United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 23, 1998 Decided July 16, 1999

No. 98–5142

UNITED SENIORS ASSOCIATION, INC., ET AL.,
APPELLANTS

v.

DONNA E. SHALALA, SECRETARY,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 97cv03109)

Kent Masterson Brown argued the cause for appellants. With him on the briefs was *Frank M. Northam. Jerome P. Friedlander, II,* entered an appearance.

Thomas M. Bondy, Attorney, U.S. Department of Justice, argued the cause for appellee. With him on the brief were

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Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Frank W. Hunger, Assistant Attorney General, *Wilma A. Lewis*, U.S. Attorney, and *Barbara C. Biddle*, Attorney, U.S. Department of Justice.

John S. Hoff, *Arthur B. Spitzer* and *Jeffrey P. Altman* were on the brief for amici Citizens Against Government Waste, et al.

Before: WILLIAMS, SENTELLE and GARLAND, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* GARLAND.

GARLAND, *Circuit Judge*: Section 4507 of the Balanced Budget Act of 1997 provides that, for certain medical services, a doctor may not contract with a Medicare beneficiary outside of Medicare unless the doctor agrees to abstain from participating in the Medicare program for two years. Plaintiffs, a senior citizens' organization and four individual Medicare beneficiaries, contend that section 4507 is unconstitutional on a number of grounds. The district court found the statute constitutional and granted summary judgment for the Secretary of Health and Human Services. We affirm the grant of summary judgment without reaching the constitutional questions because the Secretary's recently-clarified interpretation of section 4507, to which we must defer, eliminates the injury that is the basis of plaintiffs' constitutional attack.

I

Medicare is a comprehensive insurance program designed to provide health insurance benefits for individuals 65 and over, as well as for certain others who come within its terms. *See* 42 U.S.C. §§ 1395c, 1395j. The program is administered by the Health Care Financing Administration (HCFA), a part of the U.S. Department of Health and Human Services (HHS). In broad terms, Medicare Part A, which is not at issue in this case, covers care provided by institutional health care providers including hospitals. *See id.* §§ 1395c-1395i. Medicare Part B, which is the focus here, covers medical services including those provided by physicians. *See id.* §§ 1395j to 1395w–4. Part B is financed by a combination of government funding and premiums paid by beneficiaries. *See*

id. § 1395j. Doctors who provide medical services to Part B beneficiaries must submit claim forms identifying the services provided. *See id.* § 1395w–4(g)(4)(A)(i). They receive compensation in accordance with fee schedules that limit the amount they may charge and be paid. *See id.* § 1395w–4(g)(2)(C), (D).[1]

Certain kinds of medical services, such as routine physical checkups, are categorically excluded from Medicare coverage. *See id.* § 1395y(a)(7). Those that are not categorically excluded may only be reimbursed when medically "reasonable and necessary." *Id.* § 1395y(a)(1)(A). If a service is deemed not to have been reasonable and necessary, Medicare will not make payment and the doctor generally is prohibited from charging the patient. *See id.* § 1395u(b)(3)(B)(ii), (*l*)(1)(A).[2]

Because at the time a physician provides a service it may not be certain whether Medicare will regard it as reasonable and necessary, the Medicare program includes a provision for an "Advance Beneficiary Notice" ("ABN"). Under this provision, in advance of providing a service the doctor may give the patient an ABN, which advises that Medicare may not pay for the service. *See id.* § 1395u(*l*)(1)(C)(ii). If the

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[1] Under Medicare, "participating physicians" generally do not bill their patients, but instead take an assignment of their patients' rights and receive payment directly from Medicare. "Nonparticipating physicians" may accept assignments on a case-by-case basis or bill their patients directly. In the latter circumstance, it is the patient who obtains reimbursement from Medicare. In all cases, however, the fee schedules effectively limit the doctor's compensation. *See* 42 U.S.C. §§ 1395u(b), (h), (i); *id.* §§ 1395w–4(a), (b), (g); 42 C.F.R. §§ 402.1, 402.105, 405.504.

