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VIA HAND DELIVERY

September 14, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave, SW
Washington, DC 20201

Attention: CMS–1392–P

Dear Mr. Weems:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates ..."* 72 Fed. Reg. 42627 (August 2, 2007). The AAMC represents approximately 400 major teaching hospitals and health systems; all 126 accredited U.S. allopathic medical schools; 96 professional and academic societies; and the nation's medical students and residents.

Our comments focus on the following areas: the new outpatient quality reporting program; the proposed packaging approach; the proposal to require hospitals to report pharmacy overhead charges; the proposed payment for the acquisition and handling costs of separately payable drugs and biologicals; the proposed reduction in the APC payment for procedures involving the replacement of a defective device for which the hospital receives partial credit; and evaluation and management coding guidelines. But first, we would like to address whether a teaching adjustment should be included in the outpatient prospective payment system (OPPS).

AN OPPS TEACHING ADJUSTMENT

The OPPS is the only major Medicare payment system that does not include a teaching adjustment. Teaching adjustments are included in the inpatient, psychiatric and rehabilitation facilities prospective payment systems. We urge CMS to conduct a study to determine whether teaching hospitals incur higher outpatient service costs compared to other hospital types, thereby supporting the addition of a teaching adjustment to the OPPS.

The outpatient department is critical to fulfilling the missions of teaching hospitals. In addition to providing a site for clinical education for all types of health professional trainees, teaching hospital outpatient departments provide an environment in which clinical research can flourish, and are a source for specialized, unique, and referral/standby services. Because of their education and research missions, teaching hospitals offer the newest and most advanced services and equipment, and care for the nation's sickest patients. In addition, teaching hospital outpatient departments often serve as a primary source of health care for low-income Medicare beneficiaries and other disadvantaged individuals.

In the initial OPPS Final Rule, published April 7, 2000, CMS stated that it would "conduct analyses and studies of cost and payment differential among different classes of hospitals, including teaching facilities, when sufficient data under the PPS have been submitted. We will carefully consider whether permanent adjustments should be made in the system once the BBRA 1999 transition provisions expire." (65 Fed. Reg. at 18500). In addition, the Balanced Budget Act of 1997 requires the Secretary to establish adjustments "as determined to be necessary to ensure equitable payments . . . for certain classes of hospitals." (Section 4523 of the BBA).

In the 2006 final rule however, CMS asserted it does not believe "that a study of unit costs of teaching hospitals relative to other classes of hospitals is necessary at this time," because "such studies are especially warranted when hospitals experience a negative increase in payments" and for CY 2006 "major teaching hospitals are projected to experience an overall increase in payments of 1.0 percent." However, those statements were just that – assertions. We believe CMS has an obligation to do full data analysis because Medicare outpatient margins, while negative for all hospitals, are significantly lower for major teaching hospitals than for other teaching and nonteaching hospitals. For example, according to an internal analysis of 2004 hospital Medicare cost reports, the average outpatient margins were -20.2 percent for major teaching hospitals, -10.1 percent for other teaching hospitals and -11.8 percent for nonteaching hospitals.

In light of the negative margins, as well as the BBA requirement and CMS's commitment to make payment adjustments for classes of hospitals that may be negatively impacted by the OPPS, the AAMC believes that it is incumbent upon CMS to conduct a comprehensive analysis that would include the impact of the costs associated with teaching hospitals' teaching and research missions on their outpatient cost structure. If

such an analysis concludes that teaching hospitals have higher costs, we believe a teaching adjustment should be included.

QUALITY REPORTING UNDER THE OPPS

The Tax Relief and Health Care Act (the Act) that was passed in December 2006 modified the payment update for OPPS payments for services provided by hospitals in outpatient settings starting January 1, 2009. The Act required the establishment of a quality reporting program for the hospital outpatient setting and mandates hospitals to submit quality data on hospital outpatient performance measures. The penalty for not submitting quality data will be a reduction in the annual payment update factor by 2.0 percentage points. In order to meet the January 1, 2009 deadline, the proposed rule requires hospitals to submit data on the final measure set beginning January 1, 2008.

