

October 27, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
#314G
Washington, D.C. 20201

Re: Medicare Draft National Coverage For Implantable Cardioverter Defibrillators

Dear Dr. McClellan:

On behalf of the American Hospital Association's (AHA) 4,700 member hospitals and health care systems, and our 31,000 individual members, we are writing to express our concern about the draft national coverage policy for implantable cardioverter defibrillators (ICD). While the AHA supports coverage of this lifesaving equipment, our concern is with the proposed ICD registry and its link to provider payment.

Coronary heart disease is the single most common cause of death in the United States, with Sudden Cardiac Arrest (SCA) being responsible for 450,000 deaths every year. While research has shown that ICDs are 98 percent successful at preventing deaths from SCA and decrease mortality by 23 percent in patients with mild to moderate heart failure, ICDs are underutilized. Their lifesaving potential has been reinforced by the "Sudden Cardiac Death in Heart Failure" (SCD-HeFT) trial, which demonstrated the efficacy of ICDs as "primary prevention" therapy. The study results validated and demonstrated the importance of early intervention through primary prevention, where 2,500 Medicare beneficiaries would be saved during the first year of expanded Medicare coverage of ICDs.

Given the overwhelming evidence, we support CMS' coverage of ICDs, and we support continued data collection on ICDs. Given the extensive history of research into ICDs, and the funding available for important and clinically significant research on cardiac treatments through the National Heart, Lung, and Blood Institute (NHLBI), CMS should consider collaborating with NHLBI to ensure that important policy research into ICDs



will be conducted. Additionally, CMS may consider conducting demonstration projects to investigate issues of particular interest to Medicare and Medicaid patients. A national primary prevention ICD implantation data registry is another option for continued data collection and research, which would benefit the medical community, the public, and decision makers by providing information on a wide variety of issues that characterize the history of a primary prevention ICD implantation. **However, participation in the registry should not be required as a prerequisite for Medicare payment.**

CMS has proposed that providers add patients to a new national patient registry for primary prevention ICD implantations. However, these are the only details provided by CMS:

- *“CMS will work with product manufacturers and experts from the clinical community, including the National Institutes of Health, to develop a practical registry that can track the progress of patients who receive the devices. The registry will also help develop additional evidence on who is most likely to benefit from the devices.”*
- *“The national data collection system for ICD implantation will meet several criteria for facility certification, assessment and data completeness and should not present a burden that would be a barrier to eligible patients receiving the device.”*

As presented, the draft national coverage policy has no information on the structure, management, or funding of the registry. The fact sheet refers to a “practical registry” without defining “practical.” The purpose of the registry has not been specified, nor has its creation been thoroughly thought out. A registry should:

- have a definite purpose and consider all limitations of a registry;
- have a set and defined structure based on the nature of data collected; and
- address funding, management of data, and privacy issues.

Given that these issues have not been discussed or resolved, requiring providers to submit data to the registry as a prerequisite for Medicare payment is premature.

- In this proposed coverage policy, no detail or guidelines are specified for providers or new registry “managers” on criteria that will be used to certify providers and hospitals as competent for ICD implantation.
- Certification requirements are needed and hospitals, physicians, and manufacturers must be allowed to comment on any proposed measures.
- ICD stakeholders should have an opportunity to discuss both the registry and certification structure and function, since these will determine whether they can provide this service.

Given the lack of detailed information on the registry and no existing ICD-9 codes for primary prevention ICD implantation, requiring participation in a registry by January 1, 2005 is unrealistic. It is not possible to thoroughly debate, discuss and define issues relating to an ICD registry for primary prevention within the next two months.

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Taken together, these concerns greatly affect the availability and benefit of ICD implantation for primary prevention. We look forward to working with you to ensure that patients can benefit from this lifesaving service.

Thank you for your consideration of the above issues. If you have any questions or concerns, please contact me or Debjani Mukherjee at (202) 626-2368.

Sincerely,

Rick Pollack
Executive Vice President