[2] HHS enters into contracts with insurance carriers which receive and process claims for payment for medical services provided to Part B enrollees. 42 U.S.C. § 1395u(a). Claims are submitted to a carrier, which makes an initial determination as to whether the service is covered. 42 C.F.R. § 405.803; *id.* § 421.200. Medicare beneficiaries, or the physicians to whom they have assigned their rights to payment, may require carriers to review their determinations and are entitled to post-review hearings. *Id.* § 405.801.

patient agrees to pay from his or her own funds if Medicare does not, and if Medicare subsequently denies payment, the doctor may bill the patient directly. *See id.*

In August 1997, Congress enacted section 4507 of the Balanced Budget Act of 1997, Pub. L. 105–33, § 4507, 111 Stat. 251, 439 (codified at 42 U.S.C. § 1395a). The section establishes rules for what it describes as "the use of private contracts by medicare beneficiaries." *Id.* Section 4507(b)(1) permits doctors and patients to contract for certain services outside of Medicare and without its fee limitations:

> Subject to the provisions of this subsection, nothing in this title shall prohibit a physician or practitioner from entering into a private contract with a medicare beneficiary for any item or service—
>
> (A) for which no claim for payment is to be submitted under this title, and
>
> (B) for which the physician or practitioner receives . . . no reimbursement under this title. . . .

42 U.S.C. § 1395a(b)(1); *see id.* § 1395a(b)(4). Section 4507(b)(2), entitled "[b]eneficiary protections," lists certain provisions that private contracts authorized by (b)(1) must include:

> Any contract to provide items and services to which paragraph (1) applies shall clearly indicate . . . that by signing such contract the Beneficiary—
>
> (i) agrees not to submit a claim (or to request that the physician or practitioner submit a claim) under this title for such items or services even if such items or services are otherwise covered by this subchapter;
>
> (ii) agrees to be responsible, whether through insurance or otherwise, for payment of such items or services and understands that no reimbursement will be provided under this title for such items or services;
>
> (iii) acknowledges that no limits under this title . . . apply to amounts that may be charged for such items or services;
>
> . . . ; and

> (v) acknowledges that the medicare beneficiary has the right to have such items or services provided by other physicians or practitioners for whom payment would be made under this title.

Id. § 1395a(b)(2)(B).

Finally, section 4507(b)(3) further provides that such private contracts are authorized only if the physician signs an affidavit which states that he or she

> will not submit any claim under this title for any item or service provided to any medicare beneficiary (and will not receive any [Medicare] reimbursement ... for any such items or service) during the 2–year period beginning on the date the affidavit is signed....

Id. § 1395a(b)(3)(B)(ii). This means that a doctor who enters into a section 4507 private contract with even a single patient is barred from submitting a claim to Medicare on behalf of any patient for a two-year period.

II

Plaintiffs contend that section 4507 effectively makes it impossible for them to contract for medical services outside of the Medicare system—particularly for services Medicare will not cover, either because they are categorically excluded or because Medicare deems them unreasonable or unnecessary in a particular case. As plaintiffs read the section, it governs almost any agreement between a doctor and patient to provide medical services outside of Medicare, without regard to whether Medicare would pay for the service if a claim were submitted. Plaintiffs argue that it will be virtually impossible to find a doctor willing to enter into such an agreement, given the importance of Medicare to doctors' practices and the two-year bar the statute imposes for entering into even a single private contract.[3] The Secretary concedes that very few

[3] Plaintiffs note that over 96% of practicing physicians receive Medicare Part B reimbursement. Pl. Br. at 11–12. They also note that to date, only 300 doctors nationwide have filed section 4507

doctors will be willing to opt out of Medicare, Oral Arg. Tr. at 22, and generally agrees that the two-year restriction "represents a substantial barrier to the receipt of contracted services." *United Seniors Ass'n., Inc. v. Shalala*, 2 F. Supp. 2d 39, 41 (D.D.C. 1998).

Plaintiffs also reject the suggestion that the ABN procedure provides a way to relieve the constraints imposed by section 4507. They recognize that an agreement under an ABN is not a "private contract" under section 4507, and hence is not subject to its two-year bar. *See* 63 Fed. Reg. 58,814, 58,851 (1998). In theory this should mean that patients can obtain services they and their doctors consider reasonable or necessary, even if Medicare ultimately does not, by executing ABNs. But plaintiffs regard the ABN option as unworkable. First, it does not apply to services categorically excluded from Medicare. Second, plaintiffs contend that under HCFA rules, doctors who routinely use ABNs to obtain reimbursement for services Medicare deems unreasonable or unnecessary are subject to penalties and sanctions. Thus, plaintiffs do not view ABNs as a practical solution to the problem created by section 4507.