The AAMC and its hospital and physician members are committed to delivering quality care to our patients and taking responsibility for the care we provide. As founding members of the Hospital Quality Alliance (HQA), the AAMC has been at the forefront of making hospital performance data available to the public to help inform patient decision-making. To that end, we are supportive of providing performance data to patients regarding their care in the hospital outpatient setting. However, we have serious concerns with the implementation plan that is proposed.

When the inpatient quality reporting program was created, an established framework and process for data collection and submission existed. There is no such framework or process for the outpatient setting. Creating a new data collection process within the hospital, as well as modifying data vendor contracts to accommodate outpatient data is both time consuming and costly. This is further compounded by the fact that the implementation schedule for this program is extremely aggressive.

Based on our concerns and the implementation challenges outlined below we propose that CMS utilize a phased-in approach. Since the legislation only requires hospitals to submit their data for payment determination in CY 2009, CMS could technically delay the reporting deadline a few months. This would allow time for further field testing, final measure specifications, appropriate time to develop new processes for the hospitals and vendors and establish a general comfort level for this new reporting stream. Alternatively, CMS could begin data collection with the Emergency Department measures where there is more familiarity and dexterity in data collection given the inpatient measures for the Emergency Department and then phase-in the other ambulatory measures where additional time and experience are crucial.

Implementation issues

In order for performance measures to be implemented on a national basis they need to be endorsed by the National Quality Forum (NQF), be evidence based, and be fully specified and adequately field tested for validity and reliability. The measures included

in this program have only been through very basic testing and not on a national basis. We understand that CMS is finalizing plans to conduct further field testing which we applaud, however the details of the testing are not yet known and will potentially further delay the point at which the measure specifications can be finalized.

Hospitals need finalized measure specifications to make appropriate resource and information technology determinations in order to collect the necessary data. The measure specifications that have been released are not final and therefore are not actionable. As stated previously, any further field testing will introduce delays and possible changes to the measures and will impact the hospital's ability to begin data collection by the proposed January 1, 2008 deadline.

In addition to the hospitals, the data vendors that support the hospitals need final measure specifications with the appropriate amount of time in order to program for data collection. Most of our members would like to be able to utilize their Joint Commission ORYX vendors for both inpatient and outpatient reporting which would be efficient for the hospitals, and would ensure data validation and vendor assessment through the ORYX program. However, vendors have expressed their concern and reluctance to make a decision to participate in outpatient data collection due to the current ambiguity regarding final measure specifications as well as the compressed timeline to program their systems. If vendors are not willing to participate then the necessary data collection infrastructure is lacking, leaving hospitals with limited options for efficient and cost-conscious solutions.

Measures

We are in support of the initial proposed measures; however, we do have concerns regarding the diabetes measure because it is an outcome rather than a process measure. At the outset, we appreciate CMS's recognition of the attribution issue associated with this measure for multi-specialty clinics by requiring the submission of data on this measure for primary care specialties only.

We agree that a diabetes measure is important for determining improvements in the management of diabetes patients. However, many of our outpatients are unable or unwilling to adhere to the prescribed care. Consequently, the ability to control a patient's Hemoglobin A1c level is not always within the control of the physician/resident/clinic. In addition, the ability to control the hemoglobin level becomes more difficult for difficult and complex patients. Including some form of risk adjustment to recognize these cases would ensure fairness for those hospitals that treat these patients.

As far as future measures, we believe that CMS should only use those measures that are approved by the HQA. This is reinforced in the legislation, which states that the measures must reflect consensus among the affected parties.

Administrative Issues

In order to reduce additional administrative burden as well as increase efficiency, we are asking that hospitals that are submitting data for both the inpatient program as well as the outpatient program be able to submit one Participation Form. Utilizing two forms just adds to confusion and potential error.

The initial year of the inpatient reporting program did not include validation testing, in part, to allow the hospitals to gain experience with the program. We would like to suggest the same approach for the outpatient program. Once an appropriate level of experience has been gained, then the validation testing should be resumed.

We have stated in previous inpatient PPS comment letters that the Central Data Abstraction Center (CDAC) should not have the authority to both pull the charts required for validation as well as be responsible for the re-abstraction. These responsibilities should be separated and handled by two separate entities.

