United States of America

Region of Americas

Updated: February 2017

This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

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**Legal UHC start date**: 2014


**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to: [http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)
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United States Of America

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United States Of America: Regulation

2.8 Regulation

Regulation in the United States health-care system may be imposed by private or public entities at the federal, state and local county and city levels as a response to “the constant need to balance the objectives of enhancing quality, expanding access, and controlling costs in healthcare” (Field, 2007). All actors in the health-care system are subject to regulation, often from multiple government and nongovernment agencies.

As introduced in section 2.1, major federal regulatory organizations include the CMS, the CDC and the FDA, all under the umbrella of the HHS. State regulatory bodies include public health departments, provider licensing boards and insurance commissioners. Local counties and cities also regulate health care through their public health and health services departments. Independent nongovernment and provider organizations such as the AMA and the Joint Commission also have a regulatory role in the United States health-care system. This section discusses the role of regulation and governance by public and private regulators on third party payers, providers, pharmaceuticals, medical devices and aids, capital investment, patient privacy and human subjects, and public health.

2.8.1 Regulation of third party payers

Regulation and governance of private insurers, or third party payers, in the United States is shared by federal and state agencies. The current regulatory environment facing third party payers has arisen primarily out of two pieces of legislation: the McCarran-Ferguson Act and the ERISA.

In reaction to a Supreme Court ruling that the business of insurance was interstate commerce and therefore subject to Congressional regulation and federal antitrust laws, the McCarran-Ferguson Act was passed by Congress in 1945 to counteract the Supreme Court decision and reaffirm the power of states to regulate and tax insurance products of third party payers (Government Accountability Office, 2005). The Act exempted certain insurance practices from existing federal antitrust laws (i.e. Sherman, Clayton, Federal Trade Commission Acts) to which other interstate businesses were subject (Government Accountability Office, 2005). This exemption applied to activities that: constitute the “business of insurance”; are “regulated by State law”; and do not constitute an agreement or act “to boycott, coerce, or intimidate”. In essence, this Act reserved authority to regulate third party payers for state authorities. Many, if not all, states have provisions in their codes to prohibit insurers from engaging in unfair or deceptive acts or practices in their states (Government Accountability Office, 2005). However, beginning in 2011 as part of the ACA, CMS – a federal agency – will take over the review of health insurance rates increasing in excess of 10% annually from some states due to a lack of or inadequate state regulation of health insurance products sold to individuals and small businesses (The New York Times, 2011).

The other key piece of legislation regarding the regulation of third party payers is the ERISA, enacted by Congress in 1974 (CRS Report for Congress, 2009). ERISA regulations fall under the Department of Labor, in contrast to McCarran-Ferguson’s focus on state-level regulation. They set minimum standards to protect individuals participating in most voluntarily established pension and health insurance private sector employee benefit plans (i.e. self-insured employers). ERISA does not require that private employers offer health insurance but governs the administration of these plans if employers self-insure and defines how disputes are handled. Group health plans established by government or church organizations and plans that only apply to workers’ compensation or disability, or unemployment are not governed by ERISA (U.S. Department of Labor, 2011). Regulations of employer-sponsored health insurance plans imposed by ERISA include the requirement that plans provide enrollees with information about plan features and funding, fiduciary responsibilities for managers of plan assets, and procedures for establishing grievances, appealing denied claims for benefits, and rights to sue for benefits and breach of fiduciary duties (U.S. Department of Labor, 2011).

Preemption of state regulatory laws is an important cornerstone of ERISA. United States courts have upheld that ERISA preempts certain state health policies, such as employer insurance mandates, financial reserve requirements, premium taxes and managed care standards, placing constraints on states’ abilities
to regulate insurance benefits and enact health-care reforms (Butler, 2000; Gabel, Jensen & Hawkins, 2003). The preemption was included by Congress to “avoid multiplicity of regulation in order to permit nationally uniform administration of employee benefits” for employers with workers in multiple states (CRS Report for Congress, 2009). However, ERISA does not regulate benefits to the extent that the states do. Employer insurance plans that fall under ERISA have different (and often less comprehensive and less expensive) benefit structures than employer-sponsored plans that fall under state insurance regulations.

