Attachment

American Hospital Association
Comments on FY 2003 Medicare Hospital Inpatient PPS
June 23, 2002

COMMENTS ON PROPOSED CHANGES TO INPATIENT PAYMENTS

Transfer Provision. The AHA strongly opposes any expansion of the post-acute care transfer policy to additional DRGs.

In the preamble of the inpatient rule, CMS discusses the *possibility* of expanding the transfer policy to either an additional 13 DRGs with high rates of transfers or to all DRGs. The estimated impact of this policy, according to CMS, would result in reduced payments to hospitals of $916 million or $1.9 billion, respectively, in Fiscal Year (FY) 2003 alone.

Currently, Medicare patients in 10 DRGs who are discharged to a post-acute care setting – including rehabilitation hospitals and units, long-term care hospitals and units, cancer hospitals, psychiatric hospitals, children's hospitals, and skilled nursing facilities – or within three days to home health services, are defined as transfer cases when their acute care length of stay is at least one day less than the national average. These cases are paid a daily (per diem) rate, rather than a fixed DRG amount, up to the full PPS rate. Thus, if a patient has a shorter than average inpatient stay, even by just one day, the hospital is paid less than the full DRG rate.

This policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the right care at the right time in the right place. It disadvantages hospitals making sound clinical judgments about the best setting of care for patients – and this setting is more and more frequently outside of the hospital's four walls. In addition, facilities in regions of the country where managed care has yielded lower lengths of hospital stay for *all* patients are disproportionately penalized. Expansion of this unreasonable provision actually creates a perverse incentive to keep patients longer so that hospitals may retain the full DRG payment.

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Expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system. The Medicare inpatient PPS is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay. Even the *Medicare Guide* has acknowledged that, "division of a prospective payment amount, on a per diem or other basis, undercuts the principles and objectives of the prospective payment system."

The perceived "gaming" hypothesis does not exists. When Congress first called for expansion of the transfer policy in the Balanced Budget Act of 1997 (BBA), data showed that Medicare inpatient lengths of stay were dropping, and that both use and cost of post-

acute care by Medicare beneficiaries was growing. Since this time, however, inpatient length of stay has stabilized. Medicare spending on post-acute care has slowed as post-acute payment systems have moved from cost-based reimbursement to prospective payment. Additionally, studies by the AHA and others show that the majority of patients who use post-acute care have longer – not shorter – hospital stays than patients that don't use post-acute care, demonstrating that these patients are truly "sicker" and in need of additional care.

This proposal significantly expands the liability of hospitals for decisions that are not in their control. Hospitals often do not even know when a "transfer" to a post-acute setting occurs after a patient is discharged. This is because physicians, not hospitals, typically order and arrange such care. In addition, beneficiaries may request that their primary care physician (someone other than their doctor taking care of them while they were in the hospital) order skilled nursing care (which is covered as long as the admission is within 30 days of a hospital stay and related to the condition for which the beneficiary was hospitalized) or arrange for home health services. Hospitals, however, are required to code "transfer" or "discharge" each time a bill is submitted. The Office of Inspector General (OIG) has initiated studies in the past on Medicare patient transfers incorrectly paid as discharges, and we continue to fear that hospitals will find themselves the targets of unwarranted government investigations for Medicare overbilling, as well as erroneous allegations of fraud under the False Claims Act.

Patients sent home but who later receive a visit from a home health care agency should not be viewed as transfers. These patients have been discharged, and hospitals should not be penalized when valuable, and cost-efficient, follow-up care is provided to these patients.

The impact of this provision must be more fully understood before further expansion to additional DRGs. CMS did not include the two options of expanding the post-acute care transfer policy in its 2003 impact table, and it is clear that even incremental expansion of policy would result in an overall decrease in per case payments in FY 2003 as compared to FY 2002.

The statute clearly states that the Secretary is *authorized*, but not *required*, to expand this policy to additional DRGs after FY 2000. The policy was not expanded in FY 2001 or FY 2002 for sound policy reasons, and we encourage the same for FY 2003 and all subsequent years. If CMS proceeds with this unjustified and unreasonable provision, then the AHA strongly urges returning any savings to the base DRG payment rates, a policy also supported by the Medicare Payment Advisory Commission (MedPAC).

Outliers. The AHA strongly opposes the excessive 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 threshold (set annually by CMS) is exceeded. In the rule, CMS proposes setting the FY 2003 threshold at $33,450, an increase of 59 percent from the FY 2002 threshold amount of $21,025.

CMS' proposed methodology for determining the new threshold is flawed. CMS is proposing a new methodology to calculate the outlier threshold because of the unavailability of FY 2000 cost reports, owing to CMS' problems in processing claims associated with the new outpatient PPS. Outlier threshold changes are typically calculated by measuring the percent change in costs using the two most recently available hospital cost reports. Rather than use the actual rate of cost increase from hospitals' FY 1998 and FY 1999 cost reports (the most recently available), however, CMS is proposing to calculate a 3-year moving average of the annual rate of change, and then calculate the *difference* in this change. Specifically, CMS is proposing to project the annual rate of change in hospital cost per case from 2001 through 2003 using a three-year moving average of the differences in annual rates of change.

Attached in *Appendix A* is an analysis by Henry W. Zaretsky & Associates, Inc., which discusses CMS' proposed change in methodology. It finds that making projections off data that is a second derivative of the actual amount results in a highly erratic, and unreliable forecast.

CMS' estimate of cost inflation is too high. CMS' proposed methodology results in a 2-year cost inflation factor of 15.0 percent. Such an increase is more than triple the rate of change of cost inflation in FY 1999, the most recent year available. This 15 percent increase is also markedly different and significantly higher than all other governmental projections of cost inflation.

Annual Rate of Change in Various Measures of Hospital Cost Inflation

	CMS' Proposal[a]	Market Basket Increase[b]	Cost of Adjusted Admission[c]	Medicare IP Cost per Discharge[d]	CPI[e]
FY 1999	2.4%	2.7%	1.9%	1.4%	2.2%
FY 2000	**4.2%**	2.4%	2.5%	3.0%	**3.4%**
FY 2001	**5.5%**	2.9%			**2.9%**
FY 2002	**6.6%**	**3.3%**			**1.8%**
FY 2003	**7.9%**	**3.3%**			**2.2%**

Projections are in bold

[a] The calculated and predicted rate of change in cost per case for the outlier provision.
[b] Hospital market basket, CMS
[c] The actual percent change in total cost per adjusted admission from AHA Annual Survey of Hospitals.
[d] The actual percent change in Medicare inpatient cost per discharge, MedPAC.c
[e] The percent change in consumer price index (CPI) provided by Office of Management and Budget as of Nov. 2001.

