

The Impact of Medicare Modernization on Coverage Policy: Recommendations for Reform

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In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines a series of new Medicare private health plan options to be added in January 2006. Health policy analysts have begun to weigh in on the challenges that these new options present to Medicare providers and beneficiaries, raising issues regarding program complexity, risk selection, stability, geographic inequity, and plan overpayment.¹⁻³ Despite the myriad concerns, the Bush Administration appears committed to implementation of MMA in 2006.

One issue that has received little attention to date is the impact of the health plan changes on Medicare coverage policy. When the act is fully implemented, beneficiaries can choose to stay in fee-for-service Medicare and opt for a stand-alone drug benefit, or select among available Medicare Advantage (formerly called Medicare+Choice) plans that include drug coverage. Medicare Advantage will offer a new regional Preferred Provider Organization (PPO) option. PPOs will contract with providers, but enrollees can seek services outside the provider network, paying additional out-of-pocket costs. The Centers for Medicare and Medicaid Services (CMS) recently announced 26 PPO regions and 34 regions for the free-standing prescription drug plans.⁴ Medicare Advantage regional plans must serve the entire region. Existing county-wide local plans can continue, but the intent of MMA is to encourage the development of regional PPOs.

Whatever delivery model a beneficiary selects, all plans must offer the standard Medicare benefit package. The existing Medicare coverage process will continue to determine whether and under what conditions new technologies and other services will be covered.

MMA offers challenges and opportunities for the coverage process. In some ways it further complicates the procedures. Fortunately, the MMA also directs CMS to make improvements in national and local coverage determinations. We urge CMS and the US Congress to focus on these issues and strongly recommend some additional steps.

RECOMMENDATIONS

1. Align Existing Contractor Regions With the PPO Regions

Medicare has been drifting into geographic incoherence, raising significant challenges for program

accountability and equity. The vast majority of coverage decisions are made by local contractors—carriers for Part B and Fiscal Intermediaries for Part A. In 2003, CMS contracted with 20 carriers and 27 Fiscal Intermediaries, who develop local coverage policies. Many of these organizations hold more than 1 contract creating informal multicontract regional networks.⁵ The local coverage policy process is highly variable from contractor to contractor in terms of resources, productivity, use of evidence, and timeliness.⁶ In addition, consolidating contractor networks has eroded the values of “local” responsiveness because these networks are now geographically diverse.⁵

The addition of PPO regions to this already complex mix will create myriad difficulties for local coverage policy. The PPO regions are not consistent with the existing contractors’ regions. Presumably, the fee-for-service side of the program will continue to be subject to local coverage policies. However, what about a regional PPO? In many instances, a PPO region may overlap different contractor areas, with different coverage policies required for that PPO, depending on where the services are rendered.

For example, Minnesota is currently served by a carrier network that includes Minnesota, Illinois, Michigan, and Wisconsin. Minnesota’s Fiscal Intermediary holds contracts in Minnesota and North Dakota.⁷ Minnesota’s new PPO region includes Montana, Wyoming, North Dakota, South Dakota, Nebraska, and Iowa. These states are served by 5 different Fiscal Intermediaries and 4 different carriers, all of whom issue coverage policies. Additionally, these states report to 3 different CMS regional offices (Iowa and Nebraska to Kansas City regional office; Montana, North Dakota, South Dakota, and Wyoming to Denver; and Minnesota to Chicago).⁸ Because some larger states comprise a single PPO region, not all will experience the same level of complexity.

We recommend that the program simplify its regional orientation by redrawing contractor regions to align with the PPO regions and reflect more rational boundaries. In addition, we recommend that CMS combine the functions of Part A and Part B contractors to achieve

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a single contractor per PPO region. As a result, all Medicare plans and providers within a region would be subject to the policies of one contractor.

2. Develop a Process for Allocation of Local and National Decisions

The MMA calls for CMS to consider how to obtain greater consistency and rationality in its local coverage process. Alignment of contractor regions, if adopted, will provide more geographic balance, but will not inherently provide greater consistency in coverage policies across regions.

Currently, most coverage decisions are local. An interested party can request a national coverage decision or CMS can initiate one.⁹ We recommend that CMS adopt a process to guide the locus of coverage decisions in order to obtain greater consistency. A series of factors could be considered.

