



Health Care Reform and Challenges for CMS



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Agenda

- Background – the Patient Protection and Affordable Care Act, “PPACA” (Pub. L. No. 111-148), and the Health Care and Education Reconciliation Act, “HCERA” (Pub. L. No. 111-152)
- Challenges in health reform implementation
- Tools that HHS has available to smooth the transition
- The HHS decision-making process

Background – Health Reform and Part D

- Similar to enactment of Medicare Part D
 - Highly partisan environment
 - Part D passed with very few Democrat votes
 - Administration’s popularity was declining after President Bush signed MMA
 - Part D implementation began three months after Hurricane Katrina
 - Minority party saw an opportunity
 - Litigation
 - Lawsuits filed by States against HHS on clawback
 - Lawsuits filed by States against HHS on PPACA/HCERA
 - Major change in health care law driven heavily by one party’s philosophy
 - Republicans = greater role for marketplace
 - Private plans offer benefit
 - No interference with pricing negotiations
 - Democrats = greater role for government
 - Government should offer benefit or compete with private plans
 - Government should set prices
 - Historic vote seen as having the potential to make an enormous shift in the direction of government
 - Part D: begin to move Medicare to a defined contribution model
 - PPACA/HCERA: increase role of government in health care

Challenges in Implementation

- What are some of the challenges that the new Administration faces in implementing health care reform?
 - PPACA/HCERA are the law and must be implemented
 - Political and legal considerations are distractions but must be dealt with; can't be ignored
 - These will come from several angles
 - Oversight requests
 - Tough floor votes
 - Potentially significant drafting errors in the legislation
 - HHS is not staffed up to implement the provisions of the legislation that take effect within six months
 - No CMS Administrator
 - Borrowing staff from CMS will cause a backlog of work within CMS
 - White House will want to be involved in every major decision (and even some not-so-major decisions)
 - Senior Administration officials can only be in one place at one time

Tools Available to Implement Health Care Reform

■ Political tools

- Democrats control Congress and thus can control the floor agenda
- Messaging: Administration gets first crack at crafting the message
- Administration can travel around the country to promote health reform
 - Secretary Leavitt and the Medicare bus
- Popular media
 - SNL Part D skit
- Political appointees in department can craft policy solutions consistent with Administration philosophy, and can push career staff to draft and implement those policy solutions.

Tools Available to Implement Health Care Reform

■ Legal Tools

- HHS – especially CMS – has extremely broad authority to waive otherwise-applicable program rules
 - Used multiple times in Part D implementation
 - Demonstration authority
 - Waiver authority
 - New tools in PPACA/HCERA such as the Center for Medicare and Medicaid Innovation
 - DOJ has concurred with broad scope of the pre-PPACA statutory authorities
 - Courts not hesitant to weigh in
 - OMB policies regarding budget neutrality

HHS Decision-Making Process

- No matter what “tool” HHS uses to fix a problem that it identifies, the solution will go through a Departmental-wide and Administration-wide vetting process.

- Typical process – HHS
 - Executive Secretary convenes relevant political appointee stakeholders within HHS
 - Deputy Secretary (Meeting Chair)
 - Counselor to the Secretary (Meeting Chair)
 - OGC
 - Assistant Secretaries
 - Planning and Evaluation
 - Budget
 - Public Relations
 - Legislation
 - Director of Intergovernmental Affairs
 - Relevant Operating Divisions
 - CMS
 - FDA
 - HRSA

HHS Decision-Making Process

- Once the participants have developed a recommendation, it will either be agreed to by the Deputy Secretary or the Counselor to the Secretary.
 - Depending on the political sensitivity of the issue, it might be briefed to the Secretary.

- At this point, the policy will be advanced to the White House for review:
 - White House Office of Health Reform
 - National Economic Council
 - Domestic Policy Council
 - Council of Economic Advisors
 - White House Counsel's Office
 - Office of the Vice President
 - Office of Management and Budget

- HHS will not be able to implement its recommended policy until cleared by this group.
 - And, just like within HHS, depending upon the sensitivity of the issue, it may be elevated.

Example – Medicaid Drug Rebate

- Let's take a look at how this process might play out.

- Example 1: Implementation of the increase in the minimum rebate percentage for the Medicaid drug rebate is a high profile issue.
 - Significant industry concern

 - Interested parties
 - Pharmaceutical manufacturers
 - Managed care organizations
 - Pharmacies
 - Community and mail order
 - States
 - Governors
 - Legislators
 - Medicaid Commissioners

Example – Medicaid Drug Rebate (cont.)

- Main provisions of the legislation affecting the Medicaid Drug Rebate:
 - Increase in the minimum rebate percentage for the Medicaid Drug Rebate
 - Application of rebate to drugs dispensed to enrollees in Medicaid managed care organizations (MCOs)
 - Clawback, i.e. states and Federal share of rebates
 - Changed definition of AMP
 - Application of rebate to new formulations of existing products
 - Modification of transparency requirement

- Decision points for CMS:
 - Provide guidance to timing of changes to Medicaid drug rebate
 - Provide guidance on application of rebate to drugs dispensed to Medicaid MCO enrollees
 - Provide guidance on the clawback
 - Provide guidance on new definition of AMP
 - Define new formulation

Example – Medicaid Drug Rebate

- How might the process play out?
 - Starts at CMS
 - CMSO will draft State Medicaid directors letter
 - Cleared within CMS
 - Policy Options that needed to be decided and clarified in the SMD letter
 - Effective Date of changes
 - How much leeway did CMS have with the “clawback”?
 - What policy choices would be made on the expansion of rebates to managed care enrollees?
 - What is a “new formulation”?
 - How does the changed definition of AMP affect other CMS priorities
 - DRA AMP regulation
 - Existing litigation
 - Transparency of AMP
 - Moves to Department
 - Likely a “6th Floor” meeting because of significance of issues
 - CMS presents options paper/draft SMD
 - IGA weighs in with State concerns
 - ASL weights in on Hill concerns
 - OGC explains legal risks due to imprecise drafting

Example – Medicaid Drug Rebate (cont.)

- Implementation steps taken thus far:
 - CMS letter to State Medicaid Directors, April 22, 2010
 - Addressed rebates for Medicaid MCO drugs
 - Addressed changes in non-Federal share of rebates

- Forthcoming guidance
 - Guidance on process used to offset Federal amounts due to increase in rebate percentage
 - Additional letters to State Medicaid directors and other guidance, as necessary, for proper and timely implementation

Conclusion

- Numerous challenges in implementation that the Administration and HHS will face such as staffing, politics, accuracy and legal challenges
- Implementation is underway – some statutory deadlines just around the corner
- The Administration and HHS have political and legal tools available to help implement health reform