About 55% of employees in the United States work for employers who are self-insured and are therefore affected by ERISA’s preemption of state regulation (Gabel, Jensen & Hawkins, 2003; Pierron & Fronstin, 2008). Although ERISA broadly preempts state laws governing the administration of health plans and definition of how grievances are resolved, as noted earlier, states regulate many other components of the third party payer market. Since its enactment in 1974, there have been several substantial amendments to ERISA. The Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 provided some workers and their families the right to continue their health-care coverage for a limited time after job loss and other specific events (Department of Labor, 2011). This is significant because, as mentioned earlier, nearly half of Americans receive their health insurance coverage through their employer. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 amended ERISA to include limitations on exclusions from health insurance coverage based on pre-existing medical conditions events (Department of Labor, 2011). The Mental Health Parity Act of 1996 was added to ERISA so that health insurance plans offering mental health coverage had annual and lifetime benefits on a par with those for medical and surgical benefits (Department of Labor, 2011). The final two amendments to ERISA – the Newborns’ and Mothers’ Health Protection Act passed in 1996 and the Women’s Health and Cancer Rights Act passed in 1998 – respectively established minimum maternity lengths of stay and covered reconstructive surgery after mastectomies (Department of Labor, 2011).

The 2010 ACA included several new regulations governing the third party payer market. These are discussed in Box 2.2 and Chapter 6. Most importantly, health plans are required to offer and renew coverage to everyone and cannot charge more to those who have pre-existing health conditions.
Box 2.2

Efforts to provide universal health coverage in the United States

Prior to the enactment of the ACA, there had been a number of unsuccessful efforts to provide universal health coverage to the United States population. These efforts date back to the early part of the twentieth century. They failed for a variety of reasons: strong opposition from interest groups such as the AMA; Americans' reticence to allow what they sometimes perceived as a "government takeover" of the health-care system; difficulties in reaching consensus even among groups supporting the concept; and problems in reaching a consensus in and between both houses of Congress and the president. This section provides a brief recap of some of these efforts. It is based on a number of sources: Altman & Shahtman, 2011; Blumenthal & Morone, 2009; Johnson & Broder, 1996; Oberlander, 2003, 2012; and Starr, 2011.

The earliest efforts for universal coverage date back to the 1910s and were mainly spurred on by organized labour in the Progressive Movement. These efforts did not result in federal legislation; efforts were instead aimed at states but they were unsuccessful everywhere. The movement was successful, however, in enacting state-based Workmen's Compensation laws that provided income when a worker was injured on the job. In part this was the result of timing: opponents of universal health insurance argued that America did not want to emulate Germany, its enemy in the First World War, nor should it follow a socialistic path that was argued by opponents to be akin to what was happening in Russia after the revolution. Equally important was opposition from key groups, particularly employers and insurers, who did not want to see an overly strong federal presence in the private market. Interestingly, insurers did not sell health insurance at that time but they did want to protect a related business – insurance for the costs of funerals.

The first real opportunity for a federal law came in the mid-1930s when the United States approved the Social Security Act, which provided old-age pensions and unemployment insurance. Some in the Roosevelt Administration thought this was an opportune time to provide health coverage to the population as well but it became clear that inclusion of health insurance was controversial and would put at risk passage of the old-age pensions and unemployment insurance. While there is disagreement among analysts as to how committed Roosevelt was to universal coverage, it is clear that the proposals faced strong opposition, particularly from the AMA. The AMA was quite blunt in equating support of national health insurance with communism but implicit were concerns that a federal programme would lead to budgetary authority that could result in tight fee controls and a movement towards prepaid group practice.

With Roosevelt's death in 1945, President Truman became the first president to actively champion for universal coverage, believing that health insurance coverage was a basic right. A bill proposed by three members of Congress would have provided coverage to all Americans, not just workers. This effort also failed, with the bill not making it out of committee onto the floor of either chamber of the house – as a result of a forceful campaign led by the AMA, but also because even though Democrats held the presidency and both Houses of Congress, legislation was blocked by a coalition of the Republicans and conservative Democrats from the southern states.

There was little movement towards universal coverage during the 1950s. Rather, there was tremendous growth in private health insurance provided through employers. There was, however, renewed interest in health care under the Kennedy and Johnson Administrations
Box 2.2 – continued
Efforts to provide universal health coverage in the United States

in the 1960s. This interest, however, never coalesced into a cogent proposal for universal coverage but resulted in the enactment of Medicare for the elderly (and later, disabled) and Medicaid for some of the poor.

