UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

RICHARD BAGNALL, et al., **Plaintiffs,** **v.** **KATHLEEN SEBELIUS, Secretary of Health and Human Services,** **Defendant.**	**No. 3:11-CV-1703-AWT** **Hon. Alvin W. Thompson**

AMERICAN HOSPITAL ASSOCIATION'S MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

1. The American Hospital Association respectfully moves for leave to file a brief amicus curiae in support of neither party. Counsel for the parties have indicated that they take no position regarding this motion.

2. The prospective amicus is the American Hospital Association (AHA), which 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. The AHA educates its members on health care issues and advocates to ensure that their perspectives are considered in formulating health care policy. It has appeared regularly before federal courts in cases raising important legal issues. See, e.g., Brief for American Hospital Association et al. as Amici Curiae in Support of Petitioners, Dep't of Health & Human Servs. v. Florida, No. 11-398 (S. Ct. Jan. 13, 2012).

3. The issues in this case deserve close attention, and the proposed amicus brief will aid the Court's consideration. The brief describes the context in which the Plaintiffs' claims arise and highlights some of the background pressures that may be influencing decisions about the setting in which a patient receives care. Although the brief does not take a position regarding the proper outcome of this case, it explains how the current approach to observation status puts hospitals in an untenable position.

For these reasons, the Court should grant leave to file the attached brief amicus curiae.

Dated: April 27, 2012

Respectfully submitted,

/s/ Eric J. Lobenfeld

Eric J. Lobenfeld (Bar No. CT03312)
HOGAN LOVELLS US LLP
875 Third Avenue
New York, NY 10022
Phone: (212) 918-8202
Fax: (212) 918-3100
eric.lobenfeld@hoganlovells.com

Counsel for the American Hospital Association

Sheree R. Kanner
Jonathan L. Diesenhaus
David M. Ginn
HOGAN LOVELLS US LLP
555 Thirteenth St., NW
Washington, DC 20004

Melinda Reid Hatton
Maureen Mudron
AMERICAN HOSPITAL ASSOCIATION
325 Seventh Street, NW
Suite 700
Washington, DC 20001

CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2012, a copy of foregoing Motion for Leave to File Brief Amicus Curiae in Support of Neither Party was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may gain access to this filing through the court's CM/ECF System.

/s/ Eric J. Lobenfeld
Eric J. Lobenfeld (Bar No. CT03312)
HOGAN LOVELLS US LLP
875 Third Avenue
New York, NY 10022
Phone: (212) 918-8202
Fax: (212) 918-3100
eric.lobenfeld@hoganlovells.com

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

RICHARD BAGNALL, et al., **Plaintiffs,** **v.** **KATHLEEN SEBELIUS, Secretary of Health and Human Services,** **Defendant.**	**No. 3:11-CV-1703-AWT** **Hon. Alvin W. Thompson**

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

TABLE OF CONTENTS

STATEMENT OF INTEREST

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

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") recognizes, 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. 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 started denying large numbers of claims for short inpatient stays. The contractors' view, unlike the treating physician's, is always in hindsight and therefore can focus on the patient's length of stay rather than his or her presenting condition. Thus, it is not surprising that Medicare contractors conclude that many patients who were admitted as inpatients could instead have been placed in observation status. 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 hundreds of thousands of—and in some cases more than a million—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. CMS has noted, for example, that the proportion of observation stays exceeding 48 hours doubled between 2006 and 2008. 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.

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 status 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 plaintiffs' complaint. The AHA takes no position at this time regarding the proper outcome of this litigation. 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 parties' briefs make clear, the question when a patient should be classified as an inpatient is consequential for both Medicare beneficiaries and the government. 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 ("SNF"). 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 SNF care. The complaint illustrates the substantial financial consequences these classifications can have.

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).

The plaintiffs criticize that definition as "circular." Pls. Memo. in Opp. at 25, ECF No. 39. But the definition simply 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.

