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Association**

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August 29, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1589-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-1589-P, Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations; (Vol. 77, No.146), July 30, 2012.

Dear Ms. Tavenner:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our nearly 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for calendar year (CY) 2013 hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) PPS and quality reporting programs; electronic reporting pilot; inpatient rehabilitation facilities quality reporting program and quality improvement organization changes.

We provide detailed comments on several proposals in the attached document. The AHA is pleased that CMS has again proposed to delay enforcement of the direct supervision policy for certain hospitals; however, we have concerns about CMS's existing supervision policy and its process for the independent review of alternate supervision levels. We also are pleased that CMS has engaged stakeholders in a discussion of the complexities that surround determinations of whether a patient is appropriately an inpatient or outpatient and is seeking ways to improve its instructions and policies regarding patient status. Because proper consideration of these issues will require more time and effort than a 60-day comment period will allow, we encourage CMS to consider this the opening round of a more formal ongoing dialogue with hospitals, physicians, beneficiaries, skilled nursing facilities and other stakeholders.

We also include comments on the geometric mean-based payment weights, a new payment policy for separately payable outpatient drugs, coding and payment for critical care services,



a new transitional care management code, changes to the inpatient list, a payment adjustment for radioisotopes derived from non-highly enriched uranium (non-HEU) sources, requirements for outpatient quality data reporting, changes to the Quality Improvement Organization (QIO) regulations and quality reporting through an electronic health record (EHR).

In brief, the AHA makes the following key recommendations:

- We support CMS's decision to provide an additional year of delayed enforcement of the direct supervision policy for critical access hospitals (CAHs) and small rural hospitals. However, we are concerned that without a fundamental change in the supervision policy, these hospitals will be unable to adhere to CMS's supervision policy by CY 2014 and perhaps beyond, putting access to care at risk in rural communities.
- We urge CMS to take steps to improve its independent review process for reassessing the appropriate level of supervision for certain outpatient therapeutic services including:
 - more explicit guidance and instructions on what would constitute an appropriate presentation to the Advisory Panel on Hospital Outpatient Payments (HOP Panel) and how to submit a presentation to CMS;
 - more flexibility regarding its deadline for presentations to the HOP Panel; and
 - more prominent posting and sharing of information on the HOP Panel process.
- We provide initial guidance on ways to improve CMS's policy on patient status, including the value of using time-based admission policies, adopting more specific clinical criteria, using prior authorization for admissions, and exploring changes to payment policy to better align payment to the intensity of resources used in the care of patients.
- We cautiously support CMS's proposal to use the geometric mean cost of services within an ambulatory payment classification (APC) to determine the relative payment weights of services, rather than median costs. However, given that this proposal represents a fundamental change in outpatient payment methodology, we urge CMS to proceed cautiously and transparently to ensure that there are no unintended consequences, particularly regarding patient access to services with the largest proposed payment reductions.
- We support CMS's proposal to pay for separately payable outpatient drugs at the "statutory default" rate of average sales price plus 6 percent. This proposal would improve the stability and adequacy of payment for such drugs.
- We oppose CMS's proposal to remove the code for total knee arthroplasty (TKA) from the inpatient list. We do not believe that the clinical characteristics of TKA justify its selection as an appropriate candidate for removal from the inpatient list.
- We believe that CMS's proposed payment adjustment policy for non-HEU sources, as conceived, will not promote the conversion to non-HEU sources in hospitals. If CMS decides to move forward with a non-HEU payment adjustment policy, we recommend that:
 - the policy be phased in over several years;
 - the payment adjustment amount be increased to better reflect the marginal additional costs of the non-HEU sources as well as the additional administrative and compliance burden that would fall on hospitals using the new code; and

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- in the phase-in, CMS permit hospitals that use lower percentages of non-HEU derived radiopharmaceuticals to receive the adjustment.
- We recommend that CMS modify its pilot program to field test the measures used in the EHR incentive program and determine the ability of vendors and hospitals to accurately capture the necessary data in the required formats to generate valid, reliable and comparable quality measures directly from the EHR.

Thank you again for the opportunity to comment. Our detailed comments are attached. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

Attachments

AMERICAN HOSPITAL ASSOCIATION
DETAILED COMMENTS ON THE PROPOSED RULE FOR CY 2013 HOSPITAL
OUTPATIENT AND AMBULATORY SURGERY PPS AND QUALITY REPORTING
PROGRAMS; QUALITY IMPROVEMENT ORGANIZATION REGULATIONS

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DIRECT SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES

Further Delay in Enforcement of Direct Supervision Policy. The AHA appreciates the changes that CMS has made since 2009 in response to concerns raised by hospitals around the direct supervision policy. In the CY 2009 OPPTS final rule, CMS issued a policy for “direct supervision” of outpatient therapeutic services that hospitals and physicians considered to be a burdensome and unnecessary policy change but that CMS considered to be a “restatement and clarification” of existing policy in place since 2001. CMS’s policy required a supervising physician to be physically present in the hospital outpatient department at all times when Medicare beneficiaries received outpatient therapeutic services. This was a significant change from previous policy and threatened access to care for patients seen in small, rural hospitals. In response to concerns, CMS delayed enforcement of the direct supervision policy for outpatient therapeutic services furnished in critical access hospitals (CAHs) and in small, rural hospitals with 100 or fewer beds; allowed qualified non-physician practitioners (NPPs) to provide supervision; modified the definition of direct supervision to make its application more flexible; adopted a two-tiered supervision policy for certain nonsurgical extended duration therapeutic services and established an independent review process using the Advisory Panel on Hospital Outpatient Payment (HOP Panel), which allows changes to be made in supervision level for individual hospital outpatient therapeutic services. These changes provided some flexibility for hospitals with adequate resources and staff to comply with the regulations.

In the CY 2013 proposed rule, CMS proposes to extend its delay in enforcement of the direct supervision policy for CAHs and small, rural hospitals. **The AHA supports CMS’s proposal to provide an additional year of delayed enforcement and urges the agency to finalize this in the November final rule.** According to CMS, this delay is proposed to give these hospitals an additional opportunity to become familiar with the HOP Panel submission and review process. The agency further states that this extension also gives hospitals extra time to come into compliance with the supervision requirements and warns that “[w]e expect that this will be the final year for the instruction, regardless of the services reviewed by the Panel during its summer meeting.”

