The Office of the National Coordinator for Health Information Technology

Legal and Ethical Architecture for PCOR Data

APPENDIX E: GLOSSARY

Submitted by:
The George Washington University
Milken Institute School of Public Health
Department of Health Policy and Management

Accountable care organizations (ACOs). An ACO is a group of healthcare providers that is collectively reimbursed for a single patient's care. The goal of an ACO is to provide high-quality, low-cost, coordinated care. ACOs participating in the Medicare Shared Saving Program provide coordinated, high-quality care to Medicare patients in exchange for sharing in any savings the ACO realized for the Medicare program.[608]

Advanced Notice of Proposed Rulemaking (ANPRM). An ANPRM is formal invitation for stakeholders to participate in shaping a proposed rule and starts the notice-and-comment process in motion.[609]

Agency for Healthcare Research & Quality (AHRQ). AHRQ is a federal agency within the U.S. Department of Health and Human Services dedicated to improving the quality, safety, efficiency, and effectiveness of health care. AHRQ develops the knowledge, tools, and data needed to improve the healthcare system and enable informed decision-making.[610]

American Recovery and Reinvestment Act of 2009 (ARRA). ARRA (known as "the Stimulus Bill" or "the Recovery Act") was passed in response to the global economic decline in 2007 and 2008. Among other things, ARRA made investments in health care. ARRA included the Health Information Technology for Economic and Clinical Health (HITECH) Act, which called for the adoption and meaningful use of health information technology as a national policy priority and created the Electronic Health Record Incentive Programs.[611]

The Belmont Report. The Belmont Report summarizes the basic ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the course of its deliberations. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.[612]

Broad Consent. Broad consent refers to prospective consent given by an individual or his/her representative to unspecified future research. Under the Common Rule, it must include the 12 specified elements to be valid. Broad consent may be obtained in lieu of informed consent only for secondary research use, storage, and maintenance of identifiable private information and identifiable biospecimens.[613]

Business Associate (with respect to the HIPAA Rules). A Business Associate is a person or entity other than a member of a Covered Entity's workforce who:

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[608] Centers for Medicare & Medicaid Services (CMS). "Accountable Care Organizations (ACO)" (*last updated* May 12, 2017), *available at:* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html.

[609] Office of the Federal Register. A Guide to the Rulemaking Process (2011), *available at*: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

[610] Agency for Healthcare Research & Quality [home page], *available at:* https://www.ahrq.gov/ (*last visited* September 27, 2017).

[611] The American Recovery and Reinvestment Act (ARRA), P.L. 111-5, 123 Stat. 115 (2009); CMS, "Electronic Health Records (EHR) Incentive Programs" (*last updated* September 11, 2017), *available at:* https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms.

[612] U.S. Department of Health and Human Services (HHS), Office of the Secretary, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979); *available at:* https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

[613] 45 C.F.R. Part 46, Subparts A-E (2017).

1. Creates, receives, maintains, or transmits protected health information for a HIPAA-regulated function or activity (e.g., claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 C.F.R. 3.20, billing, benefit management, practice management, and repricing) on behalf of a Covered Entity;
2. Provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for a Covered Entity;
3. A Health information organization, E-prescribing gateway, or other person or entity that provides data transmission services with respect to protected health information to a Covered Entity and that requires access on a routine basis to such protected health information;
4. A person that offers a personal health record to one or more individuals on behalf of a Covered Entity; or
5. A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the Business Associate.[614]

Center for Medicare and Medicaid Innovation (CMMI). CMMI is an organization within the Centers for Medicare & Medicaid Services that was established by the Patient Protection and Affordable Care Act. Its purpose is to test out new payment and delivery models of care to reduce expenditures, while improving the quality of care within the Medicare, Medicaid, and Children's Health Insurance Program (CHIP) programs.[615]

Centers for Medicare & Medicaid Services (CMS). The federal agency within the U.S. Department of Health and Human Services that administers the Medicare, Medicaid, and Children's Health Insurance Program (CHIP) programs.[616]

Certification. Certification (in the context of the Common Rule) is the official notification by the institution to the supporting federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.[617]

Children's Health Insurance Program (CHIP). A health insurance program targeted to low-income children, established in 1997 and reauthorized in 2009, that is administered by the states either as a stand-alone program or as a Medicaid expansion and funded through a combination of federal and state payments.[618]

Clinical Decision Support System (CDSS). A CDSS is interactive computer software that provides health professionals with knowledge and person-specific information to aid in decision-making tasks, such as determining diagnosis for a patient or suggesting default values for a prescription. A CDSS usually includes multiple tools to enhance decision-making, including clinical guidelines, condition-specific order sets, patient data reports and summaries, and documentation templates.

Community Health Center. A Community Health Center is a healthcare provider that offers: primary and preventive health services to all residents of its catchment area and may also provide supplemental

[614] 45 C.F.R. § 160.103.
[615] Center for Medicare and Medicaid Innovation (CMMI), *available at:* https://innovation.cms.gov/ (*last visited* September 27, 2017).
[616] Centers for Medicare & Medicaid Services (CMS) [home page], *available at:* https://www.cms.gov/ (*last visited* September 27, 2017).
[617] 45 C.F.R. § 46.102.
[618] Social Security Act Volume I, Title 19, codified at 42. U.S.C. §§ 1396 –1396v.

health services, referrals, environmental health services, and information on the availability and proper use of health services.[619] A CHC may receive a grant under Section 330 of the Public Health Service (PHS) Act[620] as a Federally Qualified Health Center.

Comparative effectiveness research. Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.[621]

Computerized Provider/Physician Order Entry/Management (CPOE). CPOE is an electronic system in which clinicians directly enter instructions for the treatment of patients under the practitioner's care, which then transmits the order directly to the medical staff or departments (such as pharmacy or laboratory) responsible for fulfilling the order.

Consent (to disclose information). The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits, but does not require, a Covered Entity voluntarily to obtain patient consent for uses and disclosures of protected health information (PHI) for treatment, payment, and healthcare operations. Covered Entities that do so have complete discretion to design a process that best suits their needs. By contrast, an "authorization" is required by the HIPAA Privacy Rule for uses and disclosures of protected health information not otherwise allowed by the rule. To be valid, an authorization must include certain elements identified by the Privacy Rule, including the signature of the individual or his/her representative.[622]

Consent (to treatment). An individual consents to treatment when they give written or verbal permission prior to any medical exam or intervention. An individual who is unable to consent on his/her own may have an authorized surrogate who is permitted to consent for the individual.

