Chapter 2
How Does Federal Health Policy Work?

Lyle B. Dennis

Many clinicians and researchers find the basics of federal health policy, much less the subtleties and nuances, to be an enormous mystery. It has its own nomenclature; it operates on schedules that do not seem to follow a normal calendar; there are shorthand abbreviations and processes that represent a universe unto themselves. Yet, just as the practice of medicine appears unfathomable to first-year students, federal health policy is a mystery that can be understood with greater familiarity and a little effort.

It is often said that the United States is a nation of laws. But what is a law? Where does it come from, how is it enacted, how is it implemented? This chapter is designed to give the clinician a basic understanding of the legislative process and how laws are put into effect by the Executive Branch. Just as learning anatomy is needed to become clinically competent, you need to learn these basics to be an effective advocate.

But before addressing the “how,” it is worth considering the “why.” Many clinicians, whether providing patient care and treatment or immersed in the laboratory, think (to the extent they think about it at all) that the government is a distant and irrelevant foreign body, of the same consequence to them as the proverbial “bicycle to a fish.”

However, “it is the duty of every citizen according to his best capacities to give validity to his convictions in political affairs” [1]. Politics determines research funding levels, coverage and reimbursement policy, scope of practice, and more. One needs a firm understanding of how health policy works. That understanding will help provide the foundation for you to also understand why it sometimes does not work and what your role may be in the process of making it work better for your practice, your patients, your research, and for American society.

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How Does a Bill Get Introduced?

Most people believe that they have a pretty good understanding of what a “bill” is, in political parlance. A bill is a legislative proposal that creates a new program, modifies an existing program, or funds part of the government (more on the differences among bills later). What most have not thought about is where do bills come from? How are they “introduced?” What does “introduced” actually mean? Is it the same as saying a bill was “dropped?”

Bills, which are also referred to as “legislation,” are introduced in the House of Representatives (or the “House”) by elected Representatives and in the Senate by Senators. No one else can introduce a bill. You often hear people refer to “the President’s bill on health care reform” or “the administration’s Medicare legislation.” When the President has a legislative proposal, however, it can only be introduced by a Member of Congress (the collective terms for Representatives and Senators). House members cannot introduce Senate bills, nor can Senators introduce bills in the House of Representatives.

A Member of Congress may have an idea for a bill or it may be brought to him by his staff, his constituents, or national advocates interested in advancing a program or policy. He often works with his staff to develop the concept, research it, consider the implications, and draft it into a bill. The draft of the bill is sent to a congressional office known as Legislative Counsel (or “Leg Counsel” in the vernacular). There the bill is put into appropriate legislative form and is ready for introduction.

To introduce the bill, the Member of Congress must personally bring it to the floor of the House or Senate, as appropriate, and hand a signed original to the designated staff person from the Office of the Clerk of the House or the Secretary of the Senate.

At that point, the bill is “introduced” or “dropped” and it is assigned a number, sequential to all other legislation that has been introduced in the 2-year term of Congress – S. 1422 or H.R. 2987, for example. (Note that “H.R.” is an abbreviation for “House of Representatives” not for “House Resolution” as many people think.)

Members of Congress can introduce a bill alone or they can opt to ask other members to join them in dropping a bill. The Member who initiates the bill is

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referred to as the “prime sponsor;” the others who sign on are referred to as “original cosponsors.” Additional members can become cosponsors after a bill is introduced by simply signing their names to a form that is filed with the Clerk or Secretary.

### How Does a Bill Become a Law?

Once a bill has been assigned a number, it is ready to begin its journey – whether to oblivion or into the statute books remains to be seen and is influenced by many factors. We will only scratch the surface of some of them here, but the reader can extrapolate from these pages to what you see happening in the “real world” of federal health policy on a daily basis.

The first step for newly introduced legislation is to be referred to a legislative committee. Each committee of the Congress (there are 16 standing committees in the Senate and 20 in the House) has a specific area of jurisdiction, defined when the rules of each house are adopted shortly after Members of Congress are sworn in. This occurs in early January of the odd-numbered year following the November election. Legislation can be written to influence what committee has jurisdiction, which is done to enhance its chances for adoption.

For most issues that are relevant to clinicians, there are three pairs of committees that can be assigned jurisdiction:

1. The House Energy and Commerce Committee and the Senate Health, Education, Labor and Pensions Committee have jurisdiction over the Public Health Service and the programs that are implemented by them, such as the National Institutes of Health, the Ryan White Care Act, health professional education and training, organ transplantation, vaccination policy, health services research, and more.
2. The House Ways and Means Committee and the Senate Finance Committee have the major role in Medicare and Medicaid policy which has significant influence throughout the entire system of public and private health care payers.
3. The House Appropriations Committee and the Senate Appropriations Committee are responsible for legislation that funds the domestic discretionary programs in health, such as those described in number 1, above.