Nor, plaintiffs contend, is it realistic to suggest that senior citizens can avoid the restrictions of section 4507 by simply opting out of Medicare Part B altogether. Notwithstanding the government's repeated suggestion that "plaintiffs may disenroll at any time" from Part B, *see, e.g.*, HHS Br. at 3, 27, 28, 29, at oral argument it conceded there is no "meaningful equivalent to Medicare" in the private market. Oral Arg. Tr. at 18–19.[4] Accordingly, opting out is hardly a viable way for patients to bypass section 4507.

Plaintiffs' complaint charges that the restrictions imposed by section 4507 violate the First, Fourth, Fifth, Ninth, Tenth

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contracts with the Secretary of Health and Human Services. Pl. Reply Br. at 4 (citing 9 Medicare Rep. (BNA) 18 (May 1, 1998)).

[4] *See United Seniors*, 2 F. Supp. 2d at 41 n.2 ("Medicare is, in effect, the only primary health insurance available to people over 65. No private health insurance companies offer 'first dollar' insurance to this group; they offer only supplemental insurance.").

and Fourteenth Amendments to the Constitution, as well as the Spending Clause of Article I, section 8. Plaintiffs contend those restrictions violate their liberty to contract privately for health care services, violate their ability to maintain the privacy of their medical information by requiring them to file claims for all medical services, and violate their equal protection and due process rights by denying them the same liberty to contract enjoyed by other citizens. They also contend that section 4507 exceeds Congress' powers under the Spending Clause, and invades the reserved powers of the States and the people under the Tenth Amendment, by regulating health care for which the federal government does not pay.

Critical to our analysis is that the injury plaintiffs assert is to their ability to purchase services for which Medicare will not itself pay, thus rendering them unable to obtain those services on any terms. Oral Arg. Tr. at 4–6. The right they assert is to contract for services they and their doctors regard as necessary or even merely salutary, regardless whether Medicare agrees. Section 4507 abridges this right, they contend, by making it virtually impossible to find a doctor willing to enter into a private contract with a Medicare beneficiary. Plaintiffs made clear at oral argument, however, that they disavow any claim to a constitutional right to pay their doctors more than the Medicare fee limits for services they can obtain through Medicare. *Id.*

III

The district court examined plaintiffs' constitutional claims, rejected them on the merits, and granted summary judgment for the Secretary. *See United Seniors*, 2 F. Supp. 2d at 42. We review the grant of summary judgment de novo. *Hunter-Boykin v. George Washington Univ.*, 132 F.3d 77, 79 (D.C. Cir. 1998). When we do so, we find we have no need to reach the merits of plaintiffs' constitutional claims. After careful examination and clarification of the Secretary's interpretation of section 4507, we find that interpretation effectively eliminates the injury—whether of constitutional magnitude

or not—that plaintiffs fear, and provides them with all the relief they seek.

The Secretary contends that plaintiffs have simply misunderstood section 4507. The purpose of the section, she argues, is to prevent doctors from coercing elderly patients into paying more for Medicare-covered services than Medicare's fee schedules permit. HHS Br. at 10, 12. Consistent with that purpose, the section—including its two-year bar—applies only to services that Medicare *would* reimburse but for the private contract. *Id.*; Oral Arg. Tr. at 51–52. If a patient and doctor want to enter into a private contract for such services, the doctor must wholly opt out of the system for two years. HHS Br. at 14.

The Secretary stresses, however, that section 4507 does not do what plaintiffs assert—that is, it does not impose restrictions on agreements to provide services for which Medicare *would not* pay. Hence, if a doctor and patient agree with respect to a service that would not be reimbursed by Medicare—either because it is categorically excluded or because it is deemed unreasonable or unnecessary in the particular case—then the agreement does not fall within section 4507 and the doctor is not subject to the two-year bar. HHS Br. at 9–10, 18, 23; Oral Arg. Tr. at 48–49. The Secretary also contends that plaintiffs have misunderstood the ABN procedure which, she says, provides a workable way to handle those charges as to which Medicare payment is uncertain. HHS Br. at 23.

At oral argument, plaintiffs made clear that *if* section 4507 really says what the Secretary says it says, then their case is at an end. Oral Arg. Tr. at 4–5, 59. Plaintiffs have no interest, they aver, in obtaining the right to enter into agreements to pay more for services they can obtain for less under Medicare. *Id.* Rather, their interest—and the constitutional right they assert—is in obtaining services they cannot get under Medicare at any price. *Id.* at 6. The plaintiffs are skeptical, however, that section 4507 really means what

the Secretary says it means—and equally skeptical that the Secretary actually reads and applies it that way.

