

July 2, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 443-G
Washington, DC 20201

Ref: CMS-1428-P — Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates; Proposed Rule (69 *Federal Register* 28196), May 18, 2004.

Dear Dr. McClellan:

On behalf of our nearly 5,000 member hospitals, health care systems, networks and other providers of care, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule establishing new policies and payment rates for hospital inpatient services for fiscal year (FY) 2005.

The rule is one of the most complicated and lengthy in the history of the Medicare program. It not only implements a number of provisions of the Medicare Modernization Act of 2003 (MMA), but also proposes a significant number of complex regulatory changes. The AHA is pleased that Congress acknowledged that Medicare payments to hospitals were inadequate and provided \$25 billion in relief through the MMA. We are concerned, however, that the agency is proposing provisions that would reduce these gains. The Medicare Payment Advisory Commission (MedPAC) in its March 2004 report to Congress said that hospitals' overall Medicare margins had dropped from 4.1 percent in 2001 to 1.7 percent in 2002, the most recent year for which data is available. While the MMA was a good first step, we will continue to urge Congress to provide adequate Medicare reimbursement to hospitals, and, in our attached comments on this proposed rule, we encourage CMS to make changes that would prevent a further decline in Medicare payment.

The AHA is concerned about the redistribution of hospital payments due to the proposed revisions to metropolitan statistical areas (MSAs), the implementation of an occupational mix adjustment, and changes to geographic reclassification. **Specifically, the AHA urges the**



agency to implement a 3-year “stop-loss provision” to protect those hospitals that would experience a decline in their wage index value of 5 percent or more due to the revised MSAs.

We are greatly concerned about those critical access hospitals (CAHs) that now would be designated as “urban” hospitals due to the new geographic boundaries. We believe it is essential that these facilities maintain their CAH status, even though they may no longer be located in rural “statistical” areas. **We strongly urge CMS to “grandfather” these CAHs so that they may seamlessly retain their current CAH status.** We also continue to strongly oppose CMS’s 2004 proposal, reiterated in the 2005 rule, which “clarifies” that patients must be physically present in a critical access hospital when a laboratory specimen is collected in order for the hospital to continue to receive cost-based reimbursement. **This policy is shortsighted, not in the best interest of rural beneficiaries or hospitals, and must be retracted.**

Additionally, we strongly oppose the increase in the outlier threshold to \$35,085, which will make it more difficult for hospitals to qualify for these necessary payments. Given that CMS did not even spend the entire pool of funds set aside in FY 2004 – a loss of \$7 million to hospitals – **we urge CMS to lower the outlier threshold to appropriately reflect the significant changes to outlier payment policy in June 2003.**

Finally, we are disappointed that the rule contains a proposal to further expand the post-acute care transfer policy, which would reduce hospital payments by \$25 million in FY 2005 alone. There is no sound policy rationale for CMS’ proposal to adopt a new set of “alternative criteria.” **This provision must be withdrawn.**

The AHA is becoming increasingly concerned about the effectiveness of the now 20-year old inpatient PPS. Yearly policy adjustments that redistribute payments among hospitals are “band-aid” fixes to a progressively more broken payment system. We question: Is it time to examine whether the MSAs are fundamentally flawed, such that a new basis to define hospital labor market areas needs to be developed? Does it make sense that increasing a hospital’s nurse complement, which should improve quality and patient safety, would likely result in decreased Medicare payments due to the implementation of an occupational mix adjustment? How can hospitals ensure that patients receive the right care at the right time in the right place, when current policies – such as the post-acute care transfer provision – penalize hospitals for making sound clinical judgments about the best setting of care for patients? And, isn’t it alarming that hospitals can’t meet the demands to adopt new technologies, revolutionize care, and bring the “electronic” world to health care record keeping, because their ability to access capital is deteriorating?

