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June 12, 2008

Acting Administrator Kerry N. Weems
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1390-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physicians Ownership in Hospitals and Physicians Self-Referral Rules, Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians; 73 Fed. Reg. 23,528 (April 30, 2008).

Dear Acting Administrator Weems:

On behalf of the 74,000 Fellows of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments on the proposed rule CMS-1390-P: Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physicians Ownership in Hospitals and Physicians Self-Referral Rules, Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians.

The American College of Surgeons was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. A large percentage of surgical care takes place in the inpatient hospital environment; therefore, we have a strong interest in CMS' hospital value-based purchasing and quality improvement efforts and can offer significant insight into the degree to which the proposed expansion of the program will achieve CMS' intended goals.

HOSPITAL ACQUIRED CONDITIONS (HACs) – OVERALL CONCERNS

The Deficit Reduction Act requires hospitals to identify any secondary diagnosis of a Medicare patient which is present on admission (POA), effective October 1, 2007. This information must be included on claims submitted for payment of a hospital admission. In addition, CMS is required to select two or more conditions that meet the following three criteria: 1) high cost and/or high

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volume cases; 2) result in assignment to a higher paying DRG when identified as a secondary diagnosis; and 3) could reasonably have been prevented by the application of evidence-based guidelines. In the final FY2008 IPPS rule, CMS selected eight conditions which were believed to meet the above three criteria. Effective for discharges after October 1, 2008, if any of the selected conditions were not POA, the case will be paid as though the secondary diagnosis was not present.

In this proposed rule, CMS requests comments on refinements to two of the existing eight conditions – foreign object retained after surgery and pressure ulcers – and comments on ten potential new conditions. The nine proposed conditions include: 1) surgical site infections following four elective surgical procedures (i.e., knee replacement, gastric bypass, gastroenterostomy, and ligation/stripping of varicose veins); 2) Legionnaires' disease; 3) complications of diabetes resulting from poor glycemic control; 4) iatrogenic pneumothorax; 5) delirium; 6) ventilator-associated pneumonia; 7) deep vein thrombosis/pulmonary embolism; 8) Staphylococcus aureus septicemia; and 9) clostridium difficile associated disease. Methicillin-resistant staphylococcus aureus (MRSA) is discussed as a potential HAC, though CMS has chosen not to include it at this time.

Finally, comments are solicited on several further enhancements to the HAC policy including applying risk adjustment to the determination of payments involving selected HACs, considering the incidence of HACs in a hospital, the adoption of ICD-10-PCS coding, expansion of the HAC payment policy to other settings (e.g., physician offices), and other approaches to address serious reportable adverse events (i.e., “never events”).

The College is committed to improving the quality of surgical care; however, we have reviewed these proposals and have serious concerns and reservations about the expanded scope of this initiative and, more specifically, some of the proposed additions to the HAC list. Overall, we believe that adding 10 more conditions is premature, creates confusion about priorities, and excessively burdens hospitals and physicians. It is not yet clear as to the efficacy or effect of the non-payment policy for the first eight conditions. The evidence-based guidelines necessary for preventing these conditions – required as a defining characteristic for qualifying conditions – have changed for some of the current eight HACs and continue to evolve for the nine proposed.

When the HAC initiative is considered in light of the very significant increase in the number of hospital quality measures proposed in this rule, it is clear that the documentation and reporting burden for hospitals and physicians will consume significant resources and potentially impede improvements in quality of care.

In addition, there is duplication of quality indicators between the HAC program and the quality measure reporting initiative, but the measure specifications/approaches are inconsistent. For example, some quality measures contain exclusions to the denominator



based on risk factors and clinical appropriateness that are not included in the HAC reporting criteria. Thus, a hospital could indicate that they are appropriately meeting quality measurement criteria yet still lose payment under the HAC program.