The AHA in its annual member survey has tracked hospital cost inflation at a total of 4.4 percent from 1998 to 2000.[1] In its March 2002 report, MedPAC measured hospital cost inflation at a total of 4.8 percent for that same time period.[2] In fact, the Office of Management and Budget (OMB) has projected cost inflation in the overall economy at a rate of 2.2 percent for 2003, and forecasts that the annual rate will continue under 2.4 percent through 2012. Moreover, it is interesting to point out that CMS' estimate of a 15 percent increase in costs compares to only a 6.6 percent increase in the hospital market basket for this same time period, and is way off the mark of other cost indicators.[3] As Zaretsky indicates in its study, CMS' projection is extreme relative to the historical data and projections derived from other methods (Appendix A, page 4).

Zaretsky examines three alternatives: 1) using a three-year moving average of annual rates of change (rather than differences in annual rates of change), 2) using CMS' usual method in predicting cost inflation but substituting a four-year lag in data, rather than the typically three year lag due to the lack of 2000 cost reports, and 3) using changes in the hospital market basket index. These three methodologies result in a projected increase in hospital cost inflation from 2001 to 2003 of 4.1 percent, 4.8 percent and 7.1 percent, respectively.

The AHA recommends using one of the three alternative projections above. The one that most closely approximates CMS' usual method is the four-year lag approach. However, AHA also recognizes that Zaretsky's simulations of the market basket index approach tracks most closely with actual cost increase experience. These two methods would result in a new outlier threshold between $26,254 and $27,810 -- a much more realistic increase.

Counting of Beds. The AHA opposes any change to the computation of bed size for the calculation of IME and DSH.

CMS is proposing to decrease a hospital's total number of beds reported on its cost report if the hospital's annual occupancy rate is below a threshold of 35 percent. This new bed count would then be used in the calculation of disproportionate share hospital (DSH) and indirect medical education (IME) payments.

The Medicare DSH adjustment is designed to offset the higher cost of poor Medicare patients and the traditionally inadequate payments from Medicaid and other indigent care. DSH payments are calculated according to a complex formula, based on a hospital's share

[1] AHA Annual Survey data report an increase in total costs per adjusted admission of 1.9 percent in FY1999 and 2.5 percent in 2000, the most recent data available.
[2] March 2002 report to Congress determined Medicare costs per adjusted admission of 2.7 percent in 1999 and 2.1 percent in 2000, the most recent data available.
[3] Estimated at 3.3 percent for FY 2002 (August 1, 2001 inpatient PPS final rule) and 3.3 percent for FY 2003 (May 9, 2002 inpatient PPS proposed rule).

of low-income patient *days,* not total *beds*.[4] Adding average occupancy rate into the equation is an unnecessary burden that further complicates the process. Although bed size requirements and hospital location are factored into DSH payments, MedPAC and others have expressed concern about the inequity of such systems that have created separate payment rates across hospital groups. Currently, the least favorable DSH rates are given to hospitals with fewer than 100 beds. CMS' policy would further penalize small hospitals, even without a change in their low-income patient days. **An AHA analysis has indicated that the impact of this policy change would be a reduction in hospital payments of $143 million for 65 hospitals in FY 2003 alone.**

The Medicare IME adjustment provides hospitals with additional payments to reflect the higher indirect costs associated with teaching hospitals. It is calculated using a hospital's ratio of intern/residents-to-beds (IRB). In general, a hospital with fewer beds would have a higher IRB ratio, which would then result in higher IME payments. And while AHA estimates that 23 hospitals would benefit by this provision, the entire policy is disconcerting.

The AHA strongly recommends not changing the calculation of bed size for DSH and IME payments. The principal behind this policy is distressing, and the choice of a 35 percent threshold is random. If CMS believes these systems are flawed, then it should propose policy changes to the system, not re-define how it will count beds for certain hospitals. Occupancy rates should not be used as a means to challenge valid methodologies. MedPAC is currently examining DSH payments, and the current formula should not be modified until MedPAC reports its findings and recommendations.

Labor-Related Share. The AHA opposes any change to the labor-related share until, as recommended by MedPAC, more research on the appropriate methodology to determine "local labor" costs and a re-evaluation of the current assumptions is completed.

The labor-related share is used to determine the proportion of the PPS base payment rate (or standardized amount) that is "labor-related" and, therefore, to which the area wage index is applied. It includes the sum of the various weights for inputs that vary with local labor markets, such as wages and salaries, benefits, professional fees, contract labor, and other certain services. As part of the process of rebasing the hospital market basket, CMS is proposing to raise the labor share from 71.1 percent to 72.5 percent. This change will significantly redistribute payments among hospitals, resulting in a 0.2 percent average decrease in per case payments for rural hospitals.

[4] Medicare DSH equals the sum of two ratios: 1) Patient days for Medicare beneficiaries who receive Supplemental Security Income (SSI) as a percentage of total Medicare patient days, and 2) Medicaid patient days as a share of total patient days.

While AHA fully supports the rebasing of the hospital market basket, we are concerned about the significant debate surrounding the inclusion of certain inputs affected by local market wage levels. In its analysis, CMS has included costs that are "*related to, influenced by, or vary with the local labor market,"* even if these services may be purchased at the national level. The proposed result is a higher labor-related share. MedPAC, however, has recommended that the labor-related share include the weights for *only those locally purchased* inputs that are affected by local market wage levels. Utilizing MedPAC's methodology would result in a lower labor-related share. Accurately determining those labor services purchased locally and nationally, and understanding the corresponding price variation requires more study and analysis.

Considering that this policy would redistribute millions of dollars in payments among hospitals, we urge CMS not to make a change until examining more thoroughly the proportion of costs influenced by the local labor market. The AHA encourages CMS to convene a workgroup with hospital representatives to review labor costs in order to determine the most appropriate methodology. In addition, we do not recommend implementing any significant revisions to this methodology in the final rule, as suggested by CMS, without opportunity for additional notice and comment. Lastly, we are supporting legislation that would address wage index disparities in a non-budget neutral manner using additional resources, which would be a better solution to this issue.

