Policy Analysis

No. 601 October 15, 2007

Routing

The Freedom to Spend Your Own Money on Medical Care

A Common Casualty of Universal Coverage

by Kent Masterson Brown

Executive Summary

Most people would agree that a patient should always be able to spend his own money on the health care services he desires. Yet that freedom is often threatened or denied when government tries to provide universal health insurance coverage, as in the U.S. Medicare program, which provides health insurance to seniors and people with disabilities. Over the past 20 years, the Medicare bureaucracy—and to a lesser extent Congress itself—has limited the freedom of Medicare beneficiaries to purchase medical services with their own money. Those limitations violate beneficiaries' right to privacy, undermine a tool that could reduce the burden Medicare imposes on taxpayers, and may deny care to Medicare beneficiaries outright, or deny them access to the highest quality care available.

Ironically, as the U.S. government has restricted the ability of patients to spend their own money on medical care, Canada's socialized health care system is moving in the opposite direction. In a landmark case handed down in 2005, the Supreme Court of Canada ruled that the province of Quebec could not prohibit its citizens from purchasing covered services through private health insurance. That ruling recognized that imposing limits on a patient's freedom to spend his own money can result in his being denied crucial and even life-saving medical services.

This threat to patients' rights would grow under many proposals to have the federal or state governments provide universal coverage. Congress and the state legislatures should avoid universal coverage schemes that would undermine this fundamental human right, or tempt future legislatures and bureaucrats to do so. Instead, Congress should restore to American seniors the unfettered right to spend their own money on medical care.

Kent Masterson Brown is an historian, author, and attorney specializing in health, administrative, and constitutional law. He was lead counsel in Stewart et al. v. Sullivan *(1992) and* United Seniors Association et al. v. Shalala *(1999).*

CATO INSTITUTE

No issue more clearly illustrates the threat to individual rights posed by national health insurance than Medicare's attempts to prohibit enrollees from spending their own money on medical care.

Introduction

Most people would agree that a patient should always be able to spend his own money on the health care services he desires. Western liberal tradition and American jurisprudence both counsel that individuals possess a natural right to obtain medical care with their own resources, free from government interference.[1] Supreme Court Justice Joseph Story wrote that each citizen "is the proper guardian of his own health, whether bodily, or mental and spiritual,"[2] a proposition reiterated by the 19th-century legal scholar Thomas Cooley,[3] and in 1890 by future Supreme Court Justice Louis Brandeis.[4] That proposition and those writings were the fountainhead for the Supreme Court's declaration that the Constitution protects an individual's "right of privacy," which the Supreme Court has held "is older than the Bill of Rights—older than our political parties, older than our school system."[5] For years, the courts have protected the individual's right to seek and obtain health care services he deems important, free from government interference.[6] The Supreme Court has voided state statutes criminalizing abortion on the basis that such decisions involve a woman's exercise of a fundamental liberty to obtain medical services she deems necessary for her self-preservation.[7]

Government programs that attempt to provide universal coverage, such as the U.S. Medicare program, threaten that fundamental liberty. No issue more clearly illustrates the threat that national health insurance schemes pose to individual rights than the federal government's attempts to prohibit Americans in the federal Medicare program from spending their own money on medical care. Enacted in 1965 as a cornerstone of President Lyndon B. Johnson's "Great Society," Medicare is a federally financed program designed to help elderly and disabled citizens pay for health care services. At the time of its enactment, there was serious concern that Medicare would eliminate a patient's right to choose his doctor, his right to choose what health care services he receives, and his right to choose how to purchase those services. Congress claimed that it resolved those fears in 1965 when it included two provisions in the preamble to the Medicare law. The first provision guaranteed that beneficiaries would be free to obtain health care services from any provider "qualified to participate" in Medicare.[8] The second stated that nothing in the Medicare statute "shall be construed . . . to preclude" a beneficiary "from purchasing or otherwise securing protection against the cost of any health services."[9]

Both of those provisions proved to be empty promises. Over the years, the "free choice guarantee" has been stripped of all meaning. No plaintiff has ever successfully invoked it to enjoin the implementation of subsequent amendments to Medicare that actually restrict patient choice.[10] After Congress enacted Medicare, private insurers effectively ceased to offer comprehensive health insurance to the elderly, which made the second guarantee meaningless.[11] However, "protection against the cost of health care services" could also be construed to include a beneficiary's paying his own money for health care services. That option was always presumed to be available. After all, neither Congress nor any of its administrative creatures would deny anyone the right to use his own money to purchase the health care services he desired. Or would they?

In fact, the Medicare bureaucracy—and to a lesser extent Congress itself—has aggressively tried to limit the ability of Medicare beneficiaries to purchase medical services with their own money. Medicare beneficiaries have complete freedom to spend their own money on medical services that are not covered under the Medicare program. However, the federal government effectively prohibits beneficiaries from purchasing Medicare-covered services with their own money. As a result, Medicare beneficiaries effectively have no freedom to go outside the Medicare program either to obtain higher-quality care or to keep certain medical information private. Only the wealthiest seniors, who can afford to opt out of the Medicare program entirely, can avoid this

threat to their freedom to spend their own money on medical care.

Often, it is uncertain whether Medicare will cover a particular service. Medicare reimburses providers only for services that Medicare's bureaucracy deems "medically necessary." When there is ambiguity about whether Medicare considers a service "medically necessary," Medicare regulations provide an avenue for a beneficiary to pay for the otherwise-covered service himself if Medicare ultimately decides the service was not "medically necessary." However, physicians who use that avenue risk fines and other penalties. As discussed below, the Medicare bureaucracy has promised not to harass those physicians as much as it has in the past, yet that promise was issued by an unelected bureaucrat and may be revoked at any time by another unelected bureaucrat.

Medicare's efforts to restrict private payment have disturbing effects beyond just infringing on the beneficiary's right to spend his own money as he sees fit. Curtailing the right to self-pay violates beneficiaries' privacy rights. When beneficiaries receive services under Medicare, a claim must be filed with the Centers for Medicare and Medicaid Services (CMS). Those claims may contain personal medical information that beneficiaries would prefer to keep private. Self-payment enables beneficiaries to obtain services (e.g., psychiatric counseling) without that information being logged into government databases, where it could be compromised. A recent government report found that "47 percent of Medicare Advantage contractors reported privacy breaches within the past 2 years, as did . . . 42 percent of Medicare [fee-for-service] contractors."[12] Prohibiting or restricting the ability to self-pay erodes the beneficiary's right to keep such information private.

As a fiscal matter, self-payment would relieve taxpayers from paying for some aspects of beneficiaries' care. For decades, experts have warned that Medicare is in dire financial straits. In 2007, Medicare's board of trustees reported, "The [Medicare] program could be brought into actuarial balance over the next 75 years by an immediate 122 percent increase in the payroll tax, or an immediate 51 percent reduction in program outlays or some combination of the two."[13] Restricting beneficiaries' ability to self-pay undermines a tool that could relieve the burden Medicare imposes on taxpayers.

Finally, restricting this freedom can deny beneficiaries access to medical care. If the government pays so little for a "covered" service that physicians refuse to provide it, then preventing the beneficiary from purchasing that service himself cuts off access to that service entirely. As a result, the beneficiary may have to settle for lower-quality care. Access problems are likely to grow more acute in coming years. With scholars claiming that Americans pay higher prices for medical care than citizens of other countries,[14] Congress will increasingly look to provider-payment cuts as Medicare's fiscal problems mount. Prohibiting beneficiaries from spending their own money on medical care eliminates what could become an increasingly important safety valve for future generations of Medicare enrollees, including baby boomers.

Critics of the right to self-pay argue that allowing beneficiaries and providers to opt out of Medicare on a service-by-service basis would create a "two-tiered" health care system, where the wealthy could obtain better care than beneficiaries who are not affluent enough to self-pay.[15] Yet, ironically, restricting self-payment itself creates the very type of "two-tiered" health care system that opponents seek to prevent. Only those seniors who depend on Medicare find themselves subject to invasions of privacy and a loss of control over their medical decisions. The wealthiest seniors, in contrast, are beyond Medicare's grasp. They may avoid such harassment by opting out of the program entirely.