However, even with all these policy changes and an additional year of enforcement delay, the AHA remains concerned that CAHs and other small, rural hospitals will not be prepared to adhere to CMS’s supervision policy by CY 2014 and perhaps beyond. This is because health professions workforce shortages are exacerbated in rural areas, where communities struggle to attract and keep well-trained clinicians. While 19.2 percent of the U.S. population lives in rural America, only 11.4 percent of physicians practice in rural locations. Recent Health Resources and Services Administration (HRSA) -sponsored research revealed that 77 percent of rural counties in the U.S. are designated as primary care health professional shortage areas (HPSAs). As the expanded coverage available under the *Patient Protection and Affordable Care Act* (ACA) begins to take effect in fiscal year (FY) 2014, many are predicting increased demand for physicians who provide primary care and comprehensive care for those with multiple chronic conditions, thus increasing the difficulty some regions will have in attracting needed physicians.

The continued existence of CAHs and other small, rural hospitals in these communities is the result of a careful balancing of policies and practices to ensure access to essential and high-quality health care services. This includes the widespread use of telemedicine, carefully crafted and exercised nurse protocols and standing orders, and Medicare personnel conditions of participation and state licensing standards that effectively acknowledge health professions workforce challenges and are designed to preserve access to care in rural communities. Further, physicians and other health professionals who choose to practice in rural communities have private practices or group practices that are their primary obligation. With their own patient caseload, these clinicians have limited ability to be “immediately available” to provide supervision for hospital outpatient department services, particularly for those critical specialty services that cannot be supervised by a hospital emergency physician or NPP.

For these reasons, the AHA continues to believe that future enforcement of the current direct supervision policy will put access at risk. Rural hospitals will be forced to choose to either limit the hours and locations for certain services for which they cannot provide full-time direct supervision, or discontinue these services all together. We fear that the end result in rural areas will be reduced access to care for beneficiaries and increased administrative burden for hospitals, without any real impact on patient safety or quality of care. It also may mean more readmissions for patients whose path toward recovery will be undermined by lack of access to care.

We believe that fundamental changes are needed to support the ability of hospitals in rural communities to sustain access to care. Therefore, the AHA continues to support changes that are contained in the *Protecting Access to Rural Therapy Services Act of 2011* (S. 778). While this bill has not yet been enacted by Congress, we urge CMS to use its regulatory authority to adopt the changes the bill would make. **These include establishing a default standard of “general supervision” for outpatient therapeutic services and using the HOP Panel to obtain provider input to identify specific procedures that would benefit from direct supervision.** We contend that general supervision better reflects the way in which on-campus outpatient therapeutic services were furnished prior to 2009, particularly in rural hospitals, and there is no evidence that patient safety or quality of care has been compromised in past years due to inadequate or ineffective supervision. **Further, CMS should ensure that for CAHs the definition of “direct supervision” is consistent with the CAH conditions of participation and prohibit enforcement of CMS’s retroactive reinterpretation of the “direct supervision” requirements.**

Medicare Contractor Enforcement of Supervision Requirements. We have heard concerns voiced by a number of hospitals trying to come into compliance with the supervision requirements. These providers are worried about enforcement risk related to the ambiguities in CMS’s definition of direct supervision, particularly the interpretation of the term “immediately available.” These hospitals are concerned that the policies and procedures which they create and implement within their hospitals and health systems that are intended to satisfy the direct

supervision requirements will be challenged and rejected by CMS contractors, such as the Medicare Administrative Contactors (MACs) and Recovery Audit Contractors (RACs).

Due to the vast differences among hospitals in terms of services offered, facility infrastructure, staffing and patient mix, the AHA appreciates that CMS has *not* created an objective measure of distance or time to satisfy “immediately available.” **We recommend that CMS actively discourage its contractors from establishing arbitrary time and/or distance standards for direct supervision. Instead, we urge the agency and its contractors to continue to allow hospitals to develop and apply reasonable and patient-focused supervision policies and practices within their own institutions, taking into consideration their patient mix, type of services offered, physical infrastructure and workforce limitations.** As long as these hospital supervision policies reasonably satisfy direct supervision requirements, appropriately balancing patient access and safety and the hospital consistently applies its own policies, Medicare contractors should be instructed not to second-guess hospital policies.

HOP Panel Process. In the CY 2012 final rule, CMS established an independent review process that would allow for an assessment and assignment of the appropriate supervision levels for individual hospital outpatient therapeutic services. We are pleased that CMS supports our view that this process and its outcomes fall clearly within the agency’s authority. That is, while Medicare covers hospital outpatient therapeutic services as “incident to” a physician’s service, the law does not mandate a specific level of physician supervision, but rather leaves this entirely within CMS’s regulatory discretion. The AHA and its members believe that there are numerous outpatient therapeutic services that could be furnished safely under general supervision, including certain extended duration services, short duration services, minor surgical procedures and the recovery portion of certain surgical services after the patient has been cleared by the anesthesiologist.

While the AHA continues to support the HOP Panel’s efforts, we do have some comments and observations about the process and several recommendations to improve it. Our other concerns are related to the fact that so few hospitals were selected to testify at the February and August meetings of the HOP Panel. At the February 2012 meeting only two hospital witnesses were selected to make presentations. We believe that this lack of response from hospitals reflected unfamiliarity with the process as well as the short notice and compressed timeframe for responding to CMS’s request for presentations in the December 16, 2011 *Federal Register* notice. Hospitals unfamiliar with the process need a longer lead time to respond and make room in their schedule for the meeting.

The AHA is pleased with CMS’s subsequent decision to approve a change to general supervision for 27 outpatient therapeutic services. However, we are disappointed that for the August 2012 HOP Panel meeting, only three hospitals are included on the agenda, although there was greater advanced notice and a longer timeframe to respond. In addition, the notice included a short description of the process and an appeal for hospitals to testify. The AHA and other national and state hospital associations also engaged in multiple and varied efforts to encourage hospitals to submit presentations. We believe that this poor showing does not reflect a lack of interest from

hospitals, but demonstrates that CAHs and small, rural hospitals are still not familiar with this process and that more substantive guidance from CMS would be helpful. For instance, we have learned that CMS rejected several presentations due to statements and recommendations that were technically outside the scope of the HOP Panel's charter and for failing to provide an adequate justification in accordance with CMS's submission criteria. **The AHA urges CMS to provide more precise and explicit guidance on what would constitute an appropriate presentation and the type of data or evidence that would meet CMS's criteria. More detailed instructions on how to submit a presentation to CMS also would be beneficial.**

We understand that a few hospital presentations were rejected because one or more required documents were not received by the July 27 deadline. Of particular concern, we have learned that one hospital had its request to testify rejected without review because it failed to submit a "hard copy" of its presentation to CMS before the deadline – although CMS had received an electronic copy of the presentation and other required documents on time. **Given the time and effort that hospitals put into crafting a presentation and the newness of the process, we encourage CMS to be more flexible in accepting presentations, particularly if a formal request to present or a portion of the required material is submitted on time.**

In addition, the AHA has heard from hospitals as well as physician specialty societies that they were unaware of the opportunity to testify at the HOP Panel and to submit comments on CMS's preliminary decisions regarding HOP Panel recommendations. Although the AHA used various means to communicate this opportunity to hospitals and state hospital associations, wider notification from CMS also would be beneficial. **We urge CMS to more prominently post and communicate information about the HOP Panel process, especially upcoming HOP Panel meetings and the related opportunity to testify, and CMS's preliminary decisions regarding HOP Panel recommendations and the related 30-day opportunity for public comment.** We recommend that CMS consider posting these announcements on its multiple Web pages, including its main page under CMS News, the OPSS and HOP Panel pages. Further, CMS should announce these opportunities on its Hospital and Physician Open Door calls and push out listserv announcements as appropriate. The AHA also is ready to serve as a communicator when these announcements and opportunities arise.