Plaintiffs' skepticism is not unjustified. The meaning of section 4507 is hardly plain on its face. Moreover, because HCFA did not promulgate formal regulations regarding the section until ten days after the oral argument in this case, its own interpretation could only be gleaned from memoranda issued to Medicare carriers and testimony delivered to Congress, of which Medicare beneficiaries may well have been unaware. Nonetheless, as we discuss below, the Secretary's interpretation is a reasonable interpretation of the less-than-plain language of section 4507. In addition, the Secretary's current interpretation, as foreshadowed in the briefs filed in this case and expressed in the subsequent regulations, is consistent with the position HCFA has taken since the section was enacted. Under *Chevron U.S.A. Inc. v. National Resources Defense Council, Inc.*, if a statute is ambiguous we must defer to an agency's reasonable interpretation of its terms. 467 U.S. 837, 842–45 (1984); *see United States v. Haggar Apparel Co.*, 119 S. Ct. 1392, 1395 (1999). This is so regardless whether there may be other reasonable, or even more reasonable interpretations. *See Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1321 (D.C. Cir. 1998). Following the injunction of the Supreme Court, we are required to accord such deference here.

A

Section 4507 of the Balanced Budget Act does not clearly indicate the kinds of services to which it applies. Paragraph (1) of subsection (b) states that "[s]ubject to the provisions of this subsection, nothing in this title shall prohibit a physician or practitioner from entering into a private contract with a Medicare beneficiary for any item or service . . . for which no claim for payment is to be submitted under this title. . . ." 42 U.S.C. § 1395a(b)(1). This provision is the source of plaintiffs' apprehension, since it appears to apply to any service—Medicare-reimbursable or not—for which no claim for payment is submitted.

But the introductory clause of paragraph (1) makes it "[s]ubject to the provisions of this subsection." To understand the scope of paragraph (1), therefore, we must examine the balance of subsection (b). The key language is in paragraph (2), which states that "[a]ny contract to provide items and services to which paragraph (1) applies shall clearly indicate ... that *the medicare beneficiary has the right to have such items or services provided by other physicians or practitioners for whom payment would be made under this title.*" 42 U.S.C. § 1395a(b)(2)(B) (emphasis added). The Secretary argues that since "any" private contract under section 4507 must indicate that the beneficiary has "the right" to have the same services paid for by Medicare, section 4507 should be read as applying only to services that Medicare would reimburse but for the parties' private contract. Although we find the relationship between paragraphs (1) and (2) less than plain, the Secretary's interpretation of section 4507 is at least a reasonable one.

B

Our parsing of the language of section 4507 leads us to conclude that it is reasonable to read section 4507 as applying only to private contracts for services that are reimbursable under Medicare. Plaintiffs question, however, whether that truly is the way HCFA reads section 4507. Although it is unquestionably the view expressed in the Secretary's briefs in this case, plaintiffs contend it has not previously been the position of HCFA.

Even if the legal briefs contained the first expression of the agency's views, under the appropriate circumstances we would still accord them deference so long as they represented the agency's "fair and considered judgment on the matter." *Auer v. Robbins*, 117 S. Ct. 905, 912 (1997); *see Association of Bituminous Contractors, Inc. v. Apfel*, 156 F.3d 1246, 1251–52 (D.C. Cir. 1998); *Tax Analysts v. IRS*, 117 F.3d 607,

613 (D.C. Cir. 1997). In this case, however, HCFA has expressed similar views since Congress first enacted section 4507. Although until recently those views were expressed only in the form of memoranda and congressional testimony, "an agency need not promulgate a legislative rule setting forth its interpretation of a statutory term for that interpretation to be entitled to deference." *Association of Bituminous Contractors*, 156 F.3d at 1252. Moreover, although HHS' past pronouncements have not been perfectly clear, an agency's interpretation of its own rules is "controlling unless 'plainly erroneous or inconsistent' " with them. *Auer v. Robbins*, 117 S. Ct. at 911; *see United States v. Stinson*, 508 U.S. 36, 45 (1993). In this case, the agency's past and current views are not inconsistent.