Critics also object that private contracts between physicians and Medicare beneficiaries could lead to fraud, as when physicians bill both the patient and the Medicare program for the same service.[16] This criticism presents a very real concern. For almost two decades, the Government Accountability Office has designated Medicare a "high-risk" program because

Only the wealthiest seniors can avoid this threat to their freedom to spend their own money on medical care.

of its vulnerability to fraud, waste, abuse, and mismanagement. In 2005, the GAO reported, "Medicare will continue to be a high-risk program for the foreseeable future."[17] Medicare fraud, however, is an issue between the provider and Medicare. It is unjust to deny *beneficiaries* the freedom to purchase medical care with their own money based on the misdeeds of *physicians*.

This threat to the freedom of American patients may be on the rise. Many health care reformers would have government provide universal coverage to all Americans.[18] Some reformers have even proposed expanding Medicare itself to cover all Americans not currently enrolled.[19] Such reforms would give the federal government similar powers to determine whether non-elderly persons may spend their own funds on medical care.

The threat has arisen at the state level as well. In 2006, the California legislature passed a universal coverage plan that provided, "No health care service plan contract or health insurance policy, except for the [state] plan, may be sold in California for services provided by the [state-run] system."[20] Only a veto by Gov. Arnold Schwarzenegger (R) prevented the California legislature from outlawing private health insurance for most medical services.

To add another layer of irony, as the United States has moved to restrict the ability of patients to spend their own money on medical care, Canada's socialized health care system is moving in the opposite direction. In a landmark case handed down in 2005, the Supreme Court of Canada struck down a provision similar to that in the California legislation.[21] The high court ruled that the province of Quebec could not prohibit private health insurance as a means of self-payment. That ruling recognized that limiting the patient's freedom to spend his own money can result in the denial of crucial and even life-saving medical services.

Many health care reformers would give the federal government powers to determine whether non-elderly persons may spend their own funds on medical care.

The U.S. Medicare Program

The history of the U.S. Medicare program offers one illustration of how universal health care schemes threaten the patient's right to purchase medical care with his own money. Medicare consists of four fundamental parts.[22] Part A is a mandatory program that insures eligible elderly or disabled beneficiaries against some of the costs associated with hospital care. Part B provides coverage for other health-care costs, including physicians' services.[23] Part B claims are processed by private insurance companies known as "carriers" that are awarded contracts through a competitive bidding process conducted by the Secretary of the U.S. Department of Health and Human Services (hereinafter "the Secretary" and "HHS").[24] Part C of Medicare was formerly known as the Medicare + Choice Program, and is now called Medicare Advantage.[25] Part C allows beneficiaries to choose from a number of private health plans, many of which cost more, and offer more benefits, than "traditional" Medicare (i.e., Parts A & B). Part D is the new Medicare prescription drug benefit.[26]

The Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration, is the division of HHS that oversees the operation of Medicare. CMS is responsible for entering into contracts with carriers to administer Part B and for overseeing each carrier's activities. Those carriers are contractually required to administer Part B of Medicare in accordance with the Medicare statute, as well as with the regulations promulgated by the Secretary and the policies and directives issued by CMS.[27]

Although all three branches of government routinely refer to Part B of Medicare as "voluntary," it is not.[28] Nevertheless, a beneficiary may dis-enroll from Medicare altogether either by failing to pay the premiums or by forwarding a written notice of his determination to the Social Security Administration or CMS.[29] Interestingly, until 1997, neither the statutes nor regulations ever addressed declining Medicare coverage of specific services. It was always assumed that a Medicare beneficiary could privately pay for health care services when and if it was in his interest to do so. Over the past two decades, however, Congress and CMS have effectively prevented

Medicare enrollees from purchasing medical care with their own money if those services are also covered by Medicare.

For purposes of Part B, physicians must elect to be "participating" or "non-participating" each year.[30] A "participating" physician agrees to accept the amount that Medicare determines should be paid for each service. "Participating" physicians bill carriers directly. The carrier, upon favorable adjudication of the claim, pays the physician 80 percent of the Medicare-allowed amount. The beneficiary is responsible only for the remaining 20 percent as well as for an initial $100 deductible. In other words, a "participating" physician may not charge (or "balance bill") Medicare beneficiaries for an amount in excess of the price determined by Medicare.[31] A physician who elects to be "non-participating" may still see Medicare beneficiaries and may still receive payment from Medicare carriers. The main difference is that "non-participating" physicians may choose, on a service-by-service basis, either to bill the beneficiary directly or to "accept assignment" of the beneficiary's claim from the Medicare carrier.

Physicians and beneficiaries were not always subject to binding price controls. For many years after the enactment of Medicare, "nonparticipating" physicians were free to bill beneficiaries for whatever amounts they determined reasonable. In 1984, however, Congress froze physicians' fees.[32] In 1989, Congress prohibited "nonparticipating" physicians from charging Medicare Part B enrollees anything in excess of a "limiting charge" established by the Secretary.[33]

Physicians also face other restrictions regarding billing and claims. For example, CMS requires physicians to bill Medicare carriers for certain services. In the 1980s, Congress required all physicians (even "nonparticipating" physicians) to accept assignment for all clinical diagnostic laboratory services.[34] In addition, whenever a physician provides services "for which payment is made under [Part B]," he must submit a claim form to the carrier—even if the physician is "nonparticipating" and does not wish to accept assignment of the claim. If the physician fails to submit a claim to the carrier, the Secretary may sanction the physician.[35] Finally, if a physician performs a service that the carrier determines was "not reasonable or necessary," which is the criterion for whether it is a Medicare-covered service, the carrier will deny payment, and the physician must refund any payment he received from the beneficiary. If such services are performed more than once, the physician may be fined up to $10,000 per instance. He may then face exclusion from Medicare,[36] which can devastate a physician's practice.

However, if a physician believes that Medicare may not cover an otherwise-covered service because the carrier would conclude the service was not "reasonable or necessary," the physician (whether "participating" or "non-participating") can enter into an "advance beneficiary notice" (ABN) with the Medicare enrollee. Under an ABN, the beneficiary agrees to pay for the service personally if the carrier denies payment.

Although it appears to resemble a private contract between the physician and patient, an ABN is not a private contract. A private contract, whether for a Medicare-covered service or a noncovered service, would avoid any contact with the Medicare program. In contrast, the ABN is basically a bureaucratic process used to determine whether a service is or is not eligible for Medicare coverage when the physician is unsure whether the carrier will consider that service "medically necessary."[37] Under an ABN, a claim must still be filed with the Medicare carrier. If the carrier determines either that a physician has entered into ABNs "routinely" or that the physician has provided too many services that were not "reasonable and necessary," the carrier could fine the physician up to $10,000 for each item or service and possibly exclude him from the Medicare program altogether.[38]

However, if the beneficiary and physician *never sought* Medicare reimbursement—that is, if no "payment is made under [Part B]"—it was previously presumed that these regulatory requirements did not apply. It was presumed that Medicare would operate like private

The history of the U.S. Medicare program illustrates how universal health care schemes threaten the patient's right to purchase medical care with his own money.

health insurance, which generally requires claims to be filed only when a patient or a provider actually seeks reimbursement from the insurance carrier. Yet in the early 1990s, HCFA began to prohibit physicians from entering into private-pay agreements with Medicare beneficiaries.

In the early 1990s, Medicare began to prohibit physicians from entering into private-pay agreements with beneficiaries.

Stewart et al. v. Sullivan

The first test of such private contracts came in the case *Stewart et al. v. Sullivan*. Dr. Lois Copeland, a "nonparticipating" physician practicing internal medicine in Bergen County, New Jersey, had a substantial geriatric practice. Many of her elderly patients wanted her to visit them more often than HCFA deemed "reasonable and necessary."[39] In 1992, HCFA limited such visits to one per month. Dr. Copeland's patients were scattered throughout Bergen County in various nursing homes. For her to comply with her patients' requests caused a significant investment of her time. She informed them she would accede to their requests if they would agree to pay her themselves. Otherwise, she would have to file claims and ABNs with the local Medicare carrier. Not only would those claims not be paid, they would have invited the carrier to sanction Dr. Copeland for performing "unreasonable" and "unnecessary" services.[40] The patients all understood and readily agreed.

