13-4179-cv

IN THE

United States Court of Appeals for the Second Circuit

RICHARD BAGNALL, BERNICE MORSE, FREDERICK RUSCHMANN, LEE BARROWS, MICHAEL SAVAGE, GEORGE RENSHAW, SARAH MULCAHY, SHIRLEY BURTON, DENISE RUGMAN, ANN PELOW, LOUIS DZIADZIA, LORETTA JACKSON, MARTHA LEYANNA, CHARLES HOLT, IRMA BECKER, JESSIE RUSCHMANN, AND CHRISTINA ALEXANDER

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS,

Defendant-Appellee.

On Appeal from the United States District Court
for the District of Connecticut

BRIEF OF THE AMERICAN HOSPITAL ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

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CORPORATE DISCLOSURE STATEMENT

The American Hospital Association is a non-profit national trade association. It has no parent corporation, and no publicly held corporation holds 10% or more of its stock.

/s/ Catherine E. Stetson

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STATEMENT OF INTEREST[1]

The American Hospital Association represents nearly 5,000 hospitals, health systems and other health care organizations, plus 42,000 individual members. AHA members are committed to improving the health of communities they serve and to helping ensure that care is available to, and affordable for, all Americans.

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[1] No party or counsel for a party authored or paid for this brief in whole or in part, or made a monetary contribution to fund the brief's preparation or submission. No one other than amicus or its members or counsel made a monetary contribution to the brief.

The AHA educates its members on health care issues and advocates to ensure that their perspectives are considered in formulating health care policy.

All parties have consented to the filing of this brief.

ARGUMENT

This litigation highlights an important gap in the Medicare reimbursement rules. Inpatient hospital stays are reimbursed differently from "observation" stays and have different post-hospital coverage consequences, yet the government has not specified when it considers each type of stay to be appropriate. That ambiguity has led to a tug-of-war between beneficiaries and the government. Where there is doubt regarding the proper status of a given hospital stay, the beneficiaries prefer to be admitted as inpatients whereas some in the government believe observation status is more appropriate.

Hospitals and treating physicians are caught in the middle of this tug-of-war. Traditionally, the decision to admit a patient as an inpatient has been committed to the expert judgment of the treating physician, with oversight from the hospital. That is as it should be. As the Centers for Medicare & Medicaid Services ("CMS") has long recognized, the decision to admit a patient is a "complex medical judgment" that involves the consideration of many factors. Medicare Benefits Policy Manual ("MBPM"), Chap. 1, § 10. Indeed, CMS reaffirmed that fundamental principle in a recent rule, even though it also purported to adopt a

bright-line, time-based admission test. See 78 Fed. Reg. 50495, 50908, 50945-47 (Aug. 19, 2013). These fact-sensitive medical judgments do not lend themselves to second-guessing by outside individuals or government auditors.

In recent years, however, some federal contractors, Department of Justice lawyers, and qui tam relators have lost sight of the central role of the treating physician. Recovery Audit Contractors ("RACs") and similar entities—which are charged with auditing Medicare claims and paid on a contingency fee basis—have been denying large numbers of claims for short inpatient stays. The contractors' view, unlike the treating physician's, has always been in hindsight and therefore focused on the patient's length of stay rather than his or her presenting condition. It is therefore not surprising that Medicare contractors conclude that many patients who were admitted as inpatients could instead have received observation services. Hospitals must incur substantial costs appealing those decisions (the great majority of which are ultimately reversed in favor of the treating physician's judgment) or forgo payment for the claims in question.

Worse yet, certain Department of Justice attorneys and whistleblowers are substituting their own medical judgments for those of the treating physician. The lawyers have decided—apparently based on their interpretation of the medical literature—that some types of physician-approved inpatient stays are not medically necessary because the patient could have received adequate care in an observation

bed. In their view, a hospital that submits a claim to Medicare for such an inpatient stay has committed a fraud against the government. Armed with this dubious theory, they have threatened to pursue costly litigation against hospitals under the civil False Claims Act ("FCA") unless the hospitals refund "damages" to Medicare. Rather than risk an astronomical money judgment and exclusion and debarment from federal health care programs, many hospitals have been forced to settle baseless FCA claims for millions of dollars

These trends have led to predictable but troubling consequences. Faced with the prospect of claim denials by contractors and liability under the FCA, hospitals and physicians seem to have become more wary about admitting patients for what could be short inpatient stays. The contractors and prosecutors have made it clear that they believe observation status can serve as a substitute for inpatient admission in many cases. As a consequence, hospitals and physicians may feel pressure to order outpatient observation when a patient is not ready to return home but is unlikely to require a lengthy hospital stay.