The adequacy and equity of Medicare payments are essential, yet 39 percent of hospitals lost money providing inpatient services to Medicare patients in FY 2001, and preliminary estimates indicate that figure has jumped to almost 50 percent in FY 2002. The continued reliance on band-aid fixes, together with the overall inadequate level of payments, could further undermine the solvency of many already financially vulnerable hospitals. The need to create a more adequate and effective reimbursement system has never been greater. The AHA has initiated

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serious discussions about possible new payment models to meet the fiscal challenges of the future. We encourage you and your staff to have similar discussions in order to ensure America's health care system not only remains viable, but also continues to provide the most sophisticated and effective medical care anywhere in the world.

Attached are AHA's detailed comments regarding CMS's proposed changes to the inpatient payment system, including those related to the wage index, outlier threshold, transfer policy, new technology, graduate medical education, critical access hospitals, and diagnosis-related groupings. Additional comment letters on rural hospital issues and long-term care hospital provisions, including CMS' proposed changes to hospitals within hospitals, will be sent separately. The AHA appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about these comments, please feel free to contact me or Ashley Thompson, senior associate director for policy, at (202) 626-2340.

Sincerely,

Rick Pollack
Executive Vice President

Attachment

**American Hospital Association
Comments on FY 2005 Medicare Hospital Inpatient PPS
July 2, 2004**

Revised MSAs

Since the inception of PPS, the AHA has repeatedly stated its view that Metropolitan Statistical Area (MSA) definitions do not accurately reflect hospital labor market areas. The Office of Management and Budget in releasing its revised standards for defining MSAs cautions that the new definitions “should not be used to develop and implement Federal, State, and local nonstatistical programs and policies without full consideration of the effects of using these definitions for such purposes. These areas should not serve as a general-purpose geographic framework for nonstatistical activities, and they may or may not be suitable for use in program funding formulas.” **We question whether CMS has truly given full consideration regarding the effects of the revised definitions on hospital payments. However, we acknowledge that our population and the resulting “urbanity” of our communities does change over time.**

But the re-drawing of lines due to decennial census data creates almost insurmountable challenges. These challenges are then augmented by the fact that hospitals’ Medicare payments are intimately tied to their labor market area and their corresponding hospital wage index. In a budget neutral system, where any changes in the MSAs will create a significant redistribution in Medicare payments, it is unclear whether any one methodology would be better than the next – as all will create “winners” and “losers.” To this end, for FY 2005, the AHA is supporting a proposal that would limit the losses to those hospitals that are most significantly harmed by the census changes.

Specifically, the AHA recommends that CMS adopt a 3-year “stop loss” provision for all hospitals that would experience a decline in their wage index value of 5 percent or more due solely to the MSA changes. According to AHA’s calculations, this provision would protect about 110 hospitals, at what we believe to be a modest and reasonable budget neutral cost of \$10.7 million. Note that we are not suggesting that hospitals be held harmless, but rather that hospitals’ losses are limited.

In addition, we support CMS’ proposal to not adopt OMB definition of Micropolitan Statistical Areas for use in the Medicare payment system, as it would result in even more dramatic swings in hospital payment. Adopting this “third” labor area would add an additional layer of complexity to an already complicated payment system. It would significantly alter a number of hospitals’ wage indexes, especially since about 70 percent of micropolitan areas contain only one hospital, and it would potentially threaten the special payment status of a number of hospitals now deemed “rural” that could be viewed as “urban.”

And, we support CMS' proposed 3-year "hold harmless" provision for urban hospitals that would be located in now rural areas. This provision would help fully alleviate the substantial

decline in payments for hospitals currently classified as urban that would become rural, and will allow them to retain their current MSA assignment (and its corresponding wage index) for three years.