Dr. Copeland soon received bulletins issued by several carriers warning physicians about such private-pay agreements with Medicare beneficiaries. "[A] provider," one read, "must abide by all Medicare rules and regulations [as long as covered services are provided]. The law cannot be bypassed by having patients sign a disclaimer stating that services provided to them should not be billed to Medicare."[41] Later, Dr. Copeland received a copy of a letter written by Gail R. Wilensky, the administrator of HCFA, dated October 15, 1991, asserting:

> We expect almost all patients who have Part B coverage will choose to use that coverage regardless of their financial means. . . . We are not aware of any instances where a patient has initiated agreements with a physician to the effect that Medicare will not be billed for the physician's services.
>
> Furthermore, such an agreement initiated by a physician would be invalid. In the rare event, however, that a patient, for his or her own reasons, and entirely independently, chooses not to use Part B coverage, the law does not require the submission of a claim by the physician.
>
> Where patients have Part B enrollment, a patient can choose not to use Part B coverage for certain physician services. However, by law, the physician is still required to follow certain Medicare requirements other than the claims submission requirement. This would include the limiting charge provision applicable to a non-participating physician when assignment is accepted, or advance written notice to the patient when the physician furnishes services which are not considered reasonable and necessary under Medicare guidelines.[42]

Not long after Dr. Copeland received the Wilensky letter, another doctor forwarded to her a letter from a HCFA official that stated: "HCFA does not pursue or promote the use of private agreements. However, HCFA would not be bound by a private agreement if the Medicare beneficiary complained or filed a claim for the service provided under the private agreement."[43]

In other words, HCFA asserted that (1) physician-initiated private contracts were flatly prohibited; (2) when a beneficiary initiates a private contract, physicians must inform the beneficiary when HCFA thinks a service would be unreasonable or unnecessary; (3) HCFA has the authority to set the prices for those purely private transactions; and (4) HCFA could and would sanction physicians when a patient reneges on a contract that the patient himself initiated.

Notably, HCFA confined allowable private contracts to those initiated by the patient—which HCFA officials expected would never happen. The carrier bulletin went even farther, claiming that absolutely no transactions between a physician and a beneficiary—not even beneficiary-initiated transactions with which the beneficiary was perfectly satisfied—were exempt from any Medicare rules and regulations. These restrictions evinced a clear desire by HCFA officials to deny beneficiaries the freedom to spend their own money on covered services.

HCFA claimed these rules were based on a subsection of the Medicare statute that prohibits "non-participating" physicians from billing, "on a repeated basis," "individuals enrolled" in Medicare "an actual charge in excess of the limiting charge." That subsection further provides:

> For services furnished on or after September 1, 1990, within one year after the date of providing a service *for which payment is made under this part* on a reasonable charge or fee schedule basis, a physician . . . shall complete and submit a claim for such service on a standard claim form specified by the Secretary to the carrier on behalf of the beneficiary. . . . [44]

HCFA also pointed to provisions prohibiting physicians from billing beneficiaries "in excess of the maximum allowable actual charge" and from billing for services that "the carrier determines" are "otherwise covered" but are "not reasonable and necessary."[45] HCFA ignored the fact that these strictures applied only to services "for which payment is made under this part" of the Medicare statute—a standard similar to what exists in the private insurance context. In other words, if Medicare makes no payment, the federal government has no reason or authority to interfere in the doctor-patient relationship. Importantly, HCFA implemented this sweeping policy without going through the procedures required by the Administrative Procedure Act, such as giving the public an opportunity to comment before the policy became final and was enforced.[46] Instead, the agency sought to enforce its extraordinary interpretation of the Medicare statute by means of bulletins issued by the carriers and by threatening sanctions.

Dr. Copeland felt compelled to seek relief from the courts. She and five of her patients filed a civil action in U.S. District Court for the District of New Jersey seeking a declaration of rights and injunctive relief enjoining the enforcement of the threats made by HCFA and Medicare carriers. The complaint was an attack upon government interference in Medicare beneficiaries' freedom to purchase health care services outside of Medicare. The Secretary filed a motion to dismiss or for summary judgment, claiming: (1) that he had imposed no policy; (2) that there was no proof that the carrier bulletins were authorized by him; and (3) that the plaintiffs were literally attacking something that did not exist. The plaintiffs countered by illustrating: (1) that the carriers, by law and by contract, speak for the Secretary; (2) that the threats were issued by those carriers pursuant to their relationship with the Secretary; and (3) that the Wilensky letter illustrated the origin of the bulletins. The plaintiffs pointed to a 1989 case where the U.S. Court of Appeals for the Sixth Circuit found that carrier bulletins had been directed by the Secretary, concluded that the Medicare statute did not support the Secretary's interpretation, and ordered the district court to enjoin enforcement of the disputed policy.[47]

After hearing the arguments in Dr. Copeland's case, the U.S. District Court in Newark, New Jersey, found that Copeland had standing because "the Secretary has articulated a broad policy that would subject Dr. Copeland to sanctions for entering into private agreements with her patients."[48] Because the patients would have to completely dis-enroll from Medicare to obtain the desired services from Dr. Copeland, and because there was no private insurance available for them in the mar-

If Medicare makes no payment, the federal government has no reason or authority to interfere in the doctor-patient relationship.

In 1993, HCFA effectively prohibited private contracts between Medicare beneficiaries and their physicians.

ketplace, the court was further satisfied that "foregoing all Medicare benefits in exchange for care from a physician of their choice" is an "injury-in-fact" sufficient to confer standing upon the plaintiff patients. Yet on the issue of "ripeness," the court found that the Secretary had not "clearly stated his position on a posed issue." The court went on to say:

> [T]he Secretary has not promulgated any rules or regulations either formally or informally espousing the policy alleged by the plaintiffs. Nor have plaintiffs demonstrated that the bulletins supplied by the carriers were issued on behalf of or at the direction of the Secretary. Nor have plaintiffs demonstrated that the documents represent statements of the Secretary intended to have the force of law such that conformity to them in the administration process would be expected.[49]

Of course, the Secretary *had* taken a position. If he had not, the plaintiffs could not have had standing. "Standing" means the plaintiff has a private, substantive, legally protected interest that is being invaded or will be invaded by the challenged conduct.[50] If the Secretary had not taken a position, there would be nothing to invade the plaintiffs' legally protected interest. Moreover, Dr. Copeland had clearly been "placed in the dilemma of incurring the disadvantages of complying or risking penalties for noncompliance"—the standard for ripeness adopted by most circuit courts.[51] Nevertheless, judgment was entered for the Secretary.

The *Stewart* decision left the freedom to self-pay in a state of confusion. Could Dr. Copeland engage in private contracting with her patients? After all, the court found the Secretary had no "clearly articulated policy." Or would HCFA and the carriers behave as they indicated they would in the bulletins and warning letters? Not surprisingly, all sides announced victory. HCFA claimed that the court adopted its arguments. Dr. Copeland could claim that, in the absence of a clearly articulated policy forbidding the practice, she was free to contract privately with her patients. Yet only the government *really* prevailed; the rule of law and the rights of Medicare beneficiaries took a beating. The court's ruling left behind enough uncertainty that few physicians would be willing to contract privately, for fear of being sanctioned. With *Stewart*, the federal court shied away from questioning government behavior that was not only totally contrary to the Medicare statute and the requirements of the APA but was at odds with Article I, Section 1, of the U.S. Constitution, under which Congress alone has the power to legislate.[52]

In 1993, in the wake of *Stewart*, HCFA amended its official *Medicare Carriers' Manual* to adopt the more restrictive interpretation that had appeared in carrier bulletins, which went well beyond the statutory interpretation detailed in previous letters from HCFA officials. That is, the 1993 *Medicare Carriers' Manual* asserted that nothing in the law allows private contracts to avoid the requirements of the Medicare statute (including requirements to submit claims on a beneficiary's behalf, accept assignment for clinical diagnostic laboratory tests, and bill no more than the limiting charge), that those statutory requirements cannot be negotiated between a physician and beneficiary, and that any such agreement would have no legal force or effect. In other words, HCFA effectively prohibited private contracts between Medicare beneficiaries and their physicians. The Secretary later claimed that amending the Medicare Carriers' Manual was "precisely the type of expression of policy the court in *Stewart* suggested."[53] It also represented the type of legislating that the Constitution empowers only Congress to do. At a minimum, it represented precisely the type of rule-making that required public notice and comment under the APA.

Section 4507 and *United Seniors Association et al. v. Shalala*

Despite the Secretary's acknowledgment of an official policy, the issue was hardly settled. A few physicians had responded to the ambi-

guity created by the *Stewart* decision by entering into private contracts with Medicare beneficiaries. When Sen. Jon Kyl (R-AZ) introduced legislation that would protect private contracting, the Clinton administration and other opponents amended the Kyl proposal, which ultimately became Section 4507 of the Balanced Budget Act of 1997.[54] Under Section 4507, if a physician provides even a single Medicare-covered service to a single self-paying Medicare beneficiary, that physician is completely barred from Medicare for a period of two years. That change effectively gutted Kyl's proposal and preserved the ban on private contracts.

