



AMERICAN
COLLEGE *of*
CARDIOLOGY

FEDERAL AND STATE ADVOCACY OVERVIEW

Federal Legislative Process

How a Bill Becomes Law: Using Introduction of a Bill in the House as Illustration

1. When a Representative has an idea for a new law, s/he becomes the sponsor of that bill and introduces it by giving it to the clerk of the House or by placing it in a box, called the hopper. The clerk assigns a legislative number to the bill, with H.R. for bills introduced in the House and S. for bills introduced in the Senate.
2. Next, the bill is assigned to a committee (the House has 22 standing committees, each with jurisdiction over bills in certain areas) by the speaker of the House so that it can be studied. The standing committee (or often a subcommittee) studies the bill and hears testimony from experts and people interested in the bill. The committee then may release the bill with a recommendation to pass it, or revise the bill and release it, or lay it aside so that the House cannot vote on it. Releasing the bill is called reporting it out, while laying it aside is called tabling.
3. If the bill is released, it then goes on a calendar (a list of bills awaiting action). Here the House Rules Committee may call for the bill to be voted on quickly, limit the debate, or limit or prohibit amendments. Undisputed bills may be passed by unanimous consent, or by a two-thirds vote if members agree to suspend the rules.
4. The bill now goes to the floor of the House for consideration and begins with a complete reading of the bill (sometimes this is the only complete reading). A third reading (title only) occurs after any amendments have been added. If the bill passes by simple majority (218 of 435), the bill moves to the Senate.
5. In order to be introduced in the Senate, a senator must be recognized as the presiding officer and announce the introduction of the bill. Sometimes, when a bill has passed in one house, it becomes known as an act; however, this term usually means a bill that has been passed by both houses and becomes law.
6. Just as in the House, the bill then is assigned to a committee. It is assigned to one of the Senate's 16 standing committees by the presiding officer. The Senate committee studies and either releases or tables the bill just like the House standing committee.

7. Once released, the bill goes to the Senate floor for consideration. Bills are voted on in the Senate based on the order they come from the committee; however, an urgent bill may be pushed ahead by leaders of the majority party. When the Senate considers the bill, they can vote on it indefinitely. When there is no more debate, the bill is voted on. A simple majority (51 of 100) passes the bill.
8. The bill now moves onto a conference committee, which is made up of members from each House. The committee works out any differences between the House and Senate versions of the bill. The revised bill is sent back to both houses for their final approval. Once approved, the bill is printed by the Government Printing Office (GPO) in a process called enrolling. The clerk from the introducing house certifies the final version.
9. The enrolled bill is now signed by the speaker of the House and then the vice president. Finally, it is sent for presidential consideration. The president has 10 days to sign or veto the enrolled bill. If the president vetoes the bill, it can still become a law if two-thirds of the Senate and two-thirds of the House then vote in favor of the bill.

Additional Background

Under the Constitution's "Origination Clause," bills to raise revenue (taxation) must originate in the House. Bills not pertaining to revenue may also originate in the Senate and then follow the same legislative process. Committees with jurisdiction over Medicare and Medicaid include the Senate Finance, House Ways and Means and House Energy and Commerce. The Senate Committee on Health, Education, Labor and Pensions (HELP) has jurisdiction over the Food and Drug Administration, Centers for Disease Control and Prevention, and National Institutes of Health. The Energy and Commerce Committee has jurisdiction over those agencies in the House.

Federal Regulatory Process

While Congress makes the laws, the federal agencies, under the direction of the president, are the entities that implement them. The laws that Congress passes are generally broad and leave much of the details to be defined by the agencies. Like Congress, the agencies have formal and informal processes that are used to develop, implement and revise policies and programs. The federal agencies can also hold hearings and conduct investigations. These may be part of a longer policy development process that will end in rulemaking or sub-regulatory guidance, or they may be a way for the agencies to learn more about particular subjects. Additionally, federal agency officials regularly meet with experts outside of the government to gather information and to learn about the effects of the government's activities on stakeholders.

Rulemaking

One of the primary methods that the federal agencies implement federal laws is through regulation. The process used for issuing regulations is referred to as rulemaking. Regulations may also be referred to as rules. The rulemaking process is governed by the Administrative Procedures Act (APA), which outlines particular procedures that must be used for the issuance of federal regulations, including when regulations must be issued, the amount of time for which they must be available to the public before implementation and more.

All federal notices, including regulations, announcements of hearings and more, are published as part of

the *Federal Register*, a publication issued daily by the GPO.

Proposed rulemaking

Before a regulation is issued, the APA requires that federal agencies release a proposed rule, also referred to as a Notice of Proposed Rulemaking. The public must be provided with an opportunity to provide written comments. This opportunity is known as the notice and comment period and must be available for at least 30 days. The major regulations issued by the Centers for Medicare and Medicaid Services (CMS) generally have at least a 60 day comment period. The FDA's major regulations will typically have a period of either 60 or 90 days for comment.

Final rulemaking

After the public notice and comment period ends, the agencies are required to review all of the submitted comments. Those comments, along with additional input from agency staff, form the basis for the final rule or regulation. As part of the final regulation, the agencies are required to respond to all of the comments submitted during the notice and comment period. They are not required to do this individually; rather, this is done as part of the commentary that precedes the federal regulatory language. Generally, the agencies group similar questions together, summarize them and respond. Once finalized, regulations are codified in the *Code of Federal Regulations*.

Sub-regulatory guidance

The federal agencies also issue a variety of other documents referred to as sub-regulatory guidance. These documents do not have quite the same force of law as regulations, but they generally contain additional explanation of the agencies' thinking with respect to specific regulations or program implementation. For example, the FDA issues formal documents referred to as "Guidance for FDA staff, industry and public" on various topics, including clinical trial design, approval processes and more. CMS has a series of manuals referred to as the Internet-Only Manuals that contain the instructions provided to the Medicare contractors on carry out their functions, such as claims processing and provider enrollment. There are also less formal writings issued by the agencies that are considered sub-regulatory guidance, such as Frequently Asked Questions. The Office of the Inspector General for Health and Human Services issues Advisory Opinions that pertain to the implementation of the anti-kickback statute in specific scenarios.

State Legislation and Regulation: Fiscal Politics

The National Conference of State Legislatures has traditionally reported that 49 states must balance their budgets, with Vermont the exception. Other experts assert that Wyoming and North Dakota are also exceptions, citing their weak enforcement policies. Still others include Alaska in the exceptions, claiming the constitutional language is far from explicit.

Despite ambiguous constitutional and statutory language and degrees of oversight in these and a handful of other states, the overwhelming majority of states have clear balanced budget requirements that possess one or all of the following components:

- The governor's proposed budget must be balanced
- The enacted budget must be balanced
- No deficit can be carried forward from one fiscal period into the next

While ACC chapters may not have a great deal at stake in terms of appropriations or other funding sources, for better or worse, state fiscal politics often play an important role in policy formulation.

For example, appropriating money to ensure a state agency has authority to regulate health care services is tantamount to passing legislation that restricts the delivery of services.

Appropriations are often used to give regulatory agencies resources to allow them to exercise their constitutionally awarded discretion. This tactic is often used to rush a policy through when time is of the essence or if legislators believe that the usual legislative path, which involves committee hearings would only focus on the negative implications of a policy.

Finally, in many states, legislation that does not involve fiscal issues does not receive any attention during budget deliberations. This allows lawmakers to run out the clock for addressing bills lawmakers but do not want to say so publicly through a vote.