Finally, as academic medical centers with large numbers of hospital outpatient clinics as well as faculty practices, we would like to strongly advocate for coordination between hospital and physician initiatives. The measures in the outpatient program are similar to the measures for the physician reporting initiative, yet require different data collection mechanisms. If these efforts are not coordinated on an ongoing basis, it will place an additional and unnecessary burden on the hospitals and physicians.

PROPOSED PACKAGING APPROACH

Currently, services within the ambulatory payment classification (APC) groups reflect only a modest degree of "packaging" and very little "bundling." Packaging refers to the extent to which payment for minor, ancillary services associated with a significant procedure is "packaged" with the primary procedure and receives a single APC amount. Bundling refers to the extent to which payment for multiple, significant procedures related to an outpatient encounter or episode of care is "bundled" and receives a single APC amount. For the most part, the OPPS currently makes a separate payment for each individual service provided during a hospital encounter.

For CY 2008, CMS is proposing to expand packaging and bundling, so that more services that are currently paid separately would receive a single APC payment, thereby decreasing the number of APC payments that a hospital would receive. Specifically, CMS is proposing to package the costs of minor, ancillary services that fall into any of the following seven specified categories that are associated with significant procedures into a single payment for the significant procedure.

1. Guidance services
2. Image processing services
3. Intraoperative services

4. Imaging supervision and interpretation services
5. Diagnostic radiopharmaceuticals
6. Contrast media
7. Observation services

The Agency also is proposing to create two "composite APCs" by bundling multiple significant procedures related to two outpatient encounters, one for Low Dose Rate (LDR) Prostate Brachytherapy and the other for Cardiac Electrophysiologic Evaluation and Ablation. CMS believes that increasing the payment bundles through both increased packaging and the creation of composite APCs, will lead to efficiencies in the hospital outpatient departments, because it would create incentives for hospitals to use the least expensive items that meet the patient's needs and to negotiate more vigorously with manufacturers and suppliers to reduce the cost of purchased items and services.

Although we are supportive of CMS's efforts to increase efficiency in care delivery, we are concerned that the packaging proposal has not been thoroughly analyzed and the impact on hospitals still needs to be determined. For example, CMS has not released all the data for hospitals to be able to conduct their own analyses, including providing a crosswalk between the current APCs and the new "packaged" APCs.

Under the proposed rule, the median costs for many procedures will change as a result of increased packaging. CMS notes that median costs may go up, but may also stay the same or go down due not only to increased packaging but also due to the migration of HCPCS codes into and out of APCs as well as a change in the number and composition of claims CMS uses to establish APC median costs.[1] Furthermore, while the proposed rule states that the estimate of payment redistribution that would result from its packaging proposal is approximately 1.2 percent of the estimated CY 2007 base year expenditures under the OPPS, analyses sponsored by the American Hospital Association indicate that the seven categories in the proposed rule represent six percent of outpatient costs. These factors highlight the need for the public to study and understand the methodology used in determining how the costs of packaged services have been assigned to a specified APC and the level of costs assigned to an APC.

It is the AAMC's position that any major policy change, such as the one proposed, needs to be transparent and the methodology and impacts clearly understood by the hospitals affected. Therefore, although CMS's impact analysis shows that, in the aggregate, the packaging approach would have a positive impact on major teaching hospitals, we urge CMS to reevaluate its proposal. If the Agency decides to proceed with implementation, we urge the Agency to exclude observation services (see below) from the final rule.

[1] According to CMS, greater packaging led to more "natural" single bills for some codes and fewer "pseudo" single bills for others. As a result, some APCs gain while others lose single bills. Thus, for each APC, the use of more or less claims from a different mix of providers can increase or decrease the median cost of that APC.

Observation services

Observation is an important component of patient care delivery as it allows hospital staff to monitor and assess patients' conditions. Thus, any policy involving changes to these services must be carefully considered and the implications fully understood.

The AAMC is concerned that packaging the costs of all observation services without further analysis of the claims data and methodology used to determine the primary procedures to which they have been assigned could have negative consequences on health care delivery for both outpatient and inpatient services.