Finally, we are greatly concerned about those critical access hospitals (CAHs) that would be designated as urban due to the new geographic boundaries. We believe it is essential that these facilities maintain their CAH status. Even though they may no longer be located in "rural" counties, their physical location has not changed and these areas still have health care access concerns that can be adequately addressed only through protecting the local hospital's CAH status. **We urge CMS to "grandfather" these CAHs so that they may seamlessly retain their current CAH status.**

Occupational Mix / Wage Data

CMS is required by law to perform an occupational mix adjustment to the wage index beginning in FY 2005, but we are concerned about the integrity of the data used to create the adjustment. Therefore, we recommend that a maximum of 10 percent of the wage index be adjusted for occupational mix.

Specifically, AHA is concerned about the accuracy and completeness of the data used to conduct an occupational mix adjustment to the wage index, given that:

- Hospitals had a very short timeframe for collecting the occupational mix data. While an advanced copy of the instructions were available in December 2003, at a time when many hospital employees were on vacation, the formal One-Time Notification was not released until January 23, 2004. Hospitals then had three weeks to gather and submit the data by the February 16, 2004 deadline.
- Hospitals were given a very short time to review and verify the accuracy of their hospital's occupational mix data as published by CMS. CMS made hospital specific occupational mix data available March 8 on its Website, and allowed hospitals less than three weeks to correct, revise, or actually submit data if they missed the earlier deadline, their information. 
- Fiscal intermediaries were not able to review the accuracy of the data collected, and were unable to correct obvious errors. For example, many hospitals had erroneous data collection dates, i.e., from December 2004 through January 2004, and often a sum of the 19 categories of workers for which data was to be collected did not actually equal the "subtotal of the 19 categories" field.
- Hospitals experienced great confusion in determining the proper category to place certain employees (i.e., an RN who also conducts administrative duties). We are concerned that hospitals treated these situations quite differently, especially in

small rural facilities where an employee often has more than one role at the facility.

- As of March 15, only 90 percent of qualifying hospitals completed the survey.
- Hospitals' data could be submitted either on a four-week prospective basis or a one-year retrospective basis. As the wage index is a relative measure of labor costs across geographic areas, it is important that the data collected from hospitals reflect a common period.

While we believe that CMS' theoretical methodology to determine an occupational mix adjustment is sound, we're concerned that when CMS implemented the adjustment, they did not compare "apples to apples." Specifically, it appears that the total national hours for each of the occupational mix categories (published in Chart 5 of the proposed rule) were obtained from the March 8 occupational mix survey file. Yet there are an additional 263 hospitals in the May 12 occupational mix survey file. According to a recreation of CMS' analysis, it appears that these 263 hospitals received an occupational mix adjustment, but that their hours were not included in the national totals. Thus, the national totals were not recalculated based on the March 8 file amended with the May 12 file for the additional 263 hospitals. We urge CMS to recalculate its analysis using all hospitals in its files.

The AHA is also concerned because CMS' results are counter intuitive. Not only would one-third of rural areas experience a decline in their occupational mix adjusted wage index, but a number of areas with a high concentration of large academic medical centers would actually see an increase in their wage index. **Because an occupational mix adjusted wage index would redistribute Medicare payments among hospitals using data about which we are seriously concerned, we believe that CMS should proceed with extreme caution on implementation. We support a blended wage index, in which a very small portion of the wage index is adjusted for occupational mix, and believe this portion should be no higher than 10 percent.**

Hospital Redesignations

The AHA applauds CMS' interpretation of Section 505 of the MMA that provides hospitals in lower wage areas a wage index adjustment if a significant number of hospital workers commute from the lower wage area to higher wage areas nearby. We support CMS' proposal to adopt the minimum requirement that at least 10 percent of the hospital workers in a county commute to a higher wage area(s) in order for the hospitals in the county to receive the adjustment. We also fully support CMS' proposal to not require a minimum difference between the wage index that applies to the county and the higher wage index areas. Both of these proposals will allow the maximum number of hospitals to qualify for the adjustment.

