CHAPTER

3

FEDERALISM: THE CHANGING CONTEXTS OF STATE AND FEDERAL HEALTH POLICY

Learning Objectives

After reading this chapter, you should be able to

- define and briefly describe *federalism*;
- articulate the differences in the kinds of policies states and the federal government make and why those differences are important;
- understand how the national federalism concept of today impacts health policy;
- describe how states may take similar or more individualized roles in the administration of Medicaid and elements of the Affordable Care Act (ACA);
- explain how differences in policy choices among the states impact national health goals;
- discuss and provide an example of each of the six predominant categories of federal health legislation:
  1. food and drug supply,
  2. disease research and protection,
  3. system infrastructure and training for health professionals,
  4. developmental and behavioral health,
  5. environmental health and pollution, and
  6. access to care; and
- discuss why understanding the interlocking nature of federal and state health policy is important.

A Brief History of Federalism in the United States

It is well beyond the scope of this text to examine the historical development and concept of federalism in detail. Nonetheless, a brief discussion of its history in the United States is pertinent here to explain the modern interpretation of

federalism and what that means for health policy at both the state and national levels. Federalism is a system of government "in which sovereignty is shared [between two or more levels of government] so that on some matters the national government is supreme and on others the states, regions or provincial governments are supreme" (Wilson and DiIuilo 1995, A-49). The federalist system in the United States has transformed over time, progressing through somewhat distinctive eras.

When the founders replaced the Articles of Confederation with the Constitution, not only were the responsibilities—and the associated powers—of governing divided between three branches, but they were also allocated between the states, as sovereign entities, and the national government, a sovereign nation. As James Madison said in *The Federalist*, number 46, the states and the national government "are in fact different agents and trustees of the people constituted with different powers" (Madison 1788).

The Bill of Rights, part of which is a pillar of the federalism concept, was adopted on December 15, 1791, less than two years after the Constitution. The first eight amendments to the Constitution in the Bill of Rights address a variety of rights pertaining to individual liberty: freedom of speech, right to bear arms, freedom from unreasonable search and seizure, the right to a jury trial, the right to due process, and the like (Lawson and Schapiro 2020). It was the Tenth Amendment that specifically addressed limitations on the national government: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

The Tenth Amendment established a framework in which to further define the division of power between the federal government and the sovereign states. The Tenth Amendment is considered the "Police Power" clause of the Constitution because matters *not* delegated to the federal government include the inherent power of a state to protect the health and well-being of its people. It is from this language and interpretation that states have the authority to license healthcare providers of all types, regulate the type and nature of healthcare facility construction, inspect restaurants for cleanliness, and impose vaccination requirements, among a multitude of other things related to the health and safety of the states' populations.

Conversely, Article 1, Section 8 of the Constitution specifically enumerates those powers assigned to the national government, including the power to levy taxes and the power to regulate commerce between the states, among others. It likewise limits states' authority, banning states from making treaties and otherwise engaging in foreign affairs.

What states and the federal government can and cannot do is, of course, the product not only of the written words in Article l and the Tenth Amendment, but of interpretations provided by the Supreme Court and other

authoritative decision-making bodies. Those definitions about governmental power have transformed the federal–state relationship throughout the years. Over time, federalism has become more interactive between the states and federal government, fostering a higher degree of cross-sovereign policymaking.

The relationship between the states and the federal government has been a question of debate since the birth of the republic. While the subject matter of any given political question may change—health, education, regulation of industry, and so forth—the core issue frequently is the determination of the appropriate roles of states and of the federal government. In general, more conservative voices advocate a stronger role for the states and a smaller federal government. More liberal voices suggest that the federal government should be stronger in order to address problems of national dimension that transcend individual state borders and variable state capacities. Therein lies one of the fundamental and transcending political and policy debates in the United States.

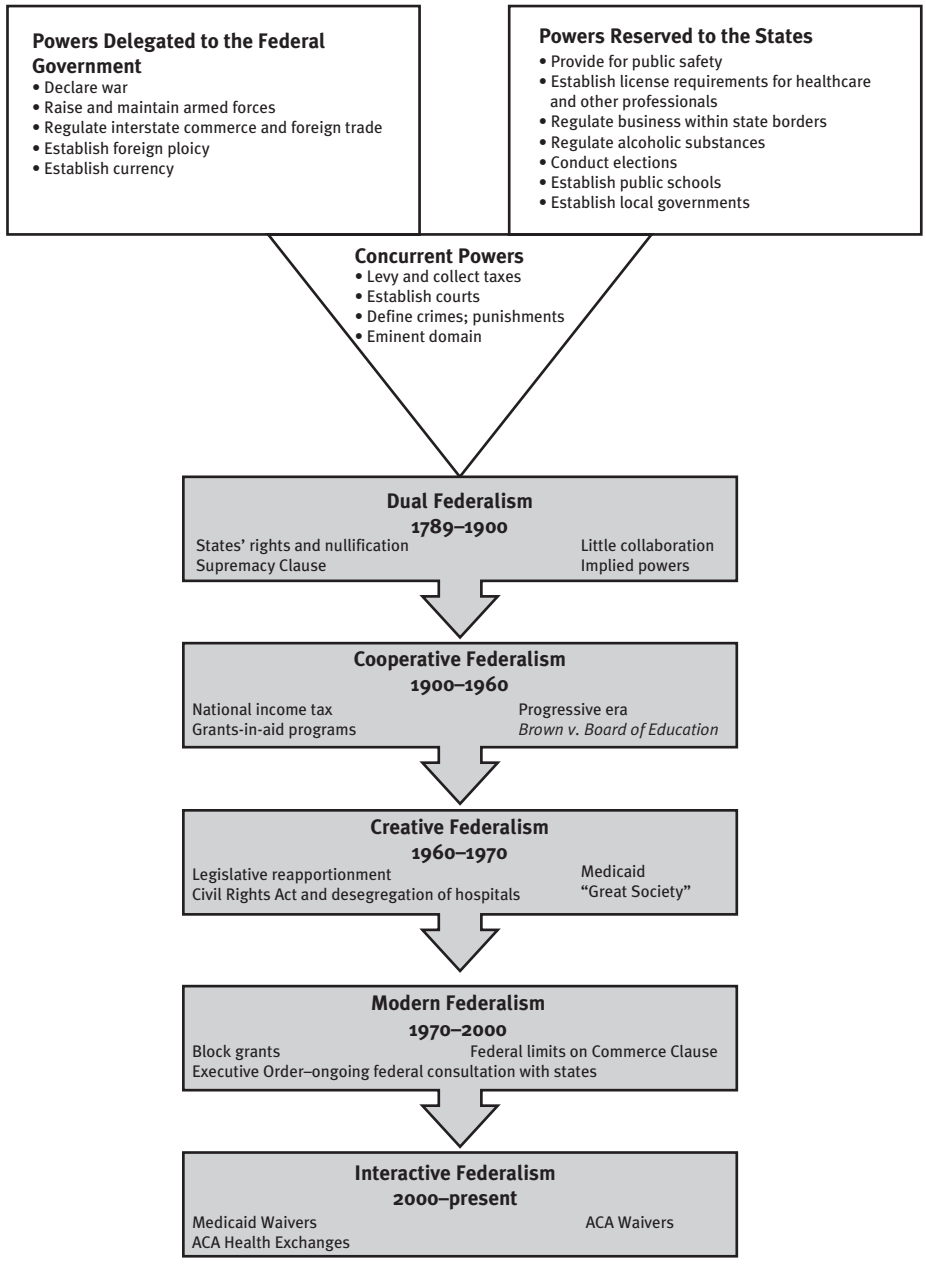
To Madison's point, the United States was a national government—a sovereign—borne of sovereign states and their people. From this germinated the concept of *separate spheres* for each of the states and the national government. The degree of separation, if you will, has narrowed over time, with each sphere becoming increasingly more engaged with the other. Exhibit 3.1 provides a shorthand reference tool representing the evolution of federalism in the United States.

