

June 26, 2012

Submitted via e-mail (ProgramIntegrityWhitePapers@finance.senate.gov)

Chairman Baucus, Ranking Member Hatch and Senators Coburn, Wyden, Grassley and Carper
Committee on Finance
United States Senate
Washington, DC 20510-6200

Dear Honorable Members:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to respond to the May 2 open letter to the health care community and present recommendations to better prevent and combat waste, fraud and abuse in the Medicare and Medicaid programs. America's hospitals take seriously their obligation to properly bill for the services they provide to Medicare and Medicaid beneficiaries.

Hospitals have a longstanding commitment to compliance, establishing programs and committing resources to ensure that they receive only the payment to which they are entitled. Hospital compliance programs are designed to meet the principles for effectiveness outlined in the U.S. Sentencing Guidelines and, more specifically, in the Office of the Inspector General's (OIG) compliance program guidance for hospitals. Every day hospital staff strive to comply in good faith with a complex and continually changing legal and regulatory environment affecting payment. Hospitals' compliance programs extend beyond having processes in place to respond to individual situations brought to their attention to include systems designed to track changes, and training and education to stay current with the evolving requirements. Hospitals invest substantial resources to monitor their bills for mistakes and assign responsibility for these proactive efforts to internal auditors and compliance officers.

Medicare and Medicaid payment rules are highly complex and the complexity is increasing. The volume of claims for hospital services submitted and processed on an annual basis is significant. And, predictably, mistakes are made by hospital staff, the Centers for Medicare & Medicaid Services (CMS) and program contractors alike. However, such mistakes are not fraud, and the powerful weapon of the *False Claims Act* (FCA) should not be wielded in a misguided attempt to correct or prevent mistakes.



The FCA imposes stiff penalties—treble damages plus a substantial per-claim penalty (31 U.S.C. § 3729(a)(1)). Consequently, the threat of an allegation of fraud is no small matter for any hospital. FCA sanctions can easily exceed \$100,000,000 in hospital cases. Moreover, a hospital that violates the FCA can be excluded from participating in the Medicare and Medicaid programs 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 the courts have recognized and 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)). A powerful weapon like the FCA must be wielded appropriately and with significant care.

This important perspective guides the discussion that follows of hospitals’ concerns about current governmental efforts to prevent and combat waste, fraud and abuse in the Medicare and Medicaid programs and the specific recommendations we offer to improve such efforts. Specifically, we recommend:

- Eliminating the overlap and duplication that exists in current program integrity oversight;
- Limiting the unfettered discretion over treatment decisions now exercised by many governmental auditors and Department of Justice (DOJ) attorneys by establishing clear payment policies that underscore the central role of the treating physician in hospital admissions; and
- Improving current proposals to facilitate hospitals’ return of overpayments that result from mistakes.

ELIMINATE THE SIGNIFICANT OVERLAP AND DUPLICATION THAT EXISTS IN CURRENT PROGRAM INTEGRITY OVERSIGHT

Congress and the Department of Health and Human Services (HHS) have enlisted a host of contractors to help detect and correct 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 (see the AHA’s May 2011 *TrendWatch* report, “[Program Integrity after the Enactment of Health Reform](#),” included herein as Attachment 1, for more information).

These payment accuracy programs are well intentioned. But hospitals continued to be frustrated with the significant overlap and duplication of efforts among these contractors. For example, MACs, ZPICs and RACs are all charged with reviewing hospital Medicare claims, and hospitals

may be required to respond to simultaneous audits of the same claims or to duplicative record requests. In fact, hospitals have hired additional staff solely to manage the government's audit processes (see [AHA May 2012 RACTrac Survey](#), included herein as Attachment 2, for additional information). More than 50 percent of hospitals of the 2,000-plus hospitals participating in the AHA's RACTrac Survey reported a significant increase in administrative burden due to the RAC program. Fifty-five percent of hospitals reported spending more than \$10,000 in the first quarter of 2012 to manage the RAC process alone, with 34 percent spending more than \$25,000 and seven percent spending more than \$100,000.

Interestingly, the AHA RACTrac Survey results indicate that two-thirds of medical records reviewed by RACs **did not** contain an improper payment. Nevertheless, despite CMS's recent acknowledgement that RACs do not find improper payments in the majority of records they request, the agency recently *doubled* the amount of medical records RACs can request from hospitals.

Medicare RACs have a strong financial incentive to deny claims. Medicare RACs are paid "on a contingent basis for collecting overpayments" (42 USC § 1395ddd(h)(1)(B)(i))—currently, between 9 percent and 12.5 percent of the overpayment amount (76 Fed. Reg. 57808, 57809 (Sept. 16, 2011)). The more claims the RAC denies, the more the RAC is 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 percent of appealed RAC decisions are ultimately reversed (see AHA, "[Exploring the Impact of the RAC Program on Hospitals Nationwide](#)", at 50 (Feb. 15, 2012) ("RAC Report"), included herein as Attachment 3).