In the early 1970s, the Nixon Administration proposed a plan for health-care coverage for the entire population. It included comprehensive benefits through an employer mandate, preserving private insurance companies, but including public coverage to replace Medicaid for the poor and others who could not obtain coverage. This effort was blocked mainly (but not entirely) by the left, particularly organized labour, which wanted to wait for a system that was more akin to a single-payer system. Politically, that time has yet to arrive. Moreover, labour objected to patient co-payments in the Nixon plan.

For nearly two decades thereafter there was little movement towards universal coverage. The last major attempt prior to the Obama Administration was that of President Bill Clinton, who proposed a comprehensive proposal to cover the entire population.

The Clinton proposal was largely based on managed competition – that is, private insurers competing against each other. But the competition would be under the umbrella of newly created Health Alliances. These were to be government-sponsored consortia through which employers and employees enrolled for coverage provided by private insurers, and which collected and disbursed premiums and enforced various price and other regulations. The administration made a number of tactical errors, including hiding the details of the proposal in secrecy and not involving Congress. Those things, combined with opposition from some insurers, and small businesses, doomed the proposal in 1994.

Universal coverage was not on the agenda again until the election of President Obama, and subsequent passage of the ACA in 2010. A detailed account of the ACA is in Chapter 6.

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A Merger Frenzy Among Large U.S. Insurers

By Andrew J. Barnes

The private insurance market in the U.S. is undergoing significant consolidation. Planned and executed mergers in 2015 include in Anthem (14%) merging with Cigna (7%) and Aetna (11%) acquiring Humana (2%) resulting in three insurers – Anthem/Cigna, Anthem/Humana, and United – covering 48% (roughly 80 million) of individuals with private insurance.[1] Consumers, health care
providers, and the federal government, which subsidizes the majority of the more than 11 million individuals with private insurance purchased through the Affordable Care Act’s marketplace, are concerned about the effect of these mergers on prices and breadth and depth of coverage.[2]

The U.S. Department of Justice and Federal Trade Commission will review the merger applications to determine how the mergers will affect competition in local markets, whether these changes violate antitrust laws, and if they will harm consumers.

All but two states in the U.S. currently have insurance markets that are considered at least moderately concentrated (Herfindahl-Hirschman Index (HHI) >0.15).[3] The result of the mergers, if approved by federal regulators, would potentially increase commercial insurance market concentration by 40% or more and increase Medicare Advantage concentration by 60% or more in some states.3 In markets where insurers provide administrative services only to large employers that self-insure, the potential merger between Anthem and Cigna may lead to reduced employer costs by leveraging purchasing power, increasing direct provider contracting and contracting with accountable care networks, and expanding wellness programs to reduce the prevalence of chronic diseases among employees.3 Further, these mergers could allow insurers to offer new products, expand into new markets, and leverage purchaser power to negotiate lower prices with providers and hasten transitions to value-based purchasing.

Consolidation among purchasers may drive hospital systems and physician groups to further consolidate to maintain selling power, increasingly creating a bilateral market of consolidated health care sellers and buyers.[4] From the consumer perspective, there is limited evidence on whether lower prices achieved through insurer consolidations – through either or both greater bargaining leverage in negotiations with providers, and as a result of increased economies of scale – are passed onto consumers. Additionally, increasing consolidation among insurers may further trends of narrowing provider networks to achieve savings, possibly limiting provider choice among beneficiaries.

As insurers increase in size they will also gain influence over state and federal legislators and regulators potentially making it more challenging for the government to enact price and quality controls on private health insurance plans.


2.8.2 Regulation of providers

Physicians and hospitals are regulated by public agencies at the federal and state level and by national nongovernmental and provider regulatory organizations. Physicians, as well as nurses and many allied health professionals, are accredited by licensing boards in the state in which they practise. Across the various health professions more than 650 state licensing boards exist (Cohen, 1980). State licensing boards issue new licences to health-care professionals with the requisite educational credentials, renew
licences and enforce basic standards of practice through their power to suspend or revoke licences to practise (Field, 2007).

In addition to state-level regulation, physicians are also regulated at the federal level by the CMS imposing criteria for reimbursing providers for services rendered. For example, Medicare requires physicians to meet certain requirements, many of which overlap with state-licensing requirements (Centers for Medicare & Medicaid Services, 2011a). Since Medicare patients make up a significant portion of many physicians’ payer mix, the requirement for reimbursement serves as a form of provider regulation. Furthermore, CMS does not reimburse physicians for self-referred services. Also known as the Stark Law, this regulation prohibits payment to physicians for referrals to services in which they or their family members have a financial interest (Centers for Medicare & Medicaid Services, 2011b).

