



# Demystifying the HHS/CMS Regulatory Process



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- Two different types of regulations
- Initial steps within CMS
- Role of other HHS staff and operating divisions
- Role of other Executive Branch agencies (OMB and White House)

## Two Types of Regulations

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- Annual fee schedule rules
  - IPPS
  - Physician fee schedule
  - OPPS
- Rules that implement Congressional or Administration policy
  - Initial part D and Medicare Advantage rules
  - EMTALA reform
  - CHIPRA Implementation

- For annual fee schedule rules, process starts with career staff policy experts:
  - Beginning ministerial, administrative calculations
    - E.g., what will be the standardized amount? What are the wage indices? What is the conversion factor?
  - Developing policy options to recommend to political leadership within the agency
    - E.g., Identifying potentially abusive situations that are not technical Stark violations; change in agency interpretation of elements of DSH fraction
      - Change in “longstanding agency interpretation” requires notice and comment rulemaking; *Alaska Hunters* doctrine

- For a rule that implements Congressional or administration policy, the process is usually reversed:
  - Political leadership in CMS will signal policy direction.
    - Part D: process was broader still and included a Departmental policy committee
    - EMTALA: response by CMS leadership to complaints by hospitals and physicians to existing agency interpretations of EMTALA
    - CHIPRA: Implementation of a major Administration priority

- Implementing new policy direction (cont'd.)
  - Once political leadership has signaled policy direction, career staff begins to prepare options paper, regulatory language, and preamble text.

- CMS Clearance Process
  - At Center Director Level
    - Three Centers in CMS
      - Center for Medicare Management
        - Annual FFS rules
        - EMTALA
      - Center for Medicaid and State Operations
        - DRA Implementation
        - CHIPRA Implementation
      - Center for Health Plan Choices
        - Medicare Advantage Rule
        - Part D Rule
  - Deputy Administrator
  - Administrator

- Regulation sent into Departmental clearance.
  - At some point, someone will make a decision whether the regulation requires a face-to-face briefing
    - Decision-maker:
      - Deputy Secretary
      - Executive Secretary
      - Counselor to the Secretary



- Departmental clearance (cont'd.)
  - Face-to-face briefing? (cont'd.)
    - Factors in decision:
      - Controversial
      - Press interest
      - Hill interest
      - Major Administration priority
      - Large shifts of money where government seems to be picking “winners and losers”
    - If there is a face-to-face briefing, it is chaired by the Deputy Secretary or his designee (usually, Counselor to the Secretary).

- Attendees at the Deputy Secretary's briefing:
  - Deputy Secretary/Counselor to the Secretary
    - Chair
  - CMS Administrator
    - Presents overview and policy items for decision-making
  - General Counsel or Deputy General Counsel
    - Career OGC involved with CMS throughout entire regulatory development process
    - Major issues will have been briefed to GC or deputy in advance of briefing

- HHS Office of the General Counsel
  - Provides legal advice to the office of the Secretary
  - Individual Operating Divisions and Staff Divisions within HHS do not have their own legal staff
  - Seven divisions within OGC
    - CMS Division
    - Food and Drug Division
    - Ethics Division
    - Public Health Division
    - General Law Division
    - Civil Rights Division
    - Legislation Division

- Office of the General Counsel (cont'd.)
  - General Counsel
    - Political Appointee
  - 3 – 4 Deputy General Counsels
    - Political Appointees
  - Each division headed by a career associate general counsel
  - Each division may have various program groups
    - E.g., Litigation division; Regulatory Review division

- Attendees at Deputy Secretary's briefing (cont'd):
  - Executive Secretary
    - Convenes meeting
  - Assistant Secretary for Legislation
    - Ensures attendees aware of Hill interest
  - Assistant Secretary for Planning and Evaluation
    - General policy direction and guidance
    - Sometimes involved in policy development
      - E.g., 2003 EMTALA amendments

- Attendees at Deputy Secretary briefing (cont'd.):
  - Assistant Secretary for Resources and Technology
    - Budget considerations
  - Assistant Secretary for Public Affairs
    - Press interest
  - Other relevant operating division heads
    - E.g., FDA Commissioner, if a payment regulation involves a drug issue

- At conclusion of Deputy Secretary review process, decision made whether a regulation or a provision of a regulation merits Secretarial review
- Based on political or press considerations; significant level of controversy; significant expenditure of program funds

- Once HHS has cleared a regulation, it goes to OMB
  - By Executive Order, OMB must clear all agency regulations. Only OMB can give permission for an agency to send a regulation to the Federal Register.
  - OMB will ask for staff-level briefings. As a practical matter, in the interests of time, these staff-level briefings often occur simultaneously with the CMS drafting process



- Depending on political sensitivity/controversy level of a regulation, the White House will often request a briefing on a regulation
  - In Bush Administration, a CMS regulation would be briefed to the National Economic Council.
  - In Obama Administration, Domestic Policy Council and the Office on Health Reform will be key players as well, possibly even on routine CMS payment regulations.
    - And on regulations such as implementing SCHIP reauthorization and the stimulus package, those offices will surely be involved

- Virtually every CMS regulation needs to be cleared more broadly than within CMS.
- There are multiple points in the process where it is possible to influence a CMS regulation:
  - Potential legal concerns: OGC
  - Potential policy concerns: Office of Deputy Secretary; Assistant Secretary for Planning and Evaluation
  - Potential legislative concerns: Assistant Secretary for Legislation
  - Potential budgetary concerns: Assistant Secretary for Resources and Technology; OMB