health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. 45 CFR § 160.103, 45 §164.500.	Information may be de-identified by removing 18 identifiers specified in the Rule, provided that the covered entity does not have actual knowledge that the remaining information can be used alone or in combination with other reasonably available information to identify a subject (safe harbor de-identification). These identifiers include personal identifiers (such as name, address, telephone number, birth date, Social Security number) and non-personal identifiers (such as geographic information smaller

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		than a state and dates directly associated with an individual). Alternatively, a covered entity may rely on a determination by a properly qualified statistician using accepted analytic techniques who determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information (statistical de-identification). 45 CFR § 164.514. The Office for Civil Rights, which enforces HIPAA, issued guidance regarding de-identification. The document is divided into three main areas, including the overview, guidance on satisfying the Expert Determination method and guidance on satisfying the Safe Harbor method. Discussion is supported with scenarios, graphics and tables. HHS De-Identification Guidance.
Family Educational Rights Privacy Act (FERPA), 20 U.S. Code § 1232g, implemented by 34 CFR Part 99.	FERPA prohibits a school from disclosing "personally identifiable information" from students' education records without the consent of a parent or eligible student, unless an exception to FERPA's general consent rule applies. 34 CFR § 99.30.	Information is de-identified if, after removal of all personally identifiable information, the educational agency or institution or other party has made a reasonable determination that a student's identity is not personally identifiable, whether through single or multiple releases, and taking into account other reasonably available information. 34 CFR § 99.31. The Department of Education established the Privacy Technical Assistance Center that provides guidance regarding de-identification of education records. The guidance offers statistical disclosure methods and examples for both types of data release – aggregate or tabular data, and microdata or student level data. Additional resources for different de-identification approaches are also listed. PTAC Guidance.
Protection of Human Research Subjects (Common Rule), 45 CFR part 46, Subpart A.	The Common Rule applies to federally supported research, when an investigator obtains identifiable "private information" of a living individual (human subject) for use, study, or analysis. 45 CFR § 46.102.	Private information is "identifiable" when the identity of the subject is or may readily be ascertained by the investigator or associated with the information. 45 CFR § 46.102. On June 19, 2018, the Department of Health and Human Services amended the Common Rule, requiring compliance with most provisions on January 21, 2019. While the revised rule includes slight changes in wording, the rule continues to apply to private information that is used for research only when it is identifiable. Additionally, the revised rule continues to define data as "identifiable" when the identity of the subject is or may readily be ascertained by the investigator or associated with the information. The revised rule requires that by June 19, 2019, and at least every 4 years thereafter, the federal departments or agencies implementing the Common Rule, through a collaborative process must do both of the following:

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		(1) Upon consultation with appropriate experts, including experts in data matching and re-identification, reexamine the meaning of "identifiable private information" as well as "identifiable biospecimen." This review process is to be conducted by collaboration among the Federal departments and agencies. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance. (2) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate "identifiable private information" or an "identifiable biospecimen." Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the Federal Register after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.
VA Claims Confidentiality Statute, 38 U.S.C. § 5701, implemented by 38 CFR §§ 1.500-1.527.	The VA Claims Confidentiality Statute protects all files, records, reports, and other papers and documents maintained by the Department of Veterans Affairs pertaining to any claim under a VA program and the names and addresses of present or former members of the Armed Forces, and their dependents. These documents are confidential and privileged. Disclosure is prohibited except as provided by the statute. The Secretary may release information, statistics, or reports to individuals or organizations when in the Secretary's judgment such release would serve a useful purpose. 38 U.S.C. § 5701(e).	The law does not define or describe de-identification directly. The Veterans Health Administration (VHA) issued Directive 1605.01 entitled Privacy and Release of Information which provides instruction regarding VHA's release of de-identified information. It states that properly de-identified information is no longer covered by this law; its release is therefore not prohibited. While the VHA utilizes the HIPAA Privacy Rule de-identification standard, it provides for additional stringency in two areas. With regard to the Expert Method, the VHA specifies that the individual who determines information to be de-identified, be a qualified biostatistician with a master's or Ph.D. degree and have extensive background in statistics, mathematics or science. Further, scrambling of names and Social Security numbers is not considered de-identification of health information. VHA Directive 1605.01.
Confidentiality of medical quality-assurance records [maintained by the Department of Veterans Affairs], 38 U.S.C. § 5705, implemented by 38 CFR §§ 17.500-17.511.	This law states that records and documents created by the Department of Veterans Affairs as part of a medical quality-assurance program are confidential and privileged and may not be disclosed by the VHA to any person or entity unless an exception applies. It also provides that for the purposes of a medical quality-assurance program, the name and other identifying information of any patient, employee or associated individual of the Department shall be deleted before any disclosure if disclosure would constitute a clearly	The VHA must remove information that implicitly or explicitly identifies a patient, employee or associated individual of the VHA who participated in the conduct of a medical quality-assurance review. 38 U.S.C. § 5705(b)(6). Disclosure of VHA medical quality-assurance records is tightly regulated. 38 CFR § 17.510. See the VHA Directive 1605.01 entitled Privacy and Release of Information, which provides instruction regarding release of de-identified information.

