

agreement and found it legal.⁵ The Third Circuit disagreed, arguing that these agreements should be presumed to be anticompetitive unless there was evidence that their purpose was not anticompetitive or that they had procompetitive effects.¹

The court noted that Congress intended Hatch–Waxman to increase competition between brand-name and generics manufacturers in order to lower drug prices for consumers. Though Hatch–Waxman is silent on the legality of pay-for-delay agreements, allowing these agreements frustrates the Act's central procompetitive purpose, since challenges settled in that way simply divide monopoly profits between patent holders and their potential competitors. Consumers continue to pay higher prices because they're still forced to buy only from the patent holder, so the agreements have the anticompetitive effect of protecting monopoly pricing.

The FTC filed for Supreme Court review of the Eleventh Circuit Court case in which the K-Dur agreement was deemed acceptable. The FTC's petition was opposed by the solicitor general because the circuit courts had agreed on the legality of pay-for-delay. The fact that the Third Circuit has now disagreed makes it more likely that the agreements' status will ultimately be decided by the Supreme Court. Indeed, the solicitor general reversed position

in October, filing a brief (regarding a different case) asking the Supreme Court to restrict pay-for-delay agreements.

More immediately, the Third Circuit's decision casts a shadow of uncertainty on the legality of pay for delay. By extending the reasoning used in cases dealing with the exploitation of Hatch–Waxman's 180-day exclusivity window — wherein courts emphasized that patent holders' attempts to pay competitors to preserve monopolistic conditions may violate antitrust laws — in order to invalidate pay-for-delay agreements generally, the court substantially broadened the scope of concern about their use. Pharmaceutical companies headquartered in Pennsylvania, Delaware, and New Jersey, all covered by the Third Circuit, are already limited by the court's decision.

As courts appeared increasingly friendly to pay-for-delay agreements, their use increased. In 2005, only 3 settlement agreements included reverse payments; by 2008, there were 19, according to the FTC. The Third Circuit decision may dampen enthusiasm for pay-for-delay arrangements even outside the court's official geographic domain, diminishing the incentives for both patent holders and generics companies to settle these disputes. Patent disputes may be more likely to proceed to court, and generics may reach the market faster,

which would result in lower prices and potentially reduce the annual cost to consumers of pay-for-delay agreements — a figure that the FTC currently estimates at \$3.5 billion. On the flip side, this limitation on settlement options may drive up litigation costs, which may be passed on to consumers.

Either way, the Third Circuit decision provides a weighty counterbalance to others, offering an analysis that emphasizes the anticompetitive effects of pay-for-delay agreements over both the rights of patent holders to exclude competitors by any means they choose and the judicial interest in promoting settlement. It may well affect the relationship between generic and brand-name pharmaceutical manufacturers, the degree of competition in the pharmaceutical market, and the prices we pay for drugs.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

From Patton Boggs, Washington, DC.

1. *In re K-Dur Antitrust Litigation*, No. 10-2077 at 11-13 (3d Cir. July 16, 2012) (<http://www.ca3.uscourts.gov/opinarch/102077p.pdf>).
2. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001).
3. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).
4. *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d.
5. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

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Growing Pains for the Medicare Hospice Benefit

David G. Stevenson, Ph.D.

For 30 years, the Medicare hospice benefit has played a key role in shaping end-of-life care in

the United States. Authorized by the Tax Equity and Fiscal Responsibility Act of 1982, the benefit

was meant to improve the dying experience for terminally ill beneficiaries and to reduce the inten-

sity and cost of health care services at the end of life. After a slow start, hospice became an integral part of Medicare, and nearly half of all people who die while covered by Medicare now use the benefit before death.

Medicare beneficiaries are eligible for hospice when physicians certify that their prognosis suggests they have 6 months or less to live and when they agree to forgo curative therapies. The benefit covers a broad array of palliative and supportive services, and hospice agencies receive per diem payments (\$151, on average) to manage all care related to patients' terminal conditions. There is no cap on the benefit's duration, provided that physicians certify that enrollees continue to meet the eligibility requirements. Medicare does, however, enforce an aggregate cap for agencies, effectively limiting the total amount they can receive (about \$24,500 per beneficiary in 2011).

By many accounts, Medicare's hospice benefit has been an enormous success. From its initial focus on community-dwelling seniors with cancer, hospice has expanded to offer access for a much wider range of Americans at the end of life. Although data on its cost-effectiveness are mixed, hospice appears to deliver valuable benefits to recipients, including a reduced number of hospitalizations, greater attention to emotional and spiritual needs, improved pain management, and greater patient and family satisfaction.¹

As hospice has grown, much has changed in terms of the populations that are served and the care that they receive (see table). In 1990, 16% of Medicare hospice recipients had noncancer diagnoses; today, more than two

thirds do, with conditions ranging from advanced pulmonary disease to heart failure to dementia. Driven by the small portion of enrollees with very long hospice stays, the mean length of use has increased considerably — from 54 to 86 days over the past decade. In contrast, the median length of use has changed little, from 17 days in 2000 to 18 days in 2010 — a figure that reflects the fact that a sizable minority of beneficiaries enroll in hospice only days before death. The market for hospice care providers has changed markedly over the past 30 years, transitioning from a relatively small base of locally run nonprofit agencies to a larger market in which a slight majority of agencies, some of them with a national presence, are run on a for-profit basis.