The Secretary first calls our attention to a program memorandum and fact sheet HCFA issued to all Medicare carriers in November 1997. *See* HCFA, Program Memorandum, Transmittal No. B–97–9 (Nov. 1997) (Joint Appendix ("J.A") 207–08). Consistent with the Secretary's position here, the fact sheet describes section 4507 as applying to "private contracts with Medicare beneficiaries to provide *covered services*." *Id.* The document then expressly states that "[w]ith respect to *non-covered services*, a private contract is unnecessary and section 4507 does not apply." *Id.* at 208. This means, the fact sheet says, that "beneficiaries continue to be able to pay for any services that Medicare does not cover out of their own pockets ... without having to enter into a private contract subject to the provisions of section 4507."

The HCFA fact sheet lists cosmetic surgery, hearing aids and routine physical examinations as examples of "non-covered" services. Although these services are all of the categorically-excluded variety, the next paragraph of the fact sheet states that a physician may also "furnish a service that Medicare covers under some circumstances but which the physician anticipates would not be deemed 'reasonable and necessary' by Medicare in the particular case." *Id.*; *see also*

Oral Arg. Tr. at 53 (HHS counsel's explanation of "non-covered" as including services not necessary in particular case). If the beneficiary receives an ABN for such a service, the fact sheet continues, "a private contract [under § 4507] is not necessary to bill the beneficiary if the claim is denied." J.A. 208.

The fact sheet concludes that when a physician and beneficiary enter into a private contract to provide services "that would otherwise be covered by Medicare," the physician must "'opt out' of Medicare for a two-year period." *Id.* The phrase, "would otherwise be covered by Medicare," is not free from ambiguity. Plaintiffs suggest, and worry, that it refers to services that would be covered but for Medicare's conclusion that they are not reasonable and necessary in the particular case. Under that reading, services the doctor believes are necessary but Medicare does not could only be provided under section 4507 (with its two-year bar). But such a reading would be inconsistent with the language discussed in the preceding paragraph, which makes clear that payment for a claim denied on the ground that the service was not necessary does not require a section 4507 contract. The Secretary, by contrast, interprets "would otherwise be covered by Medicare" as meaning "covered but for the fact that the parties have entered into a private contract." This reading is consistent both with the rest of the fact sheet, and with the Secretary's position that physicians must opt out of Medicare only if they enter into contracts for services that Medicare would reimburse but for those contracts themselves.[5]

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[5] Another HCFA program memorandum, issued to all Medicare carriers in January 1998 and specifically addressed to "the implementation of . . . § 4507," is also consistent with this interpretation. *See* HCFA, Program Memorandum, Transmittal No. B–97–17 (Jan. 1998) (J.A. 225–26) (stating that private contracts with their attendant opt-out rules are not required for services: (1) that are "categorically exclude[d]" from Medicare; (2) that are "not covered because, under Medicare rules, the service is never found to be medically necessary to treat illness or injury"; or (3) for which

On February 26, 1998, the Administrator of HCFA submitted a statement to the Senate Finance Committee intended to "clarify" "substantial misunderstanding about what section 4507 of the Balanced Budget Act does." J.A. 254. Consistent with the HCFA fact sheet just discussed, the Administrator stated that a private contract under section 4507 is one for which the service "would be covered if a claim were submitted" to Medicare, *id.* at 252, and that such a contract is the only kind to which the opt-out rule applies, *id.* at 254. "A physician does *not* have to opt out of Medicare for two years," she said, "in order to provide a non-covered service to a Medicare beneficiary." *Id.* at 255. Nor does a physician have to opt out when, employing the ABN procedure, the doctor provides a service Medicare later determines was not reasonable and necessary. *Id.* at 256.[6]

At oral argument, counsel for the Secretary advised that HCFA was planning to issue formal regulations incorporating the above-stated views. Those regulations were published on November 2, 1998. *See* 63 Fed. Reg. at 58,901. Consistent with the position recounted above, the explanatory preamble

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"Medicare denies the claim on the basis that the service was not medically necessary" in the particular beneficiary's case).