CMS is proposing to package the cost of observation services reported under HCPCS code G0378 (Hospital observation services, per hour) into the separately payable services with which the observation services are billed. That is, the cost of observation services provided to patients with any one of three diagnoses (congestive heart failure, chest pain, or asthma) will be packaged into payment for the primary procedure with which they are billed.

Since 2002, when CMS implemented separate payment for observation services, hospitals have found the billing requirements confusing and administratively burdensome. The Agency and the APC Advisory Panel have since been working with providers to clarify and simplify the billing process for separately payable observation services. Hospitals have been working to comply with the billing requirements, but the confusion spanning a number of years has led to inconsistent billing among hospitals, which in turn has resulted in poor data. Using these data to determine how to package observation services could reduce payment for these vital services and could alter care delivery by potentially increasing hospital admissions.

Furthermore, as the proposed rule notes, the Institute of Medicine's (IOM) committee on the future of Emergency Care in the U.S. recommends that CMS remove current limitations on medical conditions that are eligible for separate observation care payment. This would encourage the development of observation units that may improve the flow of patients through overcrowded emergency departments.

The AAMC strongly recommends that CMS provide hospitals with the data showing how observation services have been assigned to APCs. This is necessary to ensure that the proposed methodology of assigning packaged services to primary procedures found on the claim leads to the creation of APCs that are clinically coherent and have appropriate payment rates. In light of these concerns, we urge CMS to delay its packaging proposal for observation services until the public has the opportunity to understand the full implications of this policy.

PAYMENT FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Separate Reporting of Pharmacy Overhead Charges

For CY 2008, CMS is proposing to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological with which it is associated and instead report the pharmacy charge on an uncoded revenue code line on the claim. CMS intends to collect pharmacy overhead costs and package them into payment for the procedure associated with administering the drug or biological rather than into the payment for the drug or biological. The Agency believes this proposal would improve its packaging efforts.

The AAMC appreciates CMS's effort to try to find better ways to account for pharmacy overhead costs. However, the proposed policy of removing the overhead charges from the charge for the drug or biological and report it on an uncoded revenue code line will not accomplish this goal. This is because the proposed policy is practically untenable due to the administrative burden it would impose on hospitals and is likely to result in poor data.

As our members have pointed out, this proposed policy, if implemented, would require a major overhaul of coding and billing systems for hospitals. If hospitals are required to report overhead charges separately from the charge of the drug, it would require them to invest in separate stand-alone computer systems, that would maintain two charges for each of the potentially thousands of drugs to be charged. For bills to non-Medicare payers, this stand-alone system would have to add the two charges together before posting to the bill, while for Medicare bills, the system would simply pass the individual charges for each drug to the bill, and add together all of the overhead charges and pass this latter charge to an un-coded line on the Medicare bill.

The systems hospitals have now are not set up differently based on the type of payer and it is unlikely that they could be, at least in the short term. Making the changes envisioned by the proposed rule would be expensive, administratively burdensome and would take time to implement as hospitals would have to determine how to establish new charges for pharmacy overhead and to develop extensive training programs to educate the staff in all areas of the hospitals where drugs are administered and dispensed.

Furthermore, the proposed rule does not include any guidance as to what constitutes overhead and handling costs. Thus, without knowing what revenue codes should be used to report the information on the uncoded line, each hospital may use different revenue codes, resulting in highly variable and inaccurate data for the purpose of determining overhead and handling costs.

In sum, while we support CMS's effort to continue to determine pharmacy overhead costs, we strongly oppose the proposed separate reporting of pharmacy overhead costs.

The AAMC and our members would be happy to work with CMS to identify ways to obtain these data in a way that is more administratively feasible.

Proposed Payment for Separately Payable Drugs and Biologicals

Relying on hospital cost reports and outpatient claims data to estimate costs, CMS is proposing to pay for separately payable drugs and biologicals at the average sales price (ASP) plus five percent. This constitutes a one percent payment reduction from the payment rate hospitals receive in 2007. It also is lower than the physician office setting payment rate of ASP plus six percent.

We urge the Agency to continue to provide payment for separately payable drugs and biologicals at ASP plus six percent. This would provide a consistent payment policy across providers and increase the likelihood that hospitals receive adequate payment that covers drugs and biologicals and their associated handling costs. Providing consistent payments across providers has been CMS's long-standing policy that was implemented in part to discourage providers from treating patients in one setting over another.