We believe that CMS has the authority to implement its proposed market basket revisions but not implement any changes to the labor-related share. As indicated by statute, "the Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs…" Hence, it is not necessary for CMS to update the labor-related share at the same time as rebasing the market basket.

Removal of Wage Costs Related to Graduate Medical Education (GME) and Certified Registered Nurse Anesthetists (CRNA). The AHA strongly opposes removing from the FY 2003 area wage index 100 percent of wage costs and hours associated with teaching physicians, residents and CRNAs.

Beginning in 2000, CMS began a five-year phase-out of salaries related to GME and CRNAs in the calculation of the area wage index. This provision was based on a consensus recommendation between CMS and an AHA-convened workgroup of representatives from national, state and metropolitan hospital associations. The FY 2003 wage index is scheduled to be a blend of 20 percent of a wage index that includes GME and CRNA costs and 80 percent of a wage index that excludes these costs. In the rule, the Administration is proposing to exclude 100 percent of these costs from the FY 2003 wage index rather than continuing with the negotiated transition. Such a move would affect one in five hospitals. Moreover, it would negate an agreed upon compromise, thus questioning the rationale for AHA and other hospital associations to enter into any future negotiations with CMS.

Market Basket. In general, the AHA supports the proposed changes to the hospital market basket.

The AHA supports changing the base year of hospital market basket to 1997, and would support more frequent rebasing to better account for changes in the mix of goods and services used to deliver hospital inpatient care. Every five years, the Administration is required by law to rebase and revise the hospital market basket index. This process is essential because, while a percentage change in the hospital market basket index reflect the average change in the prices of goods and services hospitals purchase to furnish inpatient care, rebasing is the only mechanism that incorporates changes in the *quantity, mix and intensity* of those goods and services used to deliver inpatient care.

The AHA supports the proposal to change the data source for calculating market basket wage index changes to the Employment Cost Index (ECI) for Civilian Hospital Workers. Wages and salaries are the largest components of the market basket index and the proposed proxy will more accurately reflect salary changes in hospitals, rather than blending these changes with those occurring in the general economy.

The AHA supports the proposal to add a separate component to the market basket index to account for changes in blood prices. As you are aware, the price of blood has increased dramatically in recent years, and it is expected to increase even further as the Federal Drug Administration (FDA) formally mandates new screening tests to improve blood safety. Currently, changes in blood prices are incorporated into the market basket by measuring changes in the Industrial Chemical Proxy in the Producer Price Index (PPI). This index does not include blood or the significant changes in blood processing that have dramatically inflated blood prices. CMS is proposing that a separate cost category be created for blood and blood products, and that the PPI for blood and blood derivatives be used as its price proxy. The AHA has long advocated the inclusion of an explicit measure in the market basket of blood price fluctuation to more accurately reflect the price hospitals pay for providing blood products and services and thus supports the change. We will work with the Bureau of Labor Statistics to ensure that the PPI for blood and blood derivatives is as accurate as possible.

Affiliation Agreements. The AHA opposes the proposed regulatory change related to the termination of affiliation agreements and resident caps.

The BBA permitted CMS to develop a system where hospitals could elect to apply their resident limits on an aggregate basis. Currently, two or more hospitals may enter into an "affiliation agreement" whereby each hospital may change its individual resident limits, as long as the aggregate limit for all hospitals remains the same. Upon termination of the affiliation agreement, the hospitals, upon mutual agreement, could keep their new resident caps. CMS is proposing to change the regulations so that upon termination of an affiliation agreement, each hospital would be required to return to its original resident cap. In addition, the policy would be effective for agreements that terminate, not *begin*, on or after October 1, 2002.

The AHA believes the existing policy makes sense, is fair, and should not be changed. CMS should not be involved in decision-making about workforce allocation, as individual hospitals and communities are in the best position to determine the appropriate distribution of residents among hospitals within the local area. In addition, while we oppose any change to the existing policy, a number of hospitals have already entered into affiliation agreements and **we believe that under no circumstances should a charge be made that would retroactively effect an existing lawful agreement.**

New Technology

In the rule, CMS indicates that none of the four applications it received for new technology payments met the criteria in place to receive such additional payments. The timely incorporation of new technology, which includes new medical and surgical procedures as well as new pharmaceuticals, biologics and devices, has major implications for quality patient care as well as the long-run fiscal solvency of the Medicare program. The AHA continues to fully support the timely inclusion of appropriate new technologies into the hospital payment system, and we are eager to continue working with CMS to ensure that equitable mechanisms are in place to do so.

However, because current law requires that new technology payments must be made in a budget neutral manner, any increased funding for new drugs or devices is made by reducing payments for all other inpatient hospital services. Shifting money around within the inpatient PPS leaves hospitals without the additional money they need to assure beneficiaries have access to the newest medical tests and treatments. While the costs of these new treatments are significant and worthy of additional funding, the costs associated with all other inpatient procedures are not declining. **The AHA will continue to urge Congress to devise an appropriate adjustment to hospital payments so that new technologies may be sufficiently reimbursed, without redistributing payments from elsewhere in the system.**

Given the current payment structure, however, we would like to reiterate that we support maintaining new technology payments at a level of no more than one percent of total inpatient PPS payments. And, just as CMS has elected to impose a pro-rata reduction on new technology spending in excess of the estimate, we recommend that funds reserved but not spent should be restored to the standardized amount. For example, we would support carving out, say, 0.3 percent of total inpatient PPS payments, if it were estimated that this amount would be sufficient to cover the costs of the new technology. Additionally, we continue to oppose any type of quarterly coding and recalibration effort that would be incredibly burdensome on our members.

Drug-Eluting Stents

Drug-eluting stents, while not yet approved by the FDA, have shown promise to significantly advance the treatment of coronary artery disease stents by their expected

ability to combat the problem of restenosis. Effective beginning October 1, 2002, CMS has created new procedure codes for drug-eluting stents. Code 36.07 (Insertion of Drug-Eluting Coronary Artery Stent(s)) would be placed into DRG 517 ((Percutaneous Cardiovascular Procedure with Coronary Artery Stent Without AMI), which has a weight of 2.18. CMS has indicated that the manufacturer of this technology has requested that code 36.07 be assigned to DRG 516 (Percutaneous Cardiovascular Procedure with AMI), which has a higher payment weight of 2.73.