Covered Entity (with respect to the HIPAA Rules). A Covered Entity is a health plan, healthcare clearinghouse, or a healthcare provider who transmits any health information in electronic form in connection with a HIPAA-covered transaction.[623]

Critical Access Hospital (CAH). A Critical Access Hospital is a rural community hospital that receives cost-based reimbursement and meets certain conditions as set forth in the Medicare Conditions of Participation that are different for those for acute care hospitals.

Data Use Agreement (DUA) (with respect to the HIPAA Rules). A data use agreement is a contract use when nonpublic data is being transferred that spells out the terms of use of the data by the recipient. Under the HIPAA Privacy Rule, a data use agreement is required when a limited data set is shared and

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[619] 42 C.F.R. § 51c.102.

[620] 42 U.S.C. § 254a.

[621] National Information Center on Health Services Research and Health Care Technology (NICHSR), "NLM Resources for Informing Comparative Effectiveness" [citing Federal Coordinating Council for Comparative Effectiveness Research definition] (June 26, 2009), *available at:* https://www.nlm.nih.gov/nichsr/cer/cerqueries.html#definition.

[622] HHS, "What is the difference between "consent" and "authorization" under the HIPAA Privacy Rule (*last updated* July 26, 2013), *available at:* https://www.hhs.gov/hipaa/for-professionals/faq/264/what-is-the-difference-between-consent-and-authorization/index.html.

[623] 45 C.F.R. § 160.103.

must identify who will receive the limited data set, establish how the data may be used and disclosed by the recipient, and provide assurances that the data will be protected.[624]

De-identified data. De-identified data is health information that does not identify an individual and does not provide any reasonable basis on which an individual could be identified. As de-identified data is no longer protected health information, HIPAA does not restrict the use or disclosure of de-identified data.

Department or agency head. This term refers to the head of any federal department or agency, such as the Secretary of HHS, and any other officer or employee of any federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.[625]

Disclose (with respect to 42 C.F.R. Part 2). For the purposes of Part 2, 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 such identification by another person.[626]

Disclose (with respect to the HIPAA Rules). For the purposes of HIPAA, disclose means to release, transfer, provide access to, or divulge in any manner of information outside the entity holding the information.[627]

Education records (with respect to FERPA). Education records under FERPA include those records that are directly related to a student and maintained by an educational agency or institution or by a party acting for the agency or institution.[628]

Electronic Health Record (EHR). An EHR is a digital version of an individual's health information and may include information from multiple providers or sources of health care. In contrast with EMRs, EHRs are interoperable, able to collect and share information with multiple healthcare providers, so they contain information from all the clinicians involved in the patient's care.[629]

Electronic Laboratory Reporting (ELR). ELR is the automated transmission of laboratory-related data from commercial, public health, hospital, and other labs to state and local public health departments.

Electronic medical record (EMR). An electronic medical record is a digital version of a patient's paper chart that contains the standard medical and clinical data gathered in a single provider's office. An EMR is generally used by providers for diagnosis and treatment. Information from multiple EMRs for the same patient may be combined in an EHR.

Employer (for purposes of GINA). An employer is any person that employs an employee defined in § 1635.2(c) of 29 C.F.R. Part 1635.3 (GINA) and any agent of such person, except that, as limited by section 701(b)(1) and (2) of the Civil Rights Act of 1964, 42 U.S.C. 2000e(b)(1) and (2), an employer does not

[624] 45 C.F.R. § 164.514(e)(4).
[625] 45 C.F.R. § 46.102.
[626] 42 C.F.R. § 2.11.
[627] 45 C.F.R. § 164.103.
[628] 34 C.F.R. § 99.3.
[629] The National Alliance for Health Information Technology, "Report to the Office of the National Coordinator for Health Information Technology on Defining Key Health Information" (April 28, 2008). *Available online at*: http://www.hitechanswers.net/wp-content/uploads/2013/05/NAHIT-Definitions2008.pdf.

include an Indian tribe, or a bona fide private club (other than a labor organization) that is exempt from taxation under section 501(c) of the Internal Revenue Code of 1986.[630]

Expedited [IRB] review. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure authorized by 45 C.F.R. 46.110 and 21 C.F.R. 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.[631]

The Fair Information Practice Principles (FIPPs). The FIPPs are a set of eight principles set forth by the Federal Trade Commission (FTC) that are rooted in the tenets of the Privacy Act of 1974. The eight principles include: transparency, individual participation, purpose specification, data minimization, use limitation, data quality and integrity, security, and accountability and auditing.[632]

Family Educational Rights and Privacy Act (FERPA). FERPA protects the privacy of education records, including elementary and secondary student health records (e.g., records maintained by school nurse, special education student records), held by all education agencies and institutions that receive federal funding.[633]

Family member. With respect to any individual, family member means:

1. A person who is a dependent of that individual as the result of marriage, birth, adoption, or placement for adoption; or
2. A first-degree, second-degree, third-degree, or fourth-degree relative of the individual, or of a dependent of the individual as defined in § 1635.3(a)(1).
   (i) First-degree relatives include an individual's parents, siblings, and children.
   (ii) Second-degree relatives include an individual's grandparents, grandchildren, uncles, aunts, nephews, nieces, and half-siblings.
   (iii) Third-degree relatives include an individual's great-grandparents, great-grandchildren, great-uncles/aunts, and first cousins.
   (iv) Fourth-degree relatives include an individual's great-great-grandparents, great-great-grandchildren, and first cousins once-removed (i.e., the children of the individual's first cousins).[634]

The Federal Information Security Management Act of 2002 (FISMA). FISMA requires every federal agency to develop and implement an agency-wide program to protect government information and information systems from unauthorized access, use, disclosure, or destruction.[635]

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[630] 29 C.F.R. § 1635.3.

[631] HHS, Office for Human Research Protections (OHRP), "OHRP Expedited Review Categories (1998)" (*last updated* March 21, 2016), *available at:* https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html.

[632] U.S. Department of Homeland Security, Privacy Office, Memorandum: "The Fair Information Practice Principles: Framework for Privacy Policy at the Department of Homeland Security" (December 29, 2008), *available at:* https://www.dhs.gov/xlibrary/assets/privacy/privacy_policyguide_2008-01.pdf.