Hospital Reclassifications

As expressed in our July 1 comment letter, we urge CMS to use its administrative authority to protect those hospitals that have been approved for reclassifications effective in FY 2005 from any decline in their wage index due to such reclassification. Specifically, we ask that CMS grant both rural and urban hospitals the most advantageous wage index value possible for 2005. In addition, the AHA recommends that CMS allow reclassifying hospitals 30 days after publication of the 2005 inpatient PPS final rule to withdraw their reclassification request.

Outliers

The AHA strongly opposes CMS' proposed increase in the outlier threshold. By statute, Medicare provides extra payments for unusually high cost cases in order to limit hospitals' financial risk from extraordinary costs, and to diminish any financial incentive to avoid Medicare patients with especially serious illnesses. These outlier payments are made only if the DRG payment, plus IME and DSH payments, plus any payments for new technologies, plus some loss threshold (set annually by CMS) is exceeded. In the rule, CMS proposes setting the FY 2005 threshold at \$35,085, a substantial increase of over the FY 2004 threshold of \$31,000. This rise will make it more difficult for hospitals to qualify for outlier payments and will put them at greater risk when treating high-cost cases.

CMS' estimate of the FY 2005 outlier threshold does not take into account its June 9, 2003 final rule that significantly changed outlier payment policy. The rule implements the use of more up-to-date data when determining a hospital's cost-to-charge ratio (CCR) – specifically, a hospital's most recent final or tentatively settled cost report. It eliminates use of the statewide average CCR when the hospital's CCR falls below established thresholds. And, it instructs fiscal intermediaries, in certain situations, to retrospectively reconcile outlier payments when a hospital's cost report is settled. Implementing these very significant changes has decreased overall outlier spending, and the outlier threshold must be reduced to account for these more accurately calculated payments.

In fact, CMS estimates that actual outlier payments for FY 2004 will be 4.4 percent of actual total inpatient payments, which is 0.7 percentage points less than the 5.1 percent withheld from hospitals to fund outlier payments. We estimate that the FY 2004 threshold should have been set at \$26,565, rather than \$31,000, to result in outlier payments of 5.1 percent.

CMS' proposed methodology for determining the threshold is flawed. The 2005 threshold would be based on the two-year average annual rate of change in charges per case from FY 2001 to FY 2002 and FY 2002 to FY 2003. CMS estimates this increase to be 31.1 percent over two years. Yet this timeframe does not take into account those substantial changes to outlier payment policy that result in lower cost-to-charge ratios. The data that CMS is using represents rates of increases that are higher than the rates of increases under its new policy, resulting in a higher than appropriate outlier threshold.

An appropriate outlier threshold reflecting these changes is needed to ensure the accuracy of prospective outlier payments. The AHA recommends either:
Using data projections such as the hospital market basket (rather than actual data) to update charges for purposes of determining the outlier threshold, or
Returning to its previous methodology that measured the percent change in costs using the two most recently available hospital cost reports.

The outlier threshold must be lowered to reflect CMS' modifications in outlier payment policy. It is absolutely necessary to ensure hospitals receive the full 5.1 percent of payments that will be withheld from base inpatient payment in 2005, and ensure that hospitals have access to these

special payments to cover extremely high-cost patients. **The AHA urges CMS to lower the outlier threshold.**

Post-acute Care Transfers

The AHA opposes any expansion of the post-acute care transfer policy to additional DRGs. The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare PPS, and penalizes hospitals for ensuring that patients receive the right care at the right time in the right place.

Last year, after "an extensive analysis to identify the best method by which to expand the transfer policy," the agency adopted four specific criteria that a DRG must meet, for both of the two most recent years for which data are available, in order to be added to the post-acute care transfer policy:

1. The DRG must have at least 14,000 cases of post-acute care transfers;
2. The DRG must have at least 10 percent of its post-acute care transfers occurring before the mean length of stay for the DRG;
3. The DRG must have a length of stay of at least three days; and
4. The DRG must have at least a 7 percent decrease in length of stay over the past five years (1998 – 2003).

