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Medicare Coverage Strategies: Impact of the MMA and PBMs

Part 1 of an interview with Joseph Antos, PhD, of the American Enterprise Institute

American Health & Drug Benefits™ has been created to act as an ideological melting pot focusing on health and drug benefit decision makers, as well as those who may affect or may be affected by those decisions. By engaging in conversations with payors, regulators, employers, and other stakeholders, our journal hopes to enable decision makers to view the impact of benefit designs from as many perspectives as possible. Through this open dialogue, we hope that better decisions may be made, and that the greater healthcare marketplace will be positively impacted.

In following our editorial mission, American Health & Drug Benefits™ has sought thought leaders who have influenced and will continue to influence the healthcare marketplace. During a fall visit to Washington, DC, Dr. Joseph Antos was kind enough to host a visit to the American Enterprise Institute and provide his thoughts to Robert Henry, editor-in-chief, on how the Centers for Medicare & Medicaid Services (CMS) exerts its influence on drug coverage in the wake of the Medicare Modernization Act (MMA) and in the face of evidence-based medicine standards. Following a chronology of CMS's role from its inception to current events, Dr. Antos offers a lively insight into CMS's strategy and its tactical effects on the American healthcare system.

Robert Henry: At a recent Institute of Medicine annual meeting, Elliott Fisher of Dartmouth quoted Uwe Rhinehart referencing something that you had discussed in the book you co-authored with Alice Rivlin, *Restoring Fiscal Sanity 2007: The Health Spending Challenge*. You make the point that the same level of care or the same procedure provided in 2 different locations in the United States can vary dramatically in price (even twice as much or more). Dr. Fisher quoted Dr. Rhinehart as saying that, "Isn't it amazing that the best healthcare in the world can cost twice as much as the best healthcare in the world?"

Joseph Antos: Yes, this is a colorful way of making a very important point. Elliott Fisher, Jack Wennberg, Jonathan Skinner, and others have been tracking Medicare data to put this geographical variation into perspective. In *Restoring Fiscal Sanity 2007*, Alice and I emphasized 3 conclusions from this research into geographical differences in resource utilization. First, variations in resource use are huge—much larger than can be explained by differences in patients or practice traditions. Second, resource consumption follows local



resource supply availability. So geographic areas with large concentrations of a given specialty group will witness higher utilization of that specialty than areas with sparser concentrations. Third, and most surprisingly, higher healthcare expenditures do not necessarily translate into better patient outcomes. And that finding has everyone looking for ways to rein in unnecessary healthcare costs.

Robert Henry: Medicare has undergone a tremendous degree of change since the passage of MMA. Do you see this as a "sea change" in the role of CMS as a purchaser and regulator, especially with regard to pharmaceutical agents?

Joseph Antos: Yes and no. Medicare has always been a regulator, and Medicare has always been a payor. It started to interact with the drug industry with the introduction of Part B drugs. CMS now has a much greater role as payor and regulator with the addition of the Part D benefit and outpatient drugs.

CMS is well on its way to learning how to deal with the drug industry. They hired hundreds of pharmacists and other experts to help them get the drug benefit

started and to help them understand formulary issues. They have also had to deal with the United States Pharmacopeia (USP), but it is not at all clear what use that particular cul-de-sac has been for the past couple of years.

Robert Henry: *It didn't really produce a consensus, did it?*

Joseph Antos: It did not produce a consensus. It did not produce a simple, logical, and useful structure for deciding how to create a formulary or what is necessary for a specific group of patients. As far as I can tell, no new information has come out of that process, but USP will continue to refine its model formulary year after year, perhaps indefinitely.

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It is difficult to detect any substantial effect of USP on CMS regulation or on the plan sponsors in developing their formularies. However, the USP relationship was necessary politically. Congress needed an external body at the center of the process that was not wholly owned by either the government or by the pharmaceutical industry.