[633] Family Educational Rights and Privacy Act (FERPA) of 1974 (codified at 20 U.S.C. 1232g; implementing regulations at 34 C.F.R. Part 99).

[634] 29 C.F.R. § 1635.3.

[635] Federal Information Security Management Act of 2002 (FISMA), 44 U.S.C. § 3544 (2006).

Federal Trade Commission Act Section 5. Section 5 prohibits "unfair or deceptive acts or practices in or affecting commerce."[636]

Federally assisted (under Part 2). For purposes of 42 C.F.R. Part 2, a program is considered to be federally assisted if:

1. It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (2) of this section relating to the Department of Veterans Affairs and the Armed Forces);
2. It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:
   (i) Participating provider in the Medicare program;
   (ii) Authorization to conduct maintenance treatment or withdrawal management; or
   (iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders;
3. It is supported by funds provided by any department or agency of the United States by being:
   (i) A recipient of federal financial assistance in any form, including financial assistance that does not directly pay for the substance use disorder diagnosis, treatment, or referral for treatment; or
   (ii) Conducted by a state or local government unit that, through general or special revenue sharing or other forms of assistance, receives federal funds that could be (but are not necessarily) spent for the substance use disorder program; or
4. It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.[637]

Federally Qualified Health Center (FQHC). An FQHC is a community health center that receives funding under Section 440 of the Public Health Service Act or a center that has been certified as meeting the same criteria.

Federalwide Assurance (FWA). The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 C.F.R. Part 46.[638]

Final Rule. The term "final rule" refers to the most current final disposition of a particular issue that includes a preamble, summary, effective date, and supplementary information. The final rule published in the *Federal Register* begins with a summary of the issue, regulatory goals, and why the rule is necessary.[639]

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[636] 15 U.S.C. § 45.
[637] 42 C.F.R. § 2.11.
[638] OHRP, "Federalwide Assurances (FWAs)," (*last updated* March 18, 2016), *available at:* https://www.hhs.gov/ohrp/federalwide-assurances-fwas.html.
[639] Office of the Federal Register. A Guide to the Rulemaking Process (2011), *available at*: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

Freedom of Information Act (FOIA). FOIA gives any person the right to obtain access to information contained in the records of federal agencies, unless the information is specifically protected from disclosure under an exemption.[640]

Genetic information (with respect to GINA).

1. Genetic information means information about:
   (i) An individual's genetic tests;
   (ii) The genetic tests of that individual's family members;
   (iii) The manifestation of disease or disorder in family members of the individual (family medical history);
   (iv) An individual's request for, or receipt of, genetic services or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or
   (v) The genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology.
2. Genetic information does not include information about the sex or age of the individual, the sex or age of family members, or information about the race or ethnicity of the individual or family members that is not derived from a genetic test.[641]

Genetic Information Nondiscrimination Act of 2008 (GINA). GINA protects individuals' genetic information from being used by health plans and issuers to make eligibility, coverage, underwriting, and premium-setting decisions about covered individuals. GINA also prohibits employers from discriminating against employees or applicants based on genetic information and from using genetic information in employment decisions.[642]

Genetic testing (with respect to GINA).

1. "Genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.
2. Genetic tests include, but are not limited to:
   (i) A test to determine whether someone has the BRCA1 or BRCA2 variant evidencing a predisposition to breast cancer, a test to determine whether someone has a genetic variant associated with hereditary nonpolyposis colon cancer, and a test for a genetic variant for Huntington's Disease;
   (ii) Carrier screening for adults using genetic analysis to determine the risk of conditions such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome in future offspring;
   (iii) Amniocentesis and other evaluations used to determine the presence of genetic abnormalities in a fetus during pregnancy;
   (iv) Newborn screening analysis that uses DNA, RNA, protein, or metabolite analysis to detect or indicate genotypes, mutations, or chromosomal changes, such as a test for PKU performed so that treatment can begin before a disease manifests;

[640] The Freedom of Information Act, Pub. L. No. 89-487, 80 Stat. 250 (amending 5 U.S.C. 552) (1966).
[641] 29 C.F.R. § 1635.3.
[642] Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (Title I amended scattered provisions of 29 U.S.C. § 1182 et seq., 42 U.S.C. § 300gg-1 et seq., 42 U.S.C. § 1395ss, 42 U.S.C. § 1320d-9, and 26 U.S.C. § 9802 et seq.; Title II is codified at 42 U.S.C. 2000f et seq.); implementing regulations found throughout the Code of Federal Regulations.

(v) Preimplantation genetic diagnosis performed on embryos created using in vitro fertilization;
(vi) Pharmacogenetic tests that detect genotypes, mutations, or chromosomal changes that indicate how an individual will react to a drug or a particular dosage of a drug;
(vii) DNA testing to detect genetic markers that are associated with information about ancestry; and
(viii) DNA testing that reveals family relationships, such as paternity.

3. The following are examples of tests or procedures that are not genetic tests:
   (i) An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes;
   (ii) A medical examination that tests for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins, or metabolites;
   (iii) A test for infectious and communicable diseases that may be transmitted through food handling;
   (iv) Complete blood counts, cholesterol tests, and liver-function tests.
4. Alcohol and Drug Testing—
   (i) A test for the presence of alcohol or illegal drugs is not a genetic test.
   (ii) A test to determine whether an individual has a genetic predisposition for alcoholism or drug use is a genetic test.[643]

Group health plan. The term "group health plan" means a plan (including a self-insured plan) of, or contributed to by, an employer (including a self-employed person) or employee organization to provide health care (directly or otherwise) to the employees, former employees, the employer, others associated or formerly associated with the employer in a business relationship, or their families.[644]

Health care (with respect to the HIPAA Rules). The term "health care" means care, services, or supplies related to the health of an individual (e.g., preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription).[645]

Healthcare Common Procedure Coding System (HCPCS). HCPCS is a two-level set of standard codes used by Medicare and other health insurance programs, with Level I being codes for medical services and procedures, known as CPT codes, and Level II being the coding system used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. CPT codes are republished annually by the American Medical Association, whereas the Level II codes are maintained and distributed by CMS.