The AHA believes that the payment system should adequately reflect the cost of new technologies. Yet changes to the DRG system are required to be made in a budget-neutral manner, such that any increases in payment for drug-eluting stents is made by decreasing payment for all other cases. While any miscalculations in payments will be adjusted over time through the existing DRG recalibration process, we encourage CMS to consider the data it has received to best determine the most appropriate paying DRG. **The AHA would support the reassignment of 36.07 to another DRG or, if necessary, the modification of all affected DRGs, once verifiable data on the costs associated with drug-eluting stents become available.**

Occupational Mix

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) mandates that the wage index be adjusted to reflect the occupational mix of employees for acute care hospitals beginning in FY 2005. The initial data collection is to be completed by September 30, 2003. In the proposed rule, CMS announced that the agency is continuing to develop a "workable data collection tool," which balances the need to collect data that are accurate and reliable with the need for hospitals to have this data readily available. The agency also states that it will inform hospitals of the type of data it will be collecting before actually requiring hospitals to begin providing it.

The AHA is pleased with this delay, which allows CMS to thoughtfully develop an appropriate collection instrument and provide adequate time for hospitals to have the information readily available. Given the importance of the wage index in adjusting hospital payment levels across geographic areas, any changes to the current system must be carefully considered. We continue, however, to be unclear about how the additional data will be utilized and whether the mix adjustment will truly result in a more equitable or efficient payment method. **We strongly encourage CMS to take the time it needs to develop the most appropriate survey instrument. We also urge CMS to publish a detailed proposed methodology, for comment, illustrating how the occupational mix index will be calculated and how it will be used to adjust the overall wage index. The AHA looks forward to continuing to work with CMS on this effort.**

SCHs and the 3 Percent Provision

The AHA supports the new provision, which allows Sole Community Hospitals (SCH) more flexibility in obtaining and maintaining SCH status, but we question the methodology CMS will use to determine "overlapping" services as well as the apparent randomness of choosing a threshold of 3 percent. In the rule, CMS proposes to allow a hospital to receive SCH status even if there is another short-term, acute care hospital within the 35-mile limit, as long as the services provided by the two hospitals overlap by only 3 percent. We are concerned that this 3 percent limit may be too high. For example, a heart-hospital or other "niche" provider may perform inpatient services that represent closer to 10 or 15 percent of the services performed by SCHs. In this situation the SCH continues to remain the sole source of the full range of acute care services in the community, including essential emergency services, and thus deserves to retain SCH status. We are also concerned that CMS has not indicated how it would define overlapping services**.** We question whether this would be based on hospital cost reports or actual claims experience, and request further clarification of CMS' methodology in the final rule.

CAH All-Inclusive Billing

The AHA recommends that the advanced notice period for Critical Access Hospitals (CAH) to elect the all-inclusive billing option be set firmly at 30 days, rather than allowing fiscal intermediaries (FIs) to choose a time frame ranging from 15 to 60 days. Currently, CAHs may elect an "optional payment method" to receive reasonable costs for facility services associated with an outpatient visit plus a professional fee based on 115 percent of the Medicare physician fee schedule. Currently, CAHs are required to inform their FI 60 days before the start of each affected cost reporting period that they would prefer this option. While we agree that a shorter advance notice is warranted, the AHA recommends that an exact time period be set. By allowing each FI to determine this time period, which may be as short as 14 days but no longer than 60 days, we are concerned that confusion will arise, as well as the creation of different policies across the nation.

Our key concern with this provision, however, is that CAHs that have already elected this option have not received payments under the option because CMS systems have been unable to implement the provision. Under BIPA, the provision was to be effective for cost reporting periods beginning on or after July 1, 2001. The AHA recommends that the all-inclusive billing provision be made retroactive to July 1, 2001, as mandated by statute. We also encourage CMS to immediately publish specific implementation instructions via a program memorandum to clarify proper implementation of this payment option.

CRNA Provision

The AHA supports CMS' proposal to change the eligibility criteria for rural hospitals to receive reasonable cost payments for CRNAs and other non-physician anesthetists. The rule proposes raising the volume threshold for surgical procedures requiring anesthesia services from 500 to 800, thus allowing more rural hospitals to qualify for this payment

treatment. We believe this policy change helps address the unique needs and circumstances of small rural hospitals.

Elimination of the MDS for CAHs

The AHA fully supports the elimination of the requirement that CAHs complete a lengthy patient assessment form (often called the minimum data set) for skilled nursing facility patients. This initiative has been strongly advocated by the AHA, as completion of the more than 400-question comprehensive assessment was an onerous and administrative burden.

COMMENTS ON PROPOSED CHANGES TO PROVIDER-BASED PROVISIONS

In general, the AHA supports CMS' changes to the requirements for provider-based designation. The self-attestation process is less administratively burdensome and thus a step in the right direction. However, we continue to believe that on-campus facilities are clearly provider-based and thus should not be mandated to undergo either an attestation or application process. Additionally, we are concerned that an attestation process for on-site facilities and departments may place hospitals at undo risk, owing to associated new billing and reimbursement provisions that could expose hospitals to recovery of overpayments for all cost reporting periods subject to reopening.

Since the beginning of the Medicare program, hospitals have owned and operated departments, facilities, and organizations – located both on and off-campus – that were treated as part of the "main provider" for reimbursement purposes. These entities were deemed to be "provider-based," resulting in additional Medicare payments for services delivered at these sites. During the 1990s, the Administration became increasingly concerned about perceived abuses in claiming provider-based designation. On April 7, 2000, CMS published a final rule detailing strict criteria that facilities had to meet in order to qualify for provider-based status. In response to numerous hospital concerns, Congress mandated a delay in the regulations until October 2002.

Delay in Effective Date. The proposed rule would extend until July 1, 2003 the BIPA-mandated "grandfathering" clause, with the new requirements for provider-based designation phased in based on the start of a hospital's cost reporting period. This includes facilities with formal CMS determinations as well as those without formal CMS determinations being paid as provider-based as of October 1, 2000. **The AHA is pleased with this additional delay, which provides hospitals an opportunity to make contractual and organizational changes needed to comply with the new rule. However, we continue to advocate for a permanent extension of the grandfathering clause, so that facilities treated as provider-based on October 2000 will not need to go through the burdensome application process being proposed.**

Application Process. In the April 7, 2000 final rule, CMS required hospitals to submit provider-based applications and wait for the agency to make an explicit determination that the facility met the provider-based rules before the hospital could bill for services as provider-based. While CMS indicates that it is considering retaining the existing rules, it is also considering a "self-attestation" process.

