

Price Control Elements in the
Medicare Modernization Act of 2000

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Background

The Administration has proposed a new piece of legislation, the “Medicare Modernization Act of 2000” (“MMA”), which would establish a new prescription drug benefit as part of the Medicare program. To assess the MMA’s regulatory impact, Multinational Business Services, Inc. (“MBS”) was asked to identify the new mandates that the MMA would impose on federal agencies, state governments and private sector entities.

Based on a section-by-section analysis of the text, MBS issued its report (“Regulatory Mandates Under the Medicare Modernization Act of 2000”), in which MBS identified 412 new mandates, 315 of which would have to be implemented by federal agencies and taxpayer-funded “benefit managers.”¹ Hence, the costs of implementing these new mandates would be borne by the taxpayers.

The MMA is premised on the idea that HCFA will divide the country into 15 “geographic service areas,” and select a “benefit manager” to administer the new prescription drug benefit within each area. In other words, each service area will encompass approximately three states. Multiple bidders for the contract to serve as the benefit manager for a specific service area would compete triennially for the contract, which would grant a monopoly over the entire area. Thus, no competing benefit manager would be allowed to administer pharmaceutical benefits to Medicare beneficiaries within the region. Moreover, no pharmacy would be allowed to sell prescription drugs to a Medicare beneficiary unless that pharmacy had a contract with the benefit manager, and the contract would require the pharmacy to agree to adhere to the benefit manager’s price list.

¹ See MBS Report, Mandates 1-264 (mandates on federal agencies) and 279-329 (mandates on taxpayer-funded benefit managers).

Direct Price Control Regime

Based on its mandate count, MBS was asked to determine whether any of the regulatory mandates documented in its Report would result in price controls. MBS determined that, buried among the 412 other regulatory mandates in the Administration's proposal, are five specific mandates which, taken together, would impose a direct price control regime:

- (1) **Mandate 286: "Price Negotiations for Specific Drugs."** Under this mandate, each entity desiring to become the benefit manager for one of the 15 geographic service areas would be required to enter into negotiations with manufacturers and suppliers to arrive a price for each prescription drug. (If the entity were then awarded the contract with HCFA to serve as benefit manager, the fixed price would apply whenever the drug is sold to a Medicare beneficiary.)
- (2) **Mandate 279: "Development of Prescription Drug Schedule."** This mandate would require that, based on the results of the negotiations pursuant to Mandate 286, each bidding entity develop a uniform price schedule for all prescription drugs to be offered and sold to Medicare beneficiaries within the service area (*i.e.*, roughly 1/6 of the healthcare market). This price schedule would then be incorporated into the entity's bid, and would be one of the criteria considered by HCFA in awarding (or denying) the contract.
 - This mandate would also require that "price differentials" between formulary and non-formulary drugs be established as part of the price schedule, thus ensuring that virtually all products deemed to come within the definition of "prescription drug" would be subject to the price schedule.
- (3) **Mandate 163: "Consideration of Individual Entity Bidding Packages."** Under this mandate, HCFA would decide which of the competing bidders would be awarded the one benefit manager contract for each geographic service area. The MMA expressly requires HCFA to take into account the price schedules developed pursuant to Mandate 279 in deciding whether to award the contract.

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- In other words, HCFA would have the ultimate power to approve or disapprove a bidding entity's price schedule, because HCFA would decide whether or not that entity will serve as a benefit manager. HCFA could exercise that power either by rejecting a bid outright, or by requiring resubmission of an amended price list.
- (4) **Mandate 330: "Compliance with Limitations on Prices for Specific Prescription Drugs."** Once *HCFA* established the price list to govern a geographic service area pursuant to Mandate 163 (*i.e.*, by awarding a benefit manager contract to the selected bidding entity), Mandate 330 would require that all pharmacies selling prescription drugs to Medicare beneficiaries in the geographic area abide by the price list.
- (5) **Mandate 331: "Contracting with Benefit Manager."** A pharmacy would have the authority to sell prescription drugs to a Medicare beneficiary only to the extent that the pharmacy is acting pursuant to the pharmacy's contract with the benefit manager. Moreover, by express statutory mandate, the contract would have to include the requirement that the pharmacy will "adhere" to the "established prices." This requirement would be a mandatory inclusion in the pharmacy's contract with the benefit manager, without which the pharmacy could not legally sell prescription drugs to Medicare beneficiaries.

These five mandates, taken together would effectively require a federal government agency, HCFA, to approve price lists for virtually all prescription drugs. Obtaining HCFA's approval would be a precondition for obtaining a contract to serve as a benefit manager. The price lists would be mandatory on all pharmacies within each geographic service area as to all Medicare beneficiaries. In other words, HCFA would exercise control over virtually all prescription drug sales transactions through a web of contracts, starting with the HCFA-benefit manager contracts, and continuing through the benefit-manager-pharmacy contracts. The provision of this type of statutory authority to a government agency to set maximum prices for a specific category of goods (*e.g.*, prescription drugs) represents a classic price control mechanism.²

² See, *e.g.*, E. Avneyon, Dictionary of Finance at 362 (defining "price control" as "[a] limit, generally an upper limit, which a government sets for goods or services, usually during war time or under galloping inflation. The price that is set is below the

Indirect Price Control Elements in the MMA

In addition to the direct price control regime described above, the MMA contains a number of other mechanisms that would empower the federal government to exercise indirect control over the pricing of prescription drugs. Some of these regulatory mandates may be deemed by Congress and the voters to have benefits, from a public policy perspective, that outweigh the distorting impact they would have on pricing. These indirect mechanisms include Mandates 199, 200 and 203, which would require the federal government to impose “bonus and penalty incentives” on benefit managers to induce them to achieve the pricing goals of the federal government. In addition, Mandate 279 would tie the prices for non-formulary prescription drugs to the prices for formulary drugs.

equilibrium price, and it therefore affects the market forces of supply and demand....prices can only be changed by permission of a statutory agency”).