In selecting conditions for inclusion on the HAC list, we believe that the priority should be on events around which there is broad agreement that failures or errors constitute poor quality of care. For example, in the initial HAC list, foreign objects retained after surgery, blood incompatibility, and falls or trauma are events that are “reasonably preventable” and for which providers should be held accountable. In contrast, other conditions, including some of those proposed in the rule, are not associated with an evidence base that supports prevention in all cases. As we will discuss in greater detail later, some of the proposed conditions are expected consequences of some procedures or treatment regimens or are likely to occur in high risk patients despite the application of appropriate preventive measures.

We believe that conditions selected for the HAC list should be supported by ‘level 1’ clinical evidence which relies on controlled, randomized clinical studies of representative groups of patients – including those who present with a high risk of complications – that are published in recognized peer reviewed journals. Our experience suggests that, in some of the conditions proposed in this rule, when all appropriate preventive measures and practices have been applied, there remains a likelihood that patients with certain risk factors will develop complications during a hospitalization. Under the proposed HAC policy we do not find any recognition of the fact that preventive measures cannot eliminate the occurrence of these conditions in some high risk patients.

Further, we are concerned about the impact and potentially unintended consequences associated with the required documentation of secondary diagnoses at the time of admission. In many instances, medical records may not be current or accessible or the patient may be asymptomatic with respect to one or more of the underlying conditions included on the proposed HAC list. In addition, some patient risk factors are unrecognizable at admission, such as steroid use or poor nutrition. Many patients that surgeons treat suffer from acute conditions, where the urgency of the situation may interfere with assessment. For example, trauma patients may be unconscious, and patients with severe infections, pain, or obstructions are often not thinking clearly enough to accurately report their medical histories. One unintended consequence of this policy could be to commit additional resources to the evaluation of patients, which may not result in the prevention of a complication for high risk patients while increasing the cost of care. There is also the distinct possibility that this policy could create access barriers for patients as hospitals or physicians will be unwilling to initiate elective admissions and subsequent procedures for certain high risk patients.

These concerns also prompt us to emphasize the importance of applying risk adjustment models to hospitalized patients. Without stratifying patients by known risk factors for



each of the HACs, it will not be possible to focus on the cohorts for whom complications were unexpected and identify the practices that led to the occurrence of the complication. In our view, risk adjustment would enable a much more effective and equitable strategy for targeting preventable complications of a hospital stay and holding providers accountable for inferior care.

Finally, the characterization of these conditions by CMS as ‘preventable’ creates a public perception that, if the condition occurs during a hospital admission, the physician and/or hospital failed to follow prescribed protocols. This could create confusion and doubt for patients who are advised that they may be at risk for certain complications resulting from treatment and are aware that Medicare regards such complications as preventable. Thus, we remain concerned that this policy will be confusing to our patients and could create the impression of inferior care. CMS should consider substituting the term “potentially preventable” for the term “preventable”.

HOSPITAL ACQUIRED CONDITIONS – COMMENTS ON SPECIFIC CONDITIONS

CMS requested comment on refinements to two of the current hospital acquired conditions: foreign object retained after surgery and targeting Stage III and IV pressure ulcers. We are concerned that the new ICD-9-CM coding scheme for pressure ulcers does not appropriately capture the distinctions in pressure ulcer assessment used in the clinical setting. Many wound care clinicians are concerned about deep tissue injury under intact skin as a precursor to development of pressure ulcers; these cannot be adequately coded under the current scheme. Deep tissue injury represents a dangerous lesion due to its potential for rapid deterioration. Proper labeling will afford clinicians a more accurate diagnosis, and lay a foundation for the development of efficacious interventions. In addition, there are no exclusions to the HAC rule for patients, such as those with certain spinal injuries or procedures like major flap reconstructions, where moving the patient to prevent pressure ulcers creates greater risk to outcomes than dealing with an expected skin breakdown.

More specifically, the College has reviewed the list of proposed conditions to be added to the HAC list for FY2009. We have examined the references identified in the preamble of the proposed rule for the strength of the evidence base with respect to prevention of these complications and have asked our Patient Safety and Quality Improvement Committee to provide expert advice based on their knowledge and experience. Below we have summarized concerns for several of the proposed conditions.