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 "the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting." MBPM, Chap. 1, § 10. 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 properly recognizes 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, the AHA 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 HHS's resources for identifying and correcting Medicare billing errors, Congress has authorized HHS 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, it can recover the amount of the overpayment. The provider can challenge the RAC's finding, but the multi-level appeal process is expensive and cumbersome.

Notably, Medicare RACs are paid "on a contingent basis for collecting overpayments," id. § 1395ddd(h)(1)(B)(i)—currently, between 9% and 12.5% of the overpayment amount. 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 74% of appealed RAC decisions are ultimately reversed. American Hospital Association, Exploring the Impact of the RAC Program on Hospitals Nationwide, at 50 (Feb. 15, 2012) ("RAC Report").[1]

Data collected by the AHA indicate that RACs have focused much of their attention on hospital claims for short inpatient stays. See RAC Report at 4 ("The majority of medical necessity denials reported were for 1-day stays where the care was found to have been provided in the wrong setting, not because the care was not medically necessary."). 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 end of 2011, RACs recovered over $120 million—more than a quarter of the total 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. The administrative

[1] Available at http://www.aha.org/content/11/11Q4ractracresults.pdf (last visited Apr. 27, 2012).

burdens and financial consequences associated with these audits are substantial. Consequently, hospitals and physicians have begun to exercise greater caution when admitting inpatients. Where physicians and hospitals previously may 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.

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 Apr. 27, 2012).

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." Letter from AUSA Robert Trusiak, at 2 (June 10, 2010), Ex. A.[2] 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." Id. at 2. 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." Id. at 4. These assertions are evidently based on the Assistant United States Attorney's own interpretation of the medical literature. See id. at 4–5 (citing medical journals).

[2] The attached letter is one of many form letters that the United States Attorney's Office has sent to hospitals in connection with its "kyphoplasty initiative." The name of the hospital has been redacted.

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 id. at 1 & 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. Id. at 6–10. The message to hospitals from 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). The FCA can have such an extreme punitive effect that courts have occasionally held its prescribed penalties to be unconstitutionally excessive on the facts of a given case. See, e.g., United States ex rel. Bunk v. Birkart Globistics GmbH & Co., No. 02-1168, 2012 WL 488256, at *15 (E.D. Va. Feb. 14, 2012); United States v. Advance Tool Co., 902 F. Supp. 1011, 1018–19

(W.D. Mo. 1995); United States ex rel. Smith v. Gilbert Realty Co., 840 F. Supp. 71, 75 (E.D. Mich. 1993).

Thus, when the amateur medical judgments of an Assistant United States Attorney are spun into theories of fraud, the consequences for hospitals can be grave. Understandably, many hospitals 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 40 hospitals totaling over $39 million to resolve false claims allegations related to kyphoplasty claims submitted to Medicare." Press Release, U.S. Dep't of Justice, Fourteen Hospitals to Pay U.S. More Than $12 Million to Resolve False Claims Act Allegations Related to Kyphoplasty (Feb. 7, 2012).[3]

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 level of hospital care, which involves ongoing monitoring, testing, assessment, and reassessment solely for the purpose of determining the need to admit a patient.

[3] Available at http://www.justice.gov/opa/pr/2012/February/12-civ-173.html (last visited Apr. 27, 2012).

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."). 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 notes in her Reply Brief (at 23), CMS expressed concern in 2010 about the increasing trend toward longer observation stays. See Letter from Marilyn Tavenner to Richard Umbdenstock (July 7, 2010), ECF No. 48-1. 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. The auditors' and Department of Justice's push 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, Letter from AUSA Robert Trusiak, at 2 (June 10, 2010), Ex. A. Even CMS's guidance leaves much to be desired. It is fairly vague, conflicting at times, and largely non-binding in any event, see Estate of Landers, 545 F.3d at 105-07.

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. 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.