[6] The Administrator used prostate specific antigen tests (PSAs) as an example to make her point. J.A. 256. Medicare currently covers such tests only when used for diagnosis to evaluate a symptom of a particular patient, and only when such use is reasonable and necessary. Medicare will not pay for the tests when used for screening patients across the board. "Therefore," the Administrator said, "a private contract is not needed when a beneficiary wants a PSA test for screening purposes because it is not now a covered service." *Id.* Likewise, the Administrator explained, a physician may believe "that Medicare is likely to deny payment for a certain diagnostic PSA (for example, when the patient wants to have the test more frequently than Medicare would likely pay for [it])." *Id.* In such circumstances, although an ABN should be used, section 4507 does not apply. *Id.* at 256–57. *See also* Balanced Budget Act of 1997, Pub. L. 105–33, § 4103, 111 Stat. 251, 362 (codified at 42 U.S.C. § 1395*l*(h)(1)(A)) (providing coverage for screening PSA tests beginning in the year 2000).

states that "[t]he private contracting rules do not apply to . . . services that Medicare does not cover." *Id.* at 58,850. It further states that when a physician "furnishes a service that does not meet Medicare's criteria for being reasonable and necessary, and the [physician] has furnished the beneficiary with an ABN . . . , there are no limits on what the [physician] may charge the beneficiary. . . . [and] [t]he act of providing an ABN does not then require that the [physician] opt-out of Medicare. . . ." *Id.* at 58,851.

On the basis of our examination of HCFA's announced views, we conclude that the agency has consistently interpreted section 4507 and its opt-out rules as applying only to contracts for services that Medicare itself would reimburse.

C

Finally, we briefly address plaintiffs' contention that the ABN procedure is not a realistic way to ensure patients' access to services they or their doctors regard as necessary but Medicare does not. Under the ABN procedure, before providing a service the physician informs the patient that Medicare may not pay, and obtains the patient's agreement to pay on his or her own if Medicare denies the claim. *See* 42 U.S.C. § 1395u(*l*)(1)(C)(ii). As noted above, because an ABN is not considered a private contract under section 4507, if Medicare does not pay the doctor may receive payment from the patient without being subject to the opt-out rule. *See* 63 Fed. Reg. at 58,851.[7]

Plaintiffs contend that the ABN option is illusory because HCFA has a policy of sanctioning doctors who repeatedly use ABNs for services they believe warranted but Medicare regards as unnecessary and will not reimburse.[8] The Secre-

[7] An ABN is neither utilized nor necessary for services categorically excluded from Medicare, and section 4507 has no application to such services. *See* J.A. 255–57 (statement of HCFA Administrator).

[8] Plaintiffs also contend that if their doctor is a "participating physician" who bills Medicare directly, *see supra* note 1, or if the

tary vehemently denies having such a policy. HHS Br. at 24. At least on their face, HCFA's pronouncements support the Secretary since they expressly advise doctors to employ ABNs in precisely those circumstances. Standard ABN forms, for example, require a statement that the patient has "been informed by my physician that he or she believes that, in my case, Medicare is likely to deny payment." J.A. 94; *see also* 42 C.F.R. § 411.408(f) ("[T]he physician must inform the beneficiary ... that the physician believes Medicare is likely to deny payment."). Similarly, a 1998 HCFA program memorandum explains that where a service is not covered by Medicare because it is "never found to be medically necessary," the physician may charge the patient without opting out "only if he or she gives the beneficiary" an ABN. J.A. 225.[9] These pronouncements would make no sense if HCFA did not intend doctors to use ABNs for services they believe Medicare would regard as unnecessary.

The preamble to HCFA's new regulations should also give plaintiffs some comfort. It notes that ABNs may state that

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medical service they seek is one statutorily required to be provided on an assignment basis, *see, e.g.*, 42 U.S.C. § 1395*l*(h)(5)(C) (clinical diagnostic laboratory tests), then the ABN procedure may not be used. Although the language of the statutory ABN provision appears to support this contention, *see id.* § 1395u(*l*)(1)(A), the Secretary interprets other statutory provisions and HCFA regulations to permit a doctor to obtain an ABN agreement in such circumstances and to charge the patient if Medicare denies payment. HHS Br. at 25 n.5 (citing 42 U.S.C. § 1395pp; 42 C.F.R. §§ 411.402(a)(2), 411.404; HCFA, Medicare Carriers Manual §§ 7300.5, 7330.D).

