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June 13, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8011
Baltimore, MD 21244-8018

ATTENTION: CMS-1390-P

Dear Mr. Weems:

The American College of Cardiology (ACC) is pleased to offer our comments on Sections II, VII, and VIII, of the notice of proposed rulemaking (CMS-1390-P) entitled: “**Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians**” [referred to as the “IPPS” rule in this letter], as published in the *Federal Register* on April 30, 2008 (73 FR 23528).

The ACC is a 36,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician ownership and payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

§II – Proposed Changes to Medicare Severity DRG (MS-DRG) Classifications and Relative Weights

F. Preventable Hospital-Acquired Conditions (HACs), Including Infections

The ACC is strongly committed to quality improvement and we support the concept of establishing appropriate financial incentives as a tool for achieving quality improvement goals. We recognize that in implementing the Hospital Acquired Conditions (HAC) initiative, CMS is carrying out its statutory obligation under the Deficit Reduction Act (DRA) of 2005. Nevertheless, the College has serious concerns about both the approach to reducing the incidence of preventable hospital acquired conditions mandated by the DRA and the manner in which CMS is implementing its statutory obligations.

The College has a fundamental disagreement with quality improvement

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strategies that rely on only negative reinforcement, such as non-payment for hospital acquired conditions. We believe the HAC initiative is seriously flawed for a number of reasons:

- Determining and documenting that one of the selected HACs was present on admission is not always possible and creates a burden for hospitals.
- There is no provision for risk adjustment. Some patients are at substantially elevated risk for a number of the HACs.
- Non-payment for HAC could encourage hospitals to avoid patients at higher risk of complications and creates an incentive for a hospital to transfer a patient who develops complications.
- There are no provisions to re-invest savings in the system to further improve quality of care.

The ACC believes that setting ambitious goals can challenge health care providers to achieve quality improvement goals they may not have thought possible. However, those goals must be realistic and reasonably achievable. Moreover, providers need practical tools help them take steps toward achievement of the goal. In the absence of these elements, the HAC initiative is simply a punitive payment policy, not a concrete strategy for improving the quality of hospital care provided to Medicare beneficiaries and is more likely to engender unintended consequences like decreased access to care for those at highest risk and increased health care disparities.

We urge CMS to halt any expansion of this initiative beyond compliance with the DRA mandate to identify two HACs for non-payment beginning October 1, 2008. Any proposed expansion should be delayed until CMS has conducted a thorough evaluation. For example, CMS should assess the impact of the HAC initiative on the incidence of the selected HACs, the administrative burden placed on providers and CMS, and the accuracy of present on admission (POA) coding. In addition, we urge CMS to develop effective risk adjustment techniques to ensure that providers who care for high risk patients are not unfairly penalized.

CMS proposes to expand the list of HACs for which payment will not be made by adding nine new conditions. The ACC cannot support this proposal because the proposed HACs do not fulfill the statutory requirement of being reasonably preventable. These conditions should not be characterized as “never events.” Rather they are known complications which can be minimized with proper care. These conditions cannot always be prevented, even in the best circumstances. A blanket policy of non-payment for the costs associated with caring for patients who experience these complications during a hospital stay is unreasonable.

CMS has requested comments on alternative approaches to reducing the occurrence of preventable hospital acquired conditions. The ACC recommends that CMS explore alternatives that would use a data-driven approach to establishing benchmark and best practice complication rates for selected HACs. CMS could then set payment rates based on an average complication rate and provide evidence based tools to help hospitals work toward a best practice complication rate. Those hospitals whose complication rates exceeded the average would bear the costs of treating those complications, while those with better than average performance would be rewarded. As performance improved over time, payment rates would be adjusted to reflect lower complication rates. Data registries such as the NCDR™ CathPCI and ICD Registries would be an excellent source of data on complication rates.

CMS also notes in the proposed rule that the concept underlying the HAC initiative could be applied in other settings. The ACC believes that extension of the non-payment strategy for preventable health conditions acquired outside the hospital setting would be extremely

problematic, especially in the physician office setting. First, separating the physician work and practice resources solely attributable to an HAC-like preventable condition from other medical conditions managed at an office visit would be difficult. In addition, patient compliance and other factors beyond the physician's control would contribute to the likelihood that a patient would acquire a preventable condition while under a physician's care. The College strongly urges CMS to focus its quality improvement efforts for physicians on encouraging and facilitating the adoption of evidence based guidelines at the point of care in the ambulatory setting. CMS should not consider expansion of the HAC approach to other care setting until the initiative has been thoroughly evaluated.