Healthcare operations (with respect to the HIPAA Rules). Healthcare operations means any of the following activities of a Covered Entity or a Business Associate to the extent that the activities are related to covered functions:

1. Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined by

[643] 29 C.F.R. § 1635.3.
[644] 26 U.S.C. § 5000.
[645] 45 C.F.R. § 160.103.

the Patient Safety and Quality Improvement Act); population-based activities relating to improving health or reducing healthcare costs, protocol development, case management and care coordination, contacting of healthcare providers and patients with information about treatment alternatives; and related functions that do not include treatment;

2. Reviewing the competence or qualifications of healthcare professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or healthcare practitioners learn under supervision to practice or improve their skills as healthcare providers, training of non-healthcare professionals, accreditation, certification, licensing, or credentialing activities;
3. Except as otherwise prohibited, underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance);
4. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
5. Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies;
6. Business management and general administrative activities of the entity (e.g., management activities relating to implementation of and compliance with HIPAA; customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer; resolution of internal grievances; the sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a Covered Entity and due diligence related to such activity); and
7. Creating de-identified health information or a limited data set, and fundraising for the benefit of the Covered Entity.[646]

Healthcare payment (with respect to the HIPAA Rules). Healthcare payment means the activities of healthcare providers to obtain payment or be reimbursed for their services and of a health plan to obtain premiums, to fulfill coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care. The HIPAA Privacy Rule gives examples of common payment activities.[647]

Healthcare treatment (with respect to the HIPAA Rules). Healthcare treatment is the provision, coordination, or management of health care and related services among healthcare providers or by a healthcare provider with a third party, consultation between healthcare providers regarding a patient, or the referral of a patient from one healthcare provider to another.[648]

Health Information (with respect to the HIPAA Rules). Health information means any information, including genetic information, whether oral or recorded in any form or medium, that is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearinghouse and that relates to the past, present, or future physical or mental

[646] 45 C.F.R. § 160.103.
[647] 45 C.F.R. § 160.103.
[648] 45 C.F.R. § 160.103.

health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.[649]

Health information exchange (HIE). Health information exchange can be used as either a verb or a noun. As a verb, HIE means the act of electronically sharing health-related information among organizations. As a noun, an HIE is an organization that provides services to enable the electronic sharing of health-related information.

Health information organization (HIO). An HIO is an organization that oversees and governs the exchange of health-related information among organizations in accordance with nationally recognized standards.

Health Information Technology for Economic and Clinical Health Act (HITECH). HITECH is part of the American Recovery and Reinvestment Act of 2009 (ARRA). HITECH legislatively mandated the Office of the National Coordinator for Health Information Technology (ONC) to oversee the development of a national health information network as well as a strategic health information plan for the nation. HITECH strengthened standards for health information privacy and security and authorized financial incentives for certain healthcare providers and facilities that demonstrate meaningful use of certified electronic health record technology.[650]

The Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates health insurers and health benefit plans and provides privacy protection for health information. Among other provisions, HIPAA set forth guidelines for the privacy and security of individually identifiable health information. The HIPAA Privacy, Security, Enforcement, and Breach Notification Rules were established to implement those guidelines.[651]

Health insurance issuers. The term "health insurance issuer" means an insurance company, insurance service, or insurance organization (including a health maintenance organization). Such term does not include a group health plan.[652]

Health Plan (with respect to the HIPAA Rules). A health plan is an individual or group plan that provides, or pays the cost of, medical care.[653]

Healthcare Practitioner. A healthcare practitioner is any individual authorized to provide healthcare services, including a doctor of medicine, nurse practitioner, physician assistant, allied health professional, social worker, case worker, case manager, or case coordinator.

Healthcare Provider (with respect to the HIPAA Rules). A healthcare provider is a provider of services (as defined in the Medicare statute), a provider of medical or health services (as defined in the Medicare statute), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.[654]

Health Resources & Services Administration (HRSA). HRSA is an agency of the U.S. Department of Health and Human Services. It is the primary federal agency for improving health care to people who are geographically isolated and/or economically or medically vulnerable, helping those in need of high-

[649] 45 C.F.R. § 160.103.
[650] ARRA, Pub. L. No. 111-5, Div. A, Title XIII, § 13410(e), 123 Stat. 271-76 (2009).
[651] HIPAA, Pub. L. No. 104-191, 110 Stat. 139 (1996) (codified as amended in scattered sections of 42 U.S.C.).
[652] 26 U.S.C. § 9832.
[653] 45 C.F.R. § 160.103.
[654] 45 C.F.R. § 160.103.

quality primary health care, people living with HIV/AIDS, pregnant women, and mothers. HRSA also supports the training of health professionals, the distribution of providers to areas where they are needed most, and improvements in healthcare delivery. HRSA oversees organ, bone marrow, and cord blood donation. It compensates individuals harmed by vaccination and maintains databases that protect against healthcare malpractice, waste, fraud, and abuse.[655]

Human subject (with respect to the Common Rule). Under the Common Rule, a human subject is a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.[656]

Human subject (with respect to the FDA Rule). Under the FDA Rule, a human subject is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.[657]

Identifiable biospecimen. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.[658]

Identifiable private information. Identifiable private information is that for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.[659]

Individual (for purposes of the HIPAA Rules). The term "individual" means the person who is the subject of protected health information.[660]

Individually Identifiable Health Information (with respect to the HIPAA Rules). Individually identifiable health information is that which is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.[661]

Informed consent (with respect to the Common Rule). Informed consent is the formal process by which researchers inform potential participants of a study's purpose, scope, risk, harms, benefits, and other pertinent information that permits the potential participant to make an informed decision about participating in the research study.

Institution (with respect to the Common Rule). Institution means any public or private entity engaged in research.

Interaction (with respect to the Common Rule). Interaction means communication or interpersonal contact between investigator and participant.

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[655] Health Resources & Services Administration (HRSA), "About HRSA," *available at:* https://www.hrsa.gov/about/ (*last visited* September 27, 2017).
[656] 45 C.F.R. § 46.102.
[657] 21 C.F.R. § 50.3(g).
[658] 45 C.F.R. § 46.102.
[659] 45 C.F.R. § 46.102.
[660] 45 C.F.R. § 160.103.
[661] 45 C.F.R. § 160.103.

International Classification of Disease (ICD). An ICD is a classification system for diseases and injuries that groups medical terms used by physicians, medical examiners, and coroners together for statistical purposes (e.g., mortality data).[662] The ICD is revised regularly to incorporate changes in medical knowledge—the revision number is added after ICD (e.g., ICD-10).