Dual Federalism: The Nineteenth Century

The belief in the concept of duality between the states and national government—*dual federalism*—was prominent from late in the 1700s through the turn of twentieth century. There was little discernible cooperation between the states and the federal government. States' rights advocates championed the notion that the states were equal to, or even superior to, the national government, advancing what was known as the "states' rights doctrine." During this time, the Supreme Court ruled the federal government had implied powers to do those things "necessary and proper" to carry out the functions delegated to it by the Constitution (*McCulloch v. Maryland* 1819). The *McCulloch* decision was prominent for upholding the Supremacy Clause in allowing the federal government to charter a national bank. Other debates during this time included whether the federal government could engage in internal improvements such as roads and bridges (yes) and whether states could effectively nullify federal law (no). Nonetheless, states' rights advocates continued to press the idea of states having the legal capacity to render federal law null and void within the boundaries of a state choosing to do so.

The concept of nullification was a transcending issue, arising in several different ways and forums even after *McCulloch*. South Carolina passed a nullification ordinance in an attempt to prevent implementation of tariffs

EXHIBIT 3.1
Evolution of Federalism Timeline



on raw goods. Pennsylvania (among other northern states), attempting to protect fugitive slaves, enacted "personal liberty" statutes that were found to be violative of the Supremacy Clause because of a federal act—the Fugitive Slave Act—enacted in 1793. The states' rights issue cut both ways in some instances. The view that the states had a right to nullify federal law was a part of the reason for the Civil War, in addition to eradicating slavery.

During and following the Civil War, federal power expanded. The national government regained control of currency; conscription into the national army replaced state militias. In the second half of the century, federal authority continued to grow with the enactment of the Fourteenth Amendment, which applied the Constitution's Due Process and Equal Protection clauses to the states. Also, during this period, federal power grew through enactment of the Sherman Anti-Trust Act and the Interstate Commerce Act, among others. Conversely, however, the Supreme Court upheld the rights of states to create a state-regulated monopoly and to ban people from accessing some public amenities and privileges on the basis of race or sex, upheld the "separate but equal" concept of public services, and upheld state literacy tests as mechanisms for determining who could have the right to vote. No longer was the federal government a "servant of the states" in a decentralized theory of governance, but states retained the power to control matters clearly within their own borders (Boyd and Fauntroy 2000).

Cooperative Federalism, 1901–1960

In the early 1900s, the fledgling idea of using federal resources to influence state behavior to achieve national health objectives was an idea whose time was about to come. This era saw the beginning of partnership programs or a grant-in-aid approach between the federal government and the states. During this time, Presidents Theodore Roosevelt and Woodrow Wilson pioneered an expansive definition of the national government's role.

The advent of the federal income tax ratified in the Sixteenth Amendment to the Constitution in 1913 was no doubt a significant factor in the capacity to experiment and begin to use the *grant-in-aid* approach: using federal government revenue to grant money to the states in pursuit of policy objectives. This aim was matched by the willingness of the states to accept federal funds to do things they otherwise could not afford to do.

The first seed of this concept sewn in health policy was with the Maternity and Infancy Act, also known as Sheppard-Towner for its two sponsors. Enacted in 1921, this was the first major legislation to follow women's suffrage and was on the books until 1929, when it was allowed to expire. (A form of this law reemerged as part of the Social Security Act [SSA] of 1935). The thrust of the legislation was, in part, to encourage states to create birth registries and child hygiene bureaus. The "encouragement" was perhaps the most important feature of Sheppard-Towner: This legislation marked the first time in health-care that funds were appropriated by the federal government to the states on a formulaic basis that required matching participation by the state. The act brought noteworthy success to the effort, as shown in exhibit 3.2.

The Great Depression in the early part of the 1930s brought widespread and profound poverty. The scope of the economic collapse was so deep and

EXHIBIT 3.2 Comparison of the Number of State Birth Registries and Child Hygiene Bureaus Before and After Sheppard-Towner

Activity	Before Sheppard-Towner	After Sheppard-Towner
Birth registries	30 states	46 states
Child hygiene bureaus	28 states	47 states

Source: Adapted from Kotch (1997).

so broad that it necessitated intervention on a national level. The nature of the contract between the federal government and the individual citizen was forever changed by the SSA: For the first time, individual citizens would receive cash payments directly from the federal government. Likewise, various new federal programs were created as shared ventures with the states, and exclusive federal initiatives sprang from the SSA as well. If the seeds of grants in aid or federal–state partnerships began to take hold in the early days of the century, the field was in full bloom from the Depression through the 1960s (Boyd and Fauntroy 2000).

In addition, the *Brown v. Board of Education* decision in 1954 brought federal civil rights principles to the states. As a matter of resistance, some states theorized a "doctrine of imposition" that suggested a state may interpose itself between an "improper" national act and the state's citizens, though this approach was not efficacious in the long run.

The formulaic funding approach worked. The legacy of Sheppard-Towner, beyond its impact on infant mortality and child health, is that is served as a prototype for federal grants-in-aid to the states to achieve national health policy objectives.

A representative sample of legislation employing this funding mechanism provides a picture of how the federal government, with the largesse of the federal purse, can achieve national policy objectives at the state level. The proliferation of this concept changed the dynamic of the federalist system from the "separate spheres" philosophy to interactive, collaborative exchanges between those spheres. A partial list of examples appears in exhibit 3.3.

To be clear, this federal–state "partnership" approach did not end with Medicaid in 1965. Subsequent examples, and there are many, include multiple amendments to Hill-Burton and the expansion of support for state efforts in developmental health, mental health, disease prevention, and, notably, the Children's Health Insurance Program of 1997, which many states folded into their Medicaid programs. Note that this list does *not* include legislation in which new federal agencies were created or new responsibilities were assigned to those agencies, a subject to be addressed later in this chapter, along with other partnership program legislation.