The practical effect of Section 4507 is that Medicare beneficiaries can self-pay only with those doctors who opt out of Medicare entirely—a choice that would be left to the physicians, not the patients. Yet because Medicare comprises a large share of most physicians' patient base, few physicians could afford to withdraw from Medicare altogether. According to one affidavit, only 4.4 percent of family practitioners would be able to contract privately after January 1, 1998. Virtually no radiologists or anesthesiologists would be able to do so. No more than 3 percent of the nation's surgeons would be able to do so. And of course, all gerontologists accept Medicare reimbursement.[55]

With the changes to the *Medicare Carriers' Manual* and the passage of Section 4507, the right of Medicare beneficiaries to self-pay effectively disappeared. Previously, Medicare beneficiaries could purchase covered services outside the Medicare program with any physician they chose. Under Section 4507, the pool of physicians with whom the patient could self-pay was narrowed to the small minority of physicians who opt out of Medicare entirely. That effectively eliminated the right to self-pay for all but the wealthiest seniors, who can afford to opt out of Medicare themselves. (Even "participating" physicians remain free to accept self-payment from non-Medicare enrollees.)

Previous efforts by the Secretary (then Donna Shalala) to sanction physicians for providing what HCFA believed were unreasonable or unnecessary services had reduced physicians' use of ABNs. Now, with the enactment of Section 4507, there was no way for patients to self-pay for some services. In other words, Section 4507 was actually denying care to some beneficiaries. Once again, beneficiaries called upon the courts to address the issue.

The second test of private contracting came in a case called *United Seniors Association et al. v. Shalala*. This time, an organization called the United Seniors Association and four of its members who were Medicare beneficiaries filed suit in the U.S. District Court for the District of Columbia on December 30, 1997. Their complaint claimed that Section 4507 violated the First, Fourth, Fifth, Ninth, and Fourteenth Amendments to the U.S. Constitution. The plaintiffs claimed, among other things, that Section 4507 invaded the privacy of Medicare beneficiaries and represented an exercise of power not contemplated in Article I, Section 8, of the Constitution.[56]

As in *Stewart*, the plaintiffs in *United Seniors* did not ask the courts to declare that the Constitution guarantees a broad right of Medicare beneficiaries and their physicians to contract privately—despite some feeling among proponents of private contracting that the plaintiffs should have done so. Proponents of that strategy maintained, correctly, that even when Medicare makes services available through a participating physician, Congress has no legitimate power to deny a beneficiary the options of paying for those services himself, paying more than Medicare prescribes, or purchasing them from the physician of his choice. The plaintiffs reasoned, however, that the courts would be more likely to strike down an act of Congress that actually denied care to beneficiaries than to declare that the Constitution broadly forbids any infringement on the right of patients and physicians to contract privately. For strategic reasons, then, the plaintiffs argued only that Section 4507 should be struck down because, for many beneficiaries, it made certain medical services effectively unavailable. Such a denial

With the changes to the *Medicare Carriers' Manual* and the passage of Section 4507, the right of Medicare beneficiaries to self-pay effectively disappeared.

of care would infringe upon the right to privacy as embedded in the First, Fourth, Fifth, Ninth, and Fourteenth Amendments to the U.S. Constitution.

Establishing that Section 4507 denied care to beneficiaries was therefore critical to getting a court to void that provision on constitutional grounds. Without a clear presentation that Section 4507 was denying health care to Medicare beneficiaries, no court would seriously entertain a constitutional challenge. Consequently, the plaintiffs went to considerable lengths to illustrate how that provision denied care. Physicians testifying on behalf of United Seniors cited examples. Prostate-specific antigen tests, an otherwise covered service to detect prostate cancer, generally could not be provided more frequently than Medicare considered "medically necessary" unless the patient paid for the test himself. A host of other screening tests were often performed with less symptomology than the Secretary prescribed.[57] The sanctions attached to Secretary Shalala's strict policing of ABNs made physicians reluctant to pursue that option. By eliminating beneficiaries' freedom to pay for those services themselves, Section 4507 effectively denied beneficiaries access to those services. Section 4507 not only denied care to Medicare beneficiaries outright; in some cases, it could deny beneficiaries the best care available. For example, if the amount Medicare paid for arthroscopic knee surgery was too low, surgeons might instead perform a "total knee replacement"—an antiquated procedure that is more invasive and painful for the patient.[58]

No doubt some physicians over-bill Medicare for such services. However, the members of the United Seniors Association sought nothing more than the right to purchase these services with their own money. The federal government should have the power to determine what services it will and will not cover, particularly if it can base those decisions on scientific evidence. However, neither Congress nor the Medicare bureaucracy has any legitimate power to prevent seniors from spending their own money on medical care.

Plaintiffs sought nothing more than the right to purchase services with their own money.

Contrary to the position taken by the previous administration in *Stewart*, the Clinton administration's HHS Secretary responded to the *United Seniors* petition by arguing that private contracting had always been prohibited under Medicare.[59] With respect to her additions to the 1993 *Medicare Carriers Manual*, the Secretary claimed that Section 4507 was a "liberalization" of that ban in that it gave physicians the option to contract privately if they withdrew from the Medicare program for two years.[60] In other words, Secretary Shalala's argument in *United Seniors* was that Secretary Sullivan's argument in *Stewart* (that there was no policy prohibiting private contracting) was erroneous. Yet the *Stewart* court had relied upon that error in rendering its opinion.

Moving for summary judgment, the Secretary claimed that the plaintiffs had failed to demonstrate an actual case or controversy or to allege a sufficient injury to maintain standing. She further argued that the privacy of Medicare beneficiaries was not impaired by the enforcement of Section 4507 as Medicare beneficiaries had *waived* their right to privacy by enrolling in the program. At bottom, counsel for the Secretary argued:

> [The plaintiffs] don't want to get out of Medicare; they want everything Medicare will give them. But in selective cases, they want to get out when it suits their interests and they can afford it. And what you will have is a system whereby the rich can buy what they want and those many beneficiaries who are on fixed incomes will not be able to afford those services.[61]

Judge Thomas Hogan replied: "I think [the foregoing argument] is probably congressional policy, but I think it is wrong."[62]

In the end, the court awarded the Secretary summary judgment. Although stating that it was "concerned . . . that the regulations and interpretations by HCFA further limit patient's access to physicians of their own choosing," the court refused to find that the

Constitution confers upon the citizen a privacy right to seek and obtain health care services, free from governmental interference. The court said nothing about the denial of care. Rather, it commented that it "is not inclined to create new areas of constitutional protection."[63] What new areas of constitutional protection had the U.S. District Court been asked to "create"? What made the right to privacy, which the Supreme Court had recognized for decades,[64] a new area of constitutional protection?

When the *United Seniors* plaintiffs appealed that decision to the U.S. Court of Appeals for the District of Columbia, the Secretary came to oral arguments with a new approach. Counsel for the Secretary claimed that HCFA would no longer sanction physicians who utilize ABNs so long as the services rendered "are in accordance with accepted standards of medical care even though they do not meet Medicare's particular and often unique coverage requirements."[65] The Secretary argued that new regulations were being promulgated, and indeed, new regulations appeared 10 days after oral argument.

The Secretary's new policy toward ABNs reduced the risk of sanctions for physicians who use ABNs to provide care that carriers later determine to be out of step with Medicare's standards for medical necessity.[66] In other words, Medicare would less often interfere when patients used their own money to purchase *non*covered services, which reduced the likelihood that HCFA's effective ban on private contracting would deny care to beneficiaries. As such, the Secretary's new policy essentially conceded that the combined effect of HCFA's restrictions on ABNs and Section 4507's effective ban on private contracting was denying medical care to Medicare beneficiaries. Otherwise, there would have been no reason to relax its policing of ABNs.