The AAMC remains concerned however, that even the current rate of ASP plus six percent is inadequate at covering the acquisition and handling costs of separately payable drugs and biologicals and urges CMS to conduct further analyses of its methodology for setting payment rates based on acquisition costs.

EVALUATION AND MANAGEMEN (E/M) GUIDELINES

Since the implementation of the OPPS and through CY 2006, hospitals have been reporting five resource-based coding levels for clinic visits and five coding levels for emergency department visits using CPT E/M codes. The least and most resource intensive codes were combined resulting in three APC payment levels.

In CY 2007, CMS started to pay for clinic visits and emergency department visits using five rather than three levels of payment, based on the assignment of the codes to five clinic visit APCs and five emergency department visit APCs.

Because the CPT E/M codes were designed for physician payments, CMS believes that they may not adequately describe the range and mix of services provided by hospitals during these encounters. Consequently, CMS has allowed hospitals to use their own internal guidelines to determine which CPT level code to report. As a result, each hospital currently uses its own guidelines to code for clinic and emergency department visits.

Since 2003, CMS has worked with stakeholders as well as an independent panel consisting of experts from the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) to develop national guidelines that would provide consistency in the coding methodology used by various hospitals.

To date, the Agency has not developed national guidelines, but continues to study the issue. Until the national guidelines are developed, CMS is proposing to allow hospitals to continue to use their own guidelines.

In the proposed rule, the Agency sets forth principles that CMS expects hospitals should follow in developing internal guidelines. The AAMC is concerned about a potential confusion that may arise in interpreting the second principle which states "The coding guidelines should be based on hospital facility resources. The guidelines should not be based on physician resources." (72 Fed. Reg. 42765)

Hospitals have been using internal coding guidelines for clinic visits since the November 1, 2002 final rule. In that final rule, CMS did not explicitly prohibit hospitals from using physician codes to code for hospital visits. Rather, the rule specifies that hospitals not use codes based on physician resources "Facilities should code a level of service based on facility resource consumption, not physician resource consumption." (67 Fed. Reg. 66793)

Consequently, if a hospital determines that the hospital level resources correlate with the physician codes, there is no reason why the physician codes cannot form the basis of the hospital's internal guidelines. In the final rule we would like CMS to confirm that hospitals may continue to use physician coding guidelines if they see fit. Such guidelines would continue to meet the principles set forth by CMS including the second principle stating that the guidelines be "based on hospital facility resources."

If CMS, however, now believes hospitals should not base their internal guidelines on the physician coding guidelines, we urge the Agency to propose such a change formally, along with the rationale for the policy change, next year when it issues its proposed rule. We note, however, that we believe such a proposal would be unwise in that, if it were finalized, among other issues, it would be administratively burdensome, if not untenable in the short run, for affected hospitals to develop brand new guidelines. Moreover, it would not eliminate the variation that already exists among hospitals because each has developed its own set of internal guidelines. Finally, if national coding guidelines are developed at some point in the future, these hospitals would again need to change their coding guidelines.

DEVICE-DEPENDENT APCs

In recent years, some devices have been recalled and the manufacturers have offered replacement devices at no cost to the hospital or a credit for the device being replaced if the patient received a more expensive device. Thus, for CY 2007, in order to identify devices for which the hospital incurs no expense for a defective device that has been replaced, and to set payment rates for device-dependent APCs that contain such devices,

CMS requires hospitals to use modifier "FB" for procedures that use these devices and applies a payment reduction to those procedures that is based on an estimate of the device cost.

CMS is proposing to expand its policy to reduce the APC payment for selected device-dependent APCs when the hospital receives a partial credit when a defective device is replaced. Thus, under the proposed rule, the Agency would require hospitals to report a modifier for those cases in which a hospital receives a partial credit toward the replacement of a defective device.

The proposed rule would reduce the payment for the device-dependent APCs associated with devices for which hospitals have received partial credit for their replacement by half the reduction (half the offset amount) that applies when the hospital receives a device at no cost or receives full credit. CMS is proposing to apply this policy only in those cases in which the amount of the device is greater than or equal to 20 percent of the cost of the new replacement device being implanted.

