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1.0 American College of Cardiology Quality Improvement for Institutions

The American College of Cardiology Foundation (ACCF) offers a variety of products and tools to assist participating medical facilities in their quality improvement efforts:

- Clinical data registries
- National quality initiatives (e.g., Door-to-Balloon, Hospital-to-Home, Surviving MI)
- Electronic quality improvement toolkits (e.g., checklists, reminders, slide sets, apps)
- Accreditation Services

ACCF offers its suite of quality improvement programs and tools, to include the clinical data registries, national quality initiatives and electronic quality improvement toolkits under a single master participant agreement. Accreditation Services are provided under a separate accreditation agreement.

Eligible NCDR registries include the following:

- AFib Ablation Registry
- CathPCI Registry
- Chest Pain – MI Registry
- CV ASC Registry Suite
- EP Device Implant Registry
- IMPACT Registry
- LAAO Registry

Every medical facility that participates in at least one (1) eligible NCDR registry listed above will receive full access to exclusive quality improvement programs and tools, not available elsewhere. There is no obligation to become active in a specific initiative or to download or disseminate any toolkit.

2.0 NCDR Program Requirements

ACCF has developed the National Cardiovascular Data Registry (NCDR) to collect and report on standardized, national, clinical cardiovascular data in connection with different cardiovascular procedures and patient care. By signing the NCDR Participant Master Agreement and indicating the NCDR registries in which your facility wishes to participate, your facility agrees to comply with the NCDR Participant Responsibilities and Obligations outlined below. These requirements may be updated periodically. ACCF will notify you when the Program Requirements have been modified.

2.1 NCDR Participant Responsibilities and Obligations

Registry Management:

- Each participating medical facility (Participant) must designate and provide contact information for the following roles for each registry:

- **Registry Site Manager**—The Registry Site Manager is the primary point of contact for an assigned registry and will supervise the data collection, confirm the accuracy of the data, and receive the confidential reports on behalf of the Participant. This individual will act as the primary liaison for the assigned registry.
    - **Medical Director**— The physician Medical Director will serve as the medical staff liaison for the assigned registry.
    - **Executive Sponsor**—The Executive Sponsor will ensure adequate resources are in place to support registry activities.
    - **Billing Contact**—The Billing Contact is the point of contact for annual participation fees and modifications to the NCDR Participant Master Agreement.
    - **Privacy Officer**— The Privacy Officer is the individual designated by your facility responsible for compliance with HIPAA privacy and security rules.
- Participant is required to provide a valid and unique email address for all designated users at the participating facility. The email addresses will be used to communicate relevant registry-specific information.
- Participant is required to maintain an accurate and up-to-date site profile at all times.

Submission of Clinical Data:

- Participant will submit clinical data to ACCF for all relevant registries in which Participant is active.
- Participant will submit clinical data according to the Call for Data schedule found on the NCDR website. The Call for Data schedule may be updated periodically, and ACCF will post updates on the registry announcement pages.
- Participant is expected to review Data Quality Reports (DQR) for each submission and