EXHIBIT 3.3 Selected Federal "Grant-in-Aid" Legislation

Year	Legislation	Key Issue(s) Addressed
1935	Social Security Act	Incentives for maternal and child health; child welfare services and increased assistance for state and local public health programs
1938	LaFollette-Bulwinkle Act	Funding for states to investigate and control venereal disease
1946	National Mental Health Act	Grants for states' mental health activities
1946	Hill-Burton Act	Grants to states in support of hospital planning and construction
1954	Medical Facilities and Construction Act	Expansion of Hill-Burton to include other kinds of health facilities
1955	Polio Vaccination Act	Support for state-administered polio vaccination programs
1956	Water Pollution Control Act Amendments	Technical and financial support to states and municipalities to prevent and control water pollution
1960	Kerr-Mills Act	Support for states to provide care for "medically indigent" elderly
1963	Health Professionals Educational Assistance Act	Construction grants for healthcare professional teaching facilities
1963	Maternal and Child Health and Mental Retardation Planning Amendments	Support for states' efforts to prevent developmental disability through prenatal, maternity, and infant care for at-risk individuals
1964	Hospital and Medical Facilities Amendments	Expansion of Hill-Burton to include modernization and replacement of existing facilities
1965	Medicaid	Support to states to insure medically indigent individuals

Creative Federalism, 1960–1970

The 1960s saw a plethora of significant developments in the dynamic of federal and state relationships. The Supreme Court ruled in 1962 that apportionment of legislative districts in every state but Oregon violated the Equal Protection Clause of the Fourteenth Amendment to the US Constitution. Migration of population to urban areas had caused rural areas to be, relatively speaking, overrepresented in state legislatures. Fundamentally, federal standards of "one man, one vote" were imposed on the states (*Baker v. Carr* 1962).

In addition, the "Great Society" advocated by President Lyndon Johnson empowered the federal government to pursue national policy objectives through state and local governments. This concept included initiatives such as Kerr-Mills, which ultimately became Medicaid; expansion of the Hill-Burton Act to provide more support for states to facilitate construction of medical facilities; and federal support for states to address developmental issues in their respective populations.

Moreover, the Civil Rights Act of 1964 provided a strong impetus to desegregate American hospitals. That drive to desegregate was accelerated with the passage of the Medicare program in 1965. Hospitals were not allowed to participate in the Medicare program—that is, would not be paid—if they did not first integrate patient care services (Hoffman 2012).

Modern Federalism, 1970–2000

In the 1970s and 1980s, the federal government took note of overlap and waste among multiple federal matching grant programs. During this time, the concept of block grants for a number of programs emerged in an effort to shift power from the federal government to the states by giving the states more latitude in using federal resources (Boyd and Fauntroy 2000).

In general, both court cases and legislative action pushed more activity to the state level. In *New York v. United States* (1992), the Supreme Court ruled that congressional imposition of liability on the states for failure to establish low-level radioactive waste–mitigation sites exceeded its authority under the Commerce Clause (*New York v. United States* 1992). The Workforce Investment Act of 1998 consolidated improvement in employment, literacy, and vocational rehabilitation training as a block grant to states. Finally, an executive order by President Clinton required federal agencies to have a consultation process in place with states prior to the release of regulations or publication of legislation (US President 1999).

Interactive Federalism, 2000–Present

The nature of the relationship between the federal and state governments continued to evolve. Having briefly examined the history of federalism's evolution, we now turn to how more contemporary national health policy objectives are served by state action incentivized by the federal government through a variety of "partnerships" leveraging federal revenue against the states' police powers. Some call this *national federalism* (Gluck 2014) or *interactive federalism* (Schapiro 2005). Regardless of the label, the key characteristic of this brand of federalism comes directly from federal statutes, says Gluck (2014):

> When Congress calls on states to implement federal law, states act in their sovereign capacities to do so: They pass new state laws and regulations, create new state

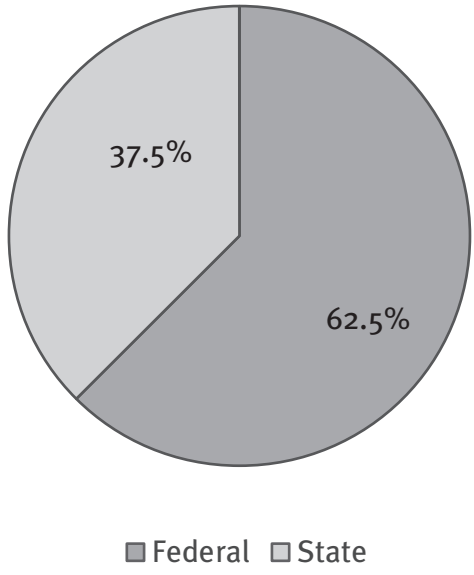
> institutions, appoint state officials, disburse state funds . . . It is true that this state action is not wholly separate from federal law; *it is shaped by the federal statutes and states often need permission* from the federal government to begin a course of federal statutory implementation [emphasis added]. But that does not change the fact that, after such approval, the states' sovereign apparatus acts in ways that are often indistinguishable from the kind of autonomy we see in exclusively state-law domains.

As it relates to health policy, the observed trend is to engage states ever more deeply in national issues. The federal government is giving the states substantial flexibility with regard to federal programs addressing a national purpose—for example during this era, the expansion of Medicaid in the ACA. In short, Congress and the president wanted to expand healthcare coverage to include a significant population not included in the original Medicaid legislation as part of a national goal to achieve universal health insurance coverage. For that reason, state expansion of Medicaid was mandatory for the states in the legislation as it was enacted into law. In *NFIB v. Sebelius,* however, the Supreme Court decision made Medicaid expansion optional for the states. By dint of that decision, implementation of this important policy was handed to the states. As an incentive to encourage states to expand their Medicaid programs, the federal executive branch, as part of *its* implementation scheme, provided states significant latitude to implement that expansion of care in ways that met local needs. Those local needs varied from state to state, which directly—and at times adversely—affected the effectiveness of the national purpose that motivated program creation in the first place (Gluck and Huberfeld 2020).

While the federal government established the precedent for *cooperative federalism* by allocating resources to states conditioned on states' pursuit of broader national goals, it specifically also permitted and encouraged state innovation in the federal statutes establishing the program. This subtle transition to "interactive federalism" is most prominent in Medicaid, the Children's Health Insurance Program (CHIP), and the ACA. (For the purposes of this discussion, because many states have folded their CHIP programs into their Medicaid programs, those two will be considered together here.)

As we move to the discussion of state flexibility in administration of programs undertaken in partnership with the federal government, briefly take note of their relative expenditure levels for Medicaid. As seen in exhibit 3.4, the amount of a state's Medicaid expenditures paid by the federal government for federal fiscal year (FY) 2018 is, on average, 62.5 percent. The state portion is, on average, 37.5 percent. New Mexico had the greatest percentage of federal assistance with Medicaid at 79.7 percent, while Virginia had the smallest at 49.9 percent (Kaiser Family Foundation 2019). (For a complete list of states and their relative share of Medicaid expenditures, see Kaiser Family Foundation [2019].)

EXHIBIT 3.4 Percentage of Federal and State Share of Medicaid Expenditure (Federal FY 2018)



Source: Adapted from Kaiser Family Foundation (2019).

