



Demystifying the HHS/CMS Regulatory Process

Thomas R. Barker
Partner
Foley Hoag LLP

Outline

- ❖ 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

- ❖ Annual fee schedule rules
 - IPPS
 - Physician fee schedule
 - OPPS

- ❖ Rules that implement Congressional or Administration policy
 - Initial part D rule
 - EMTALA reform

CMS: Initial Steps

- ❖ 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

CMS: Initial Steps

- ❖ 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

CMS: Initial Steps

- ❖ 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: Initial Steps

- ❖ Regardless of type of rule (routine notice or new policy) once the rule is written by staff, a CMS clearance process will occur, with major policy decisions made by the Center Director, CMS Deputy Administrator, and CMS Administrator.
- ❖ Once cleared through CMS, regulation enters Departmental clearance

Role of HHS

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

Role of HHS

- ❖ 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).

Role of HHS

- ❖ 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

Role of HHS

- ❖ Attendees at the Deputy Secretary's briefing:
 - 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

Role of HHS

- ❖ Attendees at the Deputy Secretary's 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

- ❖ 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.

Final Thoughts

- ❖ 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