Surgical Site Infections

With respect to surgical site infections following selected elective procedures, our experience does not support, nor do we find convincing evidence, that infections associated with these procedures can be completely eliminated. Clearly, there are a



number of protocols and evidence-based practices that are associated with a reduction in such infections, and adherence to known best practices should be promoted. However, there are a number of risk factors that increase the likelihood of a surgical site infection even when all appropriate preventive measures have been applied.

For example, in the case of a morbidly obese diabetic patient who is on steroids, there is a considerable risk for a mediastinal infection following a coronary artery bypass operation. Similarly, for patients undergoing ligation and stripping of varicose veins, obesity, skin condition, the degree of venous hypertension, blood supply, and the presence of diabetes all significantly increase the risk of a post-surgical infection. By stratifying patients on the basis of risk scores, however, it would be possible to focus on those with small or limited risk for developing surgical site infections and take steps to reduce the incidence of these infections where prevention measures have been demonstrated to be effective. The proposed condition would result in payment penalties for hospitals in cases where complications could not have been “reasonably prevented.”

We recommend that surgical site infections for elective procedures only be included as an HAC with the application of appropriate risk adjustment. Most importantly, we would recommend that in cases where appropriate evidence-based preventive measures have been followed, yet the patient still develops a surgical site infection, hospitals should receive the full payment update. The data for a hospital’s adherence to recognized preventive measures can be abstracted, confirmed, and submitted to CMS for these types of surgical site infections.

Iatrogenic Pneumothorax

The proposed rule solicits comments on the extent to which iatrogenic pneumothorax is reasonably preventable through the application of evidence-based guidelines. According to the Department of Veterans Affairs study cited in the proposed rule to support the inclusion of iatrogenic pneumothorax as an HAC, the number one cause is transthoracic needle aspiration biopsy. However, this is a procedure for which pneumothorax is an expected complication. Is CMS proposing that surgeons stop performing appropriate needle aspiration biopsies in order to prevent iatrogenic pneumothorax? In this instance, pneumothorax should not be regarded as an indicator of poor quality of care. There are a number of other conditions (such as chest injury due to trauma) and procedures for which pneumothorax is an expected complication.

The AHRQ Patient Safety Indicator for iatrogenic pneumothorax proposed as a quality measure to be reported in 2010 contains exclusions for diagnoses and procedures that carry an inherent expected risk of pneumothorax – including needle biopsy. As such, it represents a more appropriate approach to identifying preventable iatrogenic pneumothorax and targeting quality improvement efforts.



We recommend removal of iatrogenic pneumothorax from the HAC list in favor of application of a well-designed quality measure, in which a risk-adjusted percent occurrence of pneumothorax is the metric for quality.

Delirium

In the preamble to the proposed rule, CMS notes that delirium affects nearly half of hospital days in patients 65 and older and about three-quarters of elderly patients in intensive care units, and can result in one year mortality of 35 to 40 percent. The preamble goes on to assert that “30 to 40 percent of the possible cases” can be prevented. Based on this evidence alone, we do not understand how this condition satisfies the statutory criterion that a condition “could reasonably have been prevented through the application of evidence-based guidelines.” We also note that there are a number of other ICD-9-CM codes describing related types of delirium some of which, based on the evidence and best practices, are more likely to be preventable. However, for most surgical procedures or for patients on ventilators, delirium may not be preventable. This is another example of the lack of evidence to support the elimination of this condition for all hospitalized patients.

We recommend removal of delirium from the HAC list until adequate research supports the appropriate coding and understanding of preventable delirium. This may instead support the development of a more targeted quality measure, rather than inclusion in the HAC non-payment policy.

Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE)

In the case of the proposed DVT/PE condition, our major concern is that categorizing this as a preventable event and putting hospitals at risk for the costs of treating this complication could skew practice toward prophylactic measures that may not be appropriate and could predictably lead to unintended adverse outcomes. For example, when the costs of treating DVT/PE is not compensated while treatment for bleeding that results from anticoagulation is a complication that could result in assignment to a higher paying DRG, there could be a risk of hospitals using medical prophylaxis with less caution. Furthermore rigorous screening and prophylactic programs have found a not insignificant incidence of “silent DVT” in surgical patients and yet these programs have benefited overall patient outcome. A careful balance between preventing DVT/PE and excessive bleeding must be maintained. Payment policies that could inappropriately bias treatment are clearly not in the interest of the patient or improving the quality of care.

Similarly, patients with epidural catheters for pain control in a post-operative setting have a higher risk of bleeding with devastating consequences if the patient is on low molecular weight heparin, and is an absolute contraindication for the use of fondaparinux. This often leaves the clinician with the difficult choice of selecting other less efficacious



regimens such as subcutaneous heparin or to reductions in the amount of time the patient is off anticoagulation medication before the catheter is removed or disuse of epidural catheters for pain despite areas of documented superiority. In turn, this trade-off for epidural hematoma safety reasons, may result in increases in the patient developing DVT/PE. Faced with a monetary penalty for DVT/PE, hospitals may over emphasize anticoagulation, leading to a higher number of epidural bleeds and other adverse consequences for the patient. Finally, we wish to emphasize, as CMS notes in the preamble to the proposed rule, that identifying a DVT at the time of admission to the hospital can be difficult, since symptoms such as pain, redness, or swelling may occur some time after the clot has formed.

This is another instance where good process measures for DVT/PE prevention are available and enforced as part of the quality measure reporting program. DVT/PE is an area with extensive research and scrutiny. Evidence from regularly updated consensus conference documents indicate that a “zero incidence” of DVT/PE has never been produced, even in studies with comprehensive, complex guidelines and risk stratification. While the clinical trial evidence showed an overall low incidence of bleeding resulting from an anticoagulation regimen, our concern is the potential inappropriate use of anticoagulation to achieve complete prevention of DVT/PE. Clearly, coagulation is a necessary event in the course of any surgical procedure and thus the risk of DVT/PE in some patients cannot be eliminated.

Methicillin-resistant Staphylococcus Aureus (MRSA)

We recognize the serious and growing threat of hospital-acquired infections, especially from methicillin-resistant staphylococcus aureus (MSRA). However, we would note that the focus here should include any multi-drug resistant organisms. The referenced guidelines are very complete and identify the effective steps for preventing antimicrobial resistance. It is also important to emphasize the performance of certain process steps that are associated with the prevention of this infection rather than only focusing on whether a case of MSRA occurred. The practice of taking recommended steps to prevent the emergence of resistant organisms should be the standard since it is not reasonable to assume all cases can be prevented. Patient risk factors play a significant role in the likelihood of MSRA infection. Patients who are immuno-compromised, have a past history of antibiotic use, or have multiple chronic conditions will be at higher risk for these infections. In sum, the standard here, as with a number of other conditions on the HAC list should be documentation that all recommended practices were applied rather than a zero-defect standard.

We believe that conditions of this nature can be addressed more appropriately through well-designed quality measures rather than treating them as HACs.



Present on Admission (POA) Indicator Reporting

The proposed rule also solicits comments on the policy for present on admission indicators that hospitals use in reporting secondary diagnoses. There are currently four options:

Y = present at the time of inpatient admission

N = not present at the time of inpatient admission

U = documentation is insufficient to determine if condition is present on admission

W = provider is unable to clinically determine whether condition was present on admission or not.

CMS is proposing to pay only for HACs reported as POA (“Y”) or “W”.