- For **on-campus facilities**, providers would be required to submit an attestation to CMS stating that the facility meets the provider-based criteria and that it will fulfill the obligations associated with provider-based designation, and must maintain documentation so that the information is available to CMS upon its request.

- For **off-campus facilities**, providers would be required to submit the same attestation and must submit documentation at the time it submits its attestation.

While this process appears to relieve hospitals of a burdensome application process, additional changes proposed to the billing and reimbursement process suggest that hospitals will need to provide CMS with data supporting their provider-based status to ensure they will be protected from recovery of any overpayments**.**

It is still unclear whether every service on the hospital's campus would need to submit a self-attestation, or if one attestation is sufficient to cover all on-campus facilities. Moreover, it is unclear whether these sites will receive a written response from CMS, and the timeframe for this response.

The AHA believes that departments located on the hospital's main campus are clearly provider-based. These departments should not be required to "attest" that they meet the criteria. If CMS has questions or concerns, it should be incumbent upon the agency to initiate an investigation. This should include notice by CMS as well as an opportunity for the departments to fix any discrepancies prior to losing provider-based status.

Scope of Facilities Covered. In the rule, CMS proposes to exclude from provider-based determinations "non-billable" health care services, services for which separate payment could not be claimed under Medicare or Medicaid, or for those facilities whose services are paid under a fee schedule. While we are pleased that CMS has excluded the above services from requiring provider-based determination, the agency did not go far enough. CMS states throughout the rule that "a higher degree of integration can be presumed for on-campus facilities or organizations." Yet, CMS is still proposing that hospital departments providing diagnostic or therapeutic radiology services to outpatients, and specialty services providing care to outpatients (i.e., primary care clinics, ophthalmology) must continue to attest to or apply for provider-based designation**. The AHA recommends that departments located on a hospital's main campus, those that are clearly provider-based, should not be required to "attest" that they meet the criteria. The onus should be on CMS to demonstrate that on-campus facilities owned and operated by the hospital do not meet provider-based requirements. This would cut down significantly on volumes of unnecessary paperwork, for both hospitals and CMS.**

EMTALA. (Please see below for comments on the application of EMTALA to provider-based facilities)

Joint Ventures and Management Contracts. CMS is proposing to permit joint ventures, but only if the program is on the hospital's main campus. **The AHA supports this change, which is necessary in recognizing the desire of hospitals to enter into such arrangements that minimize the costly duplication of specialty services.** Additionally, CMS is proposing that off-campus facilities with management contracts may receive provider-based determinations if the hospital (or another organization that is not the management company) employs the staff of the off-site facility who are directly involved in delivering patient care. Management staff, as well as staff paid under a fee schedule

such as physicians, physician assistants and certified registered nurse anesthetists, are excluded from this requirement. **The AHA supports this modification that will allow hospitals to outsource non-clinical staff, such as housekeeping and security services.**

Billing and Reimbursement. In the proposed rule, CMS outlines the steps it will take if the agency discovers that a hospital is billing inappropriately for outpatient services. It appears that hospitals will be protected by "good faith efforts" only if they "request an advance determination of provider based status." This can be done through the self-attestation process. It is unclear, however, whether this protection applies only to off-site facilities, which are required to *submit* documentation to CMS confirming that they meet the provider-based requirements. **The AHA requests further clarification on whether on-site facilities will be protected under the good faith provision.**

In the preamble, CMS indicates that under the attestation process "there would no longer be an explicit requirement that provider-based approval must be obtained before a facility is treated as provider-based for billing and cost reporting purposes." However, section 413.65(j)(5) of the regulation states, "if the necessary applications or information are not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted." **The AHA is concerned that on-site facilities that do not submit documentation may fall under section 413.65(j)(5) and thus be at risk for recovery of overpayments "for all cost reporting periods subject to re-opening." We urge CMS to clarify this apparent contradiction, and to allow provider-based sites protection under the attestation process.**

COMMENTS ON PROPOSED CHANGES TO EMTALA PROVISIONS

In general, the proposed changes to the EMTALA regulation are a good step toward improving implementation of the statute. Hospitals take their EMTALA responsibilities seriously. They continue to support the underlying intent of EMTALA – to ensure that those needing emergency services have access to care without regard to their ability to pay. Over time, however, we have seen an expansion of requirements under EMTALA that go beyond what Congress intended, imposing unnecessary burdens on hospitals and interfering with their ability to care for their patients.

Provider-Based Facilities

We strongly support the proposed change limiting the off-campus application of EMTALA to only those hospital departments that function like an emergency department (ED). The best place for an individual in need of emergency services is an emergency department designed and operated to meet those emergency needs. In general, we believe the definition of "dedicated emergency department" will be a practical means to determine which sites are functioning as an ED.

There is a discussion in the Preamble, however, regarding the potential inclusion of urgent care centers that will create too much uncertainty for hospitals and a strong likelihood of incorrect and inconsistent interpretations across the region offices. A dedicated ED is a "specially equipped and staffed area of the hospital that is used a significant portion of the time for initial evaluation and treatment of outpatients for emergency medical conditions." **We urge that only those urgent care centers that are functioning and holding themselves out to the public as an ED should be considered a "dedicated" ED and covered under EMTALA.**

The focus should be on the ability to provide treatment for emergency medical condition. Many urgent care centers are capable of responding to an urgent need, but not an emergency medical condition. It is also important to clearly distinguish between emergency care and urgent care so that sites providing the same level of care and holding themselves out to the public in the same way are treated the same under EMTALA. Since EMTALA only applies to hospitals, to subject a hospital-operated urgent care center to EMTALA when a similar center operated by a physician or others would not be subject to EMTALA would create confusion for the public and create uneven obligations.

The use of the term "outpatient" in the definition of dedicated ED also creates confusion. The term "dedicated ED" is used only in connection with someone requesting service who is not a patient. The implication of the definition is that an outpatient may be covered under EMTALA, which is inconsistent with other provisions in the proposed rule. **The term outpatient should be deleted from the definition and be replaced by "member of the public." (**A dedicated ED is a specially equipped and staffed area of the hospital that uses a significant portion of the time for initial evaluation and treatment of a member of the

public for emergency medical conditions.) **In addition, the definition of "hospital with an emergency department" should either be deleted or revised so that it is defined as a hospital with a dedicated ED.** Under the proposed regulation, dedicated ED rather than ED is the operative term.