G. Proposed Changes to Specific MS-DRG Classifications

The ACC concurs with the Heart Rhythm Society (HRS) in supporting CMS' proposal to refine cost for defibrillator generators and leads through subdivision of current MS-DRG 245 (AICD Lead and Generator Procedures), and creation of a new MS-DRG 265 (AICD Lead Procedures) to accurately recognize the differences in resource utilization for implantation or replacement of leads from the implantation or replacement of pulse generators.

The ACC also supports the HRS recommendation that CMS consider a dual approach to offset charge compression by implementing RTI International's short-term solution for disaggregating CCRs (cost-to-charge ratio) through regression-based adjustments for 2009, along with the long-term proposal to fully implement a separate cost center for implantable devices by 2012.

§VII – Disclosure Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership:

CMS Authority to Terminate Medicare Provider Agreements for Failure to Comply with New Physician Ownership Disclosure Proposals

In relation to these new disclosure proposals, CMS is proposing to give itself authority to: “. . . terminate the Medicare provider agreement if the hospital fails to comply with the provisions of proposed §489.20(u)(1) or (u)(2)”

ACC Recommendation: The ACC recommends that CMS not adopt this proposal at this time without providing clarification of what formal investigative and administrative procedures it will follow in order to provide hospitals “due process” prior to terminating a Medicare provider agreement. It is unclear if CMS is seeking to impose a “zero tolerance” policy for enforcement of these “clerical” requirements; if so, it is especially troubling to do so where instances of non-compliance are likely to be inadvertent and unintentional. In the alternative, CMS should consider implementing a “progressive discipline” program focused on imposing financial penalties for failures to comply with disclosure requirements, commensurate with severity of the circumstances surrounding the instance of non-compliance under scrutiny.

CMS Authority to Terminate Medicare Provider Agreements for Failure to Comply with the Proposed Onsite Emergency Care Notice Requirements in §489.20(w)

To complement a new provision added in the 2008 IPPS final rule—requiring all hospitals and CAHs to furnish all patients with written notice at the beginning of their inpatient/outpatient hospital stay indicating whether or not a doctor of medicine or osteopathy will be present 24/7, and if not, how the hospital or CAH will meet any emergency care needs for patients when no physician is present in the hospital—CMS is proposing to set penalties for failure to comply with

these requirements. Specifically, CMS is looking to provide itself authority to terminate Medicare provider agreements in cases of noncompliance.

ACC Recommendation: As with the previous proposal above, ACC recommends that CMS provide clarification of what formal investigative and administrative procedures it will follow in order to provide hospitals and CAHs “due process” prior to terminating a Medicare provider agreement.

Requiring Hospitals and CAHs to Educate Patients about Availability of Ownership Disclosure Information

CMS is soliciting comments on whether or not it should require hospitals and CAHs to “. . . educate patients about the availability of information regarding physician ownership under the proposed disclosure requirements, and if so, by what means” (e.g. via signage in waiting areas or making patient brochures available).

ACC Recommendation: While the ACC supports efforts to provide patients with information concerning physician (or hospital) ownership interests in medical facilities generally, we question the utility of mandating additional signage or other educational materials being made available to patients, especially in light of other similar requirements (by states and federal agencies) in place for other, unrelated, postings. To be clear, our concerns rest on the potentially confusing nature of this proposal in that patients are already confronted with considerable visual “clutter” in waiting/admitting rooms, and the addition of new signage—without a corresponding reduction in other posting requirements—will only heighten the likelihood of the new signs being missed among the other signage. Further, any additional requirements to “educate” patients on ownership interests are redundant in light of the other disclosure proposals included in the FY 2009 IPSS proposed rule.

§VIII – Physician Self-Referral Provisions:

A. “Stand in the Shoes” [SITS] Provisions—

1. Physicians:

Conditions for Excepting Certain Physicians from “Standing in the Shoes” of His/Her Physician Organization

CMS is proposing that a physician would be deemed NOT to stand in the shoes of his/her physician organization for purposes of applying the self-referral rules’ requirements concerning direct and indirect compensation arrangements IF the compensation arrangement between the physician organization and the physician satisfies the requirements for meeting one of the following three (3) exceptions (already described in §§411.357(c), (d), and (l) respectively) for:

- (i) “Bona Fide” employment relationships;*
- (ii) “Personal service arrangements;” or*
- (iii) “Fair market value” (FMV) compensation.*

If the compensation arrangement between the physician and the physician organization meets the conditions for satisfying any of the three exceptions above, CMS would consider that arrangement to have been designed in a manner consistent with FMV, and does not take into account (directly or indirectly) either the volume or value of referrals as a basis for compensation to either the physician OR the physician organization.