This resulted in expanding the provision from 10 DRGs in FY 2003 to 29 DRGs in FY 2004. Now, only a year later, the agency is proposing to adopt an additional set of alternative criteria that would be applied to a DRG if it failed to qualify for the transfer provision under the FY 2004 criteria. The new criteria state that the DRG only needs to have 5,000 cases of post-acute care transfers, and the percentage of transfer cases that are short-stay transfer cases is at least two standard deviations above the geometric mean length of stay across all DRGs. It also adds to the four items listed above, to state "or contains only cases that would have been included in a DRG to which the policy applied in the prior year."

The agency clearly is adopting the new criteria solely to capture cases currently in DRG 483 (Tracheostomy with Mechanical Ventilation) as they also propose splitting this DRG into two

new DRGs 542 and 543, based on whether or not the case had a major operating room procedure. Given the split of the DRG, cases currently subject to the policy would no longer qualify. Yet given the proposed new criteria, the transfer policy also would capture DRG 430 (Psychoses) and reduce hospital payments by an additional \$25 million in FY 2005 alone.

If CMS' proposed split of DRG 483 into two more specific DRGs now better accounts for variation in length of stay and cost per case, then the historically stated need for a transfer policy for these two new DRGs is no longer valid. If CMS' creation of the two new DRGs for tracheostomies with and without surgical procedures do not create less variation in length of stay and cost per case, then there is no need to split DRG 483 and no need to expand the transfer policy criteria.

The agency cannot change its rules and criteria year by year in order to ensure certain DRGs are included in the transfer policy. **The AHA objects to the implementation of alternative criteria for which there is no sound policy rationale. This provision must be withdrawn in its final rule.**

Hospital Quality Data

CMS has proposed a data submission process for quality data that is consistent with the process already underway for the voluntary reporting of hospital quality data, except that a few additional forms must be completed. Hospitals appreciate the fact that CMS has kept the process consistent with the one in which many already were engaged. We applaud this decision, which has helped to reduce confusion and burden.

To ensure the hospital data submitted are accurate, timely and complete, CMS has proposed a validation process in which a contractor would re-abstract a sample of patient records. Hospitals' data would be considered acceptable if there is an 80% agreement or better between the data abstracted by the hospital originally and the data abstracted by the CMS contractor for the most recent four quarters, beginning with the data that are submitted for patients discharged during the first quarter of 2004 (data that are due to the warehouse by August 2004).

We agree with CMS that the usefulness of the public reporting is contingent upon having accurate, timely and complete data submitted. We favor having checks on the accuracy of the data, but there are several problems with CMS' proposed methodology for validation:

- Identifying the correct data. First, if the contractor re-abstracts data from a sample of a hospital's patient records, and there are significant differences between the information as recorded by the contractor and that recorded by the hospital, this merely tells us that there is a disagreement between the two parties. We do not know if the hospital is correct, the contractor is correct, or neither is correct. There must be an opportunity for the hospital and

the contractor to review and reconcile their differences, or for a third party to review and determine what data are correct.

- Differences should be significant. CMS has called for an agreement between their contractors' abstraction of all data elements and the hospital's abstraction of the same information, without regard to whether the difference in information is consequential or not. Some disparities in the information recorded may make absolutely no difference in the reported performance of the hospital on the selected measures. For example, if a hospital provided an antibiotic to a pneumonia patient 24 minutes after that patient's arrival at the hospital, but transposed the numerals and recorded 42 minutes instead, there would be a difference in the data elements, but it would have no effect on the actual total of patients recorded as having received their antibiotic within an hour of arrival.
- Phase-in of validation. While over half of the eligible hospitals have been submitting data on some of these 10 measures, less than 25 percent have been submitting data on all 10, and a substantial proportion of the smaller hospitals have not previously had to collect and submit the data. Hospitals will begin submitting data on all 10 measures starting with patients discharged during the first quarter of 2004. Even with the best of intentions, it is unlikely that the data will be abstracted perfectly the first time. CMS has not indicated that the hospitals or the re-abstraction contractors will get any feedback or help to improve the accuracy of their abstractions, so it is unclear how the data collection will be improved over time. Even if such a mechanism were established, hospitals may find it difficult to achieve the desirable level of data accuracy if they encountered significant problems in their data submission during the first quarter. Thus, we encourage CMS to consider allowing 60 percent agreement for the data that will affect the FY 2006 payment rate and phasing up to 80 percent agreement for FY 2007.

