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## [NEW PROGRAM REQUIREMENTS ON NPI INFORMATION AND PHYSICIAN TRAINING](#)

On October 7, 2007, CMS announced the transition from UPIN identifiers to the numerically longer National Provider Identifier (NPI) system. Therefore, physicians are required to obtain their NPI and assure that this information is accurately entered into the ICD Registry™. Apply for NPI information on-line at <https://nppes.cms.hhs.gov/NPPES/Welcome.do> or call the NPI enumerator to request a paper application at 1-800-465-3203.

Physicians are also required to assure the accuracy of their training credentials in the “EP Operator” section of the ICD Registry™. Access to this information is only available through your local Registry Site Manager. The National Coverage Decision for ICDs states:

“As with any invasive procedure, physicians who insert ICDs must be appropriately trained and fully competent to perform the implantation. CMS strongly encourages credentialing and certification of physicians who insert ICDs by appropriate national organizations, such as the Heart Rhythm Society (HRS) or boards of medical specialties, to ensure the safety of Medicare beneficiaries. CMS also believes that provider credentialing and certification should be tracked and included in any and all registries and data collection systems. This information is valuable for informing patients as part of effective clinical decision-making and will provide useful data on procedural outcomes associated with different levels of provider training and expertise.”

The ICD Registry™ collects and tracks certification and training information for ICD implanters.

## **BACKGROUND ON EXPANDED ICD COVERAGE FOR PRIMARY PREVENTION**

On January 27, 2005, the Centers for Medicare and Medicaid Services (CMS) announced its expanded ICD National Coverage Decision (NCD) for primary prevention ICD therapy. Immediately, coverage for primary prevention was expanded to include most SCD-HeFT patients and an expanded MADIT II population. Along with this expanded coverage, CMS implemented a data collection requirement through the Coverage with Evidence Development (CED) policy.

During 2005, facilities were required to submit data into QNET as a means for fulfilling the data collection requirement. The Heart Rhythm Society recommended to CMS that a better data collection tool would be needed to meet the intent of the CED Policy. On October 27th, 2005, CMS agreed and announced that the NCDR® ICD Registry™, a registry developed in partnership between the ACC Foundation and the Heart Rhythm Society, would fulfill the data collection requirements in the NCD. All hospital participants migrated to the new platform by the end of April, 2006. The former QNET data collection tool ceased its operations in the same month. No QNET data was migrated into the ICD Registry™; however, CMS has made this data set available to the public at the following internet address:

[http://www.cms.hhs.gov/NonIdentifiableDataFiles/10\\_ICDImplantationData.asp](http://www.cms.hhs.gov/NonIdentifiableDataFiles/10_ICDImplantationData.asp)

## **"Q0" (ZERO) MODIFIER REPLACES "QR" MODIFIER FOR OUTPATIENT AND PHYSICIAN CLAIMS**

Successfully reporting data for primary prevention ICD implants is a mandatory requirement of Medicare coverage. In order to obtain reimbursement, Medicare national coverage policy requires that providers implanting ICDs for primary prevention clinical indications (i.e., patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. For CY 2006-2007, the ["QR" modifier](#) was routinely added to the modifier section for outpatient and physician claims for Medicare primary prevention patients. Inpatient claims have no place on the form for adding any modifier since modifiers can not be appended to ICD-9 procedure codes (i.e., modifiers are only appended to HCPCS codes).

Effective January 1, 2008, CMS announced in [Transmittal 1403](#) and [Transmittal 1418](#) that the "QR" modifier has been deleted and replaced with a new "Q0" (zero) modifier that must be applied to claims with date of service on or after January 1, 2008. Physician practices must enter "Q0" (zero) in the modifier section of the Medicare claim form for CPT code 33249 (full system implant) or 33240 (replacement generator). Hospitals must enter the "Q0" (zero) in the modifier section of the Medicare claim form for CPT Codes 33249 (full system implant) and CPT code 33240 (replacement) for outpatient services.