[9] Where the service is one Medicare never finds medically necessary, the memorandum states that "no claim need be submitted." J.A. 225. A claim "must be submitted," however, if the service "is one which Medicare has determined is medically necessary where certain clinical criteria are met, but is not medically necessary where these criteria are not met." *Id.* In both cases, "if Medicare denies the claim on the basis that the service was not medically necessary, the physician or practitioner who has given the advance beneficiary notice may bill the beneficiary." *Id.*

the physician "believes that the service will not be covered by Medicare" and that the "act of providing an ABN does not then require that the physician or practitioner opt-out of Medicare so that he or she avoids being at risk of having a penalty assessed...." 63 Fed. Reg. 58,851. And it closes with an effort to assuage precisely the concern plaintiff expresses here: "[P]hysicians and practitioners should not hesitate to furnish services to Medicare beneficiaries when the physician or practitioner believes that those services are in accordance with accepted standards of medical care, even when those services do not meet Medicare's particular and often unique coverage requirements." *Id.*

It should not be missed, of course, that HCFA exempts from this note of encouragement those services not "in accordance with accepted standards of medical care." *Id.* This qualifier may well explain some of the confusion. Although a HCFA regulation does state that ABNs are not acceptable if the "physician routinely gives this notice to all beneficiaries for whom he or she furnishes services," 42 C.F.R. § 411.408(f)(2)(i), the Secretary makes clear that this rule is aimed at a doctor who "require[s] all his patients to sign ABNs on a blanket basis *in order to bill them for unwarranted procedures*." HHS Br. at 24 (citing § 411.408) (emphasis added). Needless to say, billing patients for unwarranted procedures may well be subject to sanction, *see generally* 42 U.S.C. § 1320a–7(b)(6)(B), and plaintiffs do not urge otherwise.

In sum, the evidence before us does not support the assertion that HCFA interprets the ABN procedures in a manner that denies plaintiffs access to services they regard as reasonable or necessary. We have briefly addressed this question because of plaintiffs' contention that it is linked to the section 4507 issue. We should note, however, that the ABN issue is analytically distinct from plaintiffs' facial challenge to the constitutionality of section 4507, since ABNs are not private contracts under that section and are not governed by it. To the extent plaintiffs feel HCFA enforces the ABN statute and regulations in a manner inconsistent with the

agency's own pronouncements, they are of course free to challenge such enforcement in a particular case.

IV

Because the Secretary's reading of section 4507 eliminates the constitutional injury plaintiffs allege, and because we are bound under *Chevron* to defer to that interpretation, the order of the district court is affirmed.

UNITED SENIORS WINS SWEEPING VICTORY FOR NATION'S SENIOR CITIZENS IN COURT OF APPEALS

In a published decision handed down by the United States Court of Appeals for the District of Columbia Circuit on Friday, July 16, 1999, the United Seniors Association and four of its members achieved a stunning judicial victory which guarantees to the nation's seniors the ability to obtain all the health care services they desire free from government interference. The decision is the most sweeping pronouncement ever made by any Court on the subject of Medicare beneficiaries' access to health care.

United Seniors Association filed suit in the United States District Court for the District of Columbia on December 30, 1997 seeking a declaratory judgment that Section 4507 of the Balanced Budget Act of 1997 unconstitutionally limited Medicare beneficiaries' ability to spend their own money to obtain health care under private contracts with their doctors. United Seniors asserted that, under the system then in place, a doctor could not freely give to his or her Medicare patients health care services if he or she believed the Secretary of the U.S. Department of Health and Human Services ("Secretary") would, or even might, determine they were not "reasonable or necessary" even though the doctor felt, under his or her professional standards of care, that those

services were reasonable and necessary to the patient's health and well-being. If the Secretary found that a doctor had provided a "pattern" of services that she determined were not "reasonable or necessary," the doctor could have been forced to pay stiff monetary penalties (up to $10,000 per instance) or cited for fraud. Thus, doctors were chilled from delivering many necessary health care services to Medicare beneficiaries, particularly screening laboratory tests which the Secretary's Inspector General had singled out for significant restrictions. As contracting privately for such services was the **only** means by which Medicare beneficiaries could obtain them, Section 4507, United Seniors claimed, unconstitutionally prohibited Medicare beneficiaries from using their own money to provide for their own health care.

The District Court declined to rule that Section 4507 was unconstitutional because, it said, the Supreme Court had not specifically extended the right to autonomous decision-making to give individuals a constitutional right to contract privately for health care services. The District Court upheld the restrictions of Section 4507, although it sharply criticized the policies of the Secretary that limited Medicare beneficiaries' access to health care services.