AHA data 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 more than \$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 provider can challenge the RAC's finding, but the multi-level appeal process is expensive and cumbersome. Moreover, obtaining a favorable decision on appeal has little to no precedential value: RACs continue to review and deny substantially similar claims, forcing hospitals to continually engage the same cumbersome and expensive appeals process on a claim by claim basis. Should the hospital accept the RAC's decision that medically necessary care was provided in the wrong setting, CMS policy prohibits the hospital from properly rebilling the claim at the appropriate level of care or service code determined by the RAC (e.g., properly rebilling an inpatient claim as an outpatient claim).

The AHA believes that integrity programs need to be streamlined, duplicative audits eliminated and inappropriate denials halted. Furthermore, we recommend that investments be made in provider education and payment system fixes to prevent payment

mistakes before they occur. We offer more detail in our paper “[Program Integrity and Contractor Overlap](#),” included as Attachment 4.

LIMIT THE EXERCISE OF UNFETTERED DISCRETION OVER TREATMENT DECISIONS NOW EXERCISED BY GOVERNMENTAL AUDITORS AND DOJ ATTORNEYS

In recent years, federal contractors, DOJ lawyers and *qui tam* relators have lost sight of the central role of the treating physician. 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. 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” (Medicare Benefits Policy Manual (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. These fact-sensitive medical judgments do not lend themselves to second-guessing by outside individuals and government auditors.

Unlike a treating physician, the view of federal contractors, DOJ lawyers and *qui tam* relators 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 they frequently conclude, for example, 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 (see [Brief of the American Hospital Association as Amicus Curiae](#) in Support of Neither Party in *Bagnall v. Sebelius* included herein as Attachment 5).

Worse yet, certain DOJ attorneys and whistleblowers are substituting their own medical judgments for those of the treating physician. These lawyers have decided – apparently based on their interpretation of the medical literature – that, for example, 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 FCA unless the hospitals refund “damages” to Medicare. Rather than risk an astronomical monetary 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 and have become more wary of 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.

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. **We believe that better guidance from CMS could do much to assuage the concerns of all about what care can and should be appropriately provided where. Any CMS guidance should clearly underscore the central role of the treating physician in hospital admissions.**

The AHA also is concerned that aggressive FCA investigations are being initiated upon the discovery of evidence of a mistake or overutilization, making FCA enforcement through negotiated “settlement” a self-fulfilling prophecy. The “kyphoplasty” initiative being advanced by the United States Attorney for the Western District of New York is a prime example of such enforcement (see [AHA letter to Attorney General Holder and Secretary Sebelius dated September 7, 2010](#), included herein as Attachment 6). As CMS and the OIG increasingly use large-scale computerized processing and analysis of claims data in their attempts to “uncover” patterns of overutilization and overpayment, aggressive use of the FCA to force negotiated settlements is likely to worsen.

The kyphoplasty initiative emanates from the settlement of an FCA investigation of the business practices of a manufacturer of medical devices used in a particular surgical procedure involving the artificial restoration of collapsed vertebrae. In the underlying investigation, DOJ alleged that the manufacturer misled physicians and hospitals about the medical necessity of an inpatient hospital stay following a kyphoplasty and the applicability of certain billing codes to the procedure and the inpatient stay.

The initial form “contact” letters received by hospitals across the country strongly suggests that the Western District has seized upon data analysis that flags billing errors and/or over-utilization and converted it into a presumption of FCA liability, and that DOJ is using the threat of FCA liability as an audit tool. The letter does not suggest that DOJ has reviewed the medical necessity of any admission. In fact, CMS’s guidance clearly recognizes that inpatient hospitalization may well be appropriate under certain circumstances—many of which likely apply to the Medicare-covered population.

The letter from the Western District offers to compromise any such liability if the hospital “cooperates.” It strongly suggests that the prerequisite to a “double damages” compromise is for the hospital to undertake a prescribed onerous, burdensome and very costly self audit and to provide the United States Attorney’s Office with the results of that audit in a prescribed form.

When, as here, 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 DOJ has “reached settlements with more than 40 hospitals totaling more than \$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)). Importantly, physicians’ judgments regarding appropriate treatments and settings, and hospitals’

oversight of those judgments, are now influenced by the knowledge that certain decisions will inevitably be second-guessed.

While it is possible that the FCA could be the appropriate remedy in some cases, and that some hospitals may have acquiesced in or even encouraged medically unnecessary admissions, commencing a medical necessity review with an FCA “contact letter” of this nature requires hospitals to treat each case as an FCA case, regardless of merit, because of the great risk in terms of monetary and administrative sanctions. Consequently, the threat of FCA liability leads hospitals to incur expenses related to retaining specialized counsel and outside forensic accountants and, in the event an overpayment is discovered, to negotiate a formal FCA settlement where a simple cost report adjustment is all that is really necessary.

The AHA specifically recommends that the cabinet-level Health Care Fraud Preventions and Enforcement Action Team (HEAT) undertake a policy review of ongoing enforcement initiatives proceeding under the auspices of the FCA, like the kyphoplasty initiative being directed by the United States Attorney for the Western District of New York. We believe that step can restore confidence in the working relationship between hospitals and the DOJ by offering providers a clear assurance that such oversight authority will be exercised properly and judiciously.