CONCLUSION

The AHA takes no position at this time regarding the proper outcome of this case. We note, however, that in weighing the remedial options, the Court may wish to consider a remand to the agency for the purpose of convening a stakeholders' meeting and developing a clearer policy on observation status. Better guidance from CMS may assuage some, if not all, of the parties' concerns.

Dated: April 27, 2012

Respectfully submitted,

/s/ Eric J. Lobenfeld

Eric J. Lobenfeld (Bar No. CT03312)
HOGAN LOVELLS US LLP
875 Third Avenue
New York, NY 10022
Phone: (212) 918-8202
Fax: (212) 918-3100
eric.lobenfeld@hoganlovells.com

Counsel for the American Hospital Association

Sheree R. Kanner
Jonathan L. Diesenhaus
David M. Ginn
HOGAN LOVELLS US LLP
555 Thirteenth St., NW
Washington, DC 20004

Melinda Reid Hatton
Maureen Mudron
AMERICAN HOSPITAL ASSOCIATION
325 Seventh Street, NW
Suite 700
Washington, DC 20001

CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2012, a copy of foregoing Unopposed Motion for Leave to File Brief Amicus Curiae in Support of Neither Party was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may gain access to this filing through the court's CM/ECF System.

/s/ Eric J. Lobenfeld
Eric J. Lobenfeld (Bar No. CT03312)
HOGAN LOVELLS US LLP
875 Third Avenue
New York, NY 10022
Phone: (212) 918-8202
Fax: (212) 918-3100
eric.lobenfeld@hoganlovells.com

EXHIBIT A

U.S. Department of Justice

United States Attorney

Western District of New York

Federal Centre
138 Delaware Avenue
Buffalo, New York 14202

716-843-5700
Fax 716-551-3052

[redacted]

[redacted]

[redacted]

[redacted]

Re: Site of Service Review of Kyphoplasty Procedure

Dear [redacted]

The United States Attorney's Office for the Western District of New York and the United States Department of Justice, in conjunction with the United States Department of Health and Human Services, Office of Inspector General, are conducting a review into the Medicare billing of certain zero and one day inpatient kyphoplasty admissions.[9] The review of this matter involves a deliberative assessment of the medical necessity of certain inpatient kyphoplasty admissions, and the claim submission conduct related to such procedures, based on Medicare regulatory authority. The following letter describes the procedure, relevant Medicare regulatory authority, requested discovery, and the fundamental information to be captured in any examination of provider billing conduct for zero to one day inpatient kyphoplasty claim submissions.

Kyphoplasty and the Pathogenesis of Kyphosis

[9] The following video and news link to a CBS news segment describes a fraudulent scheme to overbill Medicare based on medically unnecessary inpatient kyphoplasty stays: **http://www.cbsnews.com/stories/2008/08/08/eveningnews/main4334787.shtml**. The $75,000,000.00 settlement described in the news segment addressed the culpable conduct by Kyphon, Inc. that resulted in the loss of millions of dollars to the federal taxpayer according to the United States and denied by Kyphon, Inc. The present review seeks to address the wrongdoing by those institutional and individual providers that recklessly submitted inpatient claims for medically unnecessary kyphoplasty admissions in contravention of Medicare regulatory authority and in derogation of their independent duty to submit claims for only medically necessary services.

Kyphoplasty is a minimally invasive spinal procedure used to treat vertebral compression fractures (VCFs). A VCF is a fracture in the body of a vertebra which causes it to collapse resulting in the spinal column above it to develop an abnormal forward curve generally described as kyphosis. The pathogenesis of kyphosis is the reduction in the quantity of bone or atrophy of skeletal tissue occurring in postmenopausal women and elderly men resulting in scanty or thin bone trabeculae without osteoelastic resorption.