United Seniors Association appealed the decision. It was

joined by fifteen *amici*, including the American Civil Liberties Union. On July 16 the Court of Appeals handed down its opinion in the case. The Court declined to reach the constitutionality of the prohibition because it found that the policies of the Secretary with respect to Section 4507 had changed to such an extent during the course of the case that they no longer prohibited Medicare beneficiaries from contracting privately to obtain services for which Medicare, for one reason or another, would not pay.

The Court relied on numerous new restatements and "clarifications" made by the Secretary in both formal and informal ways: her briefs and argument to the Court; her testimony before Congress; the preamble to new regulations issued by her ten days after oral argument in the case; and letter transmittals.

From these new restatements and "clarifications," the Court found that there is now no prohibition against contracting privately where Medicare would not pay for the service, irrespective of whether it is categorically noncovered(e.g., plastic surgery); not "reasonable and necessary" in a particular case; or the Secretary never considers it to be "reasonable and necessary" (screening laboratory tests).

In general, the Court's opinion permits contracting privately for all of these services. If a service might not or would not be

paid by Medicare, the patient and the doctor can contract privately for it and the doctor need **not** comply with the requirements of Section 4507. He or she need not, for instance, opt-out of Medicare for the two-year period specified in that law. Section 4507 has been rendered useless.

The plaintiffs in the well-known case of *Stewart v. Sullivan* in 1992 sought a declaration from a federal court that they could contract privately for, among other things, more house calls per month than that for which Medicare would pay. The ruling of the Court in the *United Seniors* case confirms that they may contract privately for those services. Indeed, even where the Medicare Act requires a service to be provided on an assigned-claim basis, the Court ruled that contracting privately is permissible for services for which Medicare might not or would not pay. The Court specifically mentioned laboratory services, those hotly-contested health care services the Secretary all but eliminated from access by Medicare beneficiaries except where actual symptoms already existed! Medicare beneficiaries, therefore, can contract privately to pay for screening laboratory services that Medicare might not or would never pay for.

After many years and much confusion, consequently, the Court has found that, under the Secretary's restatements and

"clarifications," Medicare beneficiaries can make arrangements with doctors to obtain services for which Medicare might not or would not pay. It is a large step forward.

The Court reached its result by relying on the Secretary's restatements and "clarifications" that doctors may use the Advance Beneficiary Notice ("ABN") procedure in the Medicare Act to provide any service for which Medicare **might** not pay. Under that process, if a doctor believes that Medicare **might** not pay for a service, he or she can give the patient an ABN (which notifies him or her in writing that Medicare may not or would not pay and in which the patient agrees to pay if and when Medicare doesn't) and provide the service. Now, even the Medicare payment limitations do not apply in such arrangements, according to the Secretary's new "clarification" and the Court's opinion. If a doctor believes Medicare **would** not pay for a service, he or she need not follow the ABN process at all; rather he or she could simply contract privately with the Medicare beneficiary as the Court determined Section 4507 does not apply to those circumstances where Medicare **would** not pay for a service.

The Secretary has now said -- and the Court has opined -- that the ABN process should be used as though it was a means contracting privately, and, where Medicare **would** not pay, Section 4507 does not

apply at all. United Seniors had argued that the ABN procedure was not of much help because doctors using it were subject to sanctions for performing a "pattern" of services that the Secretary believed were not "reasonable and necessary." The concerns of United Seniors on that point, said the Court, were "not unjustified." The Court, however, said that United Seniors should not be concerned any longer. Because the Secretary has now stated that the ABN process **should** be used, it means, the Court held, she has surrendered any policy she once had of sanctioning doctors who do so.

The Court echoed the Secretary's assertion that doctors can provide these services only "in accordance with accepted standards of medical care." United Seniors does not disagree. This means, the Court said, that doctors cannot use the ABN process to bill patients for "unwarranted" procedures. Although the Court did not elaborate on it, this new formulation implies that there is a marked difference between services that are not "reasonable and necessary" and those that are "unwarranted." Although the difference between "reasonable and necessary" and "warranted" is unclear, the bar for the imposition of government sanctions has been unquestionably raised so high by the Court that doctors should now be free to provide services to Medicare beneficiaries in

instances where they believe Medicare might find them to be not "reasonable or necessary" or where Medicare always finds them to be not "reasonable and necessary" but doctors believe them to be otherwise.

The Court's decision thus permits Medicare beneficiaries and their doctors to contract privately where Medicare might not or would not pay, but by means of a very liberalized ABN process. The Secretary's last minute weaving and dodging again avoided a knockout of its policy, but it has suffered a blow more severe than ever before.