***Quid Pro Quo*: Medicare Proposes Coverage Guidelines that Would Require Beneficiary Participation in Data Registry**

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Current medical therapies like beta blockers have historically proven of little consolation to sufferers of congestive heart failure (CHF) who may die suddenly and unpredictably from arrhythmias associated with their illness. In the mid '80s however, an emerging technology began offering new hope to CHF sufferers—Implantable Cardioverter-Defibrillators or ICDs.

A recent clinical trial with the ungainly name of Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) showed a significant reduction (23%) of the risk of death in patients with CHF who used ICDs as opposed to the existing standard of care.[1] According to the study which appeared in a recent issue of the New England Journal of Medicine, the tiny implantable defibrillators—miniaturized internal versions of the external paddles made famous in television emergency dramas—offer better results than treatment with amiodarone, which is commonly used to prevent sudden cardiac death in patients with CHF.[2]

Responding to the perceived need for ICDs to prevent sudden cardiac death, Medicare began its incremental coverage of the emerging technology in 1986 but limited benefits to patients with a documented history of cardiac arrest caused by ventricular fibrillation.[3] Coverage for the improving ICD technology was expanded in 1999 and again in 2003 in response to data showing the technology's growing relevance to an

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[1] Gust H. Bardy, et al., *Amiodarone or an Implantable Cardioverter-Defibrillator for Congestive Heart Failure*, 352 NEW ENG. J. MED. 225 (2005).
[2] Id.
[3] Mark B. McClellan & Sean R. Tunis, *Medicare Coverage of ICDs*, 352 NEW ENG. J. MED. 222 (2005).

expanding number of patients with CHF.[4] When preliminary results from the SCD-HeFT were released in March of 2004,[5] the Centers for Medicare and Medicaid Service (CMS), proposed a further expansion of Medicare coverage of FDA-approved ICDs for beneficiaries resembling the patients taking part in the SCD-HeFT.[6] According to CMS Chief Clinical Officer Dr. Sean Tunis, the widening umbrella for Medicare ICD coverage may double or triple the number of patients eligible for an ICD to more than 500,000.[7] However, if current guideline proposals are adopted by Medicare next month, eligible patients may not be able to obtain an ICD without agreeing to participate in a large-scale observational study of the device.[8] This proposal has prompted some commentators to say that Medicare's decision to require patient participation in observational trials as a condition for coverage is coercive and also a potentially illegal circumvention of federally-mandated safeguards[9] that require institutional review board (IRB) review for clinical, human-subject research.[10]

Supporters of the data registry requirement contend that important questions still remain as to how ICDs can be used most effectively and efficiently by medical practitioners, and thus a continuing observational research study is needed.[11] CMS administrators Dr. Mark McClellan and Dr. Sean Tunis argue that this need, coupled with the fact that patient data will be strictly confidential, warrant the requirement that

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[4] Id.
[5] Gust H. Bardy, *SCD-HeFT: The Sudden Cardiac Death in Heart Failure Trial*, (Mar. 8, 2004) available at http://www.sicr.org/scdheft_results_acc_lbcc.pdf#search='SCDHeFT%20March%202004'
[6] MCCLELLAN ET AL., *supra* note 3, at 222.
[7] *HHS Officials Officially Expand Medicare Coverage for ICDs*, (visited June 1, 2005) available at http://www.medicalnewstoday.com/medicalnews.php?newsid=19436&%3Bamp%3Bnfid=rssfeeds
[8] *CMS Summary of Coverage for ICDs*, (Jan. 27, 2005, visited June 1, 2005) available at http://www.cms.hhs.gov/coverage/download/id148a.pdf
[9] 21 C.F.R. pt. 56
[10] Laurie Kellman, *Medicare Expands Defibrillator Coverage*, AP/ANCHORAGE DAILY NEWS, (Jan. 28, 2005, visited June 1, 2005) available at http://www.adn.com/24hour/healthscience/story/2063398p-10118757c.html
[11] MCCLELLAN ET AL., *supra* note 3, at 223.