Considerations To Guide any Voluntary Hospital Review: Medicare Rules and Clinical Considerations Governing the Site of Service Determination

The primary Medicare regulatory consideration governing the medical necessity of certain zero to one day inpatient kyphoplasty admissions concerns the use of observation status. Observation status provides the same intensity of service as an inpatient setting. The government review will completely address the credibility of any claim that comorbidities required an inpatient stay by assessing any post-procedure treatment directed at the allegedly compromising comorbid condition(s). The government review also will critically assess observation status as a clinical option to treat any genuine compromising comorbidities within the temporal limits of observation care. Medicare regulatory authority generally permits observation status for up to 48 hours after presentment to the facility. See MBPM Ch. 6 § 20.6(A) ("In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours."). The proceeding discussion addresses the panoply of the regulatory and clinical considerations related to any review.

The present review implicates only zero and one day inpatient stays for a kyphoplasty procedure. The dispositive inquiry to assess recklessness for the inpatient site of service and the significantly increased DRG cost to the federal taxpayer related to an inpatient kyphoplasty stay follows:

> *What medical treatment annotated in the medical record justified the inpatient level of service despite the availability of observation status such that the absence of inpatient care would have significantly and directly threatened the patient's medical condition, safety, or health?*

Medicare rules generally provide that an inpatient site of service is appropriate for a patient who is "admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services." See Medicare Benefit Policy Manual ("MBPM") Ch. 1 § 10. When assessing whether a patient requires inpatient level services, the provider must consider whether the "patient . . . demonstrate[s] signs and/or symptoms severe enough

to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis." See Medicare Quality Improvement Organization Manual § 4110 (emphasis added). "Inpatient care rather than outpatient [or observation status] care is required only if the patient's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting." Id. (emphasis added). The critical assessment as to whether patient safety or health would have been significantly and directly threatened by care in a less intensive setting requires more than a monotonous physician provider decision to perform kyphoplasty in an inpatient setting. The post-procedure medically necessary and documented treatment will be a significant factor in assessing the credibility of any safety or health claim offered by the institutional or individual provider.

The Medicare regulatory authority further provides that "[p]hysicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis." MBPM Ch. 1 § 10. The preceding Medicare regulatory authority at §4110 demonstrates the inpatient stay decision must be supported by qualitative criteria in addition to quantitative criteria. The qualitative inquiry necessary to demonstrate a medically necessary inpatient stay requires a medical record that annotates post procedure inpatient treatment such that the absence thereof would have "significantly and directly threatened" "the patient's medical condition, safety, or health" had treatment occurred "in a less intensive setting." See Medicare Quality Improvement Organization Manual § 4110. Medicare regulatory authority requires more than a perfunctory demonstration the patient simply spent a certain amount of time in a hospital bed due to the monotonous order of a physician provider. Medicare regulatory authority demonstrates keeping kyphoplasty patients overnight after the procedure to monitor the potential development of complications is inconsistent with the Medicare qualitative criteria for inpatient site of service.

The Medicare regulatory authority requiring a qualitative and quantitative assessment to support an inpatient stay is relevant to procedures, such as kyphoplasty, involving a scheduled, non-emergent procedure not expected to require inpatient level care for more than 48 hours. In such cases, the patient is "considered [an] outpatient[] for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight." See MBPM Ch. 1 § 10 (emphasis in original). If a patient requires inpatient-level services for only several hours, the patient may not be classified as an inpatient. Instead, the patient should be classified as an outpatient or observation status until a determination can be made as to whether inpatient admission is necessary based on the active treatment of post-procedure complications annotated in the medical record. The patient may be switched from observation status to inpatient status upon the advent of complications requiring inpatient-level care failing to abate within the observation status period.

As a general rule, kyphoplasty requires only limited post-procedure care, of a type typically available in an observation or outpatient setting. The safe and limited nature of kyphoplasty was recently described as follows:

> "Kyphoplasty and vertebroplasty may be performed by orthopaedic surgeons or interventional radiologists under intravenous sedation with local or general anesthetic. The bone cement hardens within 15 minutes. Incisions made to insert the tube are closed with a single stitch. Patients usually go home the same day and are able to resume normal activities; physical therapy is usually not needed."