Committees, and particularly their Chairs, enjoy a high degree of autonomy in the legislative process. The discretion to address – or not address – a bill rests with the Chair, who is always a member of the party that holds the majority in that body. While they can be subjected to pressure or persuasion from the Leadership of their party in their respective chamber, under the rules of the House of Representatives, the only way to get a bill out of committee that the Chair does not want to address is a Discharge Petition, which requires the signature of 218 Members, a majority of the House membership. As you can imagine, Members are loathe to sign a Discharge Petition and risk incurring the wrath of a Chair who has control over other legislation that they might like to see considered.
In most committees, including five of the six described above, legislation is referred to subcommittees for initial consideration. (The Senate HELP Committee considers health-related legislation directly.) Subcommittees often hold hearings at which invited witnesses can testify for or against a bill under questioning by the subcommittee members. The subcommittee will then hold a meeting, known as a “markup” – at which members of the subcommittee can offer amendments that are voted on by the members. After the markup, the subcommittee can choose whether or not to send the bill to the full Committee. At the discretion of the Committee Chair, a similar process can be followed at the full Committee (although often without the hearing).

Bills that are approved, or “reported” by a committee are often accompanied by a Committee Report. These Reports, while they do not have the effect of law, can be very important in advising the Executive Branch about the Committee’s intent in the legislation they have created. While the bill itself can be difficult to read, as it changes sections of existing law without making it clear what the context of the change is, the Committee Report is a plain English statement of intent. Such reports, for example, often become part of the debate about “congressional intent” when a law, or its implementation, is challenged in court.

Once a bill is reported by a committee, the Leadership of the chamber determines if or when to schedule the bill for a vote. In both houses, the Majority Leader’s principal responsibility is to manage the scheduling of bills. The Speaker of the House plays an advisory role, but the actual responsibility rests with the Majority Leader.

All bills that are scheduled for consideration in the House are referred to the House Rules Committee which produces a rule to govern floor debate. The rule determines the length of the debate, what amendments (if any) will be in order, and when the vote should occur. The rules themselves can be controversial as the minority party, in particular, often objects to provisions that its members perceive are stifling debate or limiting their opportunity to advance their positions.

The Senate, on the other hand, operates under traditional procedures that in today’s hyper-partisan environment have created great difficulties with even beginning debate on a bill, let alone passing it. Consistent with its description as “the world’s greatest deliberative body,” Senate debates continue until ended by unanimous consent or a vote of 60 or more Senators.

Action on legislation in the House and Senate can occur once these procedural hurdles have been met. While bills can move consecutively or concurrently, ultimately legislation must pass both houses, although the content almost always differs. At that point, one house can cede to the other and simply accept what the other house has passed, but that is rare. More commonly, a Conference Committee comprised of the subcommittees that had original jurisdiction over the bills is created to find a compromise satisfactory to both bodies.

When that is done, the conference committee files a Conference Report that includes the final legislative language that must be passed in identical form in both houses. At that point, the legislation is sent to President of the United States to sign or veto.
How a Bill Becomes a Law

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**Conference Committee Action**

After the House and the Senate have passed their respective versions of a piece of legislation, a conference committee composed of members of both Houses is appointed to work out the differences between the two pieces of legislation. A compromise version of the legislation is sent back to both chambers for final approval.

**President**

If the compromise version is approved by the House and the Senate, the bill is sent to the President who can sign it, veto it, or let it become law without his signature. If the bill is vetoed, Congress can override the veto by a two-thirds majority vote in both chambers and the bill becomes law without the President’s signature.

**Authorization vs. Appropriation: What Is the Difference?**

One of the great mysteries of the legislative process is the difference between “authorized” and “appropriated.” And, why are certain programs able to draw down funding without an annual appropriation and referred to as an “entitlement?” Let us see if we can provide some clarity.

A bill that is referred to as “authorizing legislation” usually either creates a new federal program or extends the life of an existing program. Occasionally, it even repeals an existing program! Programs are generally authorized for 3, 4, or even 5 years. Authorizing legislation specifies how long a law will last; the provisions governing the program; and the maximum level of funding – and that is where the confusion arises.

For example, a specific government program may be authorized to receive $50 million per year. However, that language actually gives the program zero – unless a
subsequent appropriations bill that includes that program contains funding for it. And if Congress chooses to appropriate $25 million to the program, that is all that is available.