This pressure appears to be having an effect on decisions about the setting in which a patient receives care. Observation status and the incidence of longer observation stays is on the rise. A recent study, for example, found that the number of observation stays doubled between 2001 and 2009. Although hospitals and physicians strive to base inpatient admission decisions on clinical

considerations, their judgments may be influenced by the knowledge that particular decisions will be questioned by contractors, government lawyers, and whistleblowers after the fact. CMS's recent decision to require physicians to certify the need for inpatient care (see 78 Fed. Reg. at 50490) will only exacerbate that dilemma.

Hospitals are left in an untenable position. On the one hand, they risk loss of reimbursement, monetary damages, and penalties from auditors and prosecutors when they admit patients for short, medically necessary, inpatient stays. On the other hand, they face criticism from patients and CMS over the perceived use of observation services as a substitute for inpatient admission. Hospitals cannot win no matter how they handle the situation.

The AHA respectfully submits this brief to provide background and context as the Court considers the issues raised in the appeal. The AHA takes no position at this time regarding the proper outcome of this litigation. But however the litigation is resolved, it should be done with sensitivity to the difficult situation hospitals find themselves in with respect to observation status.

I. Inpatient Admission Decisions Should Be Committed To The Judgment Of The Treating Physician.

As the District Court's opinion makes clear, the question when a patient should be classified as an inpatient is consequential for both Medicare beneficiaries and the government. SPA1. Inpatients are covered by Medicare Part A. They pay only a deductible for their stay in a hospital and may be eligible for a Medicare-covered stay in a skilled nursing facility. Outpatients, by contrast, must make coinsurance payments for every service they receive, are responsible for paying for certain "self-administered drugs" that Medicare does not cover, and are not eligible for skilled nursing facility care. The facts of this case illustrate the substantial financial consequences these classifications can have. SPA6-8.

Under longstanding CMS policy, inpatient status is tied to the formal admission decision. An "inpatient" is "a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services." MBPM, Chap. 1, § 10. In other words, a patient is an inpatient if, and only if, the treating physician has "formally admitted" him or her to the hospital. Estate of Landers v. Leavitt, 545 F.3d 98, 111 (2d Cir. 2008).

This definition recognizes the primacy of the treating physician in the admission decision. A patient becomes an inpatient when the treating physician formally decides that he or she should be admitted as an inpatient. A detailed enumeration of the circumstances in which a patient can be admitted as an

inpatient would impermissibly interfere with the treating physician's medical judgment. So too would the time-based admission test that CMS recently adopted.

Additional CMS guidance underscores the central role of the treating physician in hospital admissions. "The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient." MBPM, Chap. 1, § 10. Indeed, to be eligible to participate in Medicare in the first place, hospitals must ensure that patients "are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital." 42 C.F.R. § 482.12(c)(2).

The same principles apply to the decision to order observation services instead of admitting a patient. Outpatient observation is intended to help the attending physician determine the appropriate treatment setting for a patient. Observation services thus "are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge." MBPM, Chap. 6, § 20.6. Because they are so tightly linked with the decision to admit or discharge a patient, observation services must be ordered by a physician. See id.

These policies are sensible. The decision to admit a patient is a "complex medical judgment" that calls for the consideration of many factors, including "patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event." 78 Fed. Reg. at 50944, 50965 (codified at 42 C.F.R. § 412.3(e)(1)). Only the treating physician has both the familiarity with the patient and the medical expertise to weigh these considerations and determine which treatment setting is most appropriate in a given case.

II. Federal Auditors And Prosecutors Are Improperly Second-Guessing Physicians' Independent Medical Judgments.

Although CMS guidance has properly recognized the central role of the treating physician in hospital admission decisions, the government does not speak with one voice on this issue. A treating physician's decision to admit a patient can be—and often is—questioned after the fact by federal auditors and prosecutors.

That questioning would be unobjectionable if it were limited to clear cases of fraud or abuse. But it is not. In recent years, the contractors and prosecutors have been substituting their own medical judgment about whether an inpatient admission is proper for the expert judgment of the treating physician. This second-guessing has placed hospitals in an untenable position: If they give appropriate deference to the treating physician's admission decision, they risk incurring substantial costs and penalties. The pressures arising out of this situation threaten to undermine the independent judgment of the physicians on the site of care.