Physicians are also regulated by managed care organizations (e.g. HMOs, PPOs) and by the hospitals at which they practise or have admitting privileges. Through various mechanisms for controlling costs (e.g. capitation, gatekeeping and pre-authorization) and improving quality (e.g. disease management), managed care organizations regulate physician behaviour. Managed care organizations also give credentials to physicians in their network, again ensuring providers are able to demonstrate basic requirements to practise similar to those required by state licensing boards and CMS. Physicians may be disciplined by managed care organizations through exclusion from the network. Hospitals at which physicians practise also regulate physicians through providing credentials and periodically renewing them. Hospitals oversee physician practice through review boards and can discipline physicians for substandard care by requiring additional medical education or supervision by colleagues, or suspension or revocation of clinical privileges (Field, 2007).

Hospital regulation in the United States occurs primarily via certification requirements by the nongovernmental Joint Commission, by federal law on who must be treated at hospitals, and by eligibility for reimbursement criteria imposed by CMS. Some of the most important hospital oversight results from the self-policing role of accreditation by the Joint Commission. This organization is a nongovernmental regulatory body that includes more than 4000 hospitals (82%) in the United States (Joint Commission, 2011). Auditors from the Joint Commission survey hospitals, unannounced, and evaluate compliance with Joint Commission standards by tracing care delivered to patients, acquiring documentation from the hospital, tracking hospital quality measures and on-site observation. Annual fees for hospitals range from $2000 to $37 000. Re-accreditation surveys occur every three years (Joint Commission, 2011).

The Emergency Treatment and Active Labor Act (EMTALA), passed in 1986, requires that all hospitals participating in Medicare provide “a medical screening examination (MSE) when a request is made for examination or treatment for an emergency medical condition (EMC), including active labour, regardless of an individual’s ability to pay” (Centers for Medicare & Medicaid Services, 2011c). After screening, hospitals are required to stabilize patients with EMCs or, if they are unable to stabilize a patient (e.g. due to capacity constraints), transfer the patient for stabilization. As a result of EMTALA, the emergency department (ED) has become an access point commonly used by patients with otherwise limited access to primary care (e.g. uninsured).

As a result of the Hill-Burton Act, discussed in section 2.8.5, many United States hospitals are required to take Medicare and Medicaid patients and are therefore subject to CMS eligibility criteria for reimbursement through Conditions of Participations (CoPs) and Conditions for Coverage (CICs). CMS is able to regulate hospital care by ensuring facilities receiving CMS reimbursement meet minimum quality and safety standards (Centers for Medicare & Medicaid Services, 2011d). In fact, these CoPs and CICs also apply to many other health services delivery organizations (e.g. nursing homes, psychiatric hospitals). The conditions laid out by CMS cover most of the essential components of hospital or other health services facilities, including requirements for staffing, patient rights and medical records.

### 2.8.3 Regulation of pharmaceuticals

Pharmaceuticals in the United States are primarily regulated at the federal level by the FDA. The present day FDA evolved from legislation adopted in response to public health epidemics resulting from unsafe foods and drugs.

The FDA approval process for new drugs or biological products consists of animal testing and then four
phases of testing in humans, three of which are completed before the drug can go on the market and the last continues on after the drug has been released. The clinical trials stage often takes several years with costs largely borne by the sponsor (e.g., the drug manufacturer). DiMasi, Hansen & Grabowski (2003) estimated this process took, on average, 90.3 months and cost $802 million United States dollars per drug (including the cost of drugs failing to complete the clinical trials). Considering growth since then, the current figure would exceed far more than $1 billion. However, Light and Warburton have contended that the actual costs are far lower, due to methodological issues regarding the sample of drug companies and drugs chosen, the over-counting of various types of costs, and how taxes and profits were treated in the analysis (Light & Warburton, 2011). However, for biological products, the ACA includes new statutory provision to expedite the FDA approval process for drugs that are “biosimilar” with an FDA-approved biological product (Food and Drug Administration, 2012).

Similar to the European Medicines Agency, the FDA does not require economic analyses of drugs during the approval process. Therefore, drugs need only be effective, not cost-effective or comparably effective, for FDA approval. The ACA created a non-profit Patient-centered Outcomes Research Institute (PCORI) to study the comparative effectiveness of medical treatments, including drugs. However, the ACA stipulates that the comparative effectiveness findings from this institute “may not be construed as mandates, guidelines, or recommendations for the payment, coverage, or treatment or used to deny coverage” (Kaiser Family Foundation, 2011a).