The court concluded that the Secretary's new "liberalizing" of the ABN procedure allowed beneficiaries to obtain the care they were being denied by the enactment of Section 4507. As far as the court was concerned, the constitutional issue ceased to exist the moment that the Secretary changed the official policy toward ABNs. Only by backing away from her insistence on threatening physicians who utilized ABNs did the Secretary provide the court a means of deciding the issue without addressing the validity of Section 4507.[67]

The following describes the conditions under which Medicare beneficiaries are free to purchase medical care in the wake of *United Seniors* and the Secretary's relaxed policy toward ABNs:

1. When it is obvious that Medicare does not cover particular services, a beneficiary is free to spend his own money on those services without fear of reprisals against him or the provider.
2. If Medicare coverage of a particular service hinges on a "medical necessity" determination by a carrier, and the physician believes that the carrier may determine the service will not be covered, the Secretary's relaxed policy toward ABNs makes it less likely that the physician will be penalized for providing that service. The relaxed ABN policy therefore increases seniors' freedom to purchase such noncovered services and reduces (but does not eliminate) the likelihood that seniors will be denied access to such services.
3. If a service is covered by Medicare, Section 4507 effectively prohibits beneficiaries from purchasing that service themselves. At present, Section 4507 seldom denies care to beneficiaries—but only because Medicare payments to providers are generally sufficient to guarantee access. It is likely, however, that as Medicare's fiscal pressures mount Congress eventually will reduce provider payments, which will reduce beneficiaries' access to care. If and when that occurs, Section 4507 will deny care to Medicare beneficiaries, because it will prevent beneficiaries from going outside Medicare to purchase those services themselves. In the meantime, even

If and when Congress reduces provider payments, Section 4507 will deny care to Medicare beneficiaries.

though most beneficiaries enjoy full access to covered services, Section 4507 effectively eliminates beneficiaries' right to keep their medical records private, because it eliminates their freedom to purchase covered services (e.g., psychiatric care) outside the Medicare program.

Importantly, the Secretary's new ABN policy did not surrender the Medicare bureaucracy's power to interfere with the provision of noncovered services. It merely changed the standard that the Medicare bureaucracy would use to decide which of those private contracts they would prohibit. Just as Secretary Shalala unilaterally relaxed that standard, a subsequent secretary could reinstate the previous standard or curtail that freedom even further. Medicare beneficiaries are effectively barred from spending their own money on covered services and are free to spend their own money on noncovered services only at the pleasure of an unelected bureaucrat.

Medicare beneficiaries are barred from spending their own money on covered services and are free to spend their own money on non-covered services only at the pleasure of an unelected bureaucrat.

The *United Seniors* case marginally expanded the freedom of Medicare beneficiaries to obtain noncovered services at their own expense by pushing the Secretary to allow physicians to provide that care more freely without fear of sanction. However, it was that very change that allowed the court to avoid the question of whether Section 4507 is constitutionally deficient. That is, the courts have yet to consider whether Congress or CMS has any legitimate power to prevent Medicare beneficiaries from spending their own money on medical care. As a result, that freedom languishes for all but the wealthiest seniors.

Chaoulli et al. v. Quebec

Around the same time that the debate over the right to purchase medical care reached an uneasy standoff in the United States, Canada was gearing up to expand that freedom. In Canada, a national health insurance regime, also known as Medicare but covering all citizens, had been in place for many years. The provincial governments administer nearly all health care services to their citizens through Medicare programs that conform to the federal Canada Health Act. In Quebec, provincial legislation prohibited residents from purchasing health insurance that covers services already covered under Quebec's Medicare program. What made the prohibition against private insurance so onerous were the long and widely recognized waiting lists for even life-saving medical treatment.

In 1997, a physician, Dr. Jacques Chaoulli, and a patient, George Zeliotis, brought a civil action in Quebec challenging the constitutionality of this prohibition.[68] Like the plaintiffs in *United Seniors*, Chaoulli and Zeliotis claimed that the prohibition violated their rights under the Quebec *Charter of Human Rights and Freedoms*,[69] and the *Canadian Charter of Rights and Freedoms*.[70] They reasoned that because the consequences of Canada's waiting lists were so severe, and because private health insurance would give patients quicker access to medical care, the prohibition on private health insurance threatened the lives and health of Canadian citizens.[71]

Two lower courts ruled against Chaoulli and Zeliotis before the case reached the Supreme Court of Canada.[72] There, four of the seven justices found the Quebec prohibitions violated the *Quebec Charter*. They found that Canada's Medicare system forces patients to wait for necessary—and even life-saving—health care services, and that the waiting lists were so long that the prohibition on private health insurance effectively denied Quebec citizens their fundamental rights to life and personal security.[73] The majority found that there was no rational justification for the prohibition that would override the harm. Justice Deschamps wrote for the Court:

> The central question raised by the appeal is whether the prohibition is justified by the need to preserve the integrity of the public system. In this regard, when my colleagues ask whether Quebec has the power under the constitution to discourage the

> establishment of a parallel health care system, I can only agree with them that it does. But that is not the issue in the appeal. The appellants do not contend that they have a constitutional right to private insurance. Rather, they contend that the waiting times violate their rights to life and security. It is the measure chosen by the government that is in issue, not Quebec's need for a public health care system.[74]

Justice Deschamps further argued that courts should not be timid when the political branches of government threaten fundamental human rights:

> This is not a case in which the Court must show deference to the government's choice of measure. The Courts have a duty to rise above political debate. When, as in the case at bar, the Courts are given the tools they need to make a decision, they should not hesitate to assume their responsibilities. Deference cannot lead the judicial branch to abdicate its role in favor of the legislative branch or the executive branch.[75]

The majority of the Court found that the waiting times for health care services had become "an implicit form of rationing" and that prohibiting citizens from making their own arrangements to purchase care infringed upon the life and security of each citizen.[76] Consequently, the court struck down the prohibition on private health insurance on the grounds that the law violated Section 1 of the *Quebec Charter*.[77]

The *Chaoulli* decision did not completely restore the right to purchase medical care oneself. The Court found that the ban on private health insurance violated the rights to life and personal security only when the government failed to provide adequate care through its Medicare program. Moreover, Canadians have yet to sort out whether the ruling applies only to Quebec, or to Canada as a whole. Because of an abstention, the Court was deadlocked over whether the ban on private insurance violated the federal *Canadian Charter of Rights and Freedoms*.

In sum, the Canadian Medicare system continues to threaten the patient's right to purchase medical care. Nevertheless, Canada is moving in the right direction by allowing some patients to purchase covered medical services when the government-run program fails to meet their needs. Unfortunately, reformers in the United States are moving in the opposite direction.

Conclusion

Among the hazards of universal coverage is that when government fails to meet the patient's needs, it often prohibits patients from purchasing medical care on their own. That is not merely something that takes place under some foreign systems of socialized medicine. It exists today, in the United States, under the federal Medicare program.

The U.S. government effectively prohibits Medicare beneficiaries from going outside the Medicare program to obtain higher-quality care, or to keep private medical information out of government databases. What little progress has been made in preventing this policy from blocking access to medical care could be revoked at any time by an unelected bureaucrat. This policy creates the very type of two-tiered health care system its proponents fear, and the gap between those two tiers will grow as the Medicare's fiscal problems worsen. In contrast, Canada's system of socialized medicine is moving (albeit slowly) in the direction of greater protection of patients' rights.

Congress should restore the freedom of Medicare beneficiaries to spend their own money on medical care as they see fit and prevent the federal bureaucracy from interfering in purely private and voluntary transactions between patients and their doctors. Congress should do so immediately, before Medicare's looming financial troubles combine with

Canada is moving in the right direction. Unfortunately, reformers in the United States are moving in the opposite direction.

this unwise policy and begin denying care to large numbers of seniors.

Moreover, federal and state lawmakers should reject health care reforms that would encourage further interference in the private decisions of American patients. The experience with both the Canadian and American Medicare programs should serve as a cautionary note for those who support a government-run universal health care system: the right to control one's medical care is a frequent casualty of such schemes.

Notes

1. John Locke, *The Works of John Locke*, vol. 1 (London, 1812) p. 341; David N. Mayer, *The Constitutional Thought of Thomas Jefferson* (Charlottesville: University of Virginia Press, 1994), p. 75; R. Gavison, "Privacy and the Limits of Law," *Yale Law Journal* 89 (1980): 421; D. A. J. Richards, "Unnatural Acts and the Constitutional Right of Privacy: A Moral Theory," *Fordham Law Review* 45 (1977): 1281.