PATIENT STATUS

The AHA is pleased that CMS has opened a dialogue on the complex policy regarding Medicare coverage and inpatient versus outpatient status. Given the confusion and challenges surrounding Medicare policy regarding patient status, it is clear that hospitals are in an untenable and unsustainable position. On the one hand, because CMS policy allows Part B payment following a Part A denial for only a very limited set of ancillary services (and only if the timely filing requirements do not bar those claims), hospitals risk loss of reimbursement, monetary damages and penalties when they admit patients for short inpatient stays. On the other hand, hospitals face criticism from patients and CMS over the perceived excessive use of observation services as a substitute for inpatient admission.

We applaud CMS for taking this first step in what we hope will be an ongoing dialogue that will ultimately lead to a resolution of the concerns that are described in the proposed rule. Given the complexity of these issues, we do not believe that a comprehensive solution or set of solutions regarding patient status can be crafted within this 60-day comment period. Instead, the AHA encourages CMS to consider this request for comment to be the opening round of a more formal ongoing dialogue with hospitals, physicians, beneficiaries, skilled nursing facilities and other stakeholders about these issues and their possible solutions.

To contribute to this initial dialogue, our thoughts and considerations regarding the questions that CMS poses in the proposed rule are discussed below. The AHA looks forward to working with CMS as the agency evaluates the options and begins to develop options for policy clarifications and changes.

Background. Medicare pays differently for inpatient hospital stays and outpatient care. Further, outpatient care has different post-hospital coverage consequences than inpatient stays, but to date, CMS has not provided clear direction on how to determine when outpatient treatment is sufficient or when inpatient admission is medically necessary. CMS has long recognized that the authority to make inpatient admission decisions rests largely with the patient's treating physician. Recently, acting on behalf of CMS, RACs and MACs have started to inappropriately second guess physician judgment, declaring that some patients who were admitted should not have been, and patients who thought they were admitted are surprised to learn that they were actually receiving outpatient services. The second-guessing inherent in the RAC program has created ambiguity over who decides what constitutes an appropriate admission and what the criteria are for making such a determination. This serves no one's interest. Hospitals, treating physicians and patients are caught in the middle.

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 and input from the patient. This is as it should be. As CMS recognizes, the decision to admit a patient is a "complex medical judgment" that involves the consideration of many factors. These fact-sensitive medical judgments do not lend themselves to second-guessing by government officials.

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. RACs paid on a contingency fee basis and other entities – which are charged with auditing Medicare claims – 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 often focuses on the patient's length of stay and the services actually rendered during that stay rather than his or her presenting condition and risk factors. Thus, it is not surprising that Medicare contractors conclude that many patients who were admitted as inpatients could instead have been treated on an outpatient basis. Hospitals must incur substantial costs appealing those decisions or forgo payment for most of the services provided because CMS takes the position that once an inpatient claim that was paid under Medicare Part A is later – usually years later – denied, the hospital cannot receive

Medicare Part B payment except for a few ancillary services (Medicare Benefit Policy Manual, Chapter 6 §10). According to data collected by the AHA, however, when such denials are appealed, the vast majority, 74 percent of appealed RAC decisions, are ultimately reversed.

In addition to substituting their own medical judgments for those of the treating physician, Department of Justice attorneys and whistleblowers have filed *False Claims Act* suits alleging that physicians and hospitals that have admitted patients for medically necessary treatment rather than providing treatment on an outpatient basis have committed fraud on the U.S. government. These individuals have decided that some types of physician-approved inpatient stays are not medically necessary because the patient could have received adequate care on an outpatient basis. 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 or 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 short inpatient stays. The Medicare 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 care 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 are on the rise. CMS has noted 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.

This situation also has had a significant negative impact on Medicare beneficiaries in terms of increased out-of-pocket costs they bear due to higher copayments in the outpatient setting compared to what they would pay as inpatients. In addition, some beneficiaries who receive outpatient observation services rather than being admitted, find they are unable to qualify for post-acute skilled nursing facility (SNF) care, for which Medicare requires a three-day inpatient stay. This has led to a recent class action lawsuit filed by a group of beneficiaries against the Secretary of Health and Human Services (*Richard Bagnall, et al. Plaintiffs v. Kathleen Sebelius, Secretary of Health and Human Services, Defendant*). The AHA has submitted an *amicus* brief (attached) in this case in order to provide background and context as the U.S. District Court of Connecticut considers the issues raised in the plaintiffs’ complaint. However, we have taken no position at this time regarding the proper outcome of this litigation.

To help inform our comments, the AHA embarked upon a series of discussions with our hospital and health system members to identify policy options that we hope will contribute to safe and effective patient care and improved payment fairness for hospitals and patients. We plan to continue these discussions and engage in further policy development through our governance process. The options we discuss below reflect only the first of several discussions we intend to have with our members.

We established the following principles to help guide our discussions and review of options:

- Clear guidance from CMS is necessary so that hospitals and their admitting physicians have more certainty that they are making the right decisions the first time and that the risk of audits and denials is minimized;
- To ensure that patients receive timely and appropriate care in the most appropriate setting, the treating physician's judgment, which takes into consideration both the patient's conditions and other risk factors, should be the primary determining factor for inpatient admission decisions, not external rules and criteria; and
- Hospitals should receive fair and adequate payment for the services that they furnish.

Time-Based Admission Policies. In the proposed rule, CMS asks whether there would be any benefit to establishing a time-based admissions policy. That is, should there be a point in time after which an encounter automatically becomes an inpatient stay if the beneficiary is still receiving medically necessary care, or are there other possible "time-based" approaches?

In the AHA's discussions with hospitals, there was some interest in exploring time-based admission policies. The general sentiment was that patients who have been actively monitored in an outpatient observation bed for some period of time – perhaps more than 24 hours or 48 hours – and still cannot be safely discharged, are likely to be complex enough cases to benefit from being admitted as an inpatient, regardless of whether they technically meet inpatient admission criteria.