In our review of the reporting options associated with the selected HACs we are concerned that there is no option for reporting that the condition occurred despite the fact that all appropriate preventive measures were taken. We believe this is a necessary option for those conditions where the evidence and clinical experience demonstrate that it is not possible to eliminate the occurrence of a hospital-acquired condition, but that there are recognized process and procedure steps that can reduce while not completely preventing the complication. When these preventive measures have been taken and documented, then we believe hospitals should be eligible for the appropriately, higher paying DRG.

Options for Improving the HAC Payment Provision

The proposed rule includes a number of options for revising the HAC payment provision designed to strengthen efforts to prevent complications associated with a hospital stay. Among these options, we would support moving to some risk adjustment methodology either at the patient or facility level. This would help to identify the presence of risk factors that increase the likelihood of a HAC and would permit adjustments to the application of this policy based on the expected complication rate for the types of patients admitted. If the complication rate for a given condition, adjusted for the risk of the patients, exceeds the expected rate, then assignment of those cases to a higher paying DRG would not be allowed. We also support the option of determining rates for HACs for hospitals, and setting minimum performance thresholds or rates of improvement as the standard for qualifying for full payment under the prospective payment system.

We would, however, urge caution with respect to the adoption of ICD-10-PCS as this will increase the number of codes ten fold requiring significant modifications to existing coding software, billing systems, and the training of coders. While the diagnostic classification scheme should be updated, a broad-based transition plan that is the product of a collaborative effort of all stakeholders is required. This will have to take place over a number of years to ensure a smooth and cost-effective transition to a revised coding system.



Finally, given the challenges we have identified for the proposed HAC payment policy, we think expanding this policy to other settings where care is rendered would not be appropriate or contribute to improvements in the quality of care for patients. Physician offices are struggling to modernize their health information systems related to patient records and electronic prescribing. The cost and burden of these changes are especially challenging for smaller physician practices and those serving patients in medically underserved areas. We strongly recommend that CMS defer any plans to extend a modified HAC payment policy to settings outside the acute care hospital.

REPORTING OF HOSPITAL QUALITY DATA FOR ANNUAL HOSPITAL PAYMENT UPDATE

While collecting and reporting data on valid quality measures can assist providers in efforts to improve care and enable patients to make more informed decisions when the need for care arises, the College is seriously concerned about the proposed expansion of the reporting obligation imposed on hospitals and their physicians. We appreciate that 27 of the proposed 43 new measures or measure sets could be collected from information currently included in Medicare claims submitted by hospitals or from the Cardiac Surgery Data Registry maintained by the Society of Thoracic Surgeons (STS). The College strongly supports using existing registries and data sources, such as claims data, to enhance and expand quality reporting with little additional burden on hospitals and physicians. We are concerned, however, about several of the remaining 16 new measures which must be abstracted from patient records along with 26 of the existing measures. Record abstraction places a significant and costly burden on hospitals. Greater use of registry and claims data holds the potential to reduce this burden.

Moreover, CMS' intent to dramatically expand reportable measures for FY 2011 and beyond by another 63 measures and measure sets suggests to us that the reporting burden for hospitals would clearly outweigh any benefits that would accrue to hospitals or patients. We strongly believe that CMS should suspend further expansion of these measures in order to evaluate the benefits and costs of current efforts and assess their value to hospitals, physicians, and the public. Otherwise, we run the risk of diverting significant resources to collection efforts without demonstrating a commensurate improvement in the quality of care or the utility of the information collected.

Members of the College's Patient Safety and Quality Improvement Committee have reviewed the proposed list of 43 new measures for FY 2010. Below we have included more specific comments related to several of the measures that, in our judgment, require further clarification or could have adverse consequences for the quality of patient care.



SCIP-Infection 4: Cardiac surgery patients with controlled 6AM postoperative serum glucose

Use of an exact time for this measure could be very disruptive to hospital schedules for the collection of specimens from inpatients. In our view, this measure should be revised to read “morning fasting serum glucose” since this more clearly reflects the purpose of this laboratory analysis while giving hospitals some flexibility regarding the time for drawing the blood specimen.