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	unwarranted invasion of personal privacy. 38 U.S.C. § 5705(b)(1). Finally, the law states that nothing in the law should be construed as authorizing or requiring withholding from any person or entity the disclosure of statistical information regarding the VHA's health-care programs that does not implicitly or explicitly identify any patient, employee or associated individual of the VHA who participated in the conduct of a medical quality-assurance review. 38 U.S.C. § 5705(b)(6).	
Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Human Immunodeficiency Virus (HIV) Infection, and Sickle Cell Anemia Medical Records [regarding veterans affairs], 38 U.S.C. § 7332, implemented by 38 CFR §§ 1.460-1.496.	This law protects Veterans Administration records with regard to the identity, diagnosis, prognosis, or treatment of any patient or subject in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia. The law prohibits the VHA's disclosure of patient information, except as permitted, and limits permitted disclosures to information that is necessary to carry out the purpose of the disclosure. § 38 CFR 1.462(a). The term "disclose" or "disclosure" means a communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified. 38 CFR §1.460. Generally, re-disclosure of patient identifying information is tightly regulated by 38 CFR §§ 1.461, 1.476 and 1.479.	"Patient identifying information" is defined as "the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a treatment program, if that number does not consist of, or contain numbers (such as Social Security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the treatment program." 38 CFR §1.460. See the VHA Directive 1605.01 entitled Privacy and Release of Information, which provides instruction regarding release of de-identified information, which is not prohibited by this law.

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Federal Privacy Act 5 U.S.C. § 552a.	The Federal Privacy Act establishes a code of fair information practices for the federal government that governs the collection, maintenance, use, and dissemination of information about individuals that is maintained in systems of records by federal agencies. The Act protects a "record" of a U.S. citizen or alien lawfully admitted for permanent residence. A "record" includes any item, collection, or grouping of information about an individual that is maintained by a federal agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. 5 U.S.C. § 552a(a)(4).	The law does not define or describe de-identification directly, but suggests that a record is de-identified by removing all "identifying particulars." 5 U.S.C. § 552a(a)(4).
42 CFR Part 2 Implements Public Health Service Act, 42 U.S.C. § 290dd-2.	This law generally restricts the disclosure of alcohol and drug abuse patient records that are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. 42 CRF § 2.1, 42 CRF § 2.2. "Records" means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts). 42 CRF § 2.11. This law applies to disclosure of information that would identify a patient as having or having had a substance use disorder either directly, by reference to other publicly available information, or through verification of such an identification by another person. 42 CFR § 2.12. "Disclose means to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of	"Patient identifying information" is defined as the name, address, social security number, fingerprints, photograph, ***or similar information*** by which the identity of a patient can be determined with reasonable accuracy either directly or by reference to other information. The term does not include a number assigned to a patient by a program for internal use only, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy from sources external to the program. 42 CFR § 2.11. When HHS revised this definition in 2017, the responsible agency – the Substance Abuse and Mental Health Services Administration (SAMHSA) – stated in the preamble to the rules that its intent is that all identifiers listed in the HIPAA Privacy Rule at 45 CFR 164.514(b)(2)(i) that are not already included in the definition of "patient identifying information" to meet the clause "or similar information." Federal Register / Vol. 82, No. 11 / Wednesday, January 18, 2017 / Rules and Regulations, page 6064. In other words, it appears that SAMHSA intends for 42 CFR Part 2 to apply to patient information unless the 18 HIPAA identifiers have been removed consistent with the "safe harbor" method of de-identification.

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	such identification by another person." 42 CRF § 2.11.	
Federal Assurances of Confidentiality. Section 308(d) of the Public Health Service Act, 42 U.S.C. § 242m(d).	An assurance of confidentiality prohibits use, release, and publication of information, if an establishment or person supplying the information or described in it is identifiable. An assurance applies to information obtained by CDC's National Center for Health Statistics under the Public Health Service Act. An assurance may be granted to projects conducted by other components of CDC.	The law does not define or describe de-identification directly.
Federal Certificates of Confidentiality. Section 301(d) of the Public Health Service Act, 42 U.S.C. § 241(d).	A certificate of confidentiality prohibits disclosure of the name of a research subject and any information, document, or biospecimen that contains "identifiable, sensitive information" about a research subject. A certificate shall be issued for research that receives federal funding and may be issued for other research.	"Identifiable, sensitive information" is defined as information about a research subject that identifies the individual; or "for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual."
Center for Disease Control and Prevention's Foodborne Illness Surveillance System Statute, 21 U.S.C. § 2224(b)(1)(f).	This law requires the Centers for Disease Control and Prevention (CDC) to provide "timely public access to aggregated, de-identified surveillance data" from its collection of information on occurrences and causes of foodborne outbreaks in the United States.	The law does not define or describe de-identification directly.
Federal Food, Drug and Cosmetic Act, 21 USC § 355(K)(4)(F)(ii)(I).	This law requires that all organizations, that contract with the Department of Health and Human Services to provide drug safety data, possess the "research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection." Additionally, all collaborations with public, academic and private entities for advanced analysis of drug safety data shall not disclose individually identifiable health information.	The law does not define or describe de-identification directly.

SUPPORTERS

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