beneficiaries subject themselves to the observational registry.[12] "Data from registries are intended to help clinicians and patients weigh the risks and benefits of ICD use" the CMS administrators claim. "Better evidence regarding the clinical outcomes in defined subgroups of patients receiving ICDs may also help clinicians to provide the devices more reliably to the patients who will benefit the most."[13]

Yet detractors feel that the linking of Medicare payments with mandatory participation in observational registries or trials should not be the bellwether for Medicare coverage. Some believe that the CMS proposal guidelines are disguising human subject research as quality improvement (QI) that might circumvent federal regulations for the protection of human research subjects as outlined in United States Code of Federal Regulations Title 45, Part 46. Medicare QI is subject to the Health Insurance Portability and Accountability Act (HIPAA) which requires IRB review and approval, but this is merely to protect the subject's informational privacy interests and not her decisional, proprietary, and physical privacy interests—things that only a full IRB review on the merits is designed to ensure.[14] Public advocacy groups such as Citizens for Responsible Care and Research (CIRCaRe) are voicing their opposition to proposed coverage guidelines that they see as coercive and unnecessary.[15] In a recent CIRCaRe mailing, the self-proclaimed "Human Rights Organization" says that "while the wealthy can choose to forego coverage rather than enroll, finances and fear of death constrain the decision of those with fewer resources."[16] According to CIRCaRe, this compromises the autonomy

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[12] Id.
[13] Id.
[14] 45 C.F.R. pt. 164.
[15] http://www.Circare.org
[16] Elizabeth Woeckner, *Federal Guidelines, if Enacted, Would Coerce Human Subjects Into Clinical Trials Without Informed Consent*, (May 25, 2005) (on file with author) also available at http://www.Circare.org.

of the beneficiaries since they have no choice but to submit to the observational study in order to receive the ICD through Medicare. Granted, opponents argue, the observational registry may be a fruitful and worthy research study by itself, but making what would otherwise be an altruistic and voluntary participation into a prerequisite to get potentially life-saving treatment not only robs the subject's participation of its morally laudable content, but also robs her of the opportunity to decline participation without jeopardizing her eligibility for an ICD.

Proponents answer that the strings that the CMS is proposing to attach to ICD coverage are nothing out of the ordinary nor should they be regarded as something to worry about. Not only are registries mandatory for other types of Medicare coverage, but participation in clinical trials is often the only way patients can receive these cutting-edge treatments. Many patients sign up for risky research in hopes of receiving otherwise unavailable treatment modalities. However, unlike other medical device clinical trials, the research being proposed by the CMS and Medicare is on devices that have already undergone clinical trials and have been approved by the FDA. Thus, these are therapies that are available today to indicated patients outside research contexts with no obligations to participate in observational trials.

Mark McClellan, director of CMS, defends Medicare-mandated participation in observational studies, arguing that Medicare has a "fiduciary responsibility to taxpayers" that must be considered if it is to continue to offer coverage of expensive therapies such as the $30,000 ICD.[17] Other proponents downplay traditional notions of what is ethically required when potential medical benefit and generalizable knowledge are at stake. Indeed, Dr. Stephen Hamill, President of the Heart Rhythm Society, when invited by the

[17] McClellan et al., *supra* note 3, at 223.

CMS to comment on the federal requirement of IRB review for the ICD registry said that "[i]t would be quite unfortunate to have the informed consent process become a major stumbling block to entering patients and thus preventing patients from receiving prevention ICD therapy and being followed in the registry."[18] However, Medicare *could* form a registry with IRB oversight where voluntary participants are pooled from Medicare beneficiaries receiving the ICD. This solution would respect the autonomy of beneficiaries and honor ethical appeals to informed consent while still allowing for both therapy and research to take place.

[18] Stephen Hammill, *Remarks of Stephen Hammill, M.D., President, Heart Rhythm Society to the CMS Council on Technology and Innovation*, (Feb. 14, 2005) (visited on June 1, 2005) available at http://www.cms.hhs.gov/providers/cti/odfcomments214.pdf#search='stephen%20hammill%20cms'