There was confusion and concern about the role that pharmacy benefit managers (PBMs) would play in managing Part D. Congress and other stakeholders were worried that formularies might be biased against sicker beneficiaries. An overall structure imposed by a supposedly neutral third party was the answer to this problem. The resulting USP guidance was used only to the degree that it made sense. PBMs were already operating in a similar framework, so the net impact was minimal.

The future for CMS's pharmaceutical regulation and its regulation of coverage and payment for health services more generally is likely to be contentious. That is illustrated to some extent by the ongoing struggle over Medicare coverage of ESAs, the erythropoiesis stimulating agents.

Robert Henry: *They would serve as a pretty good poster child.*

Joseph Antos: They are a poster child for the financial pressures in the health system and also serve as a cautionary tale about what could happen in the future. The current situation points to some deficiencies in knowledge, to some deficiencies in decision-making. The situation sheds light on major deficiencies in the way drugs are paid for under Part B.

In 2007, CMS substantially reduced Medicare coverage of ESAs, narrowing the range of diseases for which payment would be made and, in effect, imposing tighter dosing regimens. The cancer community felt blind-sided by what they said were budget-driven rules that interfere with medical decisions. The uproar over the new rules reached all the way to Congress, but CMS has softened its position only modestly.

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This is a classic, big money Washington problem. Every party has its own particular concerns, and the political and financial incentives are misaligned. Obviously, the pharmaceutical and biotechnology companies that create these products have money at stake, but there are also concerns about what constitutes good patient care. In addition, there is a new and evolving relationship between the U.S. Food and Drug Administration (FDA) and CMS, as it becomes clear that there is no sharp line separating scientific judgment about safety and effectiveness from business decisions regarding insurance benefits and reimbursement.

CMS itself is in a continuing struggle to limit growth in the costs of the program without seeming to dictate the practice of medicine. One of Medicare's guiding principles laid out in the Social Security Act is a prohibition against federal interference with medical practice. Now, that is a bit of a façade, because payment *does* determine to a large extent what doctors will do. Like private health insurers, Medicare establishes in its coverage rules the circumstances under which they are willing to pay for various interventions. If the insurer's payment rules are clear and known in advance, they certainly influence decisions made by the doctor and the patient regarding the course of treatment.

Robert Henry: *In other words, doctors and patients cannot keep demanding unlimited availability of intervention resources while expecting the insurer to find the money to pay for them? Eventually, the insurer or payor is going to step in and practice cost containment.*

Joseph Antos: Well, you could put it that way, but that is more cosmic than what I had in mind. I am talking about the normal business of insurance companies, whose job it is to make payments for a defined set of benefits. Ideally, the criteria for payment should make sense to providers and patients alike and not foreclose necessary treatment.

These benefit and payment decisions should be supported by scientific evidence, but health insurance has been a fairly unscientific business for much of the past 40 or 50 years. That is beginning to change with improvements in our ability to collect and analyze clinical data on treatments and outcomes. Traditionally, Medicare and private insurers based their financial decisions on prevailing medical practice, reasoning that the provider is in the best position to judge what is appropriate for the patient.

Robert Henry: *This prevailing view would seem to recognize the reality implementing any new technology where there tends to be innovators, early adapters, late adapters, and traditionalists.*

Joseph Antos: It does recognize the way most new technology is adopted in the health system. The innovator tries a new treatment approach. If it offers advantages over conventional methods, a combination of published studies and word of mouth result in adoption by other physicians. However, some new approaches offer minimal benefits to the patient, and insurers (including Medicare) generally pay higher prices for the new technology. Even when an innovation improves patient outcomes or has other clinical value, that does not necessarily mean the additional value is worth the additional cost. Medicare has traditionally left the decision to cover new medical treatments to its carriers, who base their judgments on the prevailing medical practice in their local areas. This was the system Medicare used when the program was created in 1965, and it is largely the system under which Medicare operates today.

This is one of the complications facing Medicare beneficiaries, who are sometimes surprised to find that there are regional differences in what is covered by this national insurance program. Physicians in Boston are likely to have a different therapeutic strategy than physicians in Minneapolis for the same disease, and Medicare is likely to reimburse differently in the 2 cities.