The Medicaid program permits states to innovate and experiment within the federal parameters of the program. States may apply to the secretary of the Department of Health and Human Services (HHS) for a waiver releasing them from some of the requirements of the program. There are three different kinds of Medicaid-program waivers, all of which are derived from sections of the SSA. (Remember, Medicaid—including CHIP—and Medicare are amendments to the original SSA.) References in the legislation to waivers, therefore, relate to those sections of the SSA that empower the secretary to grant the waivers.

Section 1115(b) Medicaid Waivers: Research and Demonstration Projects

Waivers under this section are for experimental or demonstration projects. The secretary of HHS can waive the mandate that the patient have freedom of provider choice and requirements that there be comparability of services, and HHS may also permit a program to be less than statewide. In other words, with the waiver, the federal government will continue to provide the usual matching funds to which the state would otherwise be entitled while the state experiments with nonconforming delivery models of innovations (Mitchell et al. 2019).

Consider an example: A state might want to contract with a managed care organization (MCO) that included a large group of providers—perhaps all

the hospitals and the local medical society of a large urban area in an otherwise predominately rural state. The program might use a capitated model requiring Medicaid beneficiaries to use in-network providers. Further, the MCO might offer translation and transportation services to those patients who need them. This program would be markedly different from the Medicaid program in the rest of the state, as it would restrict provider choice, offer nonstandard services, and exist only in a subregion of the state. In this way, the program would speak to all of the conditions referenced previously.

The research or demonstration questions would be whether such an approach would be truly cost effective compared to the standard Medicaid program. Does this approach save money? Does it improve the population's health status? Does it provide more overall value than the typical approach? By the terms of the waiver, the state and the organization with which it contracted would have an initial five years to answer such questions. The waiver is renewable (Mitchell et al. 2019).

Section 1915 Medicaid Waivers: Managed Care or Freedom of Choice Waivers and Home and Community-Based Services Waivers

There are additional waivers under Section 1915(b) of the SSA that allow states, subject to the approval of the secretary of the HHS, to restrict *freedom of provider choice* not for research or demonstration purposes, but for mandatory managed care programs as standard operating procedure.

Section 1915(c) permits the secretary to waive many requirements associated with home care–based and community-based services (HCBS) similar to those referenced in Section 1115 waivers in addition to income and financial resource requirements (Mitchell et al. 2019).

See exhibit 3.5 for a synopsis of how widespread this trend has become. Waivers are an important tool for states seeking to manage Medicaid programs in a way that each state perceives to be most effective. In this way, Medicaid is not a one-size-fits-all federal program but rather multiple individual federal–state partnerships that allow states flexibility in how to meet the needs of their populations. This demonstrates Gluck's point about national federalism. Yes, the state behaves like a separate sovereign, but it does so in the framework of law that has national requirements.

Exhibit 3.5 reflects how many states have participated in each of the three waiver programs and the number of waivers granted in those states. It further displays the characteristics included in some of those waivers. For example, of the 60 waivers in 44 states under Section 1115(b), at least some—but not necessarily all—included waivers related to the characteristics mentioned in the left-hand column of exhibit 3.5. Moreover, one state may have multiple waivers in each of the categories.

EXHIBIT 3.5 Comparison of Medicaid Waivers Usage (May 2019)

Key Characteristic	1115(b) R&D	1915(b) Managed Care	1915(c) HCBS
Number of waivers	60 waivers, 44 states	78 waivers, 38 states and District of Columbia	292 waivers, 47 states and District of Columbia
Statewide requirement waived	•	•	•
Comparable-service-to-Medicaid standard waived		•	•
Guaranteed freedom of provider choice waived	•	•	
Income and resource rules waived			•

Source: Adapted from Mitchell et al. (2019).

The Affordable Care Act and State Policy Innovation: Section 1332 Waivers

Waivers apply only to state Medicaid Programs. The ACA also created a waiver process to permit states greater flexibility with respect to certain elements of the ACA that are not directly related to Medicaid. Keep in mind, however, that Medicaid expansion was a part of the original vision of ACA proponents, who planned to use it as a tool to help expand insurance coverage.

Before discussing requirements that a state can have waived under the provisions of the ACA, a brief examination of the allocation of responsibilities between the federal government and the states would be in order. In its most simplified form, the ACA delineates federal and state responsibilities in this way:

The federal government provides:

- Protections for people with preexisting health conditions
- Uniform financial assistance for people with incomes below 400 percent of the federal poverty level [FPL]
- Individual and employer mandates to ensure people gain and keep coverage.

States have authority to:

- Oversee their individual, small-, and large-group insurance markets
- Manage their Medicaid program

- Run their own insurance marketplace
- Create a Basic Health Plan for people earning between 138 percent and 200 percent of FPL
- Set up risk adjustment and rate review programs
- Make significant changes to their individual markets (through a Section 1332 state innovation waiver) so long as the coverage offered is affordable, comprehensive, and available to the same number of people as under current law (Collins and Lambrew 2019).

Section 1332 of the ACA allows the secretary of the HHS to grant waivers to states relating to certain requirements of the ACA. Referred to as *state innovation waivers*, they are also called *state relief and empowerment waivers* (CMS 2020). Specifically, the secretary may grant waivers regarding the following:

1. Benefits and subsidies
2. Insurance markets
3. The individual mandate
4. Employer mandates

Fundamentally, this section permits states to do things necessary to ensure the stability of insurance markets—compensate for adverse selection, for example (Rosso and Mach 2019).

There are, of course, some federal "guardrails" that provide parameters beyond which a state may not go with its waiver. Any waiver under Section 1332 must do the following:

- Provide coverage at least as comprehensive as that available without the waiver.
- Be at least as affordable as the coverage would be without the waiver (out-of-pocket costs cannot be excessive).
- Provide the same breadth of coverage as the coverage would be without the waiver (in other words, the waiver plan must cover at least as many people as would be covered without the waiver).
- May not add to the federal deficit (i.e., must be cost neutral) (Rosso and Mach 2019).

There is more to this than the written word. Different interpretations can be applied that yield remarkably different decisions. Those operational decisions—policy decisions—can, in turn, produce dramatically different results. The following sections contain some striking examples.

Waivers in Detail

The Congressional Research Service has published two reports with significant detail about the waivers available under Medicaid and the ACA. For a complete table of waiver-related activity and more detailed discussion of Section 1115 and 1915 waivers, see Mitchell et al. (2019). For complete information regarding Section 1332 waivers under the ACA, see Rosso and Mach (2019).

The primary point of this discussion of federalism and the specifics of the waiver provisions is the enhanced flexibility the federal government provides the states with regard to administration of both Medicaid and ACA requirements. Not only may states undertake novel approaches to Medicaid, but they can also alter ACA terms. While it has not occurred yet, there is nothing that bars a state from seeking both Medicaid and ACA waivers to be used in concert with one another to help meet the mandate of reducing the number of uninsured individuals.