Mending a vertebral fracture: kyphoplasty can ease pain quickly from vertebral compression fractures, and the effects are long lasting, Food and Fitness Advisor, p.4, March 2007. The limited nature of the typical post-procedure recovery period has been recognized by Medicare, which, effective January 1, 2008, added kyphoplasty to the list of procedures that may be performed in an Ambulatory Surgical Center ("ASC") setting. See 72 Fed. Reg. 42470, 42558 (Aug. 2, 2007). A procedure may only be cleared for performance in an ASC setting if it is a procedure "that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure." 42 C.F.R. §416.166(b) (emphasis added).

The propriety of observation status for most kyphoplasty patients has long been recognized in the published literature. See e.g., Drudney, et al. J of Clinical Oncology, 20:2382, 2384 (2002) (in study of 27 patients, 41% went home day of surgery and 48% went home next morning; patients who stayed 2 days or longer did so "all for medical/oncologic reasons unrelated to the kyphoplasty procedure"); Coumans, et al. J. of Neurosurg. (Spine) 99:44, 46 (2003) (in study of 78 patients treated between 1999 and 2000, "[p]ostoperatively, the patients were observed in a short-stay unit for a minimum of 6 hours, and then discharged home the same day or the following morning"). The general observation or outpatient site of service for a kyphoplasty is consistent with the absence of kyphoplasty on Medicare's "inpatient only" list.

Please be aware of the unpersuasive value in the judgment of the government of certain excuses offered by some providers. It has been suggested to the government that a monotonous post-procedure kyphoplasty protocol involving the monotonous use of physical therapy, CAT scans and/or IV antibiotics transforms kyphoplasties from an outpatient procedure to an inpatient stay. If such services are medically necessary and appropriate for an individual based on an individual assessment of medical necessity that requires inpatient-level services longer than the temporal limit of observation status and such assessment is documented in the medical record, then such post-procedure treatment is relevant to the site of service determination. It is important to recognize, however, a clinical protocol that monotonously requires the delivery of certain services regardless of medical necessity is irrelevant to the site of service determination. It is also imperative to include observation status care in the assessment of any perceived

clinical need to provide inpatient level of care on an individual basis. The preceding discussion concerning observation status demonstrates it generally satisfies the two most important goals of the government: first, provide the kyphoplasty patient with the best standard of care consistent with an individualized assessment and Medicare regulatory authority; and second, ensure the federal taxpayer pays for only those services intended to effect a clinical outcome rather than reimbursing a device maker or a provider for an arbitrarily priced kyphyx kit.

Please also be aware of the unpersuasive nature of a provider claim that pain justifies pre-procedure classification of a patient as inpatient. Debilitating pain that is documented in the medical record and requires inpatient site of service due to the temporal nature of the pain supports an inpatient admission. If pain was managed in a non-hospital setting (e.g., at the patient's home) prior to the surgery, then pain management does not require inpatient-level services simply because the patient entered the hospital for a kyphoplasty procedure. The rare incidence of post-procedure pain for kyphoplasty significantly limits the appropriate reliance on post-procedure pain for inpatient site of service. See, e.g., Coumans, et al. J. of Neurosurg. (Spine) 99:44, 48 (2003) (noting that pain relief, when it occurred, "was noted immediately postoperatively").

The speculative claim by a provider that kyphoplasty patients at that facility suffer from morbidities unique to that hospital population and not experienced by kyphoplasty patients treated at other hospitals is unpersuasive absent objective, comparative data supporting such contention. Please also note an objective factor that further-demonstrates the immateriality of any claimed uniquely morbid characteristics of any hospital's kyphoplasty population in the absence of any supporting comparative data: all of the relevant patients were discharged within a day of their procedure. The truly morbid patients presumably required two or more days of inpatient care. The objective one day stay factor establishes a fixed limit on the severity and complexity of patient morbidities.