Another factor driving technology adoption is the role of the specialist. Specialists are likely to use more technology, and use it more aggressively, than general-

ists. Medicare pays primary care physicians significantly less than specialists, reflecting a long-standing bias that favors surgery and other interventions over cognitive services. The unmanaged fee-for-service nature of traditional Medicare provides an incentive to expand the use of ancillary services (such as diagnostic tests performed in the physician's office) and to increase referrals to specialists (which increases a primary care physician's capacity to see more patients in shorter visits). That drives up Medicare spending but may not improve health outcomes—a point that Jack Wennberg, Elliott Fisher, and their colleagues have been making for sometime.

Over 30 years ago, Wennberg discovered variations in clinical practice that could not be explained on the basis of illness, patient preferences, or scientifically grounded treatment standards. Much of his work has relied on Medicare claims data, which have been the only source of information on health treatment that is national in scope and reasonably complete and accurate. It has taken all of that time for policymakers to realize the serious implications for cost and quality of care of clinical variations, but there is now the technical capability to analyze large databases and a growing political interest in using that analysis to inform Medicare policy.

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Robert Henry: *Because the data were only slenderly understood, can we say with confidence that the decision to get a handle on practices and to provide more standardization is tied into evidence-based medicine? Is it tied into the fact that new data methodologies are emerging that are permitting people to draw accurate resource allocation conclusions?*

Joseph Antos: Absolutely. Jack Wennberg's work 30 years ago was path-breaking, but the greater availability of billing and clinical data and 3 decades of methods development now make it possible in concept to systematically assess what we are buying in healthcare and how well it works. Of course, there is more to be done

if we hope to use the information generated by the health system to best advantage, and electronic medical records would improve our data collection capabilities. However, an equally important change is the growing realization that we can and should use evidence to make coverage decisions that previously were based on a consensus of providers rather than systematic analysis of treatments and outcomes. We will see a movement away from local coverage determinations in Medicare toward national decisions as analysis of the data becomes more routine, and those national coverage decisions are likely to become more nuanced as we develop better information on the effects of treatment on specific patient populations.

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Robert Henry: *Medicare has followed an almost intuitive process?*

Joseph Antos: Yes. Without an ability to systematically analyze the data, coverage decisions relied on limited information about the effectiveness of new treatments. A treatment that seemed effective based on initial studies and reports from physicians in the local area would be covered. Sometimes, that intuition proved to be wrong. That might have resulted in a formal decision to deny coverage, but the same technology diffusion also works in reverse: Ineffective treatments ultimately fall into disuse, although that could take years unless payments are stopped.

Rising healthcare costs in the early 1990s led to the managed care revolution, as spending was outrunning employers' and families' willingness to pay. Vigorous managed care generated a backlash a few years later as a growing economy and tightening labor markets made employers rethink their health benefits. Rather than risk losing good employees disgruntled by a health plan that relied on direct controls on the use of services, employers sought less intrusive cost containment offered by PPOs, or preferred provider organizations. The managed care revolution took a vacation, at least temporarily. Managed care is not dead because health-

care costs keep rising. The interest in evidence-based medicine stems from the need to find better ways of delivering the right kind of care, allowing us to continue to provide top-quality healthcare without breaking the bank.

Robert Henry: *Let me ask you one question about that point. Shouldn't the decisions that are made, the formulary decisions and the drug benefit designs, be made ideally to provide the sweet spot of cost, quality, and access, as well as to find and hit the second sweet spot of clinical, business, and regulatory drivers?*

Joseph Antos: Correct.

Robert Henry: *How adept are the professionals who are making these decisions at the payor and purchaser levels? Has there, to your observation, been increased acumen?*

Joseph Antos: Absolutely. The big PBMs run large, efficient distribution systems to push product to the consumer. But they make their money by designing smart benefits that can lower prescription drug cost for Blue Cross, General Motors, the small employer, and the individual insurance subscriber. PBMs recommend formularies and coverage rules, but ultimately the employer or insurer decides how generous the benefit will be based on what he is willing to pay.