2. Joseph Story, *Commentaries on the Constitution of the United States*, vol. 2 (Boston, 1873), p. 669.

3. Thomas M. Cooley, *A Treatise on the Law of Torts*, 2nd ed., (Chicago, 1888), p. 29.

4. S. D. Warren and Louis D. Brandeis, "The Right to Privacy," *Harvard Law Review* 4 (1890): 193.

5. *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965).

6. E.g., *Union Pacific Railroad Company v. Botsford*, 141 U.S. 250, 251 (1890) (Courts are without constitutional power to direct anyone to invade the privacy of one's body even if the extent of injury thereto is the subject of judicial inquiry); *Meyer v. Nebraska*, 262 U.S. 390 (1923) (State is without constitutional power to proscribe the teaching of a foreign language in an otherwise private school); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (State proscribing use of contraceptives invades the constitutionally protected right of marital privacy); *Roe v. Wade*, 410 U.S. 113 (1973) (Texas statute prohibiting abortions except on medical advice for purpose of saving life of mother, regardless of stage of pregnancy, invades constitutionally protected right of privacy); *Doe v. Bolton*, 410 U.S. 179 (1973) (Georgia statute prohibiting abortion except when determined by hospital committee and two physicians separate from patient's physician that it is necessary to save the life of the woman or protect her from serious injury, at any stage of pregnancy, invades woman's constitutionally protected right of privacy); *Planned Parenthood of Southern Pennsylvania v. Casey*, 505 U.S. 833 (1992)(Pennsylvania statute requiring spousal notification prior to abortion imposes an undue burden on woman's constitutionally protected right of privacy).

7. *Planned Parenthood*, 505 U.S. 833.

8. 42 U.S.C. § 1395(a): "Any individual entitled to insurance benefits under this subchapter may obtain health services from any institution, agency, or person qualified to participate under this subchapter if such institution, agency, or person undertakes to provide him such services."

9. 42 U.S.C. § 1395(b).

10. See, e.g., *Szekely v. Florida Medical Association*, 517 F.2d at 345 (11th Cir., 1975), cert. den. 425 U.S. 960 (1976) (government recoupment of funds paid to physician for what was alleged to be unnecessary services did not constitute impermissible supervision of practice of medicine); *College of American Pathologists v. Heckler*, 734 F.2d 859 (D.C. Cir., 1984) (a regulation providing that hospital-based pathologists reimbursed on basis of reasonable cost cannot seek compensation outside Medicare Program held not to constitute unlawful interference with practice of medicine); and *Portland Adventist Medical Center v. Heckler*, 561 F.Supp. 1092 (D.D.C., 1983) (limitations on reimbursement under Medicare to the "reasonable cost" incurred do not constitute prohibited interference with the practice of medicine). All are exemplary of the judicial pronouncements on the subject.

11. *United Seniors Association et al. v. Shalala*, 182 F.3d 965 (D.C. Cir., 1999); and *Stewart et al. v. Sullivan*, 816 F.Supp. 281 (D.N.J., 1992); *Affidavit of J. Patrick Rooney* at 1, *Stewart*, 816 F.Supp. 281 (No. 92-417).

12. U.S. Government Accountability Office, "Privacy: Domestic and Offshore Outsourcing of Personal Information in Medicare, Medicaid and TRICARE," (Washington: Government Accountability Office, September 5, 2006), p. 5, http://www.gao.gov/new.items/d06676.pdf.

13. Social Security and Medicare Boards of Trustees, "A Summary of the 2007 Annual Reports," April 23, 2007, http://www.ssa.gov/OACT/TRSUM/trsummary.html.

14. Gerard F. Anderson, Uwe E. Reinhardt, Peter S. Hussey, and Varduhi Petrosyan, "It's The Prices, Stupid: Why The United States Is So Different From Other Countries," *Health Affairs* 22 (2003): 89–105.

15. See, e.g., Jennifer O'Sullivan and Cecilia O.

Echeverría, "Medicare: Private Contracts," *CRS Report for Congress*, 97-944 EPW, October 21, 1997, pp. 3–4, www.law.umaryland.edu/marshall/crsreports/crsdocuments/97-944_EPW.pdf.

16. Ibid., p. 5.

17. U.S. Government Accountability Office, "High-Risk Series: An Update," GAO-05-207, January 2005, p. 86, http://www.gao.gov/new.items/d05207.pdf.

18. See, e.g., Physicians for a National Health Program, "What Is Single Payer?" http://www.pnhp.org/facts/what_is_single_payer.php; journalist Jonathan Cohn in Kaiser Family Foundation, "A Forum about the Book 'Sick: The Untold Story of America's Health Care Crisis–and the People Who Pay the Price,'" transcript, April 17, 2007, p. 33, http://www.kaisernetwork.org/health_cast/uploaded_files/041707_kff_cohn_transcript.pdf; and columnist Paul Krugman, "One Nation, Uninsured," *The New York Times*, June 13, 2005, http://select.nytimes.com/search/restricted/article?res=F70611F6355C0C708DDDAF0894DD404482.

19. See, e.g., Rep. Pete Stark, "Medicare for All," *The Nation* (online), January 19, 2006, http://www.thenation.com/doc/20060206/stark; Sen. Edward M. Kennedy, "Text: Sen. Kennedy on the Future of the Democratic Party," *Washingtonpost.com* (transcript), January 12, 2005, http://www.washingtonpost.com/ac2/wp-dyn/A4354-2005Jan12?language=printer; Ezra Klein, "Medicare for All," June 13, 2005, http://ezraklein.typepad.com/blog/2005/06/medicare_for_al.html; and Kucinich 2008, "Universal Health Care," November 16, 2006, http://kucinich.us/issues/universalhealth.php.

20. SB 840 § 140000.6, 2006 Leg., Reg. Sess. (Ca. September 18, 2006) (as enrolled, vetoed by governor), http://www.leginfo.ca.gov/pub/05-06/bill/sen/sb_0801-0850/sb_840_bill_20060912_enrolled.pdf.

21. *Chaoulli et al v. Quebec* (Attorney General) 2005 SCC 35, http://www.lexisnexis.ca/documents2006SCC035.pdf, paragraphs 14, 987.

22. 42 U.S.C. § 1395-1395(i).

23. 42 U.S.C. § 1395(j)-1395(w)-4.

24. 42 U.S.C. § 1395(u),(b), and (f).

25. 42 U.S.C. § 1395(w)-21, et seq.

26. 42 U.S.C. § 1395(w)-101, et seq.

27. 42 U.S.C. § 1395u(a), (b), (c), (d), and (f).

28. The regulations covering enrollment in Part B of Medicare require that, two months before an individual becomes entitled to Part A benefits, he be forwarded a notice informing him that he will be enrolled in Part B automatically unless he declines in writing. 42 C.F.R. § 407.17(a), (b)(1) and (2). With the advent of Medicare, private insurers who used to offer coverage to the elderly or disabled left the marketplace altogether. *United Seniors Association et al. v. Shalala*, 182 F.3d 965; (D.C. Cir., 1999) and *Stewart et al. v. Sullivan*, 816 F.Supp. 281 (D.N.J. 1992); *Affidavit of J. Patrick Rooney* at 1, *Stewart*, 816 F.Supp. 281 (No. 92-417). It can hardly be argued that a government insurance program is purely voluntary if that program eliminates all other insurance options. And of course, no part of Medicare is voluntary for the taxpayers who finance the program.

29. 42 C.F.R. § 407.27(d).

30. 42 U.S.C. § 1395u(b)(4).

31. See, e.g., Jennifer O'Sullivan and Cecilia O. Echeverría, "Medicare: Private Contracts," *CRS Report for Congress*, 97-944 EPW, October 21, 1997, pp. 3-4, www.law.umaryland.edu/marshall/crsreports/crsdocuments/97-944_EPW.pdf.

32. 42 U.S.C. § 1395u(b)(4), (h)-(j). The "temporary fee freeze" was challenged in the case of *Whitney et al. v. Heckler*, 603 F.Supp. 821 (N.D. Ga., 1985), aff'd, 780 F.2d 963 (11th Cir., 1986).

33. 42 U.S.C. § 1395w-4 (g)(1) and (2). According to 4§ 1395w-4(g)(1): "If a non-participating physician knowingly and willfully bills on a repeated basis for physician's services . . . an actual charge in excess of the limiting charge . . . the Secretary may apply sanctions against the physician. . . ." Such sanctions could include exclusion from the Medicare Program for up to five years and civil monetary penalties and assessments of up to $10,000 for each offense and double the amount charged or claimed for the item or service provided. § 1320a-7a(a), § 1395u(j)(2)(A) and (B).

