



NATIONAL ALLIANCE FOR
THROMBOSIS & THROMBOPHILIA

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Stop the Clot™

June 12, 2008

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

CMS-1390-P

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians; Proposed Rule

Dear Administrator Weems:

The National Alliance for Thrombosis and Thrombophilia (NATT) is a nationwide community-based patient advocacy organization. NATT's mission is to prevent, diagnose, and treat thrombosis and thrombophilia through research, education, support and advocacy. NATT's patient leadership is supported by national medical and scientific leaders to advance NATT's mission. With support from the Centers for Disease Control and Prevention (CDC), NATT is in the first year of a two year project directed at educating consumers, patients and health care professionals to prevent thrombosis-related morbidity and mortality.

Annually, there are an estimated 900,000 events of venous thromboembolism (VTE), and 300,000 deaths in the US ¹, many of which are preventable. Many VTEs and PEs occur in the hospital setting or soon after discharge. For many DVT/PEs, there are evidence-based interventions that are safe and effective in preventing thrombosis. Too often, VTE prophylaxis is

not given to patients that, by evidence based guidelines (e.g. Prevention of Venous Thromboembolism: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy ²), should receive prophylaxis.

In April 2008, the Centers for Medicare and Medicaid Services (CMS) published a proposal to expand hospital acquired conditions (HAC) for which Medicare reimbursement would be denied, and possibly include DVT and PE. Under this proposal, hospitals would be required to track DVT and PE as HACs and would not be reimbursed where they occur.

NATT Recommendations

(NATT developed the following recommendations in three categories in consultation with NATT's Medical and Scientific Advisory Board - MASAB)

NATT supports the principle of withholding reimbursement for preventable thrombosis HACs. However, not every DVT/PE constitutes a preventable HAC. NATT opposes across the board denial of reimbursement for all HAC DVT/PEs. The following is a dynamic framework (three categories) that NATT offers for consideration by CMS as to where reimbursement should be denied and where it should not.

Category 1. Deny Reimbursement for DVT/PE Now. Where evidence-based guidelines for anticoagulation management and prophylaxis are clearly established, hospital inpatients (pre-admission and discharge patients, where appropriate) should be assessed, stratified and prophylaxed, if the indication is there; if the patient meets inclusion criteria but is, for some reason, not prophylaxed (such as increased bleeding risk outweighing the benefit of prophylaxis), then this needs to be documented. Failing to prophylax or document why eligible patients are not prophylaxed, will contribute to preventable morbidity and mortality. In such instances, NATT recommends that CMS publish a final rule that would deny hospitals reimbursement for related treatment with a deferred implementation date. The deferred start-date is essential to allow for the: a) identification of 2-3 selected diagnostic categories and stratification criteria for start-up, b) identification of major contraindications to anticoagulation therapy; and c), the development of well-designed and validated "tools" to identify patients, diagnoses, treatment and outcomes without further onerous manual medical review. It is recommended that Category 1 be structured as a "Demonstration Project", with financial incentives (see gain sharing, below) for payment for the additional costs of screening and consultation, maximizing the potential of success and to pave the way for additional DVT/PE prevention targets.

Category 2. Deny DVT/PE Reimbursement in the Future. There are clinical variables where some data may support thrombosis risk reduction strategies, but definitive evidence-based interventions have not yet been established. NATT recommends that reimbursement not be denied should DVT/PEs occur in patients in such instances, provided that patients were informed of available prophylactic or treatment options.

NATT recommends that CMS review emerging clinical data and new guidelines related to VTE prevention on a biennial basis to determine whether DVT/PEs occurring in certain preventive areas should be moved to Category 1 (Deny Reimbursement for DVT/PE now).

Category 3. Do Not Deny Reimbursement for DVT/PE. DVT/PEs frequently cannot be prevented or may occur even when patients are appropriately prophylaxed or treated. Where VTEs occur in spite of appropriately applied VTE prophylaxis guidelines NATT recommends that reimbursement would not be denied.

Other NATT Recommendations

Gain Sharing Formula. As this policy is imbedded as part of the President's FY 09 budget, a formula based on a percentage of the cost-savings should be developed that would be returned to the hospital as a financial incentive. At least half of this gain sharing return should be applied to support other anticoagulation management initiatives within in the hospital in categories 1 and 2 above (e.g. hospital anticoagulation committee, anticoagulation management service personnel).

Consensus Development Conference. NATT urges CMS to work with the NIH to convene a Consensus Development Conference(s) to review hospital-based anticoagulation management. Conclusions of such a conference would sharpen the focus on category 2 patient management and risk benefit ratio issues (i.e. bleeding versus thrombosis prevention) and identify needs for further clinical studies to help define these risk-benefit ratios. This would result in identifying more opportunities to reduce thrombosis HACs.

Admission Thrombosis Risk Assessment/Stratification. Thrombosis risk assessment and stratification should be done universally for hospital admissions and integrated into hospital policy. A risk assessment tool agreed upon by experts in the field should be developed for this purpose.

Concluding Comments

DVT/PE HACs occur too frequently and are clearly preventable in many conditions. If this rule is selectively executed by CMS, as discussed under Categories 1-3 above, many DVT/PEs will be prevented, resulting in considerable cost savings for Medicare. This economic impact is of great importance, and, indeed, such a reimbursement policy will improve quality of care. These quality health outcomes, and especially the lives that will be saved, are of even greater importance. NATT believe that CMS policy is critical because what Medicare reimburses or denies serves as a bellwether for other third party payers nationwide. The ripple effect has the potential for substantially changing how primary care physicians and multiple specialists view the potential benefits of anticoagulation management for their patients.

NATT appreciates your careful consideration of these comments and is grateful that CMS understands the importance of addressing VTE in hospitals.

Sincerely,

A handwritten signature in cursive script that reads "Randolph B. Fenninger".

Randolph B. Fenninger
President

References:

1. Heit JA, Cohen AT, Anderson FA. Estimated annual number of incident and recurrent, non-fatal and fatal venous thromboembolism (VTE) events in the US. *Blood* 2005; 106:267a.
2. Geerts WH, Pineo GF, Heit JA, et al. Prevention of venous thromboembolism. The seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chest* 2004; 126:338S-400S.