From a federal policy perspective, this flexibility enhances the role of the states in crafting health policy. This flexibility permits the local sovereign to shape the program in a way most beneficial to that state. This "new" version of federalism—which emanates from federal statutes, regulations, and operating decisions—is helping states to find new ways to manage both Medicaid and the healthcare reform brought forth by the ACA.

With respect to Medicaid in particular, however, the meaning of *reform*, as used during the tenure of one administration, is not necessarily the same as the next. The primary mandate of Medicaid is to provide insurance for the economically very poor among us—to expand health insurance coverage in order to improve access to care. Recall that Medicaid, prior to the ACA, was aimed primarily at parents (most frequently single mothers) and children whose income was below 100 percent of FPL. The ACA dramatically expanded eligibility to include essentially *everyone* with an income of 138 percent of FPL or less. This expansion was so significant that the Supreme Court considered it a new program and struck down the mandatory expansion in favor of making it an option for the states.

The mandate of Medicaid in its pre-ACA form, and certainly after, was to *expand* coverage and, thus, access to healthcare services. But in the eyes of some, the ACA expansion represented a fundamental change in the type of people covered. This example is one where the outcomes of elections matter. Those who hold this view—that this expansion of Medicaid goes beyond its original mandate and that the expansion was a "clear departure from the

core, historical mission of the [Medicaid] program"—came to power in the election of 2016 (Price and Verma 2017). Thus began the modification of legislatively established policy through application of administrative regulation and operational decisions.

This view of the ACA resulted in a "shift in policy" with regard to how the HHS interprets applications for Section 1115 waivers (Rosenbaum 2017). The Trump administration announced it will consider state applications for waivers to permit the imposition of work requirements by states as a precondition to receive Medicaid benefits. Some have questioned whether this interpretation is, in fact, consistent with the program's mission (Huberfeld 2018).

Basically, the view of the political leadership of several states, and the interpretation of the Medicaid expansion by the federal government agency charged with its administration (CMS), have combined to give states a new way to manage Medicaid costs. Many people working part-time or poorly paid full-time jobs were previously denied Medicaid because their income exceeded the eligibility threshold. Now they may be eligible, thus Medicaid coverage was expanded irrespective of state-imposed work requirements for these individuals. Conversely, however, there are those who may not be able to find work or may not be able to work for reasons not accounted for in the program, and they will be disenrolled from the program. That feature of work requirements saves the states (and the federal government) money, but it comes at the cost of disenrolling people who would otherwise be eligible for Medicaid under the ACA.

The issue here is not whether one agrees with work requirements as a predicate for Medicaid eligibility. The point in this context is the level of flexibility afforded to the states by an administrative interpretation of a legislative action. State-by-state work requirements constitute a good example of how the federal government can and does permit state action that might yield dramatically different results from state to state. Work requirements imposed in one Medicaid expansion state may disqualify a person from Medicaid benefits, while a person of similar standing in another state may reap the benefits of the expanded Medicaid program. (As of this writing, the imposition of work requirements has been stayed by court order pending the outcome of litigation challenging the legality of such work requirements.) In another example, an individual who lives in a state that did not expand Medicaid, but close to the border of a state that did, may experience different health outcomes than their neighbor. Irrespective of work requirements in this instance, this schism has been referred to as the Medicaid "haves and have nots" (Ungar 2019).

The impact of the Supreme Court decision in *NFIB v. Sebelius* that vitiated the mandate to expand Medicaid certainly was a policy decision with profound consequences. Here, we see an administrative (operating) decision adding an additional policy layer, giving the states the opportunity to further

alter ACA (as to the Medicaid expansion) rules, thereby also diminishing Medicaid's impact in expanding coverage. Again, the point is not whether one agrees—the point is that judicial and administrative decisions can alter the intended outcome of the legislative body. In the context of federalism, judicial and administrative decisions that mitigate the impact of legislatively established policy take place at both the federal and state levels of government. While the ACA happens to provide a rich example, this could occur in other fields as well.

History can recount how federalism in the United States has changed in ways that one might argue permits states, with the imprimatur of the federal government, to all but thwart the design of the federal government's intended program. While one administration might deny states the opportunity to apply the interpretation recounted earlier in the chapter, the next one might permit it (Huberfeld 2018). Thus, this chapter is not only an examination of federalism but also of policy modification (as described in chapter 4 and discussed in greater detail in chapter 10). Simply put, though it feels like the left hand doesn't know what the right hand is doing, that impression is not necessarily correct. The left hand is allowing the right hand to do things previously not permitted—this is a "modification" outcome.

If operational realities of the federalist system have changed throughout the history of the United States, so too has the role of the federal government. By the breadth and depth of Congressional and presidential policy decisions, the federal government has established an ever-increasing presence in health policy (see box).

Legal Marijuana: Federal Intransigence While States Move Forward

The legalization of marijuana is an issue for which the federal power to regulate interstate commerce and the police power of the states collide. Once highly controversial and universally illegal, marijuana has found a new place in society in recent years. As of early 2020, 34 states permit the medical use of marijuana in one fashion or another. Likewise, 11 states have made recreational use legal. While legalizing the possession and cultivation of marijuana, states have developed a variety of regulatory schemes limiting the amounts that may be dispensed or possessed, or the level of THC (tetrahydrocannabinol) permitted, but in a very real sense there is no legal consequence for possession of "weed" in these states. Conversely, however, "At the federal level, marijuana remains classified as a Schedule I substance under the Controlled

Substances Act, where Schedule I substances are considered to have a high potential for dependency and no accepted medical use, making distribution of marijuana a federal offense" (National Conference of State Legislatures 2020).

As is always the case—at federal, state, and local levels—prosecutors have a measure of discretion with regard to enforcement. In other words, prosecutors may consider mitigating circumstances in deciding whether to prosecute any criminal violation. In general terms, the less violent the crime, the greater the level of discretion that may be exercised. In this particular case, the federal government is slowly ceding to the states the prerogative to regulate marijuana. In October 2009, the Department of Justice (DOJ) under the Obama administration encouraged federal prosecutors to avoid prosecuting individuals who distributed marijuana for medical purposes under state law (National Conference of State Legislatures 2020).

In August 2013, the DOJ updated its policy, asserting that states such as Washington and Colorado (which had passed laws legalizing, but also regulating, the production and distribution of marijuana) were expected to have rigorous enforcement mechanisms, setting forth eight factors that should guide prosecution. Further, the DOJ said it was reserving the right to challenge state laws legalizing the use and distribution of marijuana (DOJ 2013).

Subsequently, under a new administration, in January 2018, Attorney General Jeff Sessions rescinded the previous memo and indicated the discretion would rest with local US attorneys. The memo "directs all U.S. Attorneys to use previously established prosecutorial principles that provide them all the necessary tools to disrupt criminal organizations, tackle the growing drug crisis and thwart violent crimes across our country" (DOJ 2018). As a practical matter, this change did not affect prosecutorial decisions materially.

