The Heritage Foundation
Executive Memorandum

No. 696 September 20, 2000

THE CLINTON DRUG PLAN: A PRESCRIPTION FOR MASSIVE REGULATION

JAMES FROGUE

President Bill Clinton's Medicare reform proposal, the Medicare Modernization Act of 2000, is a prescription for enormous federal regulation of the delivery of drugs and medical services to America's senior citizens. If enacted, it would compound inefficiencies plaguing the current system, slow access to prescription drugs, and unleash an unprecedented expansion of government control over the prescription drug market.

A recently released analysis of the Clinton proposal, conducted by James Tozzi of Multinational Business Services and funded by the pharmaceutical trade group *PhRMA*, shows the extent of the problem. Tozzi, a career veteran of five presidential administrations who served primarily in the Office of Management and Budget (OMB), found that the Clinton legislative language contains 412 new government mandates, of which 182 represent various types of controls or rules governing the delivery of prescription drugs. The Health Care Financing Administration (HCFA), which runs the Medicare program, would have to administer 255 new regulatory requirements under this legislation. This regulatory complexity is eerily reminiscent of the President's ambitious 1993 proposal to micromanage the financing and delivery of health care services in the private sector.

Geographic Monopolies. Under this Clinton plan (which is the original iteration of Vice President Al Gore's proposal), the nation would be divided into 15 geographic regions. For each region, HCFA would select one pharmacy benefit manager (PBM) to run the Medicare drug benefit for beneficiaries. In other words, one PBM would be granted a monopoly, giving seniors in that region only one choice of provider and no alternative if they are dissatisfied with the cost and/or availability of the drugs. Moreover, seniors would have only one chance to sign up for the plan, either upon reaching age 65 or when their employer-provided coverage expired.

Produced by the
Domestic Policy Studies
Department

Published by
The Heritage Foundation
214 Massachusetts Ave., N.E.
Washington, D.C.
20002–4999
(202) 546-4400
http://www.heritage.org

This paper, in its entirety, can be found at: *www.heritage.org/library/execmemo/em696.html*

Deep Regulatory Reach. The government mandates in the Clinton plan would affect every aspect and player in the system, from drugs covered to regulations on PBMs and participating pharmacies. The cumulative effect of the mandates would be massive uncertainty among participants. The regulatory machinery would make implementing the plan a difficult and time-consuming exercise; but even if it were implemented in a timely fashion, it would subject plans and doctors and patients to the decisions of the Medicare bureaucracy. With unresolved problems in Medicare Part A and Part B, and with the Medicare+Choice experiment cur-

rently unraveling largely because of HCFA micromanagement, this is a recipe for disaster.

At the end of the day, the Medicare patient depending on this scheme for prescription drugs coverage will be the one who suffers most. Consider how HCFA's tasks under this proposal would affect seniors' choices:

- **Regulating specific drugs.** Section 201 of the Medicare Modernization Act includes provisions that would enable the federal government, through regulation, to define the scope of the definition of "prescription drugs," what drugs must be included in the benefits package, and how specific drugs should be excluded. Bureaucrats, not doctors, patients, or the plans chosen by seniors, would decide which drugs would be available.

- **Regulating PBM participation.** Section 201 includes provisions outlining the regulatory authority to contract with prescription benefit managers, including the bidding process, the establishment of 15 geographic areas, the review process for PBM negotiations with drug manufacturers or suppliers, and "evaluation of additional factors to be established by HCFA." A major complaint among providers participating in Medicare+Choice already surrounds HCFA's incoherent decisionmaking process, which is not likely to be better under this proposal.

- **Regulating pharmacy participation.** Proposed rules will govern PBMs contracting with pharmacies and their compliance with HCFA's rules governing provision of services. The proposed PBM system is not a consumer-based competitive process; it is a government contracting system in which federal bureaucrats determine the available alternatives. But if the rules prove cumbersome or costly, fewer pharmacies will be willing to participate.

- **Regulating drug pricing.** Administration officials emphatically deny that price controls are part of the plan, but a closer look shows that HCFA would have significant influence over pricing issues. The bill would require PBMs to submit a price schedule during the bidding process and then negotiate prices for specific drugs with manufacturers, wholesalers, and pharmacies—all under HCFA's review. This would amount to government price-setting, with negative effects on research and development and the availability of top-of-the-line drugs.

Management Crisis. HCFA is already struggling to carry out its statutory requirements. To task the agency with the responsibility of implementing a massive new Medicare drug benefit and overseeing the detailed operations of providers—soon to involve over 1 billion additional transactions per year—without serious structural reform is irresponsible. HCFA's managerial problems, outlined in U.S. General Accounting Office reports and detailed during various congressional investigations, are a source of growing bipartisan concern. If HCFA cannot ably and efficiently handle its responsibilities now, it is unclear how well it could handle administering a massive new drug benefit.

Conclusion. Real Medicare reform should seek a reduction in bureaucracy, complexity, and red tape. Policymakers should improve the system to increase innovation, efficiencies, and effectiveness in delivering medical goods and services to seniors. The Clinton Medicare proposal is taking exactly the wrong approach.

As the Tozzi study shows, the Medicare Modernization Act includes a stunning amount of cumbersome regulation. Members of Congress who serve on the committees of jurisdiction over the financially troubled and managerially challenged Medicare program should heed its conclusions and seek reforms that give seniors more choices and less bureaucracy and red tape. America's seniors deserve the type of straightforward system Members of Congress, the White House, and 9 million federal workers now enjoy.

—James Frogue is Health Care Policy Analyst at The Heritage Foundation.