34. 42 U.S.C. § 1395l(h)(5).

35. 42 U.S.C. § 1395w-4 (g)(4)(A) and (B)(ii). Sanctions may be imposed only when the physician acts "knowingly and willfully," and the sanction may not exceed $10,000.00 per instance. § 1320a-7a(a), § 1395u(p)(3)(A). If a knowing and willful violation occurs "in repeated cases," though, the physician may be subject to the same exclusionary and monetary penalties that apply to repeated and knowing and willful violations of the limiting charge. § 1395a-7a(a), § 1395u(p)(3)(B).

36. 42 U.S.C. § 1395u(b)(3)(B)(ii), 1395u(j),

1395u(l); 1395y(a)(1)(A); 1320a-7a(a).

37. Of course, the determination of whether a service is not "reasonable and necessary" is subjective. A patient may believe a service is necessary even if the carrier does not. Indeed, carriers often make such determinations on the basis of narrow economic considerations, without regard to the costs and benefits facing the patient.

38. 42 U.S.C. § 1395u(l)(I)(c)(ii); § 1320a-7a(a) (penalties).

39. *Stewart et al. v. Sullivan*, 816 F.Supp. 281, 284-85 (D.N.J., 1992); *Verified Amended Complaint for Declaratory Judgment and Injunctive Relief, Sullivan*, 816 F.Supp. 218 (No. 92-417) ("Complaint").

40. *Stewart*, 816 F.Supp. at 285.

41. Exhibit A, *Complaint, Stewart*, 816 F.Supp. 218 (No. 92-417).

42. *Stewart*, 816 F.Supp. at 285; *Affidavit of Camilla G. Taylor* at 4–5, *Stewart*, 816 F.Supp. 218 (No. 92-417).

43. *Stewart*, 816 F.Supp. at 285; *Affidavit of Joseph M. Scherzer, M.D.* at 2, *Stewart*, 816 F.Supp. 218 (No. 92-417).

44. 42 U.S.C., § 1395 w-4(g)(4)(A). Emphasis added.

45. 42 U.S.C., § 1395u and 1395w-4.

46. 5 U.S.C. § 553. Generally speaking, the APA requires federal agencies to publish notice of a proposed rule in the *Federal Register* and then provide the public an opportunity for comment before the rule is made final. The Secretary's interpretation of the Medicare statute to forbid private contracting was clearly "rule-making" that required notice and comment. Under 5 U.S.C. § 551(4), a "rule" means "an agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy . . ." Under Section 551(5), "rule-making" is defined as the "agency process for formulating, amending or repealing a rule . . ."

47. 42 U.S.C. § 13951(h)(5); *Association of American Physicians and Surgeons v. Bowen*, 909 F.2d 161 (6th Cir., 1990). In that case, Medicare carriers used bulletins to threaten "non-participating" physicians who directly billed beneficiaries for clinical diagnostic laboratory services (as the law then required). The U.S. Court of Appeals for the Sixth Circuit found for the association and private physician members and directed the U.S. District Court for the Northern District of Ohio to enter an injunction against the Secretary.

48. *Stewart*, 816 F.Supp. at 286–89.

49. *Stewart*, 816 F. Supp. at 288–91.

50. *Federal Procedure*, 1:10–1:22.

51. *Whitney et al. v. Heckler*, 780 F.2d 963, 969 (11th Cir., 1986). When the issue of ripeness was raised by the Secretary in response to a group of Atlanta-based physicians who challenged the constitutionality of the temporary fee freeze, the U.S. Court of Appeals for the Eleventh Circuit wrote: "[I]t is well established that an issue is ripe for judicial review when the challenging party is placed in the dilemma of incurring the disadvantages of complying or risking penalties for noncompliance." Almost every federal circuit has cited *Whitney* on the issue of establishing standing to challenge government action under Medicare. It is the leading case in the nation on that issue.

52. Dr. Copeland and her patients raised the Article I, Section 1, constitutional question alternatively in their case. The court addressed that alternative issue thus: "From my reading of the Verified Amended Complaint, Plaintiffs' papers and the position taken by the Plaintiffs at oral argument, I understand Plaintiffs'constitutional attack to be predicated on a finding by the court that the statutory provision being challenged authorizes the alleged policy. Inasmuch as I have concluded that plaintiffs' challenge to the alleged policy of the Secretary is not ripe for determination because plaintiffs have failed to establish the existence of such a policy, I find that it is unnecessary to address Plaintiffs' constitutional attack on the statute." *Stewart*, 816 F.Supp. at 291. Of course, the plaintiffs did not attack the statute; they attacked the HCFA's regulatory pronouncements. By not addressing the issue raised, the court allowed the Secretary to legislate.

53. *Defendant's Reply to Plaintiffs' Response to Defendant's Motion to Dismiss or, in the Alternative, for Summary Judgment* at 7, *United Seniors Association et al. v. Shalala*, 2 F.Supp.2d 39 (D.D.C., 1998) (No. 97-3109).

54. 42 U.S.C. § 1395a(b).

55. *Affidavit of Merrill Matthews, Jr., Ph.D.* at 3–5, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109). Subsequent research shows that roughly 97 percent of physicians participate in Medicare, and that participation is higher in among "procedurally oriented" specialties including surgery, cardiology, dermatology, gastroenterology, and radiation oncology. U.S. Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, March 2007, p. 104, http://www.medpac.gov/documents/Mar07_EntireReport.pdf.

56. *Verified Complaint for Declaratory Judgment and*

Preliminary and Permanent Legislative Relief, passim, United Seniors, 2 F.Supp.2d 39 (No. 97-3109) ("Complaint").

57. These included glyceated hemoglobin, glyceated protein, lipid panel, thyroid function, ferritin, carcinoembryonic antigen and glucose tests; screening for bacterial or spirochetal diseases, infectious diseases, and malignant neoplasms; screening for endocrine, nutritional, metabolic and immune disorders; screening for disorders of the blood and blood-forming organs, for mental disorders and developmental disorders, for neurological, eye and ear diseases, for cardiovascular, respiratory and genitourinary diseases, as well as other conditions. These were all otherwise covered services. *Affidavit of David V. Young, M.D. and Martha S. Young* at 2–12, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109); *Complaint* at 22–23, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109). Theoretically, the physician could draw the blood for the test under an ABN, but the laboratory would not perform the test because it would know that payment would be denied. Neither the physician nor the laboratory could bill the patient directly. Indeed, either could face sanctions as a result of having filed an ABN.

58. *Affidavit of David V. Young, M.D., and Martha S. Young* at 10, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109); *Affidavit of Robert P. Nirschl, M.D.* at 8–10, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109).

59. *Defendant's Memorandum of Points and Authorities in Opposition to Plaintiffs' Motion for a Preliminary Injunction and in Support of Defendant's Motion to Dismiss or, in the Alternative, for Summary Judgment* at 15-20, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109); *Defendant's Reply to Plaintiffs' Response to Defendant's Motion to Dismiss or, in the Alternative, for Summary Judgment* at 5-7, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109).

60. *Defendant's Reply to Plaintiffs' Response to Defendant's Motion to Dismiss or, in the Alternative, for Summary Judgment* at 5–7, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109).

61. *Transcript of Oral Argument* at 41, *United Seniors*, 2 F.Supp.2d 39 (No. 97-3109).

62. Ibid.

63. *United Seniors*, 2 F.Supp. 2d at 41, n.3.

64. *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965).

65. 63 *Federal Register* 58, 850, 58, 901; *United Seniors et al. v. Shalala*, 182 F.3d 965, 973 (D.C. Cir., 1999).

66. This change did not reduce the risk of sanctions to zero, however. Some physicians and their patients will undoubtedly run afoul of even the new, more lenient rule because they seek to purchase care that is not "in accordance with accepted standards of medical care." For example, how will CMS decide what constitutes using ABNs on a "blanket basis"? Moreover, the widespread mistrust of CMS among physicians and beneficiaries, and the fact that the Secretary could reverse this rule at any time, impose a chilling effect on ABNs, because physicians and beneficiaries may have little confidence that CMS will give deference to the wishes of beneficiaries. See, e.g., David A. Hyman, *Medicare Meets Mephistopheles* (Washington: Cato Institute, 2006), pp. 19–20.

67. *United Seniors*, 182 F.3d at 971–4.