International Classification of Disease, Clinical Modification (ICD-CM). ICD-CM is a classification system for diseases, injuries, health encounters, and inpatient procedures that groups medical terms used by healthcare providers together for billing and claims reimbursement and statistical purposes (e.g., morbidity data).[663]

Interoperability. Interoperability means the architecture or standards that enable diverse electronic health record (EHR) systems to work compatibly in an information network made up of multiple stakeholders (e.g., federal, state, and local governmental entities, private stakeholders, regional collaboratives).[664]

Intervention (with respect to the Common Rule). An intervention is a physical procedure or procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Institutional Review Board (IRB). An IRB is a group that has been formally designated to review and monitor proposed research to ensure that appropriate steps are taken to protect the rights and welfare of research participants.[665] An IRB typically has authority to approve, require modifications in, and disapprove research proposals.

Institutional Review Board (IRB) approval. IRB approval is the determination that proposed research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.[666]

Legally authorized representative (for purposes of the Common Rule). Under the Common Rule, a legally authorized representative is an individual or judicial or other body legally authorized to consent on behalf of another individual to that individual's participation in the procedure(s) involved in the research.[667] Where there is no applicable law addressing this issue, a legally authorized representative is an individual recognized by institutional policy as acceptable for providing consent in the non-research

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[662] Centers for Disease Control and Prevention (CDC). International Classification of Diseases: 10th Revision (ICD-10) (2001), *available at*: https://www.cdc.gov/nchs/data/dvs/icd10fct.pdf; *see also* World Health Organization (WHO). "Classifications: International Classification of Diseases (ICD) Information Sheet," *available at*: http://www.who.int/classifications/icd/factsheet/en/ (*last visited* September 26, 2017).

[663] CDC National Center for Health Statistics. "Classification of Diseases, Functioning, and Disability: International Classification of Diseases, (ICD-10-CM/PCS) Transition—Background" (*last updated* October 1, 2015), *available at*: https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm

[664] U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC). "Frequently Asked Questions: What does "interoperability" mean and why is it important?" (*last updated* January 15, 2013), *available at*: https://www.healthit.gov/providers-professionals/faqs/what-does-interoperability-mean-and-why-it-important.

[665] *See, e.g.,* Food and Drug Administration (FDA). "Institutional Review Boards Frequently Asked Questions—Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators" at § I: IRB Organization, Question 1 (*last updated* January 25, 2016), *available at*: https://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm.

[666] "Common Rule" Departments and Agencies. Final Rule: Federal Policy for the Protection of Human Subjects Research. (2017) 82 Fed. Reg. 7149 at 7260 (to be codified at 45 C.F.R. § 46.102(h)).

[667] 82 Fed. Reg. 7149 at 7260 (to be codified at 45 C.F.R. § 46.102(i)).

context on behalf of the prospective participant to participation in the procedure(s) involved in the research.

Limited data set (with respect to the HIPAA Rules). A limited data set is protected health information from which 16 specific identifiers have been removed.[668]

Managed care. Managed care is an arrangement that integrates healthcare financing and delivery wherein payers contract with or employ providers to deliver a defined set of services to beneficiaries at an agreed-upon per-capita or per-service price.[669]

Medicaid. Medicaid is a jointly funded, federal-state program established under the Social Security Act in 1965 to provide health insurance to certain low-income families and individuals.[670]

Medical device (for purposes of FDA Research regulations). A medical device is an article, component part, or accessory that is: recognized in the official National Formulary or the United States Pharmacopoeia; intended for use in diagnosing diseases or other conditions, intended for use in curing, mitigating, treating, or preventing disease; or intended to affect the structure or any function of the body without relying primarily on chemical action within or on the body or on being metabolized.[671]

Medicare. Medicare is a federal program established in 1965 under the Social Security Act that provides government-sponsored health insurance to individuals aged 65 and older and certain individuals under age 65 with disabilities that meet federal requirements.[672]

Memorandum of Understanding (MOU). An MOU is a non-legally binding, formal agreement creating a relationship between two or more entities that outlines agreed-upon duties and responsibilities for each party in the context of the established relationship.

Minimal risk (with respect to the Common Rule). Minimal risk refers to a classification for a research protocol indicating that the probability and magnitude of harm or discomfort anticipated in the research is equal to or less than the probability and magnitude of harm or discomfort ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Minor. A minor is an individual who has not attained the age of majority specified under applicable state law, or if no age of majority is specified under applicable state law, 18 years of age.

National Committee for Quality Assurance (NCQA). NCQA is a private, non-profit organization that develops quality standards and performance measures for a broad range of healthcare entities and accredits health plans issued in all 50 states, the District of Columbia, and Puerto Rico.[673]

National Provider Identifier (NPI). The NPI is a unique identification number for healthcare providers issued by the Centers for Medicare and Medicaid Services (CMS) that is used by providers, health plans,

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[668] 45 C.F.R. § 160.103 at "Limited data set" (2017).

[669] *See, e.g.*, Sekhri NK. Managed Care: The US Experience. *Bulletin of the World Health Organization,* 78(6): 830-44 at 831 (2000). *Available online at*: http://www.who.int/bulletin/archives/78(6)830.pdf.

[670] Social Security Act Volume I, Title 19, codified at 42. U.S.C. §§ 1396 –1396v.

[671] FDA. "Is The Product A Medical Device?" (*last updated* September 12, 2014), *available at:* https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm.

[672] *See, e.g.,* Social Security Administration. "Medicaid Information: What Is Medicaid?" *available at*: https://www.ssa.gov/disabilityresearch/wi/medicaid.htm (*last visited* September 26, 2017).

[673] National Committee for Quality Assurance (NCQA). "About NCQA: Overview," *available at*: http://www.ncqa.org/about-ncqa (*last visited* September 26, 2017).

and healthcare clearinghouses in administrative and financial transactions as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA)'s Administrative Simplification provisions.[674]

National Quality Forum (NQF). NQF is a non-profit, nonpartisan, membership-based organization that endorses healthcare measures, advises the federal government and private sector payers on optimal measures for use in specific payment and accountability programs, and provides reports and tools and hosts events for healthcare decision-makers on performance measurement.[675]

Navigator. A navigator is an individual or organization trained to help consumers and small businesses and their employees look for health coverage options through the Marketplace, including completing eligibility and enrollment forms.[676]

Notice of Proposed Rulemaking (NPRM). An NPRM is the official document published in the *Federal Register* that announces and explains a federal agency's plan to address a problem or accomplish a goal and that gives the public an opportunity to submit feedback. [677] A proposed rule and the public comments received in response form the basis of the Final Rule.