Hospital-Owned Ambulance

We also strongly support the proposed change permitting a hospital-owned ambulance to operate under a local emergency medical services system (EMS). EMS protocols are designed to get patients to an appropriate hospital as efficiently as possible. Relying on a clinical protocol to determine where an ambulance should transport someone in need of emergency care is a much better guide than ownership of the ambulance.

Application to Inpatients

Under the proposed regulation, EMTALA generally will not apply to inpatients. However, for an individual who is admitted through the ED with an emergency medical condition that has not yet been stabilized, EMTALA will follow that individual in the inpatient setting until the emergency medical condition is stabilized. The explanation for this position is to protect against a hospital using inpatient admission to evade EMTALA responsibility for stabilizing an emergency medical condition. We are aware of no evidence that this is a problem.

EMTALA was not intended to apply to inpatients and we believe there is no need to apply EMTALA to an inpatient admitted through the ED. When an individual is admitted, the hospital's assumption of responsibility for the patient and his or her care on an inpatient basis should be deemed as meeting its obligation under EMTALA. As CMS recognized in the Preamble to the proposed rule, when an individual is admitted for treatment as an inpatient, the hospital, physician and other professionals have legal, professional and ethical responsibilities that go beyond EMTALA requirements, as well as responsibilities under Medicare's general conditions of participation (COP). State licensure and accreditation are other means through which a hospital's delivery of care is overseen. In admitting an individual as an inpatient, a hospital has accepted responsibility for more than is required under EMTALA. **The final rule should provide that EMTALA does not apply in the inpatient setting.**

The proposed regulation would require a hospital to devote significant time and resources to tracking these patients, training all staff on the requirements of EMTALA and informing them of new developments, and completing EMTALA paperwork that duplicates other recordkeeping requirements – an additional burden that is not legally required and, more importantly, takes caregivers away from patient care. The effect of the proposed regulation is to cast a cloud over the admission of emergency patients for treatment. If a situation did arise in which a hospital intentionally admitted an individual to evade its EMTALA responsibility CMS could address that situation through its existing enforcement authority.

Application of EMTALA On-Campus

Use of the ED for Nonemergency Services
Applying EMTALA to everyone requesting service in the ED, including nonemergency services, contributes to the strain on very busy ED staff and resources. Patient care would be enhanced if hospitals were able to triage individuals into other, more appropriate care settings when they are not requesting emergency services. While the proposed regulation acknowledges that EDs are used for nonemergency services, it continues to apply EMTALA in all circumstances. It provides that a different screening process may be used for nonemergency requests. The problem with this solution is that having said EMTALA applies, hospitals will face a significant risk that their judgment regarding a sufficient screening will be second-guessed by the surveyors and region offices**. EMTALA should not apply to requests for nonemergency care.** The Preamble to the final rule should emphasize that EMTALA is intended to ensure access to care for emergency medical conditions and provide examples of typical requests that are outside of this definition, e.g., preventive services like flu shots or blood pressure readings, prescription refills, referral of a private patient of a physician for a nonemergency test or procedure not available in the physician's office, law enforcement requests for blood draws, after hours requests for occupational health or ambulatory care services. Hospitals would have protocols for the triage of these cases.

Request for Services Away from an ED
As applied in the past, it was difficult for hospitals to know when an EMTALA screening obligation was created by a request for service at a site on-campus but away from the ED. The proposed regulation attempts to clarify when a screening is required by establishing different expectations for requests at a dedicated ED than at other sites. Any request at a dedicated ED is covered under EMTALA. At all other sites, EMTALA would only apply if the request is for what "may be" an emergency condition. This standard is likely to continue the confusion. Instead, **EMTALA should only apply away from a dedicated ED if a request is made for emergency care services.** This would ensure that an individual who believes he or she has an emergency condition would be provided access to care. In addition, the new "prudent layperson observer" provision would ensure that the obvious emergency situation would be addressed, even if the patient is unable to verbalize a request.

An Emergency that Arises during an Outpatient Visit
We agree with the position taken in the Preamble that EMTALA would not apply if an emergency arises while an individual is being treated on an outpatient basis. It appears that this provision was inadvertently omitted from the regulation text. As explained in the Preamble discussion, in that instance an individual has an established relationship with the hospital and arrived for outpatient, not emergency, services. **We support this position and urge that it be included in the regulation text.**

<u>On-Call</u>

The proposed regulation clarifies that hospitals have discretion in maintaining an on-call list to best meet the needs of their patients; that physicians do not need to be on-call at all

times; and that hospitals must have alternate arrangements when a needed specialty is not available. We appreciate the emphasis on maintaining flexibility for hospitals in providing on call coverage and the change in direction from the very prescriptive on-call requirements imposed in some of regions. This is an area in which confusion and difficulty has been created by ad hoc development of guidance across individual region offices. However, two significant problems remain under the proposed regulation. As discussed in the Preamble, EMTALA continues to be viewed as a means to oversee the sufficiency of on-call arrangements. At the same time, there continues to be no parallel EMTALA obligation for physicians, whose participation is essential to providing on-call coverage.

The intent of EMTALA was to ensure that services available to the ED are made available to all without regard to their financial circumstances. It is a nondiscrimination statute. As the courts have repeatedly made clear, Congress did not intend that EMTALA establish a national standard of care or be a federal malpractice statute. The general Medicare COP provisions already address patient care responsibilities for providers, as does state licensure and accreditation standards. As enacted by Congress, the statute requires that a hospital maintain a list of physicians on-call to the ED to provide stabilizing treatment, ensuring that an ED knows in advance who can be called when specialty services are needed, as well as that those services are uniformly available regardless of the patient's ability to pay. **The final regulation should follow the requirements of the statute: so long as an on-call list is maintained and available to the ED, and the coverage available through the on-call list is available to each patient, regardless of their ability to pay, the hospital should be deemed as meeting its EMTALA on-call responsibility.**

If CMS intends to regulate the provision of on-call coverage, EMTALA is not a suitable or appropriate means to do so. As proposed, a hospital is placed in the position of being a guarantor of the participation of physicians in on-call coverage, which is a legally untenable and practically unreasonable position. Hospitals must and do make good-faith efforts to have a full range of services available through on-call coverage. They cannot, however, control the participation of physicians.

