The Federal Legislative and Regulatory Process

ASTRO Government Relations
• Three branches of government:
  – Executive (President and federal agencies)
  – Legislative (House and Senate)
  – Judiciary (Supreme Court and lower courts)

• Each branch can limit the others – a system of checks and balances
### Legislative Branch

**Two Chambers**

<table>
<thead>
<tr>
<th>U.S House of Representatives</th>
<th>U. S. Senate</th>
</tr>
</thead>
<tbody>
<tr>
<td>435 members serving two-year terms</td>
<td>100 members serving rotating six-year terms</td>
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<tr>
<td>Must be 25 years old and a citizen for at least seven years</td>
<td>Must be 30 years old and a citizen for at least nine years</td>
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<td>Committees almost always consider legislation first</td>
<td>Committee consideration easily bypassed</td>
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<tr>
<td>Rules Committee powerful; controls time of debate, admissibility of amendments</td>
<td>Rules Committee weak; few limits on debate or amendments</td>
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<tr>
<td>Debate usually limited</td>
<td>Unlimited debate unless shortened by unanimous consent or by invoking cloture</td>
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<tr>
<td>Non-germane amendments may not be introduced on the floor</td>
<td>Non-germane amendments may be introduced (aka, “riders”)</td>
</tr>
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</table>
Legislative Process

How a bill becomes a law
Legislative Process

• Conceptually, the process of making a law is simple:
  – Pass the exact same bill in both the House and Senate, then the president signs it into law.

• In reality, the process is complex, varied and time-consuming.

• “Laws are like sausages. You should never watch them being made.”
• The entire process starts with an idea and ends with regulation.
Part 1: Legislative Process

• Step 1: Bill introduction
• Step 2: Committee hearings and amendments
• Step 3: Floor debate
• Step 4: Final vote
• Step 5: Second chamber consideration
• Step 6: The president signs/vetos
Step 1: Introduction

• Every member in Congress has the power to introduce a bill.

• After an idea is drafted into a bill by legislative or legal counsel, it is introduced and assigned a number. This step is known as the bill’s “First Reading.”

• The bill is then referred to one or more of the standing committees and/or subcommittees for in-depth consideration.

  – For example: The Patient Protection and Affordable Care Act of 2010 (aka, “Health Reform”) was introduced in the House and referred to the Ways and Means Committee for consideration
Step 2: Committees

- Major pieces of legislation usually will have a hearing during which testimony is heard.
- Whether the committee holds a hearing or not, it has a number of options available with respect to the bill’s fate:
  - Sit on a bill and do nothing, thus eliminating it from further consideration.
  - Report the bill out of committee with either a favorable or negative recommendation.
  - Amend the bill during the committee proceedings and then report the bill out.
Step 3: Floor Debate

• After the bill has been considered by the committees, it is then scheduled for consideration and placed on the calendar to be debated by the full chamber—which is known as “Second Reading.”

• Depending on the chamber, the bill may be amended at this stage.
  – The House rules allow for limited debate and amendments.
  – The Senate has no limitations on debate or amendments.
Step 4: Final Vote

- Following floor debate, a bill is put to a final vote, sometimes referred to as “Third Reading.”
- In the Senate, which does not have strict rules like the House, Senators can filibuster a bill if they wish to delay or force compromise on the bill.
- There are two ways to end a filibuster:
  - The filibustering Senator yields his time to another Senator (assuming that next Senator is not going to filibuster also).
  - Two-thirds of the Senate vote to overturn the filibuster.
Step 5: Second Chamber

- If a bill passes the first chamber it goes to the second chamber where it must go through the same process again.
- If the bill passes the second chamber without amendments being added it goes to the president.
- If the second chamber amends the bill in any way it must be sent back to the first chamber for approval.
- If the two chambers disagree on the amendments added by the second chamber, a conference committee is formed to resolve the differences.
Conference Committee (if needed)

• The conference committee consists of members of both chambers and both parties.

• The conference committee is not allowed to substantially change the bill.
  – They may add or remove amendments that appear in one bill but not the other, but cannot add new amendments to both versions of the bill.
  – Compromise language may be proposed where there is disagreement.
  – Changes must be consistent with the bill itself.

• Once agreement is reached, both chambers vote on the compromise bill.
Step 6: The President

- The president has several options when considering the fate of a bill:
  - The president may sign the bill, in which case it becomes law.
  - The president may veto the bill, in which case it is sent back to Congress.
  - If the president lets the bill sit for more than 10 days, the bill automatically becomes law without needing his signature.
  - The president can kill a bill if it goes unsigned and Congress adjourns prior to the 10-day time limit.
    - This is known as a “pocket veto.”
ASTRO’s Role in the Legislative Process

• ASTRO advocates before Congress, the White House and other federal agencies to protect and promote radiation oncology and the interests of cancer patients.

• ASTRO is currently working to:
  ─ Protect patients and Medicare from self-referral abuse.
  ─ Stabilize Medicare physician payments and protect access to radiation oncology services.
  ─ Maintain current investments in cancer research by supporting sustainable and predictable funding.
  ─ Ensure patients receive the safest, most effective radiation treatments.
• If the president vetoes the bill, the House and Senate must either start over or override the presidential veto with a two-thirds vote.
• If the bill has been approved by the president, the legislative process is now complete.
  – However, there is still more work to be done...
Part 2: Regulatory Process

How a law is implemented
Regulatory Process

• Enacting a law is only part of the process.
• After the president signs legislation into law, the Executive Branch departments and agencies must implement it.
  – Where the law was very vague, regulations must be very specific.
What is a Regulation?