Office of the National Coordinator for Health Information Technology (ONC). ONC is an office within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS) charged with coordinating nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.[678]

Office for Civil Rights (OCR). OCR is an office within the U.S. Department of Health and Human Services (HHS) that is responsible for enforcing laws against discrimination by certain healthcare and human service providers[679] as well as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules.[680]

Opt-in. Opt-in refers to technologies that require a self-selected choice to purposefully accept a situation or condition ahead of participation or receipt of services.[681]

Opt-out. Opt-out refers to technologies that assume user inclusion unless users explicitly state a decision to leave or withdraw from services.[682]

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[674] *See, e.g.,* HHS Office for the Assistant Secretary of Planning and Evaluation (ASPE). "Frequently Asked Questions About the National Provider Identifier (NPI)," at "What Is the National Provider Identifier (NPI)?" (2000), *available at*: https://aspe.hhs.gov/report/frequently-asked-questions-about-national-provider-identifier-npi

[675] National Quality Forum (NQF). "What We Do," *available at*: http://www.qualityforum.org/what_we_do.aspx (*last visited* September 26, 2017).

[676] Centers for Medicare & Medicaid Services (CMS). "Glossary: Navigator," *available at*: https://www.healthcare.gov/glossary/navigator/ (*last visited* September 26, 2017).

[677] Office of the Federal Register. A Guide to the Rulemaking Process (2011), *available at*: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

[678] HHS Office of the National Coordinator for Health Information Technology (ONC). "Newsroom: About ONC" (*last updated* May 12, 2016), *available at*: https://www.healthit.gov/newsroom/about-onc.

[679] OCR. "Civil Rights for Individuals and Advocates" (*last updated* October 28, 2015), *available at*: https://www.hhs.gov/civil-rights/for-individuals/index.html.

[680] OCR. "HIPAA Enforcement" (*last updated* July 25, 2017), *available at* https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html.

[681] HHS Assistant Secretary for Administration (ASA) Office of the Chief Information Officer (OCIO). Implementation of OMB M-10-22 andM-10-23 (2010), *available at*: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/implementation-of-omb-m-10-22-and-m-10- 23/index.html.

[682] OCIO. Implementation of OMB M-10-22 and M-10-23 (2010), available at: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/implementation-of-omb-m-10-22-and-m-10-23/index.html.

Patient (with respect to 42 C.F.R. Part 2). A patient is any individual who has applied for, is receiving, or has been given diagnosis, treatment, or referral for treatment for a substance use disorder at a Part 2 program.[683]

Patient Identifying Information (with respect to 42 C.F.R. Part 2). Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a Part 2 program patient can be determined with reasonable accuracy either directly or by reference to other information.[684]

Patient Protection and Affordable Care Act (PPACA or ACA). The ACA is a law enacted in 2010 that represented a significant overhaul of the United States healthcare system, primarily focused on reducing the uninsured population through expanding Medicaid and developing a more robust individual healthcare marketplace, improving healthcare quality, and decreasing healthcare costs.[685]

Patient Registry. A patient registry is an organized system for the collection, storage, retrieval, analysis, and dissemination of information on individual persons who have a particular disease, a condition that predisposes them to the occurrence of a health-related event, or prior exposure to substances or circumstances known or suspected to cause adverse health effects.[686]

The Patient Safety and Quality Improvement Act of 2005 (PSQIA). PSQIA is a law creating a voluntary program for providers to share information with patient safety organizations related to patient safety events and imposing confidentiality and privilege requirements on such information to encourage providers to share the information without fear of liability.[687]

Patient-Centered Outcomes Research (PCOR). PCOR is a type of research comparing different medical treatments and interventions to provide evidence on the strategies that are most effective in different populations and situations, with the goal of empowering patients and their doctor(s) with additional information to make sound healthcare decisions.[688]

Payment (with respect to the HIPAA Rules). Payment includes the following functions undertaken by a health plan:[689]

1. Activities to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan;
2. Activities undertaken by a healthcare provider or health plan to obtain or provide reimbursement for the provision of health care and adjudication or subrogation of health benefit claims;
3. Risk-adjusting amounts due based on enrollee health status and demographic characteristics;

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[683] 42 C.F.R. § 2.11 at "Patient" (2017).
[684] 42 C.F.R. § 2.11 at "Patient identifying information" (2017).
[685] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010).
[686] National Committee on Vital and Health Statistics (NCVHS). "Frequently Asked Questions About Medical and Public Health Registries" (2012), *available at*: http://ncvhs.hhs.gov/9701138b.htm.

[687] Patient Safety and Quality Improvement Act (PSQIA), Pub. L. No. 109-41, 119 Stat. 424 (amending scattered sections of the Public Health Services Act at 42 U.S.C. 299 *et seq*.) (2005).
[688] Healthcare.gov "Glossary: Patient-Centered Outcomes Research," *available at*: https://www.healthcare.gov/glossary/patient-centered-outcomes-research/ (*last visited* September 27, 2017).
[689] 45 C.F.R. § 160.103 at "Payment" (2017).

4. Billing, claims management, collection activities, obtaining payment under a contract for reinsurance, and related healthcare data processing;
5. Reviewing healthcare services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;
6. Utilization review activities, including precertification and preauthorization of services and concurrent and retrospective review of services; and
7. Disclosure of certain protected health information (PHI) to consumer reporting agencies relating to collection of premiums or reimbursement.

Person. A person is a natural individual, trust or estate, professional association, partnership, corporation, federal, state or local government agency, or any other legal entity, public or private.[690]

Personal health record (PHR). A PHR is an electronic record of an individual's health information by which the individual controls access to the information and may have the ability to manage, track, and participate in his or her own health care.[691]

Primary Health Services (with respect to Community Health Centers).[692] Primary health services at CHCs means all of the following services:

1. Diagnostic, treatment, consultative, referral, and other services rendered by physicians, and/or physician's extenders;
2. Diagnostic laboratory services and diagnostic radiologic services;
3. Preventive health services;
4. Emergency medical services;
5. Transportation services as needed for adequate patient care, sufficient so that residents of the catchment area served by the center with special difficulties of access to services provided by the center receive such services; and
6. Preventive dental services provided by a licensed dentist or other qualified personnel and the prescription of fluorides for systemic use when not available in the community water supply.