VTE-5/6: (as combined measure) patients with unfractionated heparin (UFH) dosages who have platelet count monitoring and adjustment of medication per protocol or nomogram

We believe this measure is undesirable. Nomograms can and do vary for individual patients and acting on the basis of one nomogram can lead to ‘whipsawing’ a patient’s PTT. In our view, a better measure would be one that indicates regular monitoring of the patient’s PTT with out of range values acted on as appropriate.

VTE-8: Incidence of preventable VTE

This measure raises a concern noted earlier regarding the extent to which certain conditions, based on the evidence and taking into account patient risk factors, are in fact preventable. In the case of this measure, we are unclear about whether this includes all VTEs or a subset for patients in a lower risk cohort. We recommend further clarification for this measure.

Postoperative wound dehiscence

We believe this measure should refer to fascial dehiscence, rather than skin dehiscence. If it means skin dehiscence, this could encourage some surgeons not to close wounds that are borderline to decrease the “dehiscence rate,” when there is minimal clinical consequence and the patient is closely monitored.

Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)

In applying this measure, we believe there is a need to stratify patients by 1) whether urgent or non-urgent; 2) open or endovascular; and 3) presence of renal insufficiency. It is important not to create incentives to transfer patients who require immediate intervention.



Pre-operative beta blockade

There are reports of death from hypotension associated with this intervention. Recent results from the POISE clinical trial published in Lancet earlier this year show this intervention can be harmful in many patients. So while there are randomized controlled trials in this area, the data is now conflicting. This measure should be removed or deferred until recent evidence can be assessed.

Prolonged intubation

The practice of prolonged intubation without applying accepted clinical pathways to reduce intubation time should be avoided. However, there is still controversy in the scientific literature as to which clinical techniques, medications, and protocols are actually effective in reduction of intubation time for critically ill surgical patients. Multiple cofactors, in addition to risk stratification, come in to play in these critically ill patients. We are also concerned that excessive emphasis on intubation time with monetary penalties will result in early extubation, resultant re-intubation, inappropriately early tracheostomy with added potential short and long term morbidity, or avoidance of intubation by use of CPAP for patients with marginal respiratory reserves.

Surgical reexploration

For greater clarity, this measure should be re-titled as “Unintended surgical reexploration.” There are certainly cases – such as trauma patients and injured military personnel with open wounds – where the appropriate practice may be to return the patient to the OR for further exploration. Other emergent diseases and conditions, such as perforated viscous and necrotic bowel are best treated with judicious re-exploration to debride the abdomen, re-connect emergent stomas, and perform other critical surgical procedures demanded by the emergent nature of the original surgical procedure. We recommend that this measure be re-titled and better defined.

HOSPITAL EMERGENCY SERVICES UNDER EMTALA

In the FY 2009 IPPS proposed rule there are a number of proposed revisions to the Emergency Medical Treatment and Labor Act (EMTALA) regulations. Such changes, if adopted, would apply to Medicare-participating hospitals and critical access hospitals (CAHs). (These two classifications of facilities are hereafter referred to as “hospitals.”)

Applicability of EMTALA Requirements to Hospital Inpatients

The proposed rule would revise EMTALA so that when an individual covered by EMTALA is admitted as an inpatient and remains unstabilized with an emergency medical condition, a receiving hospital with specialized capabilities/facilities has an



EMTALA obligation to accept transfer of that individual, assuming that the transfer is an appropriate transfer and the receiving hospital with specialized capabilities/facilities has the capacity to treat the individual.

This proposal represents a significant change in policy, not merely a clarification of current regulation as CMS suggests. Clearly this policy change contradicts the current regulation regarding the non-applicability of EMTALA to inpatients that was finalized in September 2003. Current rules clearly state that once an individual presenting to the hospital's emergency department has been screened and admitted as an inpatient in order to stabilize the patient, the hospital has satisfied its EMTALA obligations for that individual. By extension, since the individual has been admitted as a hospital inpatient, there is no longer an emergent condition as regards the requirements of EMTALA. Hence, no other hospital has an EMTALA obligation for this particular individual.