The government acknowledges the value of the individual physician provider decision in initially assessing the level of care. The physician provider decision is the start of the analysis and not the end of the analysis. The hospital possesses an independent duty to assess the medical necessity of the site of service determination through, amongst other regulatory authority, condition code 44. See Medicare Claims Processing Manual ("MCPM") Ch. 1, §50.3 (discussing use of condition code 44 to indicate claims converted from inpatient to outpatient); 42 C.F.R. §482.30 (outlining duties and responsibilities of hospital utilization review committee).

Requested Documentation

In furtherance of this review, please forward within 45 days of the date of this letter the following documentation to the United States Attorney's Office, 138 Delaware

Ave., Buffalo, New York, 14202, Attn: Peggy McFarland, Investigator. The documentation request concerns the period January 1, 2000 to December 31, 2008 as follows:

a. The historical and current names of the chief financial officer, chief executive officer, chief compliance officer, materials manager, orthopedic coordinator, compliance officer, operating room director, radiology director, medical records director, neurosurgery director and the quality assurance and/or utilization director. The term "director" need not be a literal requirement that describes the relevant documentation. The term "director" refers to any person(s) in the above described categories that presently or formerly directs, manages and/or is designated as the head of such department, division or office. Please include last known address and telephone number for the former employees implicated in this request.

b. Any and all clinical and/or billing information regarding the kyphoplasty procedure, to include any internal audits or reviews, notes or summaries of any oral instruction(s) or information on how to document or bill the kyphoplasty procedure and/or the site of service, i.e. inpatient, outpatient or observation.

c. The names of all patients, regardless of insurance, that received the kyphoplasty procedure, or a procedure using a Kyphon product, to include type of insurance, date of admission, date of procedure, diagnosis code, procedure code, amount paid, amount billed, name of the physician(s) who performed the procedure, whether the patient's stay was inpatient, outpatient or observation, and date of discharge.

d. Any and all documentation regarding the site of service for the kyphoplasty procedure, as well as any and all documentation concerning the billing for the kyphoplasty procedure, including email communications between or amongst the hospital and any third parties, including any physician provider and/or Kyphon representative. Please include all documentation that relates to the site of service as well as the billing of this procedure, received or sent by this hospital, a physician or the device maker. The requested documentation includes any schedule(s), agenda(s), minutes, notes, handout(s) or other documentation from any discussion between Kyphon, Inc. personnel (e.g., sales representative, sales manager, reimbursement manager, etc.) and hospital personnel including financial or purchasing personnel (e.g., CEO, CFO, Controller, Purchasing Manager, OR Manager, etc.)

concerning the profitability of and/or reimbursement for kyphoplasty procedures.

e. Any hospital protocol, practice or policy, formal or informal, oral or written, which implicates the billing, patient status---inpatient, out-patient, observation---and/or performance of the kyphoplasty procedure.

f. Documentation concerning physician credentialing for the kyphoplasty procedure by the physician(s) that performed the kyphoplasty procedure at the hospital.

g. The name(s) of all physician(s) that performed or are performing the kyphoplasty procedure at this hospital. Please provide documentation or further indicate in lieu of documentation whether the physician(s) was a hospital employee at the time the physician(s) performed the kyphoplasty procedure(s) at the hospital and/or whether the physician(s) was designated as a physician champion, or some similar title, by Kyphon, Inc., n/k/a/ Medtronic, L.L.C. Please also provide documentation or indicate in lieu of documentation whether the physician(s) is a present or former member of the hospital Board of Directors.

h. The federal tax id number for the hospital.

i. The hospital chain, if any, that is a member or owner of the hospital.

j. Any documentation related to kyphoplasty privileged physicians that demonstrates the hospital credentialing committee monitored the performance of such physicians to ensure appropriate utilization or appropriate outcomes of the procedure

k. Any documentation that demonstrates that Interqual or other proprietary guidance informed the provider's decision at the time of the kyphoplasty claim submission(s).

l. All documentation of the current Utilization Review Plan and all iterations of such plan in effect from January 1, 2000 to the date of this letter. All documentation of the current members of the Utilization Review Committee and all historical members on such Committee from January 1, 2000 to the date of this letter. All documentation that in any way relates to the site of service for kyphoplasty based on either the Utilization Review Plan or the

Utilization Review Committee. A hospital is required to have a Utilization Review plan and Committee as a condition of participation in Medicare. [22]

m. Any documentation that describes any systems used to capture or record sound recordings in [locations or functions]. Include the manufacturer's name, model number, storage capability and locations.