Prior authorization. Prior authorization is a tool used by a health plan requiring a healthcare provider to request approval before prescribing a drug for or providing a healthcare service to a patient in order for the drug or service to qualify for coverage under the terms of the patient's benefit plan.[693]

The Privacy Act of 1974. The Privacy Act governs the collection, use, and disclosure of personally identifiable information about individuals maintained in a system of records by federal agencies, where the records are retrievable by a personal identifier (such as an individual's name or social security number).[694]

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[690] *See, e.g.*, 45 C.F.R. § 160.103 at "Person" (2017) (with respect to the HIPAA Rules) and 42 C.F.R. § 2.11 at "Person" (2017) (with respect to Part 2).

[691] OCR. Personal Health Records and the HIPAA Privacy Rule at p. 1 (2016), *available at*: https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/healthit/phrs.pdf.

[692] 42 C.F.R. § 51c.102(h) (2017).

[693] *See, e.g.*, Academy of Managed Care Pharmacy. Concepts in Managed Care Pharmacy: Prior Authorization at p. 1 (2012), *available at*: http://www.amcp.org/prior_authorization/.

[694] The Privacy Act of 1974, Pub. L. No. 93-579, 88 Stat. 1896 (codified at 5 U.S.C. § 552a).

Privacy Board. A Privacy Board is a review body established to act upon requests for a waiver or an alteration of the HIPAA Privacy Rule's authorization requirement for uses and disclosures of protected health information (PHI) for a particular research study.[695]

Private information (for purposes of the Common Rule). Private information is information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.[696]

Program (with respect to 42 C.F.R. Part 2). Under Part 2, the term "program" means:

1. An individual or entity (other than a general medical facility) or an identified unit within a general medical facility that holds itself out as providing and does provide substance use disorder diagnosis, treatment, or referral for treatment; or
2. Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.[697]

Program Director (with respect to 42 C.F.R. Part 2). Under Part 2, the term "program director" means an individual (if the Part 2 program is that individual) or, if the Part 2 program is an entity, the individual designated as director or managing director or the individual otherwise vested with authority to act as chief executive officer of the Part 2 program.[698]

Protected Health Information (**PHI**) (with respect to the HIPAA Rules). PHI is individually identifiable information created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse and that relates to:

1. The provision of care to an individual;
2. An individual's past, present, or future physical or mental health condition; or
3. An individual's payment for care, whether made in the past or present or expected in the future.[699]

Psychotherapy Notes (with respect to the HIPAA Rules). Psychotherapy notes are notes recorded by a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record.[700]

Public health authority. A public health authority is an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency that is responsible for public health matters as part of its official mandate.[701]

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[695] HHS National Institutes of Health (NIH). Privacy Boards and the Privacy Rule at p. 2 (*last updated* 2004), *available at*: https://privacyruleandresearch.nih.gov/pdf/privacy_boards_hipaa_privacy_rule.pdf.
[696] 82 Fed. Reg. at 7260 (to be codified at 45 C.F.R. § 46.102(e)(4)).
[697] 42 C.F.R. § 2.11 (2017).
[698] 42 C.F.R. § 2.11 (2017).
[699] 45 C.F.R. § 160.103 at "Protected health information" (2017).
[700] 45 C.F.R. § 160.103 at "Psychotherapy notes" (2017).
[701] 82 Fed. Reg. at 7260 (to be codified at 45 C.F.R. § 46.102(k)).

Qualified Entity (QE). QEs are entities certified under the Medicare Qualified Entity Certification Program (QECP) and authorized to: obtain Medicare fee-for-service Parts A and B claims data and Part D prescription drug event data to generate reports for providers and suppliers on performance measures; to make performance reports available to the public; to provide or sell non-public reports or combined data; and to provide Medicare data at no cost to certain authorized users.[702]

Qualified health plan (QHP). A QHP is an insurance plan that is certified by the Health Insurance Marketplace, provides essential health benefits, follows established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts), and meets other requirements. A qualified health plan will have a certification by each Marketplace in which it is sold.

Qualified Service Organization (QSO) (with respect to 42 C.F.R. Part 2). A QSO is an individual or entity that provides services to a Part 2 program and has a written agreement with the program agreeing that it will comply with Part 2 requirements regulations when dealing with patient records from the program.[703]

Quality Improvement Organization (QIO). A QIO is a private, usually non-profit organization made up of health quality experts, clinicians, and consumers that reviews medical care, helps Medicare beneficiaries with quality-of-care complaints, and implements quality improvement strategies.[704]

Records (with respect to 42 C.F.R. Part 2). Under Part 2, the term "records" means any information (recorded or not) that is created by, received, or acquired by a Part 2 program relating to a patient.[705]

Regional Health Information Organization (RHIO). A RHIO is a type of health information exchange organization (HIO) that brings together healthcare stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in the community.[706]

Regulated Entities (with respect to the HIPAA Rules). The term "regulated entities" is a collective term used to refer to Covered Entities (CEs) and Business Associates (BAs) under HIPAA.

Research. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.[707]

Rural Health Clinic (RHC). An RHC is a healthcare organization certified by the Medicare program to furnish primary care and preventive services in rural and underserved areas at a special payment rate, with the goals of addressing the lack of physician supply in rural areas. RHCs primarily serve Medicare patients and promote the use of non-physician practitioners in rural areas.[708]

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[702] *See, e.g.*, CMS Qualified Entity Certification Program. QECP Frequently Asked Questions (FAQs), at pp. 1-2 (*last updated* 2017), *available at*: https://www.qemedicaredata.org/QECP_Docs/QECP_FAQS%20__9.15.2017.pdf.

[703] 42 C.F.R. § 2.11 at "Qualified service organization" (2017).

[704] CMS. "Quality Improvement Organization" at 'What Are QIOs?' (*last updated* November 30, 2016), *available at*: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/QualityImprovementOrgs/.

[705] 42 C.F.R. § 2.11 at "Records" (2017).