CMS also has indicated that it would assess the completeness of a hospital's data submission by checking to see if the number of cases submitted corresponds to the number for whom they have bills. Since the cases reported for quality purposes are for all patients, regardless of payor, and the bills submitted to CMS are only for Medicare patients, it is clear that the number of cases reported should not be congruent with the number billed to CMS except in rare cases. CMS needs to reevaluate their process to assess completeness and provide greater clarity about how it will assess the completeness of the data submission.

New Technology Threshold

The AHA strongly urges CMS to raise the add-on payment level for new technologies from 50 percent to 80 percent of the difference between the standard DRG payment and the cost of the procedure using the new technology. This change is supported in the MMA's report language. In addition, it would mirror the current 80 percent marginal cost factor for inpatient outlier payments.

ESRD Discharges

The AHA opposes CMS' proposed change declaring that only discharges involving End-Stage Renal Disease (ESRD) Medicare beneficiaries who have received a dialysis treatment during their inpatient hospital stay are to be counted toward whether a hospital qualifies for additional Medicare payment because it treats a higher percentage of ESRD patients.

Currently, hospitals with at least 10 percent of its patients as ESRD discharges are able to receive an additional add-on payment under Medicare. CMS proposes revising its policy to reduce the number of hospitals that will qualify for this additional payment. Specifically, CMS proposes that only discharges involving ESRD Medicare beneficiaries who have *received a dialysis treatment* during an inpatient hospital stay would be counted toward qualifying for this adjustment, rather than all ESRD discharges. These payments were established because of the higher cost of treating patients who are critically ill, even though they may not receive a dialysis treatment during their inpatient admission. The adjustment is used to help defray the extra costs of treating ESRD patients in their entirety, not just to defray dialysis costs. CMS has not explained why it proposes the change in policy, nor presented a sound argument for doing so – except to say that the effect of the change would be reduced Medicare program expenditures. This is a real cut to hospitals treating these very ill and costly patients. The AHA opposes any change to this provision, which was put in place to protect access to care for Medicare

beneficiaries and help offset the financial losses associated with hospitals treating a high concentration (10 percent or more of a hospital's total Medicare discharges) of dialysis patients.

Graduate Medical Education

In addition to the comments below, the AHA supports those comments submitted by the Association of American Medical Colleges.

The AHA urges CMS to ensure that the initial residency period (IRP) for specialty physicians who complete a preliminary year in general clinical training is assigned based on the specialty the resident enters in their second year of training.

The rule discusses a potential change – but does not propose a change – in how CMS would “weight” the direct GME resident count for residents that pursue specialties requiring an initial year of broad-based training. Currently a number of programs, such as anesthesiology and radiology, require a year of generalized clinical training in internal medicine as a prerequisite to subsequent training in their chosen specialty. This requirement can be met by either spending the first year in internal medicine, pediatrics, or surgery, or participating in a one-year, freestanding “transitional year” program. CMS policy, however, bases direct GME payments on the resident’s first year of training, without factoring in the specialty in which the resident ultimately seeks board certification. For example, an anesthesiologist who does a base year of generalized clinical training would be labeled with a three-year training period – which is the time required to be board eligible in internal medicine – rather than the four years it takes to be board eligible

in anesthesiology. The result is that the resident is eligible for only partial direct GME reimbursement in the fourth year.