- A regulation is a general statement issued by an agency, board or commission that has the force and effect of law.
- Federal regulations specify the details and requirements necessary to implement and enforce legislation.
- Regulations can include operating procedures, how funds may or may not be spent, qualifications for participation, effective dates, etc.
The Rulemaking Process

• Step 1: Initiating events
• Step 2: Publication of proposed rule
• Step 3: Public comments
• Step 4: Publication of final rule
Step 1: Initiating Events

• Agency initiatives – regulations launched under the statutory authority of the agency.
  – Example: FDA/CMS Parallel Review Process. A pilot program that would overlap evaluations of premarket, FDA-regulated medical products when the product sponsor and both agencies agree to such a review.

• Statutory mandates – regulations stemming from the passage of a law.
  – Example: Patient Protection and Affordable Care Act, signed into law March 23, 2010. Reforms certain aspects of private and public health insurance systems, expands access to insurance and increases projected national medical spending while lowering projected Medicare spending.
Step 2: Publication of Proposed Rule

• Proposed rules must be published in the *Federal Register.*
  
  – Example: FDA/CMS Parallel Review proposed rule was published September 17, 2010, with a 60-day comment period.
  
  – Example: CMS “Medicare Shared Savings Program: Accountable Care Organizations” proposed rule was published April 7, 2011, with a 60-day comment period.
Step 3: Public Comments

- The public is provided the opportunity to submit comments on the proposed rule.
- Agencies must post the comments and other materials included in the docket online.
- The standard for the comment period is 60 days, though it can be shortened or lengthened depending on the complexity of the regulations.
  - Organizations like ASTRO submit comments so regulators understand the possible affects of a proposed rule.
Step 4: Publication of Final Rule

• The final rule is published in the *Federal Register* with an implementation date.

• Agencies are not required to make any changes suggested during the public comment period, however, they must address the comments in the Final Rule.
  
  – The Final Parallel Review Process Rule was published on October 11, 2011, with an effective date of November 10, 2011.
  
  – The Final Accountable Care Organization Rule was published on November 2, 2011, with an effective date of January 3, 2012.
ASTRO’s Role in the Regulatory Process

• ASTRO monitors activities at FDA, CMS and other regulatory agencies and submits comments when appropriate.
  – Submitted comments on FDA/CMS Parallel Review proposed rule (December 16, 2010).
  – Submitted comments on CMS ACO proposed rule (June 6, 2011).

• ASTRO annually submits comments on payment rules and quality measures contained in the Medicare Physician Fee Schedule and the Hospital Outpatient Prospective Payment System issued by CMS.
And that’s how the sausage is made
Resources

- U.S. Senate: [www.senate.gov](http://www.senate.gov)
- Federal Register: [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys)
- Regulations.gov: [www.regulations.gov](http://www.regulations.gov)
- Health and Human Services: [www.hhs.gov](http://www.hhs.gov)
- Food and Drug Administration: [www.fda.gov](http://www.fda.gov)
- Nuclear Regulatory Commission: [www.nrc.gov](http://www.nrc.gov)
- Centers for Medicare and Medicaid Services: [www.cms.gov](http://www.cms.gov)
- ASTRO Advocacy: [www.astro.org/Advocacy/Index.aspx](http://www.astro.org/Advocacy/Index.aspx)
• **Amendment**: A change made to a pending motion or bill or a previously adopted law or motion.

• **Cloture**: A vote taken to end debate in the Senate (60 votes are needed for approval). Cloture is the only procedure by which the Senate can vote to place a time limit on debate to overcome a filibuster. *See filibuster.*

• **CMS**: The Centers for Medicare and Medicaid Services (CMS) is a federal agency within the HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program and health insurance portability standards.

• **FDA**: The Food and Drug Administration (FDA) is a federal agency within HHS that is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, prescription and over-the-counter pharmaceutical drugs, vaccines, biopharmaceuticals, and medical devices.

• **Federal Register**: The official journal of the federal government that contains most routine publications and public notices of government agencies. The daily publication also includes proposed and revised rules and regulations. *See proposed rule; final rule.*
• **Filibuster:** A senate rule that permits a senator, or a series of senators, to speak for as long as they wish on any topic they choose. Invoking cloture is the only way to end a filibuster. House rules do not permit filibusters. *See cloture.*

• **Final Rule:** A regulation that has gone through the review and public comment process. Final rules are published with an effective date of when they become law.

• **HHS:** The U.S. Department of Health and Human Services (HHS) is tasked with protecting the health of all Americans and providing essential human services. Its agencies include CMS, FDA and NIH among others.

• **NRC:** The Nuclear Regulatory Commission (NRC) is federal agency that regulates the nation's civilian use of byproduct, source and special nuclear materials.

• **PPACA:** The Patient Protection and Affordable Care Act (PPACA) is the formal name of the 2010 health reform legislation. It is also commonly referred to as the Affordable Care Act (ACA).

• **Proposed Rule:** A regulation published by an Executive Branch department or administrative agency in the Federal Register for review and public comment prior to its adoption. Proposed rules do not have the force of law. *See Federal Register.*
Questions?

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