In short, this conflict between the states' police power and the federal government's regulation of interstate commerce seems to be shifting the balance in favor of the states with regard to the legalization of marijuana. Of course, there are multiple variables in state decisions to legalize and regulate marijuana. First, state prisons are overcrowded. By reducing the number of imprisonments attributable to use and possession of marijuana, the states can save money and alleviate heavily burdened court dockets. At the same time, by legalizing and regulating the product, states can gain tax revenues much in the same way they tax tobacco and liquor. Finally, people of color are convicted of drug possession in disproportionate numbers, so legalization makes the justice system slightly less racially

(continued)

disparate in this respect (Langan 1995; Rosenberg, Groves, and Blankenship 2017).

It remains a crime to transport marijuana across state lines. Thus, in terms of growth, production, and consumption, the marijuana industry is legally constrained to function within the individual states.

By January 2020, the following states permitted medical or recreational marijuana.

Allow Medical Marijuana		Allow Recreational Marijuana
Alaska	Missouri	Alaska
Arizona	Montana	California
Arkansas	Nevada	Colorado
California	New Hampshire	Illinois
Colorado	New Jersey	Maine
Connecticut	New Mexico	Massachusetts
Delaware	New York	Michigan
District of Columbia	North Dakota	Nevada
Hawaii	Ohio	Oregon
Illinois	Oklahoma	Vermont
Louisiana	Oregon	Washington
Maine	Pennsylvania	
Maryland	Rhode Island	
Massachusetts	Utah	
Michigan	Vermont	
Minnesota		

Source: Governing.com (2019).

Growth in the Federal Government's Healthcare Role

The federal government's influence in healthcare has grown since the beginning days of the republic. The first federal law with respect to health was the Seaman's Sickness and Disability Act of 1798 that required

> the master or owner of every ship or vessel of the United States arriving from a foreign port into any port in the United States shall . . . render to the collector a true account of the number of seamen that shall have been employed on board such vessel . . . and shall pay to the said collector, at the rate of twenty cents per month, for every seaman so employed. . . . [The act stipulated in Section 2 that] the President of the

> United States is hereby authorized, out of the same, to provide for the temporary relief and maintenance of sick or disabled seamen in the hospitals, or other proper institutions now established in the several ports.

Since that time, the federal role in health policy has grown. Consistent with changes in the concept of federalism as well as the US population and society, that growth has been significantly greater in the 20th and 21st centuries than in the 18th or 19th. Indeed, federal growth in healthcare and health services has accelerated since the Great Depression. That event, leading to the SSA of 1935, brought a sea change in how individuals would relate to the federal government's new role in their lives. The SSA fundamentally changed the relationship of the federal government and US citizens—for the first time, individuals received a benefit directly from the federal government, not from the states. Likewise, the SSA amplified the "grant-in-aid" practice between the federal and state governments. Once enshrined into law, the SSA became the foundation for a multitude of federal interventions in both the lives of individuals and in the dynamic between the federal government and the states.

Expansion of the federal role in healthcare is, in many ways, predicated on the statutory base provided by the SSA. Keep in mind that Medicare, Medicaid, the Children's Health Insurance Program, and parts of the ACA are all amendments to the SSA. Likewise, a variety of grant programs to states and local communities for maternal and child health also spring from the SSA. Title V of the SSA can be portrayed as a Sheppard-Towner redux, along with similar matching grant programs embodied in Title V.

Likewise, as Congress saw threats to people's health from adulterated drugs and from communicable diseases, and as science learned more about terminal diseases, the federal government responded by establishing agencies such as the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH). In their infancy, those agencies had different names and relatively narrow missions. But as industry, agriculture, and science advanced, the health professions learned more about threats from drugs, pollutants, cancers, and the transmission of disease. Concomitantly, the missions of these agencies grew and, of course, new agencies were created. Sometimes agency names were changed to reflect an expanded mission. The FDA, the CDC, and the NIH are all good examples of this development.

Note, however, that in some policy subcategories, intervention is almost exclusively federal, with very little state interaction, while in other areas the federal program may be highly integrated with the states at multiple levels. Most of federal legislation that addresses health can be organized into six categories (see appendix 1.3). Many individual laws address more than one subject, but a law's primary purpose is the one used for this classification. Using

this prism contributes to understanding the historical development of federal health policy. So, for discussion purposes, we will examine federal legislation using the following categories:

1. Food and drug supply
2. Disease research and protection
3. System infrastructure and training health professionals
4. Developmental and behavioral health
5. Environmental health and pollution
6. Access to care

These categories reflect healthcare issues that transcend state borders. Water quality assurance in one state, for example, may not mean much in terms of efficacious policy if a state upstream permits profligate polluting. Similarly, keeping food unadulterated in one state will not prevent illness in another that may not regulate food as closely. As we have seen previously, only the federal government can create policies that cross state lines to address issues affecting all states.

Food and Drug Supply

Public interest in food and drug safety began well before the first significant legislation on the subject. There were interest groups and several administrative appointments along with minor legislation concerning adulterated food. The federal Bureau of Chemistry evolved into FDA with the passage of the Pure Food and Drug Act of 1906.

Adulterated food and drugs have been—and remain— health concerns for many. As the incidence of events involving either began to accelerate, so too did Congressional response. Recall germ theory arose in 1864, when Louis Pasteur first purified wine by heating, then cooling, it. By the 1880s, pasteurization of milk was becoming common in Europe. It would be close to the turn of the century before the process became more widespread in the United States. With this advancement came new awareness of the impact of impurities in food and drugs. Congress acted to improve the purity of food and drugs in 1906 in response to studies of adulterated food and drug products done by the chief chemist of the United States, Dr. Harvey Wiley (FDA 2018).

Assurance of pure food and unadulterated pharmaceuticals is an area in which the federal government has taken the lead over states. The transmission of food and drugs flowing through interstate commerce puts the federal government in the superior position for this purpose. There are but a few "partnerships" between the federal government and the states in the category of food and drug purity. We see little evidence of interactive federalism, as

discussed earlier in the chapter, in this body of legislation. The laws are all aimed at products that are trafficked across state lines. Further, it is a federal agency that is charged with administration and enforcement of US law and policy as it relates to food and drugs.

During the last part of the twentieth century and first part of the twenty-first, it was increasingly apparent that research and development of new pharmaceuticals and biologics was accelerating and exceeding the capability of the FDA to review such proposals thoroughly using contemporary analytical protocols. The 21st Century Cures Act (P.L. 114-255), signed into law in December 2016, made several changes to the drug and device approval pathways through the FDA to support innovation and accelerate development and review of certain medical products (e.g., combination products, antimicrobials, drugs for rare disease, regenerative therapies) (Dabrowska and Green 2019).