Current CMS policy violates the statute, does not reflect congressional intent, and results in inequitable payments to teaching hospitals for residents training in certain specialties.

The MMA conference report language clearly states, “the initial residency period for any residency for which the Accreditation Council on Graduate Medical Education (ACGME) requires a preliminary or general clinical year of training is to be determined in the resident’s second year of training.”

CMS discusses the possibility of reweighing these residents to allow hospitals their full direct GME payments. Given that it has been CMS’ longstanding policy to allow an appropriate calculation of the full residency period for those residents training in “transitional year” programs, we also feel strongly that this interpretation should be extended to those spending their first year in internal medicine, pediatrics or surgery. **The AHA believes that this issue needs to be addressed and corrected in the final regulation.**

Dual-Eligible Patient Days

The AHA would like to reiterate its opposition to CMS’ proposed changes last year in the counting of dual-eligible patient days for the purpose of calculating the DSH patient percentage. CMS did not finalize its proposal last year, but indicates in this year’s proposed rule that it will respond to last year’s comments and make a decision in its FY 2005 final rule.

The DSH patient percentage is a sum of two fractions, the “Medicare fraction,” calculated as the number of patient days attributable to patients eligible for both Medicare Part A and SSI benefits divided by total Medicare days, and the “Medicaid fraction,” calculated as the number of patient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A benefits divided by total patient days. CMS proposes changing how it treats dual eligible patients who have exhausted their Medicare coverage. Rather than continue to include these patients as part of the Medicare fraction, CMS proposes to exclude them from the Medicare fraction and count them in the Medicaid fraction.

There are important reasons not to make this change. First, CMS clearly states in the FY 2004 proposed rule that the current formula is consistent with statutory intent. Second, the proposed change would place a significant new regulatory and administrative burden on hospitals. CMS indicates, “it is often difficult for fiscal intermediaries (FIs) to differentiate days for dual-eligible patients whose Part A coverage has been exhausted. The degree of difficulty depends on the data provided by the States, which may vary from one State to the next.” The shift of this administrative burden to hospitals is unjustified, especially given the inability of hospitals to access this information. Government agencies, specifically the FIs and the states, have records regarding the Medicaid and Medicare status of patients as well as whether they have exhausted their benefits.

It also is likely that this proposed change would result in reduced DSH payments to hospitals. Any transfer of a particular patient day from the Medicare fraction (based on total *Medicare* patient days) to the Medicaid fraction (based on *total* patient days) will dilute the value of that day, and therefore reduce the overall patient percentage and the resulting DSH adjustment. **The calculation of dual-eligible days must not be changed.**

ICD-9-CM Code Changes

ICD-9-CM code changes have traditionally been implemented once a year on October 1. The Medicare Modernization Act (MMA) required that new diagnosis and procedure codes be implemented April 1 of each year (without DRG recalibration of weights or rates) in addition to the longstanding October 1 update.

The AHA believes that codes considered for the April 1 update be limited to new technologies that present a strong and convincing case for new technology add-on payment only. The AHA recommends that the annual April 1 update be limited to as few codes as possible for the following reasons:

- The addition of a significant number of new codes outside the traditional October 1 implementation will result in doubling the costs associated with the purchase of new code books and updating encoder software programs, requiring hospitals to purchase new code books twice a year. In anticipation of the twice-yearly ICD-9-CM code update, at least one publisher already has announced that two editions of the code books will be published every year.
- Many health plans, including Medicare, require a significant lead-time to incorporate new codes into their systems. We are concerned that payers, such as Medicaid, currently struggling to maintain their systems on the most current code set version will not be able to support a large number of codes being implemented outside the traditional October 1 update.
- A considerable amount of education and coder training takes place every year with the introduction of new and updated codes. Introducing a large number of new codes on a twice-yearly basis, rather than annually, will increase this burden.