CMS' proposed "clarification" contradicts the regulation in that it would expand a hospital's EMTALA obligations. The proposed change would again subject the admitting hospital to EMTALA under the obligation for conducting an "appropriate transfer" and certain other hospitals would continue to have an EMTALA obligation for the now hospitalized inpatient.

We believe this change in policy is unnecessary. We do not think that a hospital would knowingly admit an unstabilized patient with an emergency medical condition to an inpatient unit if the facility was not able to provide the appropriate services necessary to stabilize the patient.

CMS offers no compelling description of an existing problem in this area. Instead, to justify the need for a change in policy, CMS states that it is relying on the recommendation of the EMTALA Technical Advisory Group (TAG). The characterization of the TAG's recommendation does not mention the TAG's lengthy and heated discussion on this recommendation. CMS fails to note that the recommendation was strongly contested within the TAG and that it passed with only a slim majority, with most of the physician and hospital representatives voting against the proposal. In fact, one of the TAG members indicated that if such a recommendation is adopted, it would have the potential to worsen the challenges confronting the nation's emergency departments. The support for this recommendation came largely from the TAG's government representatives.

Most importantly, this proposal represents poor public policy. In spite of the many larger issues affecting the emergency department such as overcrowding, patient boarding, ambulance diversion, and the precarious operational and financial situation in which many trauma centers find themselves, CMS has decided to move forward with the most controversial TAG recommendation.



ACS urges CMS not to adopt the proposed EMTALA policy change, which would extend EMTALA obligations even after the unstabilized EMTALA eligible individual has been admitted as a hospital inpatient.

Shared/Community Call

CMS proposes that, as part of the obligation to have an on-call list, hospitals may choose to participate in a community call plan to provide on-call coverage for an area. A community call plan must be a formal plan among the participating hospitals and include, at a minimum, a number of specific elements outlined in the proposed regulations.

Such an approach would allow communities to provide for access to specialty care in a more reasonable, practical, and efficient manner. However, we urge CMS to provide greater flexibility concerning the requirements imposed on hospitals.

ACS supports the CMS proposal to allow hospitals to meet their on-call list obligations through a shared or community call plan.

PHYSICIAN SELF-REFERRAL

The proposed rule includes several proposals related to the physician self-referral law. Before addressing the specific proposals, ACS wants to encourage CMS to balance more evenly the need to address program and patient abuse with the need to support the ability of hospitals and physicians to work together for the benefit of all patients.

Stand in the Shoes Provisions

The proposed rule, attempts to address problems raised by academic medical centers (AMCs) and non-profit integrated healthcare delivery systems (IHCDSs) with the "stand in the shoes" regulations issued in Phase III of the Stark regulations, which were finalized in September 2007. In these regulations, certain contracts between a provider of designated health services (DHS) and a physician organization (i.e., practice or group practice) are treated as arrangements with the physicians who are affiliated with the physician organization. Thus, individual physicians in a group are regarded as "standing in the shoes" of their physician organization. As a result, the regulatory exception related to indirect compensation arrangements is no longer applicable and some existing arrangements are required to meet a different exception in order to be permissible under the physician self-referral statute. In response to these comments, in November 2007, CMS issued a final rule that delayed for 12 months the Phase III provisions as they applied to certain physician arrangements involving AMCs and IHCDS.



CMS' decision to revisit these regulations is, in part, a response to concerns raised by AMCs and IHCDS, particularly related to compensation arrangements involving "mission support payments" apart from the delivery of clinical services. Such payments are intended to support the overall mission of an AMC or maintain the operations of an IHCDS and are not tied to specific items or services provided to patients.

While the preamble to the proposed rule indicates that the intent of these revisions to the "stand in the shoes" provisions is to simplify the analysis of many existing financial arrangements and reduce program abuse by applying these rules to a broader array of financial arrangements under the physician self-referral law.

In the proposed rule, CMS offers two alternative approaches for revising the physician "stand in the shoes" provisions. Under the first approach, a physician would be deemed not to stand in the shoes of the physician organization if the physician's compensation arrangement with a physician organization satisfies the requirements of any of the current exceptions for bona fide employment relationships, personal services arrangements or fair market value compensation. The second approach would leave the Stark Phase III provisions in place and, using its broad regulatory authority, the agency would create new exceptions specific to "nonabusive payments or arrangements that warrant protection not otherwise available under any existing exceptions." The exceptions, which would be specified at a later time, would be designed to protect the interests of the program and beneficiaries.

ACS believes that the proposed alternatives are overly complex; thus failing the CMS goal of simplification. Further, since the proposed rule did not include proposed text for the new exceptions that would be created under the second alternative, we cannot comment on the reasonableness or appropriateness of that option. The ACS recommends that these provisions be withdrawn and urges CMS to issue a separate proposed rule with comment period including a simplified exception for financial arrangements between AMCs and IHCDSs that support services that are critical to the mission of these institutions and are of general benefit to the communities they serve.

Period of Disallowance

In response to an earlier Stark Phase II physician self-referral rule, a number of commenters raised questions about the time period during which a physician could not refer patients for designated health services (DHS) to an entity where a financial relationship between the referring physician and the entity failed to satisfy the existing exception requirements. In essence, all payments made pursuant to such referrals would have to be recouped. In the FY2009 IPPS proposed rule, CMS offered two proposals in response to the above question:



Where the reason(s) a financial relationship does not meet any applicable exception is not related to compensation, the period of disallowance would begin on the date the arrangement first was out of compliance and end no later than the date the arrangement was brought into compliance. This would cover all defects – clerical and otherwise – that were identified as not meeting the full requirements of the regulation.

Where the reason a financial relationship does not meet any applicable exception is related to the payment or receipt of excess (not fair market value) compensation, the period of disallowance would begin on the date the arrangement first was out of compliance and end no later than the date the excess compensation was returned by the party receiving it to the party that provided it.

Our concern with respect to the first proposal relates to the seemingly extreme requirement to return all payments for services for a relatively minor infraction such as a missing signature or other minor defect. We recommend that in the case of administrative or clerical errors, no period of disallowance would be imposed. Such infractions can be quickly remedied, and should not result in financial penalties that are not commensurate with the seriousness of the error. As an alternative, we urge CMS to consider providing a timely appeal mechanism that would permit a thorough review of the circumstances and a more equitable result.

In general, we are concerned that the above proposals appear to focus on immediate sanctions rather than reasonable opportunities for correcting compliance problems. In other CMS documents, we note that there appear to be a number of other options still under development and consideration. These include consideration of a related “alternative method of compliance” included in the CY2008 physician fee schedule proposed rule as well as a CMS statement that it “may propose rulemaking in the future” as regards a “period of “disqualification.” Further, CMS observes that the above proposals do not address the implications of the anti-kickback statute and the applicability of civil monetary penalties. This leaves us in considerable doubt about how CMS may apply this statute to financial arrangements that may be found defective in some manner under Stark regulations.

ACS urges CMS to adopt a more reasonable regulatory standard to the enforcement of the period of disallowance under the Stark statute. While the proposals set forth in the proposed rule reflect an appreciation of the difference between intentional and inadvertent violations of these complicated rules, we believe that it is critically important to provide recognition and support for educational efforts, self-reporting and self-correcting compliance plans, and to reserve sanctions for cases of flagrant and willful violations of this statute.



We appreciate the opportunity to comment on this proposed rule. The College looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Elizabeth Hoy in our Washington office. She may be reached at ehoy@facs.org or (202) 672-1508.

Sincerely,

A handwritten signature in cursive script that reads "Thomas R. Russell".

Thomas R. Russell, MD, FACS
Executive Director