A time-based admissions policy would more accurately reflect the fact that observation care, both in terms of the type of services provided as well as the cost of those services, is more comparable to inpatient care than it is to other types of outpatient services. According to CMS, observation care involves "a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment, that are furnished while a decision is being made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital." The nature and duration of observation care's evaluation of the patient's progress or regression varies significantly depending on the patient's presenting symptom, his or her co-morbidities, medical history and other factors and may involve tracking the effectiveness of medication or infusions, ordering and reviewing the results of diagnostic results and other steps that are deemed medically necessary

by the patient's treating physician. This distinction between inpatient services and observation care is blurred even further when hospitals house observation patients in inpatient units.

A policy that would result in automatic admission after a certain time period in outpatient observation also would help address beneficiary concerns about qualifying for SNF care. That is, with automatic admissions based on time, more beneficiaries would meet the SNF three-day inpatient stay requirements.

Hospitals are concerned, however, that setting a firm time period after which an observation patient would automatically be considered an inpatient would expose the hospital to increased risk of retrospective review and audit by RACs and MACs who would challenge the medical necessity of the patient's length of stay as an outpatient and the level of monitoring that the patient underwent during his or her observation stay. Hospitals also are concerned that a time-based admissions policy would likely generate additional short inpatient stays, thereby triggering more RAC audit and denials. To address the audit risk, hospitals might have to expend substantial additional resources on medical record documentation and progress notes by the attending physician and nursing staff so as to provide written evidence acceptable to the RACs that the patient was being actively monitored while in observation.

Implementing a time-based policy also would likely require a comprehensive review and revision of other Medicare requirements including other payment regulations and Medicare conditions of participation. The application of existing payment policies for outpatient copayments obligations, coverage of self-administered drugs and the three-day inpatient stay requirement for SNF coverage also would need to be reviewed and addressed in the context of a time-based admission policy.

Some hospitals were concerned that a time-based admission policy would undermine the historic reliance on physician judgment as the basis for making an admission decisions. One way to address this would be to implement a policy in which observation time beyond the specified limit would not trigger an automatic admission but rather would become a new decision point for the attending physician to decide whether to admit the patient. While this would incorporate physician judgment into the time-based admission policy, it would have the downside of adding complexity and an additional opportunity for RACs to second-guess physician judgment.

Finally, CMS asks if time-based admission policies would present opportunities for taking advantage of the Medicare program. Hospitals believe that they and the patients' treating physicians have made significant investments in trying to make the admission decision correctly in the first place and that the *False Claims Act* and CMS's administrative authority are sufficient enforcement safeguards to capture and punish hospitals that engage in a pattern of abusive behavior.

More Specific Clinical Criteria. In the proposed rule, CMS asks whether more specific clinical criteria for admission and payment should be established.

In our initial discussions with hospitals, it is clear that hospitals and health systems are wary of the notion of applying more specific clinical criteria and measures for inpatient admission as an overall strategy. Their concerns are several. First, the currently available clinical criteria, such as InterQual and Milliman, do not incorporate the essential elements of clinical risk – the probability of harm to the patient if he or she is removed from the medical oversight provided by inpatient hospital status – into the admission criteria and it is likely that they could not adequately do so given the tremendous variety of conditions and situations with which patients present. Second, external clinical criteria are intended to be used only as guidelines, not as the final determining factor in an admission. Third, relying more heavily on expanded external clinical criteria would reduce the role of physicians' judgment in making inpatient admission decisions. CMS has said that "the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of 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 Benefit Policy Manual, Chapter 6 §10. Simply put, the treating physician knows most about the patient and is therefore in the best position to assess his or her condition and risk in the complex decision-making involved with deciding whether to admit a patient. Hospital utilization review committees also play a role in assessing the treating physician's decision and their review is a preferable approach to that of applying more specific clinical admission criteria.

Hospitals are interested in engaging CMS in further discussions about making judgments about admissions in light of what is known at the time the patient presents versus the "Monday-morning quarterbacking" that occurs when CMS contractors assess whether the patient could have been treated as an outpatient based on the care he or she actually received. Hospitals and physicians are frustrated by the current approach taken by MACs and RACs in rejecting clinical uncertainty and the probability of risk to the patient as relevant factors for admitting patients. For example, the MAC in Jurisdiction 13, National Government Services, has said outright that the Medicare program does not pay for risk. Despite CMS's recognition that the decision to admit a patient is a "complex medical judgment" that involves the consideration of many factors, in practice, Medicare contractors tell attending physicians that these multiple risk factors, including co-morbidities and the patient's history of serious recent health care system encounters that increase the probability of an adverse outcome, are irrelevant. Instead, it is only the actual occurrence of an adverse event that should be a factor in a patient's admission. Contractors indicate that patients with a high probability of decompensating while under the hospital's care should instead be placed in outpatient observation.

One area for which hospitals saw some promise in establishing more explicit clinical criteria is in the SNF coverage qualifying criteria. While the three-day minimum inpatient stay criterion for SNF coverage has served its purpose over the years as a proxy for whether the patient is sick enough to benefit from SNF care, the policy is now obsolete and should be replaced. In the current environment in which inpatient length of stay is declining, requiring a patient to be in inpatient for at least three days before he or she can get SNF coverage does not make sense. However, hospitals do not advocate simply eliminating the requirement, which would be

extremely costly to the Medicare program and would not adequately screen patients for the need for SNF care. Instead, hospitals felt that this policy should be replaced with a more clinically based policy to justify SNF coverage. We recognize that such a change would require a change in current law. **Nevertheless, we encourage CMS to work with hospitals, physicians and SNFs to develop a more meaningful set of clinical criteria for SNF care.**

Prior Authorization. In the proposed rule, CMS asks whether prior authorization should be required for payment of an admission.

In our initial discussion with hospitals and health systems, the idea of using prior authorization on a targeted basis was seen as promising and deserving of further consideration. This reflects a desire to alleviate the “audit exhaustion” that hospitals feel due to the time and cost of responding to the multiple contractors who are conducting retroactive and pre-payment reviews of hospital inpatient claims. The view is that hospitals may be better off knowing in advance that a service is approved and that the claim will be paid.

Because prior authorization would add another layer of administrative burden to hospital admission practices, it would be critical that Medicare guarantee that once a service has been pre-reviewed and pre-authorized, it would not be subject to further review and denial. Further, this approach requires a commitment from CMS’s contractors to staff the program on a 24-hours-a-day, seven days-a-week (24/7) basis, and that the staff be able to adequately respond to inquiries from nearly 6,000 hospitals and health systems. Since so much of the focus here is on short-stay patients, this approach will work only if hospital staff members are able to communicate directly with those who can provide authorization to admit the patient at all times.