In addition:

- New codes should be made publicly available with the same lead-time as currently exists for the October update. Codes for October 1 implementation are currently published in May of the same year (a five month lead time). Codes for April 1 implementation therefore should be published by November of the prior year.
- Since the ICD-9-CM classification is a Health Insurance Portability and Accountability Act (HIPAA) standard code set and applies beyond the Medicare IPPS, CMS should ensure that the new ICD-9-CM update process is communicated to the Office of HIPAA standards, so that all payers, providers and clearinghouses may be notified.

- Traditionally, the new ICD-9-CM codes have been published in the Federal Register, as part of the “Proposed Changes to the Hospital Inpatient Prospective Payment Systems” proposed rule. We urge CMS to develop a process for the wide dissemination of new/modified ICD-9-CM codes for April 1 implementation. We request that the process be published in the Hospital Inpatient final rule to inform users of the process.

We remind CMS that twice-yearly updates to the ICD-9-CM is only a temporary solution to meeting the coding needs of providers who may need to report new technology. A more permanent and long-term solution would be the implementation of ICD-10-CM and ICD-10-PCS as quickly as possible.

DRG Reclassifications

In general, the AHA supports CMS’ proposed changes to the DRG system, which seem reasonable given the data and information provided, with the following exceptions:

- **360-Degree Spinal Fusions:** We agree that 360-degree spinal fusions should be moved from DRG 496 (Combined Anterior/Posterior Spinal Fusion) to DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC). Patients receiving two surgical approaches have a longer recovery period and use more hospital resources. Based on several questions received by the AHA’s Central Office on ICD-9-CM, we believe that there is confusion regarding the use of code 81.61, 360-degree spinal fusion, single incision approach. The Coding Clinic Editorial Advisory Board has discussed code 81.61 several times to clear up the confusion regarding the appropriate application and usage of this code. The confusion stems from physicians who do not use the term “360-degree spinal fusion” in the medical record, and hospital coders who need to review the operative report to determine which surgeries in fact qualify for code 81.61. **We agree that code 81.61 should be moved from DRG 496 to DRG 498, but that the data for code 81.61 be reviewed in the future once coding has improved.**
- **Tracheostomy:** We oppose the proposed deletion of DRG 483 (Tracheostomy for Face, Mouth, and Neck Diagnoses) and splitting the assignment of cases to two new DRGs on the basis of the performance of a major operating room procedure.
- **Pancreatic Islet Cell Transplantation in Clinical Trials:**
CMS proposes applying an add-on payment for pancreatic islet cell transplantation to DRGs 302, 315 and 468. In reviewing DRG 315 specifically, we question how pancreatic islet cell transplantation would group to DRG 315. The rationale states that since the procedure would be performed via an open approach the case would group to DRG 315. Official coding guidelines for this procedure, however, state that only code 52.84 or 52.85 would be assigned, not an additional code for the open approach. This guidance is consistent with basic coding guidelines that normally prohibit coding the approach when a more specific procedure is performed. As a result, coding and grouping of the example provided assigns

this case to DRG 331, Other Kidney and Urinary Tract Diagnoses with CC. **The AHA requests that CMS rethink their rationale for including only specific DRGs within the add-on payment for pancreatic islet cell transplantation until further data is available to justify singling out specific DRGs.**

The AHA also requests clarification for proposing equal add-on payments for both autograft and allograft pancreatic islet cells transplants. It is our understanding that add-on payments are proposed to cover the cost of pre transplant tests and services, organ procurement and islet isolation services. Autograft transplants, however, have no associated organ procurement costs, as the islet cells are taken from the patient's own organ. There are still the costs of pre transplant services and the actual islet isolation procedure itself, but the cost of organ procurement is perceived as a major portion of the actual expense. **As a result, the AHA suggests two levels of add-on payment for these procedures to capture the additional costs of organ procurement associated with allograft transplants, while still providing an adjusted payment for the pretest transplant services and islet isolation procedure associated with autograft pancreatic islet cell transplants.**