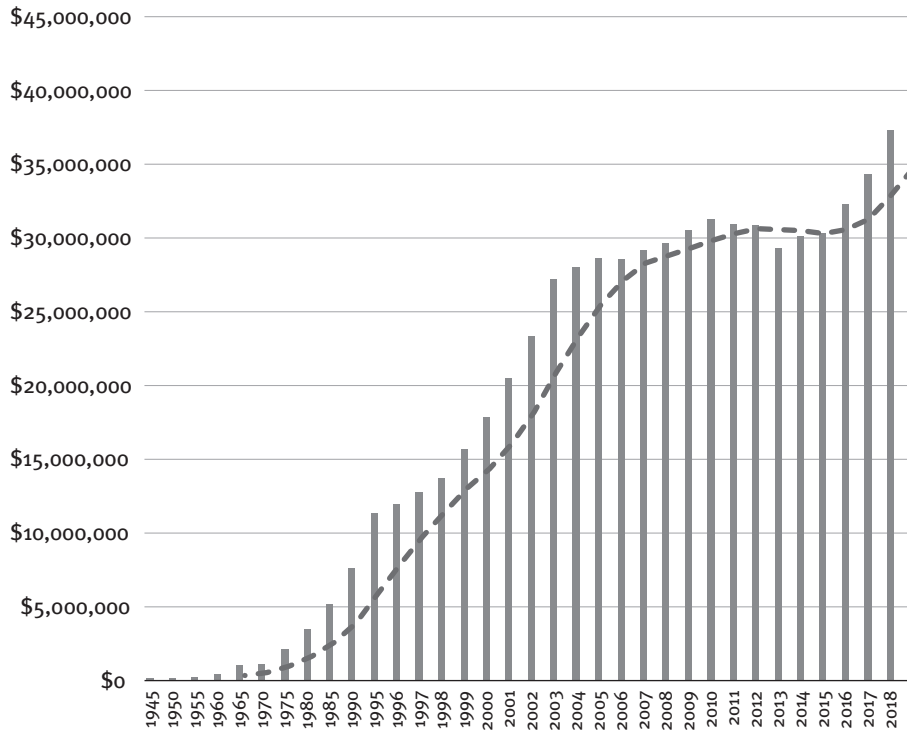
See appendix 1.3, section A, "Food and Drug Supply Legislation," for summaries of selected legislation related to food and drugs.

Disease Research and Protection

The NIH and the CDC have very different, but complementary, missions. Their respective mission statements and orientations highlight those differences. The NIH mission is focused on research: not just any research, but foundational research that will lead to knowledge of disease causes and, ultimately, cures. The NIH mission is to "seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability" (NIH 2017).

In fulfilling that mission, the NIH is a collection of federal agencies dedicated to specific disease research. It has a mere handful of state partnerships related to selected data reporting and sharing. NIH funds research at universities and health science centers across the United States in addition to its own internal research. The volume of legislation directly impacting the NIH understates the importance of this agency and its mission; in this case, appropriation of budget is the more accurate reflection over time of the growth in, and importance of, the NIH's function. During the postwar era, America invested in science through its budget and expansion of research agencies. The first institute was created in 1945, and the number of institutes and agencies in the NIH purview grew to 24 by the end of the century. The budget underscored the value of science to the United States. As you can see in exhibit 3.6, America's interest in scientific research was increasingly robust from 1945 through approximately 2006. At that juncture, America's investment in science diminished and appropriations flattened or grew much more slowly until more recent times which have seen an uptick in this form of public investment. This increased funding for the NIH is a compromise that facilitated the 21st Century Cures Act, discussed in more detail in chapter 6.

EXHIBIT 3.6
NIH Appropriations, 1945–2019 (in billions)



Note: The dotted line is a trend line using a five-year rolling average.

Source: Adapted from NIH (2019).

If the NIH represents the United States investment in foundational science, the CDC is the epitome of applied science in protecting against disease, as well as the quintessence of integration with state and local governments. The CDC's work represents the next step in science—applying what has been learned to benefit the population. In some ways, the CDC's work is an extension of federalism because of its deep state and local government engagement. Further, the CDC conducts its own research on a wide range of health-related topics. Its mission: "As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise." In "provides health information," the mission statement looks past the breadth and depth of reporting information that is collected by the CDC. Disease outbreaks as well as routine prevalence data are collected at the local and state levels, then aggregated and analyzed by the CDC. When it provides its analysis and user-supplied information (from state and local units of

government), the CDC provides a foundation for evidence-based policy. This output happens as a result of a remarkable degree of collaboration between all levels of government. The evidence-based nature of the CDC's work permits and facilitates integrated state and local policy, particularly in important areas such as national preparedness, travelers' health, and diseases and conditions, all representing the public health frontier in federalism. The CDC is leading in the core functions of public health: assessment, policy development, and assurance. Beyond that, the CDC facilitates the continuing improvement in communities' public health capabilities through its education and reporting (Kronstadt et al. 2016).

See appendix 1.3, section B, "Disease Research and Protection Legislation," for summaries of selected legislation related to disease research and protection.

System Infrastructure and Training Health Professionals

As foundational and translational research combined to provide new approaches to diagnoses and treatments, and as medicine became increasingly complex, the federal government intervened to support the advancement of science and to improve educational opportunities to provide further support for scholarships, fellowships, and other financial incentives for Americans to enter into one of the growing—and growing number of—health professions. Communicable disease knows no boundaries; as societal mobility increased, so did the spread of disease. As research revealed more to our society about the complexity of health, our need for more providers, including new kinds of specialist providers, also grew. The policy responses have included a plethora of legislation to address needs both growing in number and in clinical scope.

Beyond addressing the supply of nurses, doctors, and (later) other kinds of providers, the federal government made a major contribution toward the growth in the number of hospitals and (ultimately) other forms of healthcare facilities. Known as *Hill-Burton*, the Hospital Survey and Construction Act provided support to states for building new hospitals and adding beds to address a wartime shortage in the aftermath of World War II. Later amendments expanded the scope of the act to include ambulatory care facilities as well as nursing homes.

In this context, federal engagement has relied heavily on the concept of collaboration with state governments and educational institutions. To be clear, this realm has included the creation of federal agencies such as the HHS, its predecessor agencies, and many subcabinet agencies. However, education in the United States is primarily the province of state and local governments. In order to increase the supply of health professionals and provide new or expanded medical facilities, the federal government's primary option has been to partner with states and local governments.

Digital infrastructure is a relatively new area of governmental engagement. As electronic health records gained market share in the 1990s, policymakers soon began to focus on the interoperability of such records. In 2004, the George W. Bush administration established the Office of National Coordinator (ONC) in the Department of HHS to begin the effort of fashioning the transfer of confidential health information among those providers who had legitimate need for it, while protecting the same from unnecessary disclosure. In 2009, the ONC was given official structure as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act. In the same year, Congress enacted the American Recovery and Reinvestment Act, which allocated $150 billion in incentives to accompany requirements for providers to switch from paper to electronic health records. The effort to achieve a higher degree of interoperability continues, as demonstrated by the 2016 enactment of the 21st Century Cures Act.

See appendix 1.3, section C, "System Infrastructure and Training Health Professionals Legislation," for summaries of legislation related to system infrastructure and training of health professionals.

Developmental and Behavioral Health

Advocates have long complained that developmental and behavioral health have been given limited attention by federal (and state) policymakers. Part of this disinclination on the part of policymakers to advance the causes of developmental and mental health is the absence of a clear political constituency. Mental illness retains a stigma: patients are not inclined (generally) to make public their disease; some stakeholders misunderstand the nature of the illness; others simply prefer not to engage in this issue.