IMPROVE CURRENT PROPOSALS TO FACILITATE HOSPITALS’ RETURN OF OVERPAYMENTS THAT RESULT FROM MISTAKES

The AHA and its member hospitals have long advocated for a clear and efficient process for the return of overpayments that result from mistakes. Providing a safe and reliable way in which hospitals can return payments mistakenly received from the government directly complements the work that hospitals already do as part of their established compliance efforts to identify overpayments received.

We viewed – and believe Congress intended – the provision in the *Patient Protection and Affordable Care Act* (ACA) that created a reporting and repayment obligation for providers and suppliers who receive an overpayment as a means to correct mistakes. The provision was specifically meant to fill an existing statutory gap by making clear a duty to repay arose when a provider “identified” an overpayment. Prior to enacting this overpayment provision in the ACA, there was no explicit statutory obligation in the *Social Security Act* to return overpayments and no clearly defined process for actually doing so.

Unfortunately, as [our comments to CMS](#) (included herein as Attachment 7) suggest, the agency’s proposal to implement that provision of the law would create another confusing, onerous, and legally risky set of expectations for hospitals. The proposal is confusing because it does not acknowledge or consider of the overlap, inconsistency and contradictions with the already existing world of Medicare billing processes and the program’s many and varied post-payment audits and reviews. It also is onerous because hospitals would be required to divert resources – staff time, dollars and information technology (IT) systems – to make needed changes to *try* and

meet unreasonable and often impossible timeframes for conducting sweeping and unfounded reviews of current, past and long-past records and claims submissions. Moreover, it is legally risky because the proposed rule attempts (without legal authority) to wrap all of these unreasonable and impractical expectations in the cloak of FCA liability.

We urge CMS to revisit the proposed rule's framework for implementation of the law in its entirety. The agency's emphasis should be on minimizing unnecessary burden and ensuring coordination with the many existing and varied reviews, reviewers and processes already imposed on hospitals. And, the agency should do so in accord with the clear intent of the law to provide a safe and reliable way in which hospitals can return payments mistakenly received from the government.

We also were disappointed in the earlier agency attempt to implement the self-referral disclosure protocol (SRDP) also required under the ACA (see [AHA letter to HHS Secretary Kathleen Sebelius on the Medicare Self-Referral Disclosure Protocol, Patient Protection and Affordable Care Act \(PPACA\)](#), Section 6409 dated July 16, 2010, included herein as Attachment 8). The SRDP, which the AHA supported throughout the legislative process, would create a realistic mechanism for settling non-fraud violations of the self-referral law.

As its implementation has evolved, the self-referral law (Section 1877 of the *Social Security Act*) has left hospitals at risk for draconian compliance penalties that have no relationship to the harm, if any, to the Medicare program. While originally intended to provide a "bright line" standard to assure hospitals and others clear guidance, the self-referral law has evolved into a series of increasingly complex, confusing and continually changing rules. Form and audit-type requirements are given the same weight as the core requirements of a legitimate arrangement for compliance purposes. The ACA provision grants the HHS Secretary authority to address this increasingly significant problem in the implementation of the self-referral law.

The AHA letter urges the Secretary to act promptly in establishing the SRDP and to make full use of the authority newly granted by Congress to assure fair enforcement of the self-referral law. As we noted, delivery system reforms demanded by patients and payers alike call for closer working relationships between hospitals and physicians and only heighten the importance of fair and workable implementation of the self-referral law. Consequently, for the SRDP to be effective, it will need to offer providers a clear and understandable process for presenting and resolving disclosed issues – a framework that is fair; adjusts repayments to the harm, if any, to patients and the program; takes financial condition of the provider into account; and offers reasonable certainty or predictability of outcomes.

According to a statutorily required report to Congress, 150 disclosures from 148 providers, including 125 hospitals, have been made to CMS since the SRDP was originally published; and to date, only seven of the disclosures have been resolved through settlement.

We encourage members of the Finance Committee to urge HHS and CMS to take providers' concerns and recommendations seriously in final implementation of both important programs and to take an active role in monitoring how effectively the programs

encourage and facilitate provider disclosure and repayment. In addition, as the Finance Committee is looking at the goal of eliminating waste, fraud and abuse, it should be alert to how these laws are interfering with or inhibiting accomplishment of another of the Committee's goals – reforming the delivery system to advance quality, safety and efficiency. (see [Moving Health Care Forward: Five Barriers to Clinical Integration in Hospitals](#) (and what to do about them), included herein as Attachment 9).

The AHA and its member hospital look forward to working with members of the Committee to improve federal efforts to reduce fraud and abuse in Medicare and Medicaid. We agree that together we can improve program integrity and encourage better stewardship of taxpayer dollars. Please contact me or Tom Nickels, senior vice president, federal relations, at (202) 626-2314 or tnickels@aha.org with any questions about our concerns and recommendations.

Sincerely,

/s/

Rick Pollack
Executive Vice President

Attachments