Because of the increased use of hospice care and increased lengths of stay, Medicare spending on such services has more than quadrupled over the past decade to its current level of \$13 billion. Beyond the scrutiny that inevitably accompanies increased government spending, policymakers have paid particular attention to the emergence of a robust for-profit hospice sector and increased use by nursing home residents, raising questions about the extent to which some agencies are aggressively targeting more profitable patients.² On the other hand, there are also the continuing challenges of patients' either enrolling too late to benefit from hospice or having to disenroll because of prognostic uncertainty or agencies' concerns about exceeding the aggregate cap.³

Despite the changes described above, the hospice benefit itself has changed little since it began, with eligibility and payment poli-

cies that generally take a uniform approach for all users. Although a one-size-fits-all approach was feasible when most enrollees had cancer diagnoses and lived at home, it falters in the face of the diverse diagnostic and residential profiles of today's users. Equally important to consider is the hospice benefit's role relative to the broader health care system. To date, Medicare has treated hospice as separable from the other services and supports that beneficiaries receive. Even in the Medicare Advantage program, in which plans receive a capitated amount to manage enrollees' care, hospice is the only traditional Medicare benefit that is carved out (i.e., financed and delivered separately).

The current approach to hospice ensures Medicare beneficiaries the freedom to choose a well-defined end-of-life care benefit, but it has important trade-offs. First, defining hospice eligibility relative to the 6-month prognosis mark is clinically arbitrary and practically difficult, especially for people with noncancer diagnoses. Second, limiting hospice to patients who disavow disease-modifying therapy enforces an artificial distinction between curative and palliative therapy and potentially impedes both enrollment and quality of care.⁴ Finally, carving out hospice from other Medicare services reinforces the notion that such care falls outside the core competencies expected of providers such as nursing homes and Medicare Advantage plans and conflicts with efforts to integrate care and align incentives across providers and settings.

To date, most efforts to reform Medicare's hospice benefit have centered on the "long-stay problem," with proposals focused on increasing oversight of the

The Medicare Hospice Benefit, 1990–2010.*			
Variable	1990	2000	2010
Number of hospice users	76,500	513,000	1,159,000
Percent of patients who died while covered by Medicare who had used hospice	5.5	22.9	44.0
Length of hospice stay (days)			
Mean	67	54	86
Median	25	17	18
Percent of hospice users with noncancer diagnoses	16	49	69
Number of Medicare-certified hospice agencies	806†	2318	3555
Percent of hospice agencies that are for-profit	14.5†	32.6	53.9
Total hospice spending (\$)	309 million	2.9 billion	13 billion

* Except where noted, data for 1990 are from the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, and data for 2000 and 2010 are from the Medicare Payment Advisory Commission. Dollars are not adjusted for inflation.

† The listed value is from the National Hospice and Palliative Care Organization.

certification process and altering the financial incentives that reward long stays. Effective January 2011, hospice physicians or nurse practitioners must have face-to-face visits with patients before recertifying them for benefit periods beyond 180 days. Under the Affordable Care Act (ACA), the Centers for Medicare and Medicaid Services has authority to revise hospice payment methods, as long as changes are budget neutral. One recommendation from the Medicare Payment Advisory Commission is to make long stays less profitable by adjusting payments to reimburse providers at higher rates at the end of a hospice episode but at lower rates in between.

Although these targeted reforms might effectively address the narrow problems they seek to mitigate, policies should also aim to integrate timely, high-quality palliative and end-of-life care into the continuum of services that beneficiaries receive. Key to achieving this goal is envisioning the role of hospice as operating within a coordinated system of care rather than func-

tioning apart from it. The 15-site concurrent care demonstration project that was authorized by the ACA to allow patients to receive hospice and curative care simultaneously is one step in this direction. Another, more substantial step would be the meaningful integration of hospice into care delivered by Medicare Advantage plans, by accountable care organizations, and under bundled payment models more broadly. In this context, beneficial hospice and palliative care services could be introduced at any point in patients' care, regardless of their prognosis. This approach could ensure greater continuity of care and would be consistent with the broader aim of reorienting Medicare toward the delivery of flexible, patient-centered care driven by patients' needs rather than by narrow and potentially inefficient eligibility and payment policies.

Despite the potential benefits, subsuming hospice under an integrated payment approach entails risks that would need to be monitored.⁵ A cornerstone of hospice is its interdisciplinary, team-based delivery of medical

and nonmedical supports, and beneficiaries must continue to have access to these specialized services and providers. It would be a Pyrrhic victory if greater efficiency in end-of-life care were achieved at the expense of needed patient care. Consequently, the ultimate verdict concerning hospice's integration into the broader health care system will be determined by the quality of end-of-life care that patients receive.

For the past 30 years, the Medicare hospice benefit has offered beneficiaries an essential alternative to traditional care at the end of life, substantially improving their dying experience. Although recent policy has increasingly centered on ensuring appropriate use, policymakers and providers should also focus on the broader aim of further incorporating hospice and palliative care into the continuum of services. If such efforts are successful, hospice will ultimately be viewed less as an escape from traditional care at the end of life and more as a central component of high-quality care.

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From the Department of Health Care Policy, Harvard Medical School, Boston.

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