Hospitals felt that prior authorization policies should be targeted at select MS-DRGs for procedures that generate what CMS believes are large numbers of inappropriate admissions or those services with short lengths of stay. These are the services that are frequently reviewed and denied by RACs and MACs. MS-DRG 247 (*percutaneous cardiovascular procedure with drug-eluting stents without Major Comorbid Condition (MCC)*) is a good example of the type of MS-DRG for which a prior authorization policy may be helpful.

Another approach worth exploring would be combining the application of clinical criteria, such as InterQual, with prior authorization for certain MS-DRGs. Those patients satisfying InterQual criteria would be admitted without further review. A prior authorization process would be used for patients whose conditions failed to satisfy admission criteria but the attending physician still felt strongly that care should be provided in an inpatient setting. This approach has the advantage of promoting physician judgment via the request for prior authorization. It also would help ensure that, under current CMS policy as contained in its manuals, the hospital would still receive some payment for services furnished, even if it is ultimately only OPPS payment.

Hospitals generally felt that prior authorization would be best suited to patients requiring procedures that are done on an elective basis rather than those patients that present through the emergency department as observation patients. This is because in an emergency or observation

situation, getting prior authorization for admission may not be practical as it would be too time-consuming and labor intensive. The types of elective procedures that were mentioned as possible candidates for this sort of approach are those that have short lengths of stay and are frequently reviewed and denied by Medicare contractors, such as stents and automatic implanted cardioverter defibrillators.

Finally, hospitals' willingness to accept prior authorization could be affected by a change in CMS policy. For example, if CMS were to change its manuals to allow payment under Part B for all medically necessary services furnished during an inpatient stay that is denied by a contractor, prior authorization would not necessarily be needed. Similarly, if CMS revised its manuals to permit hospitals to change a beneficiary's care from inpatient to outpatient *after discharge*, the burdens associated with prior authorization might make it an undesirable option.

Better Aligning Payments with Resources Used. In the proposed rule, CMS asks whether payment rates should be aligned more closely with resources used by hospitals when providing outpatient care versus inpatient care of short duration.

CMS apparently believes that there is an excessive number of short inpatient stays and has therefore allowed its audit contractors, particularly the RACs, to target short inpatient stays for review and denial. This has had cascading consequences, with RACs aggressively pursuing short stay denials, hospitals increasingly using outpatient observation care and beneficiaries expressing concern about high out-of-pocket costs in the hospital outpatient setting and the inability to qualify for SNF care.

The hospital and health system representatives with whom we spoke were interested in exploring whether a payment approach that better aligns payment rates to the resources used to furnish services could address the concerns that have been raised regarding patient status. In particular, there was interest in exploring payment policy options that could address these payment differences. For example, CMS could revise its manuals to permit payment under Part B for denied inpatient stays or allow hospitals to change an inpatient stay to an outpatient one after a beneficiary's discharge.

Hospital Best Practices. In the proposed rule, CMS asks whether hospitals could do a better job in initial admission decisions. Specifically, what is the responsibility of hospitals to use all the tools necessary to make appropriate initial admission decisions?

We believe that there are some things that hospitals could do to improve decision-making for initial admissions. One common best practice that a growing number of hospitals are putting into place is expanding the availability of utilization review staff on a 24/7 basis. This helps to reduce incidents of improper inpatient admissions, particularly for those short-stay cases where it is unclear whether the patient should be admitted. In addition, taking steps to improve physician documentation of the rationale for admitting patients also would be beneficial. Hospitals could promote better documentation by incorporating a required field in the hospital's electronic documentation system that asks why the patient needs to be admitted.

In addition, there are practices that could help beneficiaries better understand their status and related consequences when they are receiving outpatient observation services. The use of a dedicated observation unit can help promote this type of situational awareness. We understand that close to 40 percent of hospitals now furnish observation services in a dedicated observation unit. Also, hospitals could do a better job communicating to Medicare beneficiaries under observation that they are outpatients and what that means in terms of their potential responsibility for certain additional out-of-pocket costs, as well as the implications for qualifying for any necessary SNF care.

GEOMETRIC MEAN-BASED PAYMENT WEIGHTS

The AHA cautiously supports CMS's proposal to use the geometric mean cost of services within an ambulatory payment classification (APC) to determine the relative payment weights of services, rather than the median costs that have been used since the inception of the OPPS. The agency states that it is proposing this change because geometric mean costs reflect average costs of services more accurately than the median, including capturing more accurately the variation in costs that occur when providing a service; promote stability in the payment system by making the relative payment weights more reflective of the service costs; and provide consistency with the inpatient PPS methodology, which also utilizes mean costs.

The AHA applauds changes that are intended to improve the accuracy and stability of the OPPS payments; however, CMS's proposal represents a fundamental change in outpatient payment methodology, and thus, we urge CMS to proceed cautiously and transparently to ensure that there are no unintended consequences for hospitals and their patients. Since the relative payment weights are the basis for determining the payment rates for OPPS services, the use of geometric mean costs would affect the proposed CY 2013 payment rates for most services, as well as copayments, the fixed dollar outlier threshold and other components of the OPPS. And while aggregate OPPS payments would not change under this budget-neutral proposal, payment rates for individual services would change, with some services experiencing significant increases or decreases.

In the AHA's analysis of the impact of using geometric mean rather than median cost for calculating payment rates, we reviewed which medical specialties would be affected the most by the proposed change in terms of the projected payment differences by specialty, using Berenson-Eggers Type of Service (BETOS) categories. We found that, in the aggregate, imaging services and tests would experience significant reductions in payments – declining by about \$144 million and \$14 million, respectively. By contrast, evaluation and management services and procedures would experience significant increases in payments – increasing by about \$31 million and \$86 million, respectively. Advanced imaging services, including computed tomography (CT scans) and computed axial tomography (CAT scans) in particular, would experience large aggregate reductions in payment levels. **In the event that CMS finalizes this proposal, the AHA recommends that the agency closely monitor changes in the service frequency and**

distribution as well as patient access to those services with the largest payment reductions. Significant reductions in service volume that may be evidence of reduced patient access should be brought to the attention of CMS leadership and dealt with expeditiously.