The FDA also regulates pharmaceutical advertising through its labelling requirements and its ability to penalize drug companies conducting advertising it deems excessive or misleading. From the 1990s, drug companies started advertising directly to consumers. Among the high-income countries, the United States and New Zealand permit direct-to-consumer advertising of prescription-only drugs (Magrini, 2007). While no laws exist in the United States preventing drug companies from advertising prescription drugs to consumers directly, the FDA can prosecute manufacturers for advertising that is false or misleading. Since 2004, major United States pharmaceutical companies have paid more than $7 billion in fines related to off-label marketing of their products (Evans, 2009).

The United States does not have national price regulations on pharmaceuticals, although Medicaid and the VA are exceptions (Adams, Soumerai & Ross-Degnan, 2001). Under the auspices of patent protection and the FDA regulatory framework, drug manufacturers in the United States long held de facto monopolies in the pharmaceutical market often resulting in much higher prices compared to some other countries. Prior to 1984, generic versions of branded drugs were held to the same standard of the four-phase clinical trial process. This stymied the entry of generics into the market. In 1984, Congress adopted legislation that would allow generics to use some of a branded drug’s FDA safety and efficacy data in exchange for extending patents on branded drugs from 20 to 25 years (Field, 2007). Under the ACA, the FDA can approve generic biological products after 12 years’ patent protection to further promote the use of generics (Kaiser Family Foundation, 2011a).

During the 1980s, in an effort to rein in spending on pharmaceuticals, states began repealing anti-substitution laws and enacting substitution laws to facilitate the prescribing and filling of cheaper therapeutic alternatives to branded drugs (Field, 2007). The Medicaid Drug Rebate Program, created in 1990 as part of the Omnibus Budget Reconciliation Act, required pharmaceutical companies to give states and the Federal government rebates for drugs sold to Medicaid and VHA patients (Centers for Medicare & Medicaid Services, 2011e). More than 500 drug companies participate in the rebate programme, a requirement for Medicaid drug coverage, with rebates ranging from 10% to 15% of the average market price for the drug (Centers for Medicare & Medicaid Services, 2011e).

The United States does not allow the re-importing of drugs previously manufactured in the United States but sold at lower prices in foreign markets or the importing of drugs by individuals directly from foreign producers. The 1987 Prescription Drug Marketing Act made it illegal for drugs to be imported into the United States except by the original United States manufacturer. The ACA continued the ban on importation of prescription drugs (see Chapter 6). In response to increasing prices and shifting control of Congress and the White House, the importance of drug importation as a policy goal vacillated in the following decades. The Medicine Equity and Drug Safety Act of 2000 and the Medicare Modernization Act of 2003 both aimed to increase the availability of re-imported drugs (U.S. Department of Health and Human Services, 2011b). However, Congress required the Health and Human Secretary to assure that re-imported drugs were safe and effective. With the Health and Human Secretary unable to verify the safety
of re-imported drugs, a stalemate is created wherein the legislation has been passed but cannot be implemented (Center for American Progress, 2004; U.S. Department of Health and Human Services, 2011b). Consequently, re-importation of drugs from Canada and Western Europe remains limited in scope. Recent scandals involving the importation of fake cancer treatment drugs has served to reinforce the continued ban on re-importation and mail-order purchase from foreign pharmacies (Weaver, Whalen & Faucon, 2012).

2.8.4 Regulation of medical devices and aids

In addition to regulating pharmaceuticals, the FDA is also the principal regulator of medical devices and radiation-emitting products used in the United States. FDA’s Center for Devices and Radiological Health (CDRH) regulates firms that manufacture, repackage, re-label and/or import medical devices and radiation-emitting electronic products (medical and nonmedical) such as lasers, X-ray systems, ultrasound equipment, microwave ovens and colour televisions (Food and Drug Administration, 2011a). CDRH divides medical devices into Classes I, II and III with the level of regulatory control increasing with the class. Generally, Class I devices are exempt from FDA notification before marketing, most Class II devices require premarket notification and most Class III devices require premarket approval from the FDA. The FDA also monitors reports of adverse events and other problems with medical devices and alerts health professionals and the public when needed to ensure proper use of devices and the health and safety of patients (Food and Drug Administration, 2011b).