Appropriations bills make money available to fund an authorized program. They are annual bills that must be passed in some form for the government to continue to operate. Ideally, Congress should pass 12 separate bills although often they are combined into a lesser number. At the very least, Congress must pass a “Continuing Resolution” or “CR” to fund the government at the previous year’s level. Article I, Section 9 of the US Constitution says, in part, “No money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law….” Absent that, the agencies of government covered by a specific appropriation bill would be forced to close down until money is appropriated to support their functioning.

So, what is an “entitlement” and why does it not need annual appropriations? An entitlement is a special kind of authorization bill in which Congress grants what amounts to a permanent appropriation. Perhaps the example best known to clinicians is Medicare. If a patient meets all of the eligibility requirements of Medicare (age, sufficient time in the Social Security program, etc.) and receives covered medical services, the government is legally obligated to pay for those services without any Appropriations Committee action. (The chronic battles over the adequacy of those payments and which clinicians should be eligible are among the most contentious areas of federal health policy.) The money comes from the Medicare Trust Fund but, if that Fund were empty, the federal treasury would be legally obligated to pay.

Entitlements lead to interesting situations in federal health policy. The budget of the Department of Health and Human Services is approximately $950 billion per year, but only about $170 billion of that is appropriated by the Congress. The balance is for entitlement programs including Medicare, Medicaid, the State Children’s Health Insurance Program (SCHIP), the Medicare prescription drug benefit, and the Social Security program.

The intersection of entitlements and appropriated spending is another interesting facet of health policy. As we saw above, Medicare is an entitlement program. However, the personnel in the Centers for Medicare and Medicaid Services who administer Medicare are paid with appropriated funds. When funds to administer an entitlement program are inadequate, it can impact public perception of the efficiency of the program and its ability to monitor fraud and abuse.

When Congress Did Not Fund the Government

In 1995, Congress failed to enact appropriations bills that led to a widespread closure of federal government offices and a major political crisis, initially for President Bill Clinton, but ultimately for then-Speaker of the House Newt Gingrich. Essentially, what happened was that the new Republican Majority in Congress demanded budget cuts that President Clinton refused to agree to. With a Continuing Resolution (CR) expiring on November 13, nonessential services of the federal government were closed from November 14 through November 19. At that time, Congress passed another CR, running through December 15.
When Congress Did Not Fund the Government (continued)

When agreement was not reached by that date, the government closed again from December 16, 1995 to January 16, 1996. TV news reports about tourists being turned away from the Smithsonian museums and national parks began to turn public opinion against Congress and in favor of the President. Then Speaker Gingrich told reporters that he forced the shutdown because President Clinton made him sit in the back of Air Force One. The public perception that they were inconvenienced and their country humiliated “began to look like the tirade of a spoiled child [2].”

In January, Congress returned to session and quickly reached an accommodation with White House, bringing to an end the 2-month long budget melodrama.

Budget and Appropriations: What Is the Annual Cycle?

There are several categories of federal funding that are of considerable interest to clinician-advocates. Included among them are biomedical and health services research, service programs for patients such as the Ryan White AIDS Care Act, and public health funding related to specific diseases and specific constituencies.

In early February each year, the President sends to the Congress his proposed budget for the federal fiscal year that begins on October 1 of that year. The proposed budget contains significant detail about funding levels, federal employment levels, and program accomplishments. Its submission begins a process that in theory ends in Congress’ enactment of appropriations bills to fund the entire federal government.

As required by the Budget Impoundment and Control Act of 1974, the first step for Congress is to enact a Budget Resolution. This is a concurrent resolution that is not signed into law by the president but binds Congress by placing limits on federal spending in broad functional categories (i.e., health, transportation, agriculture, or defense). It also proposes changes in tax and other policies to modify total federal spending and revenue to hit deficit or surplus targets.

Other committees of the Congress determine the specifics of how these targets are to be met. For example, the House Ways and Means and Senate Finance Committees are responsible for recommending the detailed changes in tax policy so that revenue reaches the amount anticipated in the budget resolution. Likewise, the House Energy and Commerce Committee and the Senate HELP Committee would have to develop changes to the law governing healthcare programs to meet target spending figures. These changes are essentially “stapled together” into a bill called a Reconciliation Bill.

The Budget Resolution also establishes the total amount that can be appropriated in the fiscal year for discretionary (i.e., non-entitlement) programs. That amount is
allocated to the House and Senate Appropriations Committees and then to the 12 subcommittees in each of House and Senate. This is a complex budgetary and political process. The budget complexity results from the functional categories not lining up with the jurisdiction of the Appropriations’ subcommittees. Thus, for example, the Agriculture Subcommittee is allocated funding from the Agriculture function, but it also receives funding from the Health function, because that subcommittee funds the Food and Drug Administration. The political complexity stems from the fact that budget documents are political documents [3]. They necessarily reflect the political priorities of the majority party that produces them.