A. Audit Contractors

Congress and the Department of Health and Human Services have enlisted a host of contractors to help detect and correct Medicare billing errors and abuses. These contractors are known by a variety of acronyms—RACs, MACs, ZPICs, and so on. The differences between the types of contractors are not material for present purposes; all of them essentially function as auditors. For the sake of simplicity, we will limit the following discussion to RACs. It should be noted, however, that many of the problems described here are common to all types of contractors.

To add to the Department of Health and Human Services' resources for identifying and correcting Medicare billing errors, Congress has authorized the Department to hire RACs "for the purpose of identifying [Medicare] underpayments and overpayments and recouping overpayments." 42 U.S.C. § 1395ddd(h)(1). RACs review past Medicare claims for compliance with the payment rules. The process is fairly mechanical. Typically, a nurse employed by the contractor decides whether to approve or deny a claim based on a proprietary screening guide. If the RAC determines that a claim resulted in an improper overpayment, Medicare can recover the amount of the overpayment. The provider can challenge the RAC's finding, but the multi-level appeal process is expensive, cumbersome, and frequently includes lengthy delays beyond the statutory timeline.

Notably, Medicare RACs are paid "on a contingent basis for collecting overpayments." Id. § 1395ddd(h)(1)(B)(i). They can receive up to 12.5% of the overpayment amount for most types of claims, and even more for some types of claims. 77 Fed. Reg. 11127, 11127 (Feb. 24, 2012); 76 Fed. Reg. 57808, 57809 (Sept. 16, 2011). This payment system creates a strong financial incentive for RACs to deny claims. The more claims they deny, the more they are paid. Unsurprisingly, the evidence suggests that these incentives encourage the improper denial of large numbers of claims. According to data collected by the AHA, an astonishing 67% of appealed RAC decisions are ultimately reversed in favor of the provider. American Hospital Ass'n, Exploring the Impact of the RAC Program on Hospitals Nationwide, at 55 (Nov. 21, 2013) ("RAC Report").[2]

Data collected by the AHA indicate that RACs have focused most of their attention on hospital claims for short inpatient stays. See RAC Report at 33-41. This focus is likely driven by financial considerations. Denying payment for an entire inpatient stay is far more lucrative for the contractors than identifying an incorrect payment amount or an unnecessary medical service. Through the third quarter of 2013, RACs recovered nearly $300 million—more than 60% of the total

[2] Available at http://www.aha.org/content/13/13q3ractracresults.pdf (last visited Feb. 19, 2014).

amount recovered—for care that was supposedly provided in the wrong setting. Id. at 34.

The RACs' intense focus on short inpatient stays has made it costly for hospitals to admit patients for such stays. When a RAC questions a claim, the hospital must submit medical records and other documentation supporting the billing classification; challenge and appeal the RAC's denial; and repay the funds in question if the denial is upheld.[3] The administrative burdens and financial consequences associated with these audits are substantial. And to make matters worse, a recently-imposed moratorium on administrative hearings means that hospitals now must wait three or four years before receiving a hearing to challenge a RAC denial. See Office of Medicare Hearings and Appeals, Memorandum to OMHA Medicare Appellants (Dec. 24, 2013).[4]

As a consequence, hospitals and physicians have begun to exercise greater caution when admitting inpatients. Where physicians and hospitals previously may

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[3] A recent rule change theoretically allows providers to "rebill" some of the denied claims as outpatient services under Medicare Part B. See 78 Fed. Reg. 50496, 50909 (Aug. 19, 2013). In practice, however, the vast majority of RAC denials cannot be rebilled because the filing deadline has expired by the time the RAC issues its decision. See American Hospital Ass'n, The RAC Burden (Jan. 6, 2014), available at http://www.aha.org/research/policy/infographics/pdf/info-rac.pdf (last visited Feb. 19, 2014). The AHA has filed a lawsuit challenging CMS's ineffective rebilling policy. See American Hospital Ass'n v. Sebelius, No. 12-cv-1770 (D.D.C.).

[4] Available at http://www.hhs.gov/omha/letter_to_medicare_appellants_from_the_calj.pdf (last visited Feb. 19, 2014).

have erred on the side of more care for vulnerable Medicare patients, who often are quite elderly and have multiple and chronic illnesses, the added enforcement risks appear to be forcing health care providers to place beneficiaries in observation status and see if it suffices.