[706] *See generally*, Healthcare Information and Management Systems Society (HIMSS). "Privacy & Security for RHIOs/HIEs," *available at*: http://www.himss.org/privacy-security-rhioshies-0 (*last visited* September 27, 2017).

[707] 82 Fed. Reg. at 7260-61 (to be codified at 45 C.F.R. § 46.102(l)) and 45 C.F.R. § 160.103 at "Research" (2017).

[708] *See generally* CMS. Rural Health Clinic (2017), *available at*: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/RuralHlthClinfctsht.pdf.

Social Security Act. The SSA is a 1935 law establishing a federal old-age pension system that has been amended and expanded numerous times, including to establish the Medicare, Medicaid, and S-CHIP programs, and to provide funding to states to offer public health services to certain vulnerable populations and administer state unemployment compensation laws.[709]

Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA is an agency within the U.S. Department of Health and Human Services (HHS) that leads public health efforts to advance the behavioral health of the nation and aims to reduce the impact of substance abuse and mental illness on U.S. communities.[710]

Substance use disorder (with respect to 42 C.F.R. Part 2). Under Part 2, the term "substance use disorder" means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal.[711]

Supplemental Health Services (with respect to Community Health Centers).[712] At CHCs, supplemental health services are non-primary health services that are:

1. Inpatient and outpatient hospital services;
2. Home health services;
3. Extended care facility services;
4. Rehabilitative services and long-term physical medicine;
5. Mental health services;
6. Dental services other than those provided as primary health services;
7. Vision services;
8. Allied health services;
9. Pharmaceutical services;
10. Therapeutic radiologic services;
11. Public health services;
12. Ambulatory surgical services;
13. Health education services;
14. Services, including the services of outreach workers, which promote and facilitate optimal use of primary health services and the above 13 services; or
15. Services of outreach workers and other personnel fluent in the language or languages spoken by individuals in the population served by the Center, if a substantial number of such individuals are of limited English-speaking ability.

Supplemental Notice of Proposed Rulemaking (SNPRM). An SNPRM is a notice and request for public comment published in the Federal Register when an agency has made significant substantive changes to a proposed rule between issuance of the original Notice of Proposed Rulemaking (NPRM) and the subsequent Final Rule.[713]

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[709] Martin PP and Weaver DA. Social Security: A Program and Policy History. *Social Security Bulletin* 66(1) (2005), *available at*: https://www.ssa.gov/policy/docs/ssb/v66n1/v66n1p1.html.

[710] Substance Abuse and Mental Health Services Administration (SAMHSA). "About Us," *available at*: https://www.samhsa.gov/about-us (*last visited* September 27, 2017).

[711] 42 C.F.R. § 2.11 at "Substance use disorder" (2017).

[712] 42 C.F.R. § 51c.102(j) (2017).

[713] 33 C.F.R. § 1.05-40 (2017).

System of records (for purposes of the Privacy Act of 1974). A system of records is a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.[714]

Test article. A test article is any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food Drug and Cosmetics Act or under sections 351 and 354-360F of the Public Health Service Act.[715]

Title 21 C.F.R. Part 50—Protection of Human Subjects (FDA). These regulations apply to all clinical investigations regulated by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the FDA (including foods, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products).[716]

Title 21 C.F.R. Part 54—Financial Disclosure by Clinical Investigators (FDA). These regulations require an applicant whose submission relies in part on clinical data to disclose certain financial arrangements between the sponsor(s) of the covered studies and the clinical investigators and certain interests of the clinical investigators in the product under study or in the sponsor of the covered studies.[717]

Title 21 C.F.R. Part 56—Institutional Review Boards (FDA). These regulations include general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration (e.g., foods, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products).[718]

Title 21 C.F.R. Part 312—Investigational New Drug Application (FDA). These regulations govern all clinical investigations of products subject to section 505 of the Food, Drug, and Cosmetic Act or to the licensing provisions of the Public Health Service Act.[719]

Treating provider relationship (with respect to 42 C.F.R. Part 2). A treating provider relationship is where a patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation for any condition by an individual or entity that undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient or consultation with the patient, for any condition.[720]

[714] 5 U.S.C. § 552a (2017).
[715] 21 C.F.R. § 50.3(j) (2017).
[716] 21 C.F.R. Part 50 (2017).
[717] 21 C.F.R. Part 54 (2017).
[718] 21 C.F.R. Part 56 (2017).
[719] 21 C.F.R. Part 312 (2017).
[720] 42 C.F.R. § 2.11 at "Treating provider relationship" (2017).

Treatment (with respect to 42 C.F.R. Part 2). Under Part 2, the term "treatment" means care of a patient suffering from a substance use disorder, a condition which is identified as having been caused by the substance use disorder, or both, in order to reduce or eliminate the adverse effects upon the patient.[721]

Treatment (with respect to the HIPAA Rules). Under HIPAA, the term "treatment" means the provision, coordination, or management of health care and related services by one or more healthcare providers, including the coordination or management of health care by a healthcare provider with a third party; consultation between healthcare providers relating to a patient; or the referral of a patient for health care from one healthcare provider to another.[722]

U.S. Department of Health and Human Services (HHS). HHS is a federal department tasked with enhancing and protecting the health and well-being of all Americans by providing for effective health and human services and fostering advances in medicine, public health, and social services.[723]

Use (with respect to the HIPAA Rules). Under HIPAA, the term "use" means the sharing, employment, application, utilization, examination, or analysis of individually identifiable health information within an entity that maintains such information.[724]

Utilization Review. Utilization review is a tool utilized by health plans involving a critical evaluation by a healthcare provider of healthcare services provided to patients for purposes of controlling costs and monitoring care quality.

42 C.F.R. Part 2. Part 2 is a federal regulation that restricts the use and disclosure of substance use disorder patient records maintained in connection with the performance of any Part 2 program (i.e., a federally assisted program that provides substance use disorder diagnosis, treatment, or referral for treatment).[725]

[721] 42 C.F.R. § 2.11 at "Treatment" (2017).
[722] 45 C.F.R. § 160.103 at "Treatment" (2017).
[723] HHS. "About HHS," *available at*: https://www.hhs.gov/about/ (*last visited* September 27, 2017).
[724] 45 C.F.R. § 160.103 at "Use" (2017).
[725] *See generally* 42 C.F.R. § 2.2 (2017).