68. Jacques Chaoulli, the physician who prosecuted the civil case *Chaoulli et al. v. Quebec*, discussed the importance of that ruling in "A Seismic Shift: How Canada's Supreme Court Sparked a Patients' Rights Revolution," Cato Institute Policy Analysis no. 568, May 8, 2006, http://www.cato.org/pub_display.php?pub_id=6378.

69. Section 1 of the *Quebec Charter of Human Rights and Freedoms* reads: "Every human being has a right to life, and to personal security, inviolability and freedom. He also possesses judicial personality." *Quebec Charter*, R.S.Q., c.C-12, s.1.

70. Section 7 of the *Canadian Charter of Rights and Freedoms* reads: "Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice." *Canadian Charter*, s.1.

71. *Chaoulli et al v. Quebec* (Attorney General) 2005 SCC 35, http://www.lexisnexis.ca/documents2006SCC035.pdf, paragraphs 14, 987.

72. *Chaoulli,* 2005 SCC 35, http://www.lexisnexis.ca/documents2005SCC035.pdf., paragraphs 6, 7, 8, 11.

73. The latter is Quebec's equivalent to what is referred to in the United States as the "right to privacy," the primary argument in *United Seniors*.

74. *Chaoulli*, 2005 SCC 35, paragraph 14.

75. *Chaoulli*, 2005 SCC 35, 5, paragraph 87.

76. *Chaoulli*, 2005 SCC 35, paragraph 39.

77. *Chaoulli*, 2005 SCC 35, paragraphs 200, 101.

OTHER STUDIES IN THE POLICY ANALYSIS SERIES

600. **Taiwan's Defense Budget: How Taipei's Free Riding Risks War** by Justin Logan and Ted Galen Carpenter (September 13, 2007)

599. **End It, Don't Mend It: What to Do with No Child Left Behind** by Neal McCluskey and Andrew J. Coulson (September 5, 2007)

598. **Don't Increase Federal Gasoline Taxes—Abolish Them** by Jerry Taylor and Peter Van Doren (August 7, 2007)

597. **Medicaid's Soaring Cost: Time to Step on the Brakes** by Jagadeesh Gokhale (July 19, 2007)

596. **Debunking Portland: The City That Doesn't Work** by Randal O'Toole (July 9, 2007)

595. **The Massachusetts Health Plan: The Good, the Bad, and the Ugly** by David A. Hyman (June 28, 2007)

594. **The Myth of the Rational Voter: Why Democracies Choose Bad Policies** by Bryan Caplan (May 29, 2007)

593. **Federal Aid to the States: Historical Cause of Government Growth and Bureaucracy** by Chris Edwards (May 22, 2007)

592. **The Corporate Welfare State: How the Federal Government Subsidizes U.S. Businesses** by Stephen Slivinski (May 14, 2007)

591. **The Perfect Firestorm: Bringing Forest Service Wildfire Costs under Control** by Randal O'Toole (April 30, 2007)

590. **In Pursuit of Happiness Research: Is It Reliable? What Does It Imply for Policy?** by Will Wilkinson (April 11, 2007)

589. **Energy Alarmism: The Myths That Make Americans Worry about Oil** by Eugene Gholz and Daryl G. Press (April 5, 2007)

588. **Escaping the Trap: Why the United States Must Leave Iraq** by Ted Galen Carpenter (February 14, 2007)

587. **Why We Fight: How Public Schools Cause Social Conflict** by Neal McCluskey (January 23, 2007)

586. **Has U.S. Income Inequality *Really* Increased?** by Alan Reynolds (January 8, 2007)

585. **The Cato Education Market Index** by Andrew J. Coulson with advisers James Gwartney, Neal McCluskey, John Merrifield, David Salisbury, and Richard Vedder (December 14, 2006)

584. **Effective Counterterrorism and the Limited Role of Predictive Data Mining** by Jeff Jonas and Jim Harper (December 11, 2006)

583. **The Bottom Line on Iran: The Costs and Benefits of Preventive War versus Deterrence** by Justin Logan (December 4, 2006)

582. **Suicide Terrorism and Democracy: What We've Learned Since 9/11** by Robert A. Pape (November 1, 2006)

581. **Fiscal Policy Report Card on America's Governors: 2006** by Stephen Slivinski (October 24, 2006)

580. **The Libertarian Vote** by David Boaz and David Kirby (October 18, 2006)

579. **Giving Kids the Chaff: How to Find and Keep the Teachers We Need** by Marie Gryphon (September 25, 2006)

578. **Iran's Nuclear Program: America's Policy Options** by Ted Galen Carpenter (September 20, 2006)

577. **The American Way of War: Cultural Barriers to Successful Counterinsurgency** by Jeffrey Record (September 1, 2006)

576. **Is the Sky *Really* Falling? A Review of Recent Global Warming Scare Stories** by Patrick J. Michaels (August 23, 2006)

575. **Toward Property Rights in Spectrum: The Difficult Policy Choices Ahead** by Dale Hatfield and Phil Weiser (August 17, 2006)

574. **Budgeting in Neverland: Irrational Policymaking in the U.S. Congress and What Can Be Done about It** by James L. Payne (July 26, 2006)

573. **Flirting with Disaster: The Inherent Problems with FEMA** by Russell S. Sobel and Peter T. Leeson (July 19, 2006)

572. **Vertical Integration and the Restructuring of the U.S. Electricity Industry** by Robert J. Michaels (July 13, 2006)

571. **Reappraising Nuclear Security Strategy** by Rensselaer Lee (June 14, 2006)

570. **The Federal Marriage Amendment: Unnecessary, Anti-Federalist, and Anti-Democratic** by Dale Carpenter (June 1, 2006)

569. **Health Savings Accounts: Do the Critics Have a Point?** by Michael F. Cannon (May 30, 2006)

568. **A Seismic Shift: How Canada's Supreme Court Sparked a Patients' Rights Revolution** by Jacques Chaoulli (May 8, 2006)

567. **Amateur-to-Amateur: The Rise of a New Creative Culture** by F. Gregory Lastowka and Dan Hunter (April 26, 2006)

566. **Two Normal Countries: Rethinking the U.S.-Japan Strategic Relationship** by Christopher Preble (April 18, 2006)

565. **Individual Mandates for Health Insurance: Slippery Slope to National Health Care** by Michael Tanner (April 5, 2006)

564. **Circumventing Competition: The Perverse Consequences of the Digital Millennium Copyright Act** by Timothy B. Lee (March 21, 2006)

563. **Against the New Paternalism: Internalities and the Economics of Self-Control** by Glen Whitman (February 22, 2006)

562. **KidSave: Real Problem, Wrong Solution** by Jagadeesh Gokhale and Michael Tanner (January 24, 2006)

561. **Economic Amnesia: The Case against Oil Price Controls and Windfall Profit Taxes** by Jerry Taylor and Peter Van Doren (January 12, 2006)

560. **Failed States and Flawed Logic: The Case against a Standing Nation-Building Office** by Justin Logan and Christopher Preble (January 11, 2006)

559. **A Desire Named Streetcar: How Federal Subsidies Encourage Wasteful Local Transit Systems** by Randal O'Toole (January 5, 2006)

558. **The Birth of the Property Rights Movement** by Steven J. Eagle (December 15, 2005)

557. **Trade Liberalization and Poverty Reduction in Sub-Saharan Africa** by Marian L. Tupy (December 6, 2005)

556. **Avoiding Medicare's Pharmaceutical Trap** by Doug Bandow (November 30, 2005)

555. **The Case against the Strategic Petroleum Reserve** by Jerry Taylor and Peter Van Doren (November 21, 2005)

554. **The Triumph of India's Market Reforms: The Record of the 1980s and 1990s** by Arvind Panagariya (November 7, 2005)

Published by the Cato Institute, Policy Analysis is a regular series evaluating government policies and offering proposals for reform. Nothing in Policy Analysis should be construed as necessarily reflecting the views of the Cato Institute or as an attempt to aid or hinder the passage of any bill before Congress. Contact the Cato Institute for reprint permission. Additional copies of Policy Analysis are $6.00 each ($3.00 each for five or more). To order, or for a complete listing of available studies, write the Cato Institute, 1000 Massachusetts Ave., N.W., Washington, D.C. 20001 or call toll free 1-800-767-1241 (8:30-4:30 eastern time). Fax (202) 842-3490 • www.cato.org

CATO INSTITUTE