B. Federal Prosecutors

Inpatient admission decisions have come under a second type of pressure as well. Inspired by a few whistleblowers and their lawyers, certain Department of Justice attorneys have started using the FCA to challenge physicians' inpatient admission decisions. In their layperson's view, many Medicare beneficiaries who have been admitted as inpatients actually should be placed in observation status. When the treating physician instead determines that such a beneficiary should be admitted as an inpatient, these attorneys contend that the resulting services are not "reasonable and necessary for the diagnosis or treatment of illness or injury," and therefore are not covered by Medicare. 42 U.S.C. § 1395y(a)(1)(A). This leads them to a stunning conclusion: Every claim submitted to Medicare for these "unnecessary" inpatient stays amounts to a fraud against the government, punishable under the FCA. CMS's new rule requiring physicians to certify the need for inpatient care only increases the likelihood that a physician's admission decision will be investigated and deemed fraudulent.

One Assistant United States Attorney in the Western District of New York has spearheaded a "kyphoplasty initiative" that dramatically illustrates this new fraud-based approach. Kyphoplasty is a procedure used to treat compression fractures in the spine. In the procedure, the physician makes an incision in the patient's back, drills a small hole through the outer layer of the spine, inflates a special balloon within the vertebra, and then fills the resulting cavity with bone cement. See Mayo Clinic, Kyphoplasty, http://www.mayoclinic.org/vertebroplasty/kyphoplasty.html (last visited Feb. 19, 2014).

In many cases, kyphoplasty can safely be performed on an outpatient basis. But an inpatient stay is more appropriate in some cases because of the patient's complicating conditions or other complicating factors. That is particularly true for the Medicare population, which is older than the general population and tends to suffer from a greater number of health problems. As with all admission decisions, determining the appropriate treatment setting for a kyphoplasty procedure entails a "complex medical judgment" best made by the treating physician. MBPM, Chap. 1, § 10.

The United States Attorney for the Western District of New York takes a different view, however. In letters sent to hospitals across the country, his office has questioned whether inpatient stays for kyphoplasty are "justified" in light of "the availability of observation status." JA318 (Letter from AUSA Robert Trusiak

(June 10, 2010)).[5] The Assistant United States Attorney leading the effort views observation status and short inpatient stays as medically interchangeable: "Observation status provides the same intensity of service as an inpatient setting." JA318. Physicians can therefore place kyphoplasty patients in observation status rather than admitting them as inpatients. "As a general rule," he has said, "kyphoplasty requires only limited post-procedure care, of a type typically available in an observation or outpatient setting." JA320. These assertions are evidently based on the Assistant United States Attorney's own interpretation of the medical literature. See JA320-21 (citing medical journals).

Such letters to hospitals are not intended to be friendly suggestions. They indicate that any Medicare claim for an inpatient stay following a kyphoplasty will be presumed to violate the FCA. See JA317 & n.9. Under the kyphoplasty initiative, an inpatient stay is not medically necessary if the patient could have received equivalent care or achieved an equivalent outcome, in hindsight, through outpatient observation. To avoid liability and corroborate the admitting physician's decision, hospitals have been "requested" to compile a staggering amount of documentation beyond the physician signature that would normally serve as evidence of medical necessity. JA322-26. The message to hospitals from

[5] This letter is one of many form letters that the United States Attorney's Office sent to hospitals in connection with its "kyphoplasty initiative."

the kyphoplasty initiative is clear: Admissions for one day create a presumption of fraud, and unless a hospital relied on more than the judgment of the admitting physician, it risks penalties and FCA liability.

These allegations of fraud are no small matter. FCA violations carry stiff penalties—treble damages plus a substantial per-claim penalty. 31 U.S.C. § 3729(a)(1). The sanctions can easily exceed $100,000,000 in hospital cases. Moreover, a hospital that violates the FCA can be excluded from participating in Medicare and Medicaid and debarred from receiving government contracts and grants; this is often "the equivalent of the death penalty in the health care industry, where much of a provider's business typically is dependent on Medicare reimbursement." Michael Rich, Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in Out-of-Control Qui Tam Litigation Under the Civil False Claims Act, 76 U. Cin. L. Rev. 1233, 1252 (2008).