One option is to redefine which decisions can be made locally, allocating some to the national level based on category. Research has shown that there are 3 types of coverage decisions—new technology, technology extensions, and utilization management.¹⁰ In relation to new technology, these authors found that local contractors: have fewer resources or less expertise to perform evidence-based technology assessments; rely heavily on other carriers and Fiscal Intermediaries; and vary widely in terms of when the contractors implement policies related to new technology. While the policies emerge at different times, often they are quite similar—evidence that the contractors copy the decisions of others. This outcome contrasts with utilization management policies, which show more variation because they respond to concerns about utilization of widely diffused procedures tied to variations in practice patterns from region to region.

Other factors CMS could consider include program costs (ie, more costly technologies or widely used technologies undergo national evaluation), uncertainty (ie, interventions of uncertain value go through the more rigorous national assessment process), and the likely costs and benefits of collecting additional information. There has been concern that centralization could potentially stifle innovation.¹¹ Existing creative national coverage policies along with the reforms discussed in the next recommendation will go a long way toward addressing these concerns.

It is time to abandon decentralization for its own sake, use national policy to encourage efficiency and equity, and develop regional policymaking in more focused and specific ways.

3. Reform the National Process

Medicare also makes national coverage decisions

each year for some 10 to 15 technologies projected to have a major impact on the program, or for which there is considerable clinical controversy.

In recent years CMS has implemented a series of reforms aimed at making its national coverage process more open, participatory, and evidence-based.^{9,12-14} The reforms have worked to a good extent: the availability of information on the CMS Web site has made it substantially easier to follow national coverage decisions and the rationale underlying them; the creation of the Medicare Coverage Advisory Committee has provided CMS with external expertise and advice, as well as a public forum for deliberation. CMS decisions have generally been consistent with the strength of evidence.¹⁵

The MMA seeks to open and improve this process further by imposing stricter standards for CMS reviews, by requiring CMS to make its rationale for decisions public, and by adding a public comment period before national coverage decisions are implemented.¹⁶ The legislation also creates a council for technology and innovation within CMS to coordinate coverage, coding, and payment for new technologies.

Still, more could be done. For one thing, the MMA will tighten timeframes for making decisions, yet CMS is not currently meeting its own self-imposed timeframes. More resources earmarked for national coverage decisions would help, akin to giving the US Food and Drug Administration more resources to speed drug approvals. Medicare could also move to establish clear criteria for coverage, including a role for formal cost-effectiveness analysis. This could help CMS target resources to improve health more efficiently.¹⁷

Yet history suggests that adding cost-effectiveness will be difficult. Medicare has tried on several occasions to add cost-effectiveness criteria but was thwarted by strong political opposition.¹⁸⁻²¹ MMA is conspicuously silent about cost-effectiveness, but Congress and CMS should continue to contemplate ways to use this technique. For example, Congress should consider cost-effectiveness analysis when adding new services to the basic Medicare benefit package, and CMS should consider such analysis when implementing congressionally mandated benefits. CMS should also require cost-effectiveness analysis for new demonstration projects (as it does with MMA's replacement drug demonstration, under which Medicare will temporarily cover oral drugs prescribed as substitutes for injectable drugs).

Congress should also provide additional resources to the Agency for Health Care Research and Quality for research to inform local and national coverage decisions. Research shows the quality of much of the evidence available to CMS for coverage decisions is fair or poor.¹⁵

Section 1013 of MMA provides funds for “comparative-effectiveness” (not cost-effectiveness) research, but only \$15 million of the original \$50 million targeted for this purpose was appropriated. This amount should be increased and the scope expanded to include cost-effectiveness analysis, as well as value-of-information analysis, which could help determine priorities for research.²²

Finally, Medicare should expand its use of creative approaches, such as “coverage under protocol,” whereby CMS conditionally covers a technology while the agency enrolls beneficiaries in clinical studies to determine the effectiveness of the technology.²³ Coverage under protocol continues the agency’s longstanding policy to cover new technologies with conditions. That is, CMS rarely issues blanket coverage policies, but instead renders more nuanced judgments that place restrictions based on patient characteristics or setting of care.

Coverage under protocol also recognizes an important reality about evidence: all decisions reflect a judgment about the costs and benefits of collecting additional information. CMS should also consider other innovative arrangements, including requiring manufacturers to pay for patient registries and exploring risk-sharing arrangements whereby CMS covers a technology but holds manufacturers at risk if expectations about its effectiveness do not develop.

CONCLUSION

Implementation of the MMA presages major changes for Medicare. Millions of beneficiaries and providers will face many new and confusing choices. It is essential that Medicare mesh the new options with the existing program. This is an opportunity to update and improve the entire coverage process as well. If the recommendations presented here are considered, we believe that Medicare’s coverage process will be more accountable, efficient, and equitable for all beneficiaries.

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