Further, CMS's analysis of the impact of this proposal by provider type shows that community mental health centers (CMHCs) would experience the largest reduction – a 6.9 percent cut in payments – due to the use of geometric mean-based payment weights (which works out to a 4.4 percent reduction when all the proposed rule changes are considered). Hospitals are concerned that such a significant reduction in payment for CMHCs in a single year, especially as this follows several consecutive years of precipitous payment declines, could result in many of these organizations going out of business, particularly those that see a high proportion of Medicare beneficiaries. As there is already inadequate inpatient and outpatient capacity in many communities to care for mentally ill individuals, additional CMHC closures would have substantial and serious consequences for Medicare beneficiaries requiring partial hospitalization services and for hospitals that serve them. Such potential consequences include reduced access to an appropriate partial hospitalization program for this vulnerable Medicare beneficiary population, increases in emergency department crowding, and increased readmissions. **If CMS finalizes the use of geometric means, the AHA urges the agency to carefully track the impact on CMHC services in terms of frequency and distribution as well as patient access to outpatient mental health services in general.**

In addition, as part of CMS's rationale for proposing the use of geometric mean relative payment weights for the OPSS, the agency notes that its use would provide consistency with the inpatient PPS methodology, which also utilizes mean costs. However, we note that the inpatient PPS uses *arithmetic* means, not geometric means, to set the payment weights for the MS-DRGs. **While the AHA has no preference at this time regarding which type of mean should be used for calculating payments for the OPSS, given that there is no discussion of this issue in the proposed rule, we request that CMS clarify why it has proposed to use geometric mean rather than the arithmetic mean.**

PAYMENT POLICY FOR SPECIFIED COVERED OUTPATIENT DRUGS

The AHA strongly supports CMS's proposal to pay for separately payable drugs and biologicals at the "statutory default" rate of average sales price (ASP) plus 6 percent. Paying at the rate of ASP plus 6 percent, which is allowed in section 1833(t)(14)(A) of the *Social Security Act*, is administratively simple, would improve stability of drug and biological payments and would better cover the costs of drug acquisition and pharmacy overhead costs than the payment rates CMS has finalized in previous years. By contrast, the current payment methodology involves complex calculations and an annual "overhead adjustment" in which costs are redistributed from packaged drugs to separately payable drugs. We appreciate and agree with the agency's recognition of flaws in its current rate-setting methodology, especially that the current payment methodology "still may not appropriately account for average acquisition and

pharmacy overhead costs and, therefore, may result in payment rates that are not as predictable, accurate, or appropriate as they could be.”

CODING AND PAYMENT FOR CRITICAL CARE SERVICES

CMS proposes to continue its CYs 2011 and 2012 policy to recognize the existing Current Procedural Terminology (CPT) codes for critical care services and establish a payment rate based on historical claims data. It also proposes to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

As we did in 2011, the AHA recommends that CMS, in setting the payment rate for packaging ancillary services into the critical care services, establish a methodology that includes review of multiple cost report revenue centers. For example, the critical care services provided in the emergency department would be reflected in the emergency department cost report line. However, costs for ancillary services (e.g., chest x-ray, EKG, ventilator management) would be reflected in the revenue centers for the respective departments providing the service, such as radiology, cardiology and respiratory therapy.

TRANSITIONAL CARE MANAGEMENT

As part of a multi-year strategy exploring the best means to encourage the provision of primary care and care coordination services to Medicare beneficiaries, CMS proposes to create a Healthcare Common Procedure Coding System (HCPCS) G-code for transitional care management. The code would address the non-face-to-face work involved in hospital or SNF discharge care coordination. CMS recognizes that certain elements of the transitional care coordination services described by the proposed G-code could be provided to a hospital outpatient as an ancillary and supportive service in conjunction with a primary diagnostic or therapeutic service that would be payable under the OPSS, such as a clinic visit. Since CMS typically packages payment for ancillary and supportive services, the agency proposes to package the G-code into the primary service provided to a hospital outpatient.

The AHA supports the use of a HCPCS G-code to identify the non-face-to-face work involved in hospital or SNF discharge care coordination.

INPATIENT LIST

The AHA opposes CMS’s proposal to remove from the inpatient list CPT code 27447 (*Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)*). We do not agree that the clinical characteristics of

a total knee arthroplasty (TKA) justify its selection as an appropriate candidate for removal from the inpatient list.

In most cases, total knee replacement includes a large operation with the potential for serious intra-operative blood loss, multiple days in the hospital, arduous rehabilitation, and prolonged time for recovery. Feedback from AHA members indicate that TKA patients are generally hospitalized 72 or more hours, often have significant post-operative pain, are often dehydrated, and many have post-operative anemia requiring transfusions. In general, these patients have more post-operative medical conditions and complications that require extended stays. While a younger and healthier non-Medicare population may be able to safely undergo outpatient TKA, Medicare patients are far more likely to suffer from conditions that would be clear contraindications for outpatient TKA, such as cardiac conditions, severe diabetes, obesity or need blood transfusions.

Further, there is evidence that patient outcomes are worse with outpatient TKA. In a February 2012 presentation presented at an American Association of Orthopedic Surgery meeting ([Lovald S, et al "Outpatient total knee arthroplasty: a cost and outcomes analysis" AAOS 2012; Abstract 411](#)) presenters noted that this study found that patients having total knee replacement surgery as outpatients were significantly more likely to die or need readmission within 90 days compared with inpatients remaining in the hospital for three to four days. Rates of subsequent revision surgery were nearly doubled in patients having one-day hospital stays compared with the three-to-four-day standard. The data came from an analysis of a 5 percent sample of Medicare beneficiaries undergoing TKA from 1997 to 2009.

TKA also does not appear to meet all of CMS's own criteria for removal from the inpatient list. CMS lists the five established criteria but does not describe their specific application to the codes proposed for removal. In particular, we note that one of the five criteria for removal of a procedure, "*A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list,*" is notably not the case for TKA. To the contrary, CMS makes a determination that the procedure is not appropriate for the ASC list, stating "We believe that these two procedures [*which include CPT 27447*] should continue to be excluded from the ASC list of covered surgical procedures for CY 2013 because they would be expected to pose a significant risk to beneficiary safety or to require an overnight stay in ASCs." (77 FR 45167)

The AHA recommends that at this time TKA remain an inpatient-only procedure. We believe that there would likely be very few, if any, Medicare beneficiaries who could safely be discharged home just hours after undergoing a total knee replacement, as would occur in hospital outpatient settings. In fact, many beneficiaries who receive total knee replacement subsequently receive SNF care during their recovery from this incapacitating surgery. We are concerned that if this service is removed from the inpatient list, Medicare contractors, including MACs and RACs, will apply inappropriate pressure on hospitals and physicians to perform total knee replacements in the hospital outpatient setting, through crafting ill-conceived local coverage decisions and retroactively denying TKA services when done in inpatient settings. The expected

pressure imposed by Medicare contractors on hospitals to perform TKA as an outpatient service could result in patients receiving care in a setting inappropriate to their needs and many beneficiaries who would otherwise benefit from SNF care not qualifying, to the detriment of patient health and safety.

PAYMENT ADJUSTMENT FOR RADIOISOTOPES DERIVED FROM NON-HIGHLY ENRICHED URANIUM SOURCES

CMS proposes to make a \$10 per dose payment adjustment for hospitals that use technetium-99 (Tc-99m) – the radioisotope used in the majority of diagnostic imaging services – when it has been produced in reactors that do not use highly enriched uranium (HEU). This payment adjustment is intended to support an Administration policy to eliminate reliance on reactors outside the U.S. that produce HEU and to promote the conversion of all medical isotope production to non-HEU sources.