---

22 42 C.F.R. § 482.30

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

***

(b) Standard: Composition of utilization review committee. A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution--

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who--

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) Standard: Scope and frequency of review.

(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of--

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

***

(f) Standard: Review of professional services. The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

n. Any documentation that describes connections to any network. Provide a diagram that illustrates the system components, and which identifies all of the telephone channels, extensions, or other audio sources which are recorded.

o. Any documentation that describes lines or channels in the recording locations – such as a trading desk – that are NOT recorded or monitored.

p. Any documentation that describes any systems used to store or archive sound recordings. Include the manufacturer's name, model number, storage capability and locations, and connection to any network. Provide a diagram that illustrates the system components, and which identifies all of the data sources for data stored in the storage system.

q. Any documentation that describes the software used to record, archiving, backup, extract, review, or otherwise process sound recordings. Include the program name, version number, and schedules for moving audio data from the recording system to a storage system.

r. Any documentation that identifies any location, including any local or network drive or other storage device where sound recordings are stored. Identify the media on which sound recordings are stored. State which of those media are erasable and/or rewriteable.

s. Provide a copy of record retention policies for sound recordings in the recording or storage systems. Describe any changes to these policies during the period 2000 to the date of this letter.

t. Any documentation that describes the software configurations, methods, policies, or business rules applied to the audio recording system. Include screen shots or descriptions of the process used to set those configurations, methods, policies or business rules. The purpose of this request is to determine the types of data that the system is set up to capture. Many systems are not set up by the users to capture all of the available metadata. This allows identification of what is available, such as extensions ("DNIS") or agent identifiers.

u. Any documentation that describes the software configurations, methods, policies, or business rules applied to sound recordings in

the audio storage system. Include screen shots or descriptions of the process used to set those configurations, methods, policies or business rules.

v. Any documentation that identifies the person or persons most knowledgeable about the administration of the audio recording and storage system(s). Identify the custodian(s) of the sound recordings.

w. Any documentation that identifies all persons who have been granted electronic access rights to sound recordings in either the recording system or storage system.

x. Any documentation that states the amount of capacity currently used to store sound recordings in the recording system, and in the storage system.

y. Any documentation that identifies any sound recordings which you do not intend to produce on the basis that they are not reasonably accessible.

z. Any documentation that describes all sound recordings that relate to above items b-g, j and k, including audio files and any associated data or metadata from the recording and storage systems.

aa. Any documentation relating to any PEPPER Reports received by the provider between January 1, 2000 to present concerning zero and/or one day discharges. A PEPPER Report is an electronic data report that contains a hospital's claims data statistics for certain Medicare DRGs. PEPPER is an abbreviation that means Program for Evaluating Payment Patterns Electronic Report.

Please provide the above documentation in hardcopy form except for the utilization data requested in item c and the e mail production. Please provide the utilization data in item c in both hard copy and an electronic Excel spreadsheet in the form described in the attached medical record review template. Please provide the email return with all attachments in its native file format permitting metadata analysis and in a searchable form. Please identify with the document production a hospital custodian, not counsel, competent to swear or affirm as to the completeness of the search yielding the production. Please ensure such custodian is aware such statement is made to a law enforcement officer for the executive branch as that phrase is used in 18 U.S.C. §1001.