Prior Authorization/Insurance Information

The proposed regulation prohibits a hospital from requesting, or having a patient request, authorization from an insurer for screening or stabilization services until the screening has been completed and any necessary stabilizing treatment has been initiated. The proposed regulation does not address what information a hospital may request from or discuss with a patient waiting for a screening examination. **We urge CMS to clarify that financial or coverage information may be requested so long as it does not delay a screening or stabilization; and that conversation about the limitations of an individual's insurance coverage may occur as individuals ask whether there will be a charge for the emergency room visit.** In a busy ED there is often a wait time while other more serious or emergency cases are treated. During that time, questions are often asked about wait times or costs of care. These are legitimate questions and hospitals should be able to respond. While the interpretive guidelines provide that a hospital may follow its normal registration process, hospitals continue to be challenged by region offices and surveyors on the use of

those procedures. The AHA and its members continue to be willing to work with CMS and others to develop language or signage so that patients can be adequately informed of their right to a screening and stabilization without regard to ability to pay and potential financial responsibility.

Due Process

Hospitals should be provided due process before a notice of termination from the program may be issued. We urge CMS to change the regulation to clarify that the appropriate standard for evaluating compliance with EMTALA is whether the hospital followed its usual procedures in responding to an individual. Currently, a hospital under investigation cannot appeal if it is found in violation of EMTALA by the region office until after termination from the program, effectively leaving a hospital with no meaningful opportunity to challenge a non-compliance decision. With no means of review, region offices can and do impose requirements beyond the statute or regulation, misinterpret the agency's policy, or make incorrect findings of fact. The hospital is left with no recourse. As currently enforced, EMTALA is also used to second-guess the treatment provided by a physician or other clinician. A disagreement among peers can form the basis for termination of a hospital. This is not what Congress intended. As the courts have repeatedly held, EMTALA does not create a standard of care, nor a federal malpractice statute. So long as a hospital uniformly applies its procedures and standards, and provides uniform care to all patients based on their medical conditions, the intent of EMTALA and a hospital's obligations have been met.

COMMENTS ON PROPOSED DRG CHANGES

Proposed DRG Reclassifications

DRGs 1 and 2

We support the proposal to redefine and retitle DRGs 1 and 2 from "Craniotomy age >17 except for trauma" (DRG 1) and "Craniotomy for trauma age >17" (DRG 2) to "Craniotomy age >17 with CC" (DRG 1) and "Craniotomy age >17 without CC" (DRG 2)

DRGs 14 and 15

The current proposal is to continue to group patients with intracranial hemorrhage and infarction together in DRG 14; remove code 436 (Acute, but ill-defined, cerebrovascular disease), from DRG 14 and reassign it to DRG 15; and create DRG 524 (Transient ischemia). DRG 14 would be retitled from "Specific Cerebrovascular Disorders Except Transient Ischemic Attack (TIA)" to "Intracranial Hemorrhage and Stroke with Infarction." DRG 15 would be retitled from "Transient Ischemic Attack and Precerebral Occlusions" to "Nonspecific Cerebrovascular and Precerebral Occlusion Without Infarction."

We strongly oppose making any changes to DRGs 14 and 15 until better data is available. Moving approximately 80,000 cases from a higher paying DRG to a lower paying DRG will significantly impact the finances and operations of a number of hospitals. Currently, there are significant inconsistencies in the coding and reporting of both strokes and cerebral infarctions. The AHA recommends conducting further study on this issue once the coding issues are clarified.

Code 436 (Acute, but ill-defined cerebrovascular disease) is a very common code for stroke or cerebrovascular accident (CVA) patients when the physician does not specify which artery sustained the infarction. This is a very common scenario when the physician may elect not to perform a CT scan or MRI of the brain. The clinical presentation may be very specific, indicating a stroke. Performance of additional MRI or CT scan would add specificity to determine which artery was involved, but would not change the course of treatment for that stroke. Rather than incur the additional expense of additional testing, and delaying treatment, which may adversely affect the patient's outcome, the physician may elect to go ahead and treat the stroke without the CT or MRI. The only code available in this situation would be 436. This is still a stroke and should not be grouped as a transient ischemic attack.

Even if further testing were performed and there was evidence of a cerebral (433) or precerebral (434) occlusion or stenosis, unless the physician documentation makes a direct link between the stroke or infarction and the occluded artery, the fifth digit for cerebral infarction may not be used. The fifth digit for cerebral infarction modifies only the specific code to which it is applied (e.g. basilar artery, carotid artery, etc.).

Discussions by the Coding Clinic Editorial Advisory Board last year revealed that cerebral infarction codes are being used inconsistently and improperly. There has been conflicting information and interpretation in the field regarding the application of fifth digits for cerebral infarction. We strongly encourage the National Center for Health Statistics (NCHS) and CMS to work on clarifying the rules for application of the fifth digits for cerebral infarction.

Heart Assist Systems

We support the creation of a new DRG 525 (Heart Assist System Implant) to contain left ventricular assist devices.

Moving Diagnosis Code 398.91 (Rheumatic Heart Failure) From DRG 125 to DRG 124

We support the proposal to add code 398.91, rheumatic heart failure as a complex diagnosis to DRG 124 (Circulatory disorders except acute myocardial infarction with cardiac catheterization and complex diagnosis).

Radioactive Element Implant

We support the proposal to reassign cases with code 92.27 (Implantation or insertion of radioactive elements) without a percutaneous cardiovascular procedure to DRG 120 (Other circulatory system O.R. procedures).

MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders

We support the assignment of the new cystic fibrosis manifestation codes to DRGs based on the specific manifestation being treated – namely:

- Pulmonary manifestation – DRG 79 (Respiratory infection and inflammations age >17 with CC), DRG 80 (Respiratory infection and inflammations age >17 without CC), or DRG 81 (Respiratory infection and inflammations age 0-17).
- Gastrointestinal manifestation – DRG 188 (Other digestive system diagnoses age >17 with CC); DRG 189 (Other digestive system diagnoses age >17 without CC); and DRG 190 (Other digestive system diagnoses age 0-17).
- Other manifestations (includes a number of manifestations excluding pulmonary and gastrointestinal) – DRGs 296, 297 and 298 where existing code for cystic fibrosis without meconium ileus is currently grouped.

MDC 11 (Diseases and disorders of the kidney and urinary tract)

Insertion of Totally Implantable Vascular Access Device (VAD)
We support the proposed reassignment of insertion of totally implantable vascular access devices (VAD) from a medical DRG 316 to surgical DRG 315 (Other kidney and urinary tract O.R. procedures).