Once the budget allocations are made to the Appropriations Committees and then to the subcommittees (most health-related funding is handled by the Labor-HHS-Education Subcommittee in both houses), a series of hearings with federal agency officials and sometimes the general public begin. This input is used in the production of a draft appropriations bill in each subcommittee known as the “chairman’s mark.” From this point, the legislative process resembles that described in the section headed “How does a bill become a law?” The fundamental difference is that the October 1 start of the federal fiscal year looms over appropriations bills. What happens if it is not met?

In recent years, the reality is that Congress has rarely gotten any, and certainly not all, of its appropriations bills done on time. To keep the government operating, Congress must pass a Continuing Resolution – a stop-gap funding measure that most often funds existing programs at their previous year’s level.

The processes of Congress, even when explained simply, are clearly complicated and inefficient. As you will see in the next section, the processes of the Executive Branch are no less so. But, it is important to remember that “whenever you have an efficient government you have a dictatorship” [4]. There was a reason why Mussolini could promise to make the trains run on time!

How Does the Executive Branch Bring It All Together?

After the many moving parts of the congressional apparatus pass legislation that establishes federal health policies, the responsibility for implementation falls to the Executive Branch. For the programs that most clinicians care about, that implementation rests primarily with the Department of Health and Human Services (HHS).

HHS has many parts. Among the best known are:

- National Institutes of Health (NIH)
- Centers for Medicare and Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Agency for Healthcare Research and Quality (AHRQ)
- Health Resources and Services Administration (HRSA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
For some of these agencies, implementation of health policy is relatively straightforward. NIH, for example, has an authorizing statute that governs its operations. Funds are appropriated each year, and it is the function of NIH to fund high-quality biomedical research both by NIH researchers and at laboratories across the country. If they do that without overspending their budget, life proceeds rather uneventfully. Occasionally controversial issues such as funding for stem cell research arise, but in general, health policy at NIH is implemented without controversy.

However, for other government agencies, such as CMS, controversy is more the rule than the exception. Because CMS operates the largest government-run health insurance program (Medicare) and because CMS’s policy positions have a substantial impact on the coverage and payment decisions made by private insurers, their actions are often steeped in controversy. For example, if CMS decides not to cover a specific medical procedure or product deeming it ineffective or experimental, private insurers generally follow suit. That could represent a substantial reduction in the profitability of the device or pharmaceutical company involved. They in turn could enlist the patient advocacy groups in the field to protest the lack of access to the product or service. All of this can lead to congressional involvement and possibly to further legislation to clarify Congress’s position.

Other agencies are less subject to these kinds of outside pressures, but no less subject to controversy. The FDA, as an example, is a regulatory agency that is quasi-judicial and not subject to the normal pressures of a governmental agency. However, because its decisions on the approval of pharmaceutical and biological products, and medical devices, often involve life and death for the American public and millions in profits to industry, it is subjected to a remarkable level of scrutiny and second-guessing, particularly from the media.

When federal agencies like those in HHS are implementing federal policy, they often do so through the promulgation of regulations. The process often begins with the publication of a Notice of Proposed Rule Making (NPRM) in the Federal Register, a daily publication of the federal government available both in hard copy and online. The NPRM will describe what the agency is proposing, how to get more information, and provide a time frame (usually 30 days) for submitting written comments. By law, the agency proposing the regulation must consider all comments before promulgating its final regulation, which is also published in the Federal Register and then compiled annually in the Code of Federal Regulations.

Because legislation is often written in broad terms, regulations can be critical in implementing a program. But, they can also delay the implementation of legislation enacted by Congress. For example, when Congress enacted the Health Insurance Portability and Accountability Act (HIPAA) in 1996, the draft regulations promulgated by the Department of Health and Human Services were thousands of pages long and resulted in tens of thousands of comments. It was more than 5 years later before the privacy regulations were implemented and another 4 years after that for the security regulations to take effect. Even then, several sections of the regulations were challenged in lawsuits claiming that HHS had misinterpreted Congress’s intent, causing further delays.
Conclusion

Now you are grounded in the history of health policy and have a broad overview of how federal health policy is made. The subsequent chapters of this book will bring you more detail about influencing the legislative process in Congress, the “whys and wherefores” of the Executive Branch, and take you into some of the techniques of advocacy from the role of individuals to associations to coalitions. But through it all, there is an underlying truth that explains why your role as an advocate is critical. It has become a cliché to say that “all politics is local [5].” But, quotations become clichés for a reason. And you cannot get any more local than the individual. Let us keep reading and see what you can do.

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