The conversion to non-HEU sources, which CMS says is expected to be completed within a five-year period, will introduce new costs into the payment system that are not accounted for in the historical claims data. Therefore, CMS proposes to establish a new HCPCS code, QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, per dose) for which an additional payment of \$10 will be made. The payment adjustment, which would be budget neutral to the OPPIs, is intended to cover the marginal cost of hospital conversion to the use of non-HEU sources of Tc-99m. Hospitals would be able to report this code once per dose along with any diagnostic scan or scans using Tc-99m as long as the Tc-99m doses used can be certified by the hospital as coming from non-HEU sources and have been priced using a Full Cost Recovery accounting methodology. While hospitals would not be required to make a separate certification on the claim of the non-HEU source, in the event of an audit, hospitals would be expected to be able to produce appropriate documentation.

The AHA supports CMS's intent to encourage hospitals to use non-HEU sources; however we do not believe that the agency's proposed policy, as conceived, will promote the conversion to non-HEU sources in the hospital outpatient department setting. A payment of \$10 per dose is inadequate to incentivize hospitals to change their current practices and transition purchases to non-HEU sources. In addition, the \$10 is insufficient to cover the costs passed on to hospitals from the various levels of the supply chain, including the producer, the generator manufacturer and the nuclear pharmacy. **We encourage CMS to explain in more detail how it arrived at the conclusion that a \$10 adjustment would be adequate to incent hospital behavior.**

Further, the requirement of 100 percent non-HEU sources to obtain the \$10 add-on payment is unrealistic given the current lack of availability of a reliable and consistent non-HEU supply. To make this policy more feasible, CMS should, at a minimum, allow a payment adjustment for lower percentages of non-HEU sources and institute a multiyear phase-in period. CMS's proposed policy currently offers no phase-in option for the hospitals' use of non-HEU product.

We also are concerned about this proposed policy's administrative burden and cost, which is more than the marginal additional cost of moving to non-HEU sources. While CMS states that its intention is to not require hospitals to report and document on the individual patient claim, the policy nonetheless would demand this approach with the resulting additional administration and documentation burdens. These additional costs include:

- Expenses for developing and maintaining policies to track, certify and document HEU versus non-HEU sources in order to use the new required Q-code, which is necessary to obtain the \$10 per dose payment adjustment.
- New compliance program checks and monitoring to ensure appropriate codes are used and documentation is maintained should an audit be conducted.
- Additional personnel time and resources to create and maintain line items on the hospital charge master for non-HEU versus HEU codes and charges. (Hospitals will need to use a more complicated charging system because there will not initially be adequate supply of non-HEU sources to allow a hospital to purchase only one type of supply in 2013.)
- Additional resources to develop nuclear medicine department information technology infrastructure, as well as billing policies for documentation and use of the new Q HCPCS Level II code.

In conclusion, we believe that, as conceived, this policy will not incentivize hospitals to convert to non-HEU sources, especially since there is very little existing supply of non-HEU sources. If CMS moves forward with a non-HEU payment adjustment policy, we recommend that:

- **The policy be phased in over several years as the nation converts all medical isotope production to non-HEU sources;**
- **The payment adjustment amount be increased to better reflect the marginal additional costs of the non-HEU sources as well as the additional administrative and compliance burden that would fall upon hospitals who choose to use the new code; and**
- **Through the course of the transition, CMS permit hospitals that use lower percentages of non-HEU derived radiopharmaceuticals to bill for and receive the payment adjustment.**

OUTPATIENT QUALITY REPORTING PROGRAM

The Tax Relief and Health Care Act of 2006 required CMS to establish a program under which hospitals must report data on the quality of outpatient care in order to receive the full annual update to the OPPS payment rate. Hospitals failing to report the required data will incur a 2.0 percentage point reduction in their annual payment update factor.

The AHA commends CMS for not proposing any new measures for the Hospital Outpatient Quality Reporting (OQR) program in the proposed rule. It is incumbent upon all stakeholders to ensure that if CMS adds measures to the required data collection, it do so only because there is good reason to believe that measuring an outcome or process will lead to significant and meaningful improvements for patients. Given the current state of evidence regarding improvement opportunities, the availability of meaningful measures, and the impending coding changes that will affect all quality data collection, it is commendable that CMS has chosen to take a pause in adding measures to the OQR. The AHA also applauds CMS's proposal to suspend the use of three measures that were previously finalized for the CY 2014 OQR program.

Of the 26 previously finalized measures for the CY 2014 program, CMS proposes to suspend:

- *OP-15*: Use of brain computed tomography in the emergency department for atraumatic headache as a requirement for payment is being suspended because public reporting is not planned prior to July 2013, at the earliest;
- *OP-19*: Transition record with specified elements received by discharged patients is being suspended while it undergoes maintenance review by the National Quality Forum (NQF).
- *OP-24*: Cardiac rehabilitation – patient referral from an outpatient setting because the specifications for this measure have not yet been released, so data collection is being deferred for the CY 2014 payment determination.

The AHA also notes that there is a significant disparity between the recommendations of the Measures Application Partnership (MAP) and CMS's proposed actions for the OQR program. The MAP is a multi-stakeholder board charged with making annual recommendations to the Secretary of the Department of Health and Human Services (HHS) regarding which measures should be included in national quality reporting programs. In early 2012, the MAP conducted a review of measures from CMS, including measures in the current OQR program. The MAP suggested that seven of the previously finalized OQR measures were directionally right, but not appropriate for use in the OQR program as currently constructed.

The AHA has commented to CMS on several occasions in the past that the imaging efficiency measures (OP-9, OP-10, OP-14 and OP-15) should not be included in the OQR program because several of them have failed the NQF-endorsement process. Further, we have heard from members that the implementation of OP-20, OP-22 and OP-25 has been difficult and produced

results that are not accurate or suitable for public reporting. **Given this assessment and the MAP recommendations, the AHA urges CMS to immediately remove these measures (see chart below) from the OQR program.**

OQR Measures Not Recommended by the MAP
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-14: Simultaneous Use of Brain CT and Sinus CT
OP-15: Use of Brain CT in the Emergency Department for Atraumatic Headache
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
OP-22: ED Patient Left Without Being Seen
OP-25: Safe Surgery Checklist Use

Program Compliance. Currently, CMS recognizes only the hospital outpatient department (HOPD) CEO as the official party who is able to certify compliance with certain aspects of the OQR program. In this proposed rule, CMS proposes to allow a HOPD to designate a party other than the CEO to certify both reconsideration/appeals and an extraordinary circumstances extension/waiver. **The AHA strongly supports this change.**

CHANGES TO THE QUALITY IMPROVEMENT ORGANIZATION REGULATIONS

The proposed rule makes a number of changes to procedures for Quality Improvement Organizations (QIO).