While we understand the rationale for this proposal, especially since it was implemented in 2007 for replacement devices without cost to the hospital or when the hospital receives a full credit for the device, we believe that the additional administrative burden imposed by this proposal on hospitals, in the form of the significant number of claims that must be re-billed in conjunction with replacement devices for which the hospital receives only partial credit is not justified by the potentially insignificant savings to the OPPS program as a whole. On page 42724 of the proposed rule, in the discussion of hospitals that do not reduce charges for devices upon which they receive partial credit, CMS states, "It is likely that the reduced hospital costs associated with steady, low volume warranty replacements of implantable devices may never be reflected in the cost-to-charge ratios (CCRs) used to adjust charges to costs for devices, because those CCRs are overwhelmed by the volume of other items attributed to the cost centers." This statement seems to suggest that credits for replacement devices are insignificant in relation to the median costs for the all devices being adjusted.

The additional reporting burden on hospitals arises from probability that 50 percent or more of all situations involving replacement devices for which the hospital receives partial credit will require the hospital to re-bill the procedure to Medicare. Many vendors require the failed device be returned to them for examination and evaluation before any credit is granted to the hospital. Thus, at the time a hospital bills Medicare for a procedure to replace a failed device, the hospital does not know the amount of a possible credit it may or may not receive on the returned device. The hospital does not know the amount of any such credits for one to three months after the procedure is performed, and thus will have to re-bill Medicare when the credit is received. The whole process of applying billing adjustments for such "device return credits" is highly manual. The common billing and charge systems used by most hospitals do not have an automated interface with the materials management systems which may track and record the device returns and credits. Also, given the infrequency of these returns, it is highly unlikely that

most materials management systems track these returns and credits in an automated fashion at all. It is not common for material management departments to routinely match purchases and return data with specific patients, which must be done to apply billing adjustments required by the Medicare billing requirement implemented for 2007. This proposal would make the billing requirements even more burdensome for hospitals without resulting in significant savings for the Medicare program.

Thus, we urge CMS to apply a similar policy to that adopted in the FY 2008 final inpatient rule. In that rule, CMS implemented a payment policy that reduces payment for DRGs in which the hospital receives credit equal to 50 percent or more of the cost of the device. In order to address hospitals' concerns regarding the administrative burden and proper billing, CMS gave hospitals two options: 1) submitting the claims immediately without the special condition code (Condition Code 49 under the inpatient PPS) and then submitting a claim adjustment with the condition code at a later date once the credit determination is made, or 2) holding the claim until a determination is made on the level of the credit. The AAMC urges CMS to give hospitals the same billing options under the OPPS as they have under the inpatient prospective payment system.

NEW TECHNOLOGY APCs

CMS is proposing to move certain procedures from "new technology APCs" to clinical APCs in less than two years. A number of these procedures will experience payment reductions due to these new assignments. Although it is the purview of CMS to move services from new technology APCs to clinical APCs in less than two years, we are concerned that the data that CMS obtains in the first two years after services are approved may not be accurate because diffusion of new technologies can be slow and hospitals need time to update their charge masters to appropriately reflect charges that reflect the actual costs of the new services. We ask CMS to consider maintaining procedures in the new technology APC categories for a minimum of two years before assigning them to a clinical APC.

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Teaching hospital's outpatient departments are critical to providing needed services to beneficiaries as well as fulfilling the mission of teaching hospitals. Medicare outpatient payments are critical for teaching hospitals to continue their missions in the outpatient setting, including serving important access roles for outpatient services that range from clinic and emergency room visits to technically-advanced innovations. We would be pleased to work with CMS as it continues to refine and improve this important Medicare payment system.

If you have questions concerning these comments, please contact Diana Mayes, at dmayes@aamc.org, 202-828-0498 or Karen Fisher at kfisher@aamc.org, or 202-862-6140. You may also contact Jennifer Faerberg at jfaerberg@aamc.org or 202-862-6221 for quality-related questions.

Sincerely,

Robert Dickler

cc: Karen Fisher, AAMC
Diana Mayes, AAMC
Jennifer Faerberg, AAMC