2.8.5 Regulation of capital investment

Federal-level regulation on capital investment arose with the Hospital Survey and Construction Act of 1946 – also referred to as the Hill–Burton Act – and also the National Health Planning Law of 1974. The Hill–Burton Act provided construction funds to increase the capacity of health services throughout the country. In exchange for the funds, hospitals, nursing homes and other health facilities were required to provide a certain amount of uncompensated care to individuals living in the area (U.S. Department of Health and Human Services, 2010d). Hill–Burton funds were distributed through local and state health planning boards. These boards in turn regulated the construction of the facilities built within their jurisdiction. Hospitals had to present a CON in order to access Hill–Burton construction funds (Starr, 1982). The CON programme is discussed in more detail in section 2.2.

From 1972 to 1995, the Office of Technology Assessment (OTA) aided Congress in the identification and consideration of existing and probable impacts of technologies, including medical technologies (Federation of American Scientists, 2011). During its existence, the OTA conducted a number of cost–effectiveness studies related to capital investment so as to inform regulators about policy decisions regarding these investments. The OTA was similar to government offices in other high-income countries in its cost–effectiveness research. In 1995 Congress de-funded the OTA (Princeton University, 2012).

2.8.6 Regulation of patient privacy and human subjects

Regulations regarding the privacy of health information in the United States were initiated in the HIPAA Privacy and Security Rules passed by Congress in 1996. The privacy component of the law provides federal protections for personal health information and gives patients rights with respect to that information (U.S. Department of Health and Human Services, 2011c). The security portion has administrative, physical and technical safeguards to ensure the confidentiality of patients’ electronic information. HIPAA privacy and security rules are enforced by the Office of Civil Rights under HHS. The Patient Safety and Quality Improvement Act of 2005 (PSQIA) Patient Safety Rule protects “identifiable information being used to analyze patient safety events and improve patient safety” (U.S. Department of Health and Human Services, 2011c).

The Office for Human Research Protections (OHRP) within the HHS regulates the protection of human subjects used in clinical and nonclinical research. Its purview “applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency” and includes “research conducted by federal civilian employees or military personnel” and “research conducted, supported, or otherwise subject to regulation by the federal government outside the United States” (Office for Human Research Protections, 2011). Since the vast majority of the research on health in the United States is funded by various government grant mechanisms or regulated by some federal
agency, OHRP regulations regarding human subjects research affect much of the research involving people. In addition to OHRP, many individual research institutions, such as universities, also have departments that verify whether human subjects research is warranted and will be conducted safely, effectively and with dignity.

2.8.7 Regulation of public health

Regulation of public health occurs at multiple levels of government. At the federal level, the CDC (discussed earlier), the EPA, the United States Department of Agriculture (USDA), and the Occupational Safety and Health Administration (OSHA) all regulate various aspects of public health. State and local offices of public health also play important roles in regulating public health.

The United States has 50 state-level public health agencies. In addition, many of the more than 3000 counties and 15 000 municipalities have some type of local health department or have their own public health regulations (Diller, 2007). These governmental agencies regulate a range of public health topics including: air quality, alcohol, animals, cemeteries and burial, communicable diseases, emergency medical services and ambulances, fair and affordable housing, firearms, food, garbage collection and disposal, housing and building codes, mass gatherings, massage establishments, noise, nuisances, pest control, sewer systems, smoking, swimming pools and spas, tobacco sales and water wells (McCarty et al., 2009).

The USDA regulates and inspects food services. It also recommends nutritional guidelines and the fortification of certain food staples (e.g. milk, bread, salt), regulates the import and export of animals and plants, and regulates the marketing of foods (U.S. Department of Food and Agriculture, 2011). The EPA regulates public exposure to harmful environmental contaminants. In 1970 Congress passed the National Environmental Protection Act, the Clean Water Act, and the Clean Air Act, giving the newly created EPA the authority to establish and enforce environmental protection standards (U.S. Environmental Protection Agency, 2011). The EPA’s reach expanded in 1980 when Congress, in response to chemical contaminants in groundwater from toxic dumps, passed the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). CERCLA gave the EPA the charge of cleaning up toxic waste at “Superfund” sites, assessing liability and financial responsibility for the contamination, and suing to recover clean-up costs (U.S. Environmental Protection Agency, 2011).

OSHA also plays a role in public health regulation. Its charge is to mitigate the harm caused from employee exposure to workplace hazards through regulation and training (Office for Human Research Protections, 2011).