Beneficiary Complaints. The proposed rule outlines a new review process called “immediate advocacy,” a concept already described in chapter five of the QIO Manual. Immediate advocacy is an informal process that aims to quickly resolve concerns brought through oral complaints. CMS proposes to limit the timeframe available for immediate advocacy to six months. That is, the complaint must be made within six months of the date on which the care giving rise to the concern took place. However, CMS seeks comments on whether this period should be longer. All parties must consent to the use of oral advocacy, and the beneficiary would need to agree that his or her name could be disclosed (though other confidentiality requirements would apply).

Because immediate advocacy is an informal process, it would not be allowed for situations that “rise to the level of being a gross and flagrant, substantial, or significant quality of care concern.” However, CMS seeks public comment on whether immediate advocacy should be allowed in significant situations where quality of care is questioned. Those concerns relate to a QIO determination that the standard of care was not met and was a noticeable departure from the standard “that could reasonably be expected to have a negative impact on the health of the beneficiary.”

The AHA believes that the interests of the beneficiary or family filing the complaint, the public, and the hospital and health care professionals involved are best served when a swift and effective resolution can be found to a complaint regardless of whether that complaint is oral or written. We encourage CMS to think about bringing formality to the process of resolving a complaint only when needed to ensure actions are taken to address potential patient safety issues or quality of care issues.

CMS also is proposing new regulatory language in the QIO regulations to address the submission of written beneficiary complaints. The proposed regulations outline the QIO responsibility for reviewing written complaints of beneficiaries and limit the timeframe for filing a complaint to three years. CMS clarifies that electronically-submitted complaints are sufficient.

The AHA believes that three years is too long from the time of occurrence for beneficiaries to file a complaint. We urge CMS to consider a one-year timeframe with a potential allowance for additional time to file a complaint in those rare circumstances when the untoward outcome was not discovered until after the year had elapsed.

The proposed regulations broadly outline the scope and procedures for a beneficiary complaint review, emphasizing an “episode of care” framework, underscoring that some information may be confidential, and clarifying that evidence-based standards would be used as much as possible. When a standard of care for a particular circumstance does not exist, the QIO would determine the standard, and this determination would not be subject to appeal.

The AHA emphatically opposes the suggestion that the QIO determine a standard of care when one does not exist. Standards of care are complex and are reliably developed only with clinical experts assessing the available medical evidence. There is no reason to believe that the QIOs will have more relevant medical expertise available to make such determinations for all medical care issues. Further, there are numerous areas of medical practice for which insufficient evidence exists to guide the conclusion of what should be the standard of practice. The QIOs should not be expected to make up a standard where evidence to support it does not exist.

Equally troubling is CMS’s suggestion the QIO’s decision would not be subject to appeal. In other words, according to this proposal, the QIO’s staff could make a decision about what the care should have been, based on their own interpretation of whatever clinical evidence might be available, but the hospital’s experts who are both familiar with the individual patient and the clinical issues in question, could not provide a rationale for a different approach to caring for the patient. **We find this an unacceptable approach to adjudicating these matters and urge CMS to provide for an appeals process for any decisions the QIO might make about what the relevant standard of care is for a case.**

General Quality of Care Reviews. The proposed rule outlines the procedures for conducting a general quality of care review, which may be based on: (1) referrals from individuals, federal or state agencies, contractors, and others; (2) issues that arise during other QIO activities (such as medical necessity reviews); and (3) analysis of data. CMS emphasizes the use of evidence-based

standards, but if a standard does not exist, the QIO will determine the standard, and that determination is not subject to appeal. Here, too, the AHA wonders how the QIO will develop standards that can be sufficiently relied upon in the absence of clinical expertise and scientific evidence. As above, **the AHA finds it unacceptable to suggest the QIO should adjudicate these matters without opportunity for a counter argument to be made to an independent third party. We urge CMS to provide an appeals process regarding any decisions the QIO might make about the relevant standard of care during general reviews of quality.**

CMS does specify that for reviews initiated after July 31, 2014, providers and practitioners would be able to request reconsideration by the QIO, but the request must be made “no later than noon of the calendar day following initial notification ... of the QIO’s determination” with limited exceptions. The QIO must notify the provider within 72 hours after receiving the reconsideration request (or receiving information needed for reconsideration) of its final decision. While we appreciate the sense of urgency these timeframes suggest, they may not provide sufficient time for preparing a request for reconsideration or for the QIO to review and make a determination based on the additional information provided. **We urge that CMS provide a reasonable amount of time for both filing the request for reconsideration and for the QIO to consider the additional information.**

Active Staff Privileges. Currently, QIOs must use individuals with “active staff privileges in one or more hospitals” to make initial denial determinations. In order to increase the number of peer reviewers, CMS proposes to remove this requirement. **The AHA believes that it is critically important that the clinicians used in making denial determinations have active staff privileges in a hospital.** Clinical practice changes rapidly and new, relevant medical information emerges frequently. It is imperative that individuals making judgments about the appropriateness of care be in active practice and cognizant of the emerging clinical evidence and practices.

Photocopying Reimbursement. CMS also requests comments on whether it should make changes to reimbursement methodologies for paper copies of records submitted to the QIO. **CMS’s payment amounts for photocopying do not adequately cover the cost of what it takes to generate the requested records. The agency’s methodology needs to be routinely updated to keep pace with inflation.** Further, in a world that is trying to be more ecologically sound and move to electronic health records, CMS needs to consider how it can more effectively and efficiently accept electronic records.

QUALITY REPORTING THROUGH ELECTRONIC HEALTH RECORDS (EHRs)

CMS proposes to extend its ongoing EHR Incentive Program Electronic Reporting Pilot for hospitals and CAHs to FY 2013. The pilot was proposed and finalized in the 2012 OPPS rule, but pertains to quality measures required for the “meaningful use” incentive program, and not for reporting under the OPPS. The AHA continues to have significant concerns about the reporting of quality measures through EHRs, as detailed in our comment letter on the proposed rules for

Stage 2 of meaningful use. In particular, we are concerned that the technical specifications for the measures are not accurate and have not been sufficiently field-tested to ensure that quality data reported from EHRs are valid, reliable, and comparable across hospitals. **Therefore, the AHA recommends that CMS modify its pilot program to field test the measures used in the EHR Incentive Program and determine the ability of vendors and hospitals to accurately capture the necessary data in the required formats to generate valid, reliable and comparable quality measures directly from the EHR. In addition, CMS should establish a clear process to manage updates to specifications for quality measures, and a mechanism through which vendors and providers can offer feedback on problematic or unclear measures.**

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

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

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

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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,

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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.

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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]

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