Bladder Reconstruction
We support the reclassification of bladder reconstruction surgery from a minor bladder to a major bladder procedure. This would reassign the procedure from DRGs 308 and 309 to DRG 303 (kidney, ureter and major bladder procedures for neoplasm), DRG 304 (kidney, ureter and major bladder procedures for nonneoplasm with CC, and DRG 305 (kidney, ureter and major bladder procedures for nonneoplasm without CC).

MDC 15 (Newborns and other neonates with conditions originating in the perinatal period

Definition of MDC 15
We support the proposal to reclassify congenital anomaly diagnoses from MDC 15 and reassign them to other DRGs depending on the anomaly.

DRG 386 (Extreme immaturity or respiratory distress syndrome, neonate)
We support the new ICD-9-CM diagnosis codes to differentiate between extreme immaturity or gestational age, or both. We also support the redefinition of DRG 386 to "Extreme Immaturity."

DRG 387 (Prematurity with major problems) - DRG 389 (Full term neonate with major problem) - DRG 391 (Normal newborn)

Our understanding is that the National Association of Children's Hospitals and Related Institutions (NACHRI**)** made recommendations to improve MDC 15 at CMS' request. There are only seven broadly defined neonatal DRGs, and we agree that further refinement would be beneficial to allow more accurate grouping of neonatal admissions.
The proposed recommendation modifies the definition of DRG 391 (Normal newborn) to expand the number of minor problem newborn diagnoses included in both the list of principal diagnoses and the list of minor problem diagnoses. These codes were identified by NACHRI as occurring with some frequency in the newborn population and having costs more similar to those of normal newborns than those in DRG 390 (neonates with other significant problems).

Careful further analysis of the data as well as clinical input is needed before making these changes. The proposed deletions from the "major problems" list include serious conditions requiring the use of additional facility resources (pages 31417-31419). Resources would be used to assess the patient and make the diagnosis determination, as well as develop a plan to determine whether the condition is to be managed or treated during the birth encounter, or at a later date. These conditions include fetal malnutrition, bacteremia, fever, meconium aspiration syndrome, fetal blood loss, hemolytic disease due to other and unspecified isoimmunization of fetus or newborn, neonatal hypoglycemia, hemorrhagic disease of newborn, cardiac dysrhythmias, neoplasms, polydactyly, rashes, hematemesis, etc. While these conditions may not be as costly as other "significant problem" conditions, they are minor problems that require additional testing and care. Some of these diagnoses may be the result of ruling out suspected major problems. For example, "bacteremia (790.7)" refers to an abnormal lab finding of bacteria in the blood. A series of blood

cultures may have been performed in order to rule out a more significant problem like septicemia. Nevertheless, the diagnostic work-up had to be carried out to rule out the septicemia.

The AHA opposes the proposed change to reassign a large number of diagnosis codes from the "major problems" list in DRGs 387 and 389 to DRG 391 (Normal newborn) at this time. We recommend that CMS work with NACHRI, AHA and the American Academy of Pediatrics (AAP) to develop a separate DRG that would group neonates with minor problems. The current DRG classification recognizes full term neonates with major problems (DRG 389), neonates with significant problems (DRG 390) and normal newborn (DRG 391). We believe that the list of ICD-9-CM diagnosis codes on pages 31417-31419 would be more accurately classified in a DRG that recognized neonates with minor problems.

MDC 23 (Factors influencing health status and other contacts with health services)

We support the addition of code V10.53 (history of malignancy, renal pelvis) to DRG 465 (aftercare with history of malignancy as secondary diagnosis). This will make it consistent with all other codes for history of malignancy, which are currently included in DRG 465.

Pre-MDC (Tracheostomy)

We support the modification of DRGs 482 and 483 to differentiate the classification based on the presence or absence of continuous mechanical ventilation that lasts more than 96 hours (code 96.72).

Medicare Code Editor (MCE) Changes

We support the proposal to remove code 436 (acute, but ill-defined cerebrovascular disease) from the nonspecific principal diagnosis edit. This is a very common code and is the only correct code when the documentation only states "stroke" or "cerebrovascular accident" without additional physician documentation.

Surgical Hierarchies

We support the revision of the surgical hierarchies for pre-MDC DRGs and for MDC 5 (Diseases and disorders of the circulatory system) as proposed:

Pre-MDC DRGs – reorder DRG 495 (Lung transplant) above DRG 512 (Simultaneous pancreas/kidney transplant)
MDC 5 – reorder DRG 525 (Heart assist system implant) above DRGs 104 and 105 (Cardiac valve and other major cardiothoracic procedures with and without cardiac catheterization)

Intestinal Transplantation

We support the proposal to not create a separate DRG for intestinal transplants. This procedure is not being widely performed.

Myasthenia Gravis

We support the creation of a new diagnosis code so that myasthenia gravis in crisis can be uniquely identified and the mild and severe forms of the disease be distinguished.

Cardiac Mapping and Ablation

We support the proposal to not make any changes for these procedures.

Platelet Inhibitors

We support not making any changes to the assignment of these procedures.

Cardiac Resynchronization Therapy

We support the proposed assignment of 00.51 into DRG 514 or 515, and code 00.50 into DRG 115 and 116 at the present time. This is a new technology which recently received FDA approval and is still not widely used in hospitals in the United States. We believe there is insufficient information at the moment with regards to clinical efficacy and costs. However, the technology seems to be similar to pacemakers and defibrillators, so the DRG grouping proposed is logical.

The AHA would also support the reassignment of 00.51 and 00.50 to another DRG or, if necessary, the modification of all affected DRGs, once verifiable data on the costs and efficacy of cardiac resynchronization therapy becomes available.

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Multiple Level Spinal Fusions

We support the proposal to not make DRG changes for multiple level spinal fusions. ICD-9-CM historically has not been used to differentiate among cases by the number of repairs or manipulations performed during a single procedure. Developing a logical and easy to understand coding methodology for multiple level spinal fusions will require careful consideration as it will be introducing a new concept into ICD-9-CM coding. We have worked with CMS on the ICD-9-CM Coordination and Maintenance Committee and with the *Coding Clinic for ICD-9-CM* Editorial Advisory Board on this issue. We have found this to be a complicated issue, likely to create confusion if care is not taken. We look forward to continue working with CMS on this coding issue and offer our assistance in disseminating educational information once a code is created. For the time being, we support making no changes for multiple level spinal fusions.

Open Wound of the Hand

We support making no DRG changes for open wounds of the hand at the present time.

Cavernous Nerve Stimulation

We support making no changes for this procedure.