There is, within the penumbra of agencies that comprise the NIH, a National Institute of Mental Health; it and other mental and developmental health–related agencies have become the foundation for programs related to people with mental health disorders. To the extent the policy process gives way to improvements in mental or developmental health services, it is usually done in a way consistent with the concept of interactive federalism. Developmental and behavioral health is an area in which the federal government initiatives nearly all take the form of federal assistance to state and local units of government to provide or improve services for people suffering these afflictions.

See appendix 1.3, section D, "Developmental and Behavioral Health Legislation," for summaries of legislation related to developmental and behavioral health.

Environmental Health and Pollution

Environmental issues have been particularly challenging for the federal government. The science behind the public health concerns is unrefuted—people living in environments of polluted air and water have poorer health status

than those who do not. They are at increased risk for a variety of cancers and respiratory and cardiovascular diseases (Brunekreef and Holgate 2002). Children, especially those from lower-income zip codes, are more vulnerable to asthma-related hospitalizations (Neidell 2004). The crisis of lead in the water supply of Flint, Michigan, spurred additional studies that found water pollution to be associated with Legionnaires' disease in Flint as well (Schwake et al. 2016). Clearly a polluted environment leads to increased risk of adverse health status and outcomes.

Balanced against that, however, are the considerable economic interests of a variety of businesses and the people employed by them. While the Flint episode emanates from a governmental decision to change the source of community water, sources of air and water pollution are manifold: businesses associated with manufacturing and energy production, pesticides used in agribusiness, and the use of aerosol sprays, among other things, all contribute to depleted ozone layers, particulate matter in the air, and toxic substances in water. In addition, the use of internal combustion engines in cars, buses, and other modes of transportation contributes significantly to degrading the quality of air in particular. Millions of people are employed by entities that increase pollution, and millions more use aerosol sprays and automobiles. Thus, the question: Should we raise the cost of goods and services, or even prevent some from existing, in order to mitigate damage to the environment to protect the public at large and our overall health status?

In the late 1960s and early 1970s, there was heightened awareness of the environmental impact on human development and well-being. During this time, there were several notable legislative achievements promoting and ensuring clean water and air.

This conflict between environmentalists and business, most particularly energy and manufacturing interests, has reemerged in recent years in the debate over climate change. While many deny its existence, science points to a connection between a variety of adverse health effects, as well as increased severity in weather events, as a consequence of human impact on the earth's environment (Dessler and Parson 2019). Legislative response to this growing concern about (and evidence of) climate change's impact on our collective health has been mixed. This area also has seen the interpretations controlling administrative implementation change from administration to administration.

The posture of the federal government has changed over time. Early environmental legislation appeared to support state efforts to clean up polluted water. Over time, however, the concept of pollution has become one which transcends state borders, necessitating a more national response, as evidenced by federal legislation. Indeed, currently observers can point to ample evidence that this has become an international issue, which introduces a new dimension of policy.

See appendix 1.3, section E, "Environmental Health and Pollution Legislation," for summaries of legislation related to environmental health and pollution.

Access to Care

The most active area of federal legislation and federal government involvement in healthcare is in access to care. There are several issues associated with access to care by a prospective patient—the "Five As of Access"—access (physical), availability (of provider within a reasonable time), affordability (financial), acceptability (cultural), and accommodation (of patient needs). The federal government has addressed availability through its efforts to expand the number of providers, as we saw in the "System Infrastructure and Training Health Professionals" section earlier in this chapter.

Likewise, a number of those initiatives speak to improving quality of care. It is in the area of affordability that the federal government has acted most frequently. The issue of cost of healthcare services has been at the forefront of federal efforts. Sometimes this has taken the form of buying services for designated populations, such as programs like Medicare. Sometimes this takes the form of supporting states' efforts to prevent the spread of specific diseases, such as the federal initiatives in support of polio vaccination, or supporting states' attempts to limit the spread of sexually transmitted disease. As the legislative history suggests, the federal government has actively engaged the concept of interactive federalism in efforts to improve access to care. At the same time, the federal government has asserted its role singly in other cases. In short, the federal government, in pursuit of improved health for all Americans, has responded demographically on behalf of certain populations, geographically in assisting certain regions in the United States, and etiologically to stop the spread of specific diseases.

The great conundrum of federal intervention in healthcare is how the issue of cost is perspective dependent, resulting in vastly different interpretations. With passage of Medicare and Medicaid in 1965, the federal government was unequivocally saying that it would help defray the cost of healthcare for the nation's elderly and indigent: a recognition that for many people in these groups, the cost of healthcare was prohibitively high. More than 50 years later, that reality remains for many uninsured Americans—but of greater prominence in recent times is the growing belief that the escalating costs borne by the states and federal governments for healthcare simply are not sustainable. Thus, as noted earlier in the chapter, the federal government is now allowing states to modify Medicaid and ACA programs to reduce state (and federal) costs. Will this perspective adversely affect the underlying mission of the programs (to expand healthcare coverage)?

See appendix 1.3, section F, "Access to Care Legislation," for summaries of legislation related to access to care.

Summary

This chapter has focused on the historical underpinnings of *federalism*, with particular emphasis on health policy, and how that concept has evolved into the current relationships between the states and the federal government. The federal government's grant-in-aid legislation, which exists to a greater or lesser extent in all six categories of federal healthcare law, in many cases confers broad authority on the states to adapt national policy objectives to accommodate local needs. Can such accommodation lead to undermining national goals, particularly with regard to Medicaid and the ACA, however? Several states, with the support of CMS, recently adopted administrative policy modifications that may contravene the national purpose underlying the creation of either, or both, of those programs. Does national (or interactive) federalism mean subordinating the national agenda to needs of the states? Or is this an accommodation that strengthens the bond between the states and the federal government in furtherance of the national agenda? The chapter then provides an overview of the most significant federal legislation through the framework of six categories:

1. Food and drug supply
2. Disease research and protection
3. System infrastructure and training health professionals
4. Developmental and behavioral health
5. Environmental health and pollution
6. Access to care

One observation highlighted by the framework was that the "federalist" approach constitutes a more engaged and engaging relationship with the states (e.g., some CDC reporting requirements, some Medicaid programs) in some categories, while other categories reflect a largely "national" approach to their roles (e.g., NIH, FDA). Conflicting policies emanating from the interlinking of state and federal policy through national federalism are potentially sources of profoundly different outcomes among the states, in some ways thwarting the promotion of a universal health policy with regard to populations affected by Medicaid and the ACA. Finally, the growth of the federal role in health policy is undeniable, accelerating from the Great Depression into the beginning of the twenty-first century.

Review Questions

1. Describe what *federalism* means in the United States.
2. Discuss the pros and cons of requiring work or community service to be eligible for Medicaid.

3. Discuss how states and federal government work together to shape health policy. In what ways do they work at odds with one another?
4. Explain the source of differences between state health policy and federal health policy.
5. Describe briefly the six general categories of federal health legislation.

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