Robert Henry: *The purchaser, not the payor.*

Joseph Antos: Right.

Robert Henry: *And not the PBM.*

Joseph Antos: Well, let's be careful, because the purchaser is a lot of people, including me as an individual insurance subscriber, and I am certainly not making a specific decision about what the formulary should be in my health plan—and I probably did not select my plan solely on the basis of the prescription drug benefit. We are really talking about the employer as the decision maker, since the employer selects the plan or plans offered to workers. Insurers offer the employer a variety of insurance products that typically include a pharmacy benefit. That benefit might vary according to the breadth of the formulary, the structure of cost-sharing, the aggressiveness of cost management methods (such as requiring the use of generics where available), and the availability of retail and mail order sales outlets, among other considerations. The employ-

er decides what he is willing to offer his workers given the total premium cost, the generosity of benefits, the adequacy of the provider network, the reputation of the insurer, and his judgment about employee reaction to any benefit changes.

Robert Henry: *You are describing this combination of clinical, business, and regulatory.*

Joseph Antos: It all has to go together.

Robert Henry: *And they are getting better at it.*

Joseph Antos: And they are getting better at it, partly because PBMs can use data from their own operations to understand physician prescribing patterns, shifting demands among drug classes, and other factors that determine the cost of pharmacy benefits and the value received by patients. Companies such as Express Scripts, Medco, and Caremark are very large organizations with data on millions of covered lives spanning multiple years, which provide them with the ability to make sensible recommendations about benefit design and the effectiveness of specific drugs for specific diseases. With some modest changes in the information provided on the prescription, particularly the inclusion of the patient's diagnosis, these databases could even give us systematic information about the effectiveness of drugs in off-label uses. That capability to learn from our own experience will increasingly lead to improvements in patient care and ultimately could lead to verifiable improvements in health status. The PBM industry has the potential to become a major source of *sensible advice* to the rest of the healthcare industry about coverage, and then through coverage to actual treatment decisions by physicians.

In Part 2 of our interview, Dr. Antos follows up his observations about Medicare strategy with a discussion of Medicare tactics regarding biologics coverage. He examines the rise of virtual regulations that increasingly determine payment and the interaction of CMS, the FDA, and the biotech industry. ■

Dr. Antos is the Wilson H. Taylor Scholar in Health Care and Retirement Policy at American Enterprise Institute (AEI) for Public Policy Research. He is also a Commissioner of the Maryland Health Services Cost Review Commission, and an Adjunct Professor at the School of Public Health of the University of North Carolina at Chapel Hill. Before joining AEI, Dr. Antos was Assistant Director for Health and Human Resources at the Congressional Budget Office, Director of the Office of Research and Demonstrations, and Deputy Director of the Office of the Actuary at the Health Care Financing Administration (currently CMS). He served as Health Financing Consultant to the World Bank and the Organisation for Economic Co-operation and Development, as well as Senior Economic Advisor to the U.S. Agency for International Development. He currently is a member of the Panel of Health Advisors to the Congressional Budget Office, and is Commissioner of the Maryland Health Services Cost Review Commission.

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AHDB Stakeholder Perspective

CMS and Prescription Drugs: Winners and Losers

The Part D outpatient prescription drug benefit has ratcheted up CMS's direct involvement and influence on every aspect of the pharmaceutical industry, from research and development of new products to pricing and distribution to the end-user. The immediate impact

of Part D has largely been beneficial to manufacturers, distributors, health plans, employers, and Medicare beneficiaries. However, the substantial shift in pharmaceutical spending from private payors and Medicaid to Medicare will focus intense political pressure on every part of the supply chain. More money is at stake, but the risks have also risen sharply. Here is how the winners and losers stack up:

- **MANUFACTURERS:** In the near term, pharmaceutical manufacturers may be the biggest winners. First, the transfer of Medicare dual eligibles into Part D

plans shifted a substantial share of the market from the Medicaid “best price” world of mandated rebates into a less regulated market. Second, Part D plans are required to cover essentially all drugs in 6 protected classes, including antidepressants and antipsychotic drugs. That requirement virtually eliminates plan leverage on manufacturers, allowing them to increase their prices and profits. Third, Part D expanded the number of Medicare beneficiaries with drug coverage, bumping up demand for the products. A quarter of Medicare beneficiaries had no prescription drug coverage prior to Part D, and perhaps another quarter had less generous coverage (mainly through Medigap or other private insurance).