ACC Recommendation: Inasmuch as a SITS provision is proposed to be established, we are encouraged that CMS recognizes the need to except certain physician compensation arrangements from scrutiny. While the ACC questions whether there is a need for a SITS provision—as noted in our comments submitted in response to the CY 2008 Medicare Physician Fee Schedule (PFS)—at all, the proposed conditions a physician compensation arrangement must meet appear reasonable on their face. If CMS elects to proceed with implementing the proposed exception discussed above, the ACC recommends it—and the several related proposals included in the proposed IPPS rule—be expanded to accommodate compensation arrangements involving any broad-based employer, not just simply between a physician organization and physician-employee.

Proposed Revisions of Certain Definitions to Provide Exceptions from SITS for AMCs

CMS is proposing to also revise its rule definitions for “financial relationships,” “compensation,” and “ownership or investment interest” to provide exceptions from SITS for referrals meeting the requirements for an exception for services provided by an Academic Medical Center (AMC). Referrals that do not meet the requirements for the AMC exception would require the referring physician to stand in the shoes of his/her physician organization. CMS is further requesting comments on how best (from a technical perspective) to revise the regulatory language to achieve the results sought in the discussion.

ACC Recommendation: Again, while the ACC opposes implementation of SITS standards in general, the College would support the revised definitions providing exceptions for AMCs if they are also made available to any broad-based employer of physicians, not just AMCs.

2. **“DHS Entities:”**

Ownership Percentages Triggering SITS

CMS is also proposing to implement SITS provisions to address the “DHS entity” side of physician-DHS entity financial relationships. Specifically, CMS would provide that: “. . . an entity that furnishes DHS would be deemed to stand in the shoes of an organization in which it has a 100% ownership interest and would be deemed to have the same compensation arrangements with the same parties and on the same terms as does the organization that it owns. CMS contends that under this approach a DHS entity would stand in the shoes of ANY wholly-owned organization, not merely a wholly-owned DHS entity.

ACC Recommendation: It is unclear if CMS is attempting, through this and similar proposals in the IPPS proposed rule, to extend the application of the self-referral rules into businesses a DHS entity owns, but that do not provide DHS themselves to beneficiaries. The ACC strongly opposed CMS attempt to extend its regulatory reach to proscribe self-referrals between physicians and entities they own—but that do not provide DHS—in the CY 2008 PFS proposed rule. If CMS is proposing a similar extension of scrutiny to DHS entities, the College believes such an approach is clearly outside the scope of its authority under the Stark Law, whose purpose is to prevent self-referrals involving the provision of DHS. On its face, the rule seems unnecessary, because indirect compensation rules should apply in arrangements in which a DHS entity owns another entity; and again, scrutiny is only supposed to be warranted if the owned entity is providing DHS to beneficiaries.

Lastly, the ACC strongly opposes any attempts to apply the Stark Law to entities that involve—but do not *provide* DHS to beneficiaries. The College also believes that “percentage of ownership” is an irrelevant measure for physicians and DHS entities to trigger SITS provisions, since the controlling factor is whether or not the entity is providing DHS.

3. Proposing Issue of “Conventions” for Application of SITS:

Guidelines CMS Proposes for Applying SITS

CMS is also proposing several “conventions” under which it will apply SITS provisions to physicians and/or DHS entities. Specifically:

- (i) SITS will be applicable in situations where physicians/physician organizations are involved and the rules apply;*
- (ii) If, after using the physician SITS provisions one “link” relationship remains between the DHS entity and the physician organization, and an ownership interest exists, then the “entity” SITS provisions apply; and*
- (iii) If two organizations remain after collapsing the physician and physician organization (i.e. two links in the chain of ownership), then the “entity” SITS rules would apply.*

ACC Recommendation: The ACC opposes the issuance of “conventions” for the application of SITS in the absence of first providing a NPRM for SITS provisions. Further, CMS should also allow public comment on any subsequent guidance materials issued upon completion of the NPRM through its normal guidance promulgation process. In general, the College is gravely concerned with the growing complexity of ownership rules, and we question whether physicians and their entities will be able to navigate this treacherous regulatory landscape without incurring costly legal counsel. Ultimately, the ACC believes that the most relevant question to be answered by CMS before applying any of the SITS provisions is whether either entity involved in the relationship under scrutiny is providing DHS to beneficiaries in the arrangement, and if so, whether such “transactions” involving DHS cannot be evaluated by simply applying the indirect financial relationship rules. Absent the provision of any DHS by either entity, CMS should not be reviewing any transactions or relationships.

B. *“Period of Disallowance” Provisions—*

Proposal Creating

CMS is proposing that where the reason for a financial relationship’s non-compliance with the self-referral rules is NOT related to compensation (e.g. unintentional clerical errors), the period of disallowance would begin on the date the arrangement was first non-compliant, and end no later than the date the arrangement was brought into compliance.