The “Q0” (zero) modifier should be used in the same way that the “QR” modifier was previously used.

### **ICD REGISTRY™ CLINICAL SUPPORT**

For issues related to the ICD Registry™, please contact the NCDR® Customer Support line at 800-257-4737 or via e-mail: [ncdr@acc.org](mailto:ncdr@acc.org). Indicate your participant ID and the “ICD Registry™” name in your communication in order to receive prompt response. Also, feel free to inquire about up-coming free educational web casts and monthly teleconferences to obtain new information about the ICD Registry™ program. On-line information can be found at: <http://www.accncdr.com/webncdr/ICD/Default.aspx>

### **ENROLLMENT INFORMATION FOR NEW PARTICIPANTS OR NEW FACILITIES**

Enrollment in the ICD Registry™ is required for new facilities where ICD implants occur. Facilities will need to determine whether they will collect and submit all ICD patients (Option 1) OR only submit Medicare-covered ICD primary prevention patients (Option 2).

#### **OPTION 1 - Collect and submit data on all ICD patients**

The Heart Rhythm Society recommends that facilities collect and submit data for all ICD patients. One of the primary purposes of the Registry is to determine if the findings of all the controlled clinical trials are seen in the general population. If ICD implant data includes only CMS primary prevention patients, there is a strong potential bias to this evaluation. In the SCD-HeFT clinical trial, the median age was 60 years. If the registry is restricted to CMS patients, the youngest patient would be 65 and the median age would approach 70+; thus nearly eliminating the ability to draw comparisons of the findings in controlled clinical trials to the general population. In addition, private health plans (e.g., UnitedHealthcare – May, 2007) recognize ICD Registry™ participation in their regional and state pay-for-performance programs.

#### **OPTION 2 – Collect and submit data on Medicare primary prevention patients**

At this time, the NCD requires data collection and submission for CMS covered primary prevention patients who receive an ICD implant. Participants who do not take advantage of submitting all ICD patient data will only receive benchmark reports including comparative data from other hospitals derived from the “primary prevention” subset of patients instead of for all ICD patients.

### **EXPANDED ICD COVERAGE INDICATIONS FOR PRIMARY PREVENTION**

CMS has revised and expanded ICD coverage as indicated in the ICD national coverage determination. This expanded coverage is in addition to already indicated patients.

<http://www.cms.hhs.gov/coverage/download/id148a.pdf>

This National Coverage Determination includes the following indications:

1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause (effective July 1, 1991).
2. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause (effective July 1, 1999).
3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy (effective July 1, 1999).
4. Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF) < 0.35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 4 weeks prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.)
5. Documented prior MI and a measured LVEF < 30%.
6. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior myocardial infarction (MI), New York Heart Association (NYHA) Class II and III heart failure, and measured left ventricular ejection fraction (LVEF) < 35%.
7. Patients with nonischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF < 35%.
8. Patients who meet all current CMS coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure.
9. Patients with NIDCM > 3 months and < 9 months, NYHA Class II or III heart failure, and measured LVEF < 35% at this time are only covered by Medicare if these patients are enrolled in "either an FDA-approved category B IDE clinical trial (42 CFR §405.201), a trial under the CMS Clinical Trial Policy (NCD Manual §310.1), or a prospective data collection system". The ICD Registry™ meets the CMS requirement for an approved prospective data collection system and these patients can receive an ICD as long as their data is entered into the ICD Registry.

The following additional criteria for all of the above patients must also be met:

- a. Patient must be able to give an informed consent;
- b. Patient must not have:
  - Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm;
  - Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the past 3 months;
  - Had an acute MI within the past 40 days; [NOTE: This requirement has changed from previous coverage which required an acute MI within the past month]
  - Clinical symptoms or findings that would make them a candidate for coronary revascularization;
  - Irreversible brain damage from preexisting cerebral disease;
  - Any disease, other than cardiac disease (e.g. cancer, uremia, liver failure), associated with a likelihood of survival less than one year;