When the amateur medical judgments of an Assistant United States Attorney are spun into theories of fraud, the consequences for hospitals can thus be grave. Many hospitals understandably have elected to settle with the Department of Justice rather than force it to prove FCA allegations. To date, the Department of Justice has "reached settlements with more than 100 hospitals totaling approximately $75 million to resolve allegations that [the hospitals] mischarged Medicare for kyphoplasty procedures." Press Release, U.S. Dep't of Justice, Fifty-

Five Hospitals To Pay U.S. More Than $34 Million To Resolve False Claims Act Allegations Related To Kyphoplasty (July 2, 2013).[6]

III. Misguided Fraud Prevention Efforts May Be Encouraging The Overuse Of Observation Status.

The message from auditors and prosecutors is clear: When an inpatient stay may be brief, place the patient in observation status. That message—backed by the threat of substantial penalties—has put unfortunate pressures on physicians and hospitals. Physicians' judgments regarding the appropriate treatment setting, and hospitals' oversight of those judgments, are now influenced by the knowledge that certain decisions will inevitably be second-guessed by outsiders. Fear of audits and FCA liability may be leading physicians to order observation stays instead of inpatient stays. Health care providers strive to get it right the first time.

But observation status is not a substitute for an inpatient admission. Outpatient observation is a distinct type of hospital care, which involves ongoing monitoring, testing, assessment, and reassessment solely for the purpose of determining the need to admit a patient. MBPM, Chap. 6, § 20.6; see also id. ("Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.").

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[6] Available at http://www.justice.gov/usao/nyw/press/press_releases/2013/july/55_Hospitals.html (last visited Feb. 19, 2014).

It is different from inpatient, emergency, clinic, and recovery services and does not substitute for or duplicate the services delivered in another setting.

CMS has long held this position. The agency does "not consider observation services and inpatient care to be the same level of care and, therefore, they would not be interchangeable and appropriate for the same clinical scenario." 72 Fed. Reg. 66580, 66814 (Nov. 27, 2007). Indeed, as the Secretary noted below, CMS expressed concern in 2010 about the increasing trend toward longer observation stays. See Dist. Ct. Dkt. 48-1 (Letter from Marilyn Tavenner to Richard Umbdenstock (July 7, 2010)). CMS pointed out that it is "not in the hospital's or the beneficiary's interest to extend observation care rather than either releasing the patient from the hospital or admitting the patient as an inpatient" and solicited the AHA's views regarding the reasons for the trend. Id. And CMS reiterated those concerns in a recent rulemaking. See 78 Fed. Reg. at 50906-07. The push by auditors and the Department of Justice's for greater use of outpatient observation plainly does not represent the considered judgment of the agency charged with administering the Medicare program.

Hospitals are thus in a bind. On the one hand, they risk penalties from auditors and prosecutors when they admit patients for short inpatient stays. On the other hand, they face criticism from patients and CMS over the perceived use of observation status as a substitute for inpatient admission.

The difficulty is traceable in part to the absence of a clear federal policy on observation status. Different officials and agencies have taken different positions on when observation services are appropriate. For example, whereas CMS believes that observation services and inpatient care are "not * * * interchangeable," 72 Fed. Reg. at 66814, the Department of Justice has indicated that observation status "provides the same intensity of service as an inpatient setting" and should be used in lieu of short inpatient stays, JA318. Although CMS attempted to address some of this uncertainly in a rulemaking last year, the resulting policy was deeply flawed and did not provide the clarity needed for consistent decision-making. See Letter from James L. Madara & Rich Umbdenstock to Marilyn B. Tavenner (Nov. 8, 2013).[7]

The current approach to observation status is unsustainable. Without adequate guidance, hospitals will continue to be exposed to claim denials and FCA liability simply for deferring to the medical judgments of patients' admitting physicians.

[7] Available at http://www.aha.org/advocacy-issues/letter/2013/131108-let-aha-ama-cms.pdf (last visited Feb. 19, 2014).

CONCLUSION

The AHA takes no position at this time regarding the proper outcome of this appeal. But however the Court resolves this case, it should do so with sensitivity to the difficult situation hospitals find themselves in with respect to observation status.

Respectfully submitted,

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Dated: February 20, 2014

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitations of Fed. R. App. P. 29(d) because it contains 3,905 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Times New Roman in Microsoft Word 2010 14-point font.

/s/ Catherine E. Stetson

CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2014, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of the filing to all registered users of the CM/ECF system.

/s/ Catherine E. Stetson