That good news for manufacturers is tempered by concerns from Congress that Part D plans may not be getting the best possible prices. Critics have called for direct price negotiation authority for CMS. Such authority might be granted under a Democratic president, possibly focusing negotiation on new innovative drugs that can run tens of thousands of dollars per treatment. In addition, concerns about the effectiveness and safety of pharmaceuticals could cause CMS to expand its “coverage with evidence development” program, slowing the adoption of new products for the elderly. As Part D spending grows, expect greater pressure on manufacturers to prove the effectiveness of their drugs and justify their prices.

- **PBMs AND HEALTH PLANS:** Concern in Congress that PBMs and private health plans might not be willing to offer drug-only benefits led to provisions that substantially reduced the financial risk of entering this new kind of business. Those provisions, the promise of increasing drug spend fueled by government subsidies, and the demand from many employers for seamless health coverage for their retirees led to an explosion of interest by firms seeing new marketing opportunities. The big players—including Humana, United HealthCare (cobranded with AARP), Caremark, and others—captured the lion’s share of the market. Despite aggressive bidding in a highly competitive market, profitability was good for many plan sponsors and several wrote checks to CMS because their net earnings exceeded the upper limit on the risk corridors. Somewhat surprisingly, there has been no consolidation in the Part D market, which continues to offer most consumers 50 or more plan options.

Medicare Advantage plans also appear to have come out on top, despite the new competition from stand-alone prescription drug plans. During the 1990s, private health plans in Medicare became popular pri-

marily because they could offer a prescription drug benefit unavailable in traditional Medicare. That advantage is gone with Part D, but the private plans have greater flexibility to offer more comprehensive drug benefits that are coordinated with coverage for inpatient and outpatient services. Some sponsors, including Humana, offered low-premium drug plans in the hope of later shifting those enrollees to their more profitable Medicare Advantage plans.

Many in Congress remain skeptical about a Medicare benefit delivered by competing private plans without a government default plan. Such a plan might be given special authority to negotiate prices, and might be designated the default plan for Medicare beneficiaries who do not explicitly select another option. That could significantly erode the market position of existing Part D plan sponsors. At the extreme, existing risk-bearing Part D plans might be replaced by a few regional drug carriers that administer a benefit dictated by Washington.

- **CONSUMERS:** Despite the early difficulties some seniors encountered in the enrollment process, most Part D beneficiaries seem satisfied with the benefit. Out-of-pocket costs have been reduced for many, particularly for those who did not previously have drug coverage, and the use of pharmaceuticals is up. Fears that employers would drop their retiree drug benefits have not materialized, partly because employers offering equivalent coverage are eligible for a subsidy. Low-income beneficiaries are eligible for special subsidies and low out-of-pocket costs, but a substantial number of those people have not come forward to claim their subsidy. In addition, beneficiaries who are dually eligible for Medicare and Medicaid may have to shift enrollment to another Part D plan to avoid having to pay premiums. CMS has exercised temporary authority to minimize such disruptions, but this problem has not been permanently resolved.

Consumers face an uncertain future with Part D. CMS will be under growing pressure to contain program costs, and that could translate into higher premiums and cost-sharing requirements for Part D enrollees. Higher-cost drugs are likely to move to third and fourth (specialty) tiers on plan formularies, and access may be further restricted through the use of prior authorization. Cost cutting could also chill the atmosphere for financially risky drug development. Seniors have gained a drug benefit, but poorly-targeted policies could reduce their access to the breakthrough drugs and biologics of the future.

Joseph Antos, PhD