The attached review template will be utilized by the government for any

government medical record review. If the hospital chooses to conduct an internal review of all zero and one day inpatient kyphoplasty procedures, then kindly utilize the template and give every consideration to permitting government personnel the opportunity to describe fundamental clinical, data and site of service information to the review team prior to any hospital review to ensure a complete and credible result. Please escrow any overpayment amount pending further conversations with this office rather than remitting any overpayment to HHS OIG or the Medicare Contractor.

Please preserve all relevant electronically stored information related to the above documentation requests. Please further account in correspondence to the government within ten days of the date of this letter the safeguards that preserve electronically stored information, including archived and nonarchived information, as well as storage locations and file saving backup protocols.

If you have any questions regarding this request, then please call Peggy McFarland at 716-843-5877 or me at 716-843-5847. Thank you for your consideration, courtesy and cooperation.

Very truly yours,

WILLIAM J. HOCHUL Jr.
United States Attorney

Robert G. Trusiak

BY: Robert G. Trusiak
Assistant U.S. Attorney

MEDICAL RECORD REVIEW SHEET

1. Admitting Physician: _____

2. Rendering Physician: _____

3. Patient's Name: _____

4. Patient's DOB: _____

5. Admission From (ER, Home, Etc): _____

5a. Elective (circle): Y N

6. Admit Date: _____ Admit Time: _____

7. Discharge Date: _____ Discharge Time: _____

8. Procedure Date: _____

9. Length of Stay, provided in the number of hours: _____

10. Did the patient stay overnight after or before the procedure (circle)? AFTER

BEFORE

11. Levels Treated: _____

12. Biopsy (circle): Y N

13. Path Report Results: _____

_____

14. Other Procedures Performed: _____

_____

15. Admitting Diagnosis: _____

16. Other Diagnosis: _____

_____

Medical Review Sheet
Hospital Name: _____
Page 2 of 3

17. Type of Sedation: _____

18. ASA Sedation Risk Level: _____

19. Length of Time in Recovery: _____

19a. Time In: _____

19b. Time Out: _____

20. Were there any anesthesia related complications documented in the medical record (circle)? Y N

20a. If yes, identify them and explain the treatment rendered:

_____

_____

_____

21. Discharged To/Disposition: (Department Name): _____

22. Medications Dispensed after Recovery Room Discharge:

1.) _____	4.) _____	7.) _____
2.) _____	5.) _____	8.) _____
3.) _____	6.) _____	9.) _____

23. Were any co-morbidities actively treated, as documented in the medical record (circle)? Y N

23a. If yes, identify them and explain the treatment rendered:

_____

_____

_____

Medical Review Sheet
Hospital Name: _____
Page 3 of 3

24. Were any surgical complications treated, as documented in the medical record (circle)? Y N

24b. If yes, identify them and explain the treatment rendered:

_____

_____

_____

25. If no comorbidites, anesthesia or surgical complications were actively treated, as documented in the medical record, then what medical treatment or assessment documented in the medical record justified the inpatient level of service such that the absence thereof would have significantly and directly threatened the patient's medical condition, safety, or health.

_____

_____

_____

_____

26. Provide a Summary of the Findings:

Date of Review: _____

Name of Person Performing Review: _____

Title and Credentials of the Person Performing the Review: _____

_____

	MEDICARE ONLY					
	Total #	# Greater than 1 Day Inpatient Stay	# of 1or 0 Day Elective/ Scheduled Inpatient Stay	# of Other 1or 0 day Inpatient stay	# Overnight Observation	# Outpatient
2000						
2001						
2002						
2003						
2004						
2005						
2006						
2007						
2008						

	ALL PAYORS EXCEPT MEDICARE					
	Total #	# Greater than 1 Day Inpatient Stay	# 1or 0 Day Elective/ Scheduled Inpatient Stay	# of Other 1or 0 day Inpatient stay	# Overnight Observation	# Outpatient
2000						
2001						
2002						
2003						
2004						
2005						
2006						
2007						
2008						