ACC Recommendation: The ACC appreciates CMS’ efforts to provide some flexibility to providers and other entities in its application of Civil Monetary Penalties (CMPs) for non-compliant financial relationships. While “intent” is not a mitigating factor for providers and other entities who are engaged in non-compliant relationships, we commend CMS for seeking to codify its authority to employ wide discretion when deciding whether, and to what degree it applies any penalties.

The ACC recommends that, when deciding whether to finalize this proposal, CMS take into account the likelihood that parties to an arrangement that is non-compliant for reason of inadvertent (e.g. clerical) error(s) may not be aware—neither through negligence or intent—of their own accord that their arrangement is non-compliant. Should CMS become aware of an arrangement’s non-compliance for this or similar “innocuous” reasons and notifies the parties of the non-compliance, it would seem unfair to impose any period of disallowance for any length of time longer than it would take to make the necessary corrections to the errors and notify CMS that the corrections were made.

Under this proposal, it is unclear if CMS would require parties to a non-compliant arrangement (for the reasons discussed) to reimburse CMS for any payments received from Medicare for DHS improperly billed during the period of disallowance. Using the example provided in the preamble, where an arrangement—but for lack of a signature, etc.—was otherwise compliant with the self-referral rules for two years, it would be unfair for the period of disallowance to be two years, even if the parties to the arrangement made the necessary corrections immediately upon notification from CMS.

Alternatively, CMS should instead propose that the period of disallowance should last only as long as the parties to the non-compliant arrangement for clerical errors first became aware (i.e. through notice from CMS, etc.) of their non-compliant status, ending when the necessary corrections are completed and approved by CMS. This provision must also make it explicitly clear that where the arrangement's non-compliance was inadvertent, the parties are not required to reimburse CMS for payments made/received during the period prior to the discovery and correction of the error responsible for making the arrangement non-compliant—and all other elements of the arrangement are otherwise compliant. It would also be reasonable for CMS to impose a time limit under which parties to an arrangement that is non-compliant—upon receiving notice from CMS—for such reasons discussed above must have in place an agreement to make the necessary corrections or face sanctions.

C. *“Gainsharing Arrangements” Request for Comments—*

If Exceptions for Gainsharing Arrangements should be Established, What Safeguards should be Included

While not making any specific proposals at this time, CMS is soliciting comments on “. . . what types of requirements and safeguards should be included in any exception for gainsharing arrangements . . . and . . . whether certain services, clinical protocols, or other arrangements should not qualify for the exception.”

ACC Recommendation: The ACC supports development of exceptions for gainsharing arrangements to the self-referral and anti-kickback rules. As guidance for developing “workable” exceptions the College recommends using common features of several favorable Advisory Opinions issued by the HHS Office of the Inspector General (OIG) regarding individual gainsharing arrangements (also discussed in the IPPS preamble), including:

- (i) Measures that promote accountability and transparency;
- (ii) Adequate quality controls (i.e. efforts to ensure no decline in quality of care occurs due to implementation of the arrangement); and
- (iii) Controls on payments related to self-referrals.

D. *“Physician-Owned Implant and Other Medical Device Companies [POCs]” Request for Comments—*

Application of Self-Referral Rules to POCs and Similar Physician-Owned Companies

CMS is not offering a specific proposal at this time, but is requesting comments on whether the self-referral rules should address POCs and similar physician-owned companies.

ACC Recommendation: The ACC believes CMS does not have the statutory authority under the physician self-referral rules to scrutinize POCs and similar physician-owned companies, and opposes any proposal that seeks to self-referral prohibitions to entities that do not provide DHS.

Since POCs are not providing DHS to beneficiaries, but are merely supplying physicians or DHS entities with the DHS/items they will in turn provide to patients, or services in support of the entity (e.g. administrative services, billing, etc.) actually providing the DHS to beneficiaries.

In other words, a DHS supplier is not providing DHS to patients, but to providers who then provide DHS to patients. The College recommends that CMS refrain from any rulemaking to address POCs and similar arrangements, as we believe that both the anti-kickback statute and FCA adequately address the concerns CMS has raised in this discussion.

We appreciate your attention to this letter, and remain eager to assist you and your staff as it considers whether to finalize these proposed changes to the FY 2008 IPPS rule. If you have any questions, please contact Rebecca Kelly, Director – Regulatory Affairs at 202.375.6398, or by e-mail at rkelly@acc.org.

Sincerely,



W. Douglas Weaver, M.D., F.A.C.C.
President
American College of Cardiology

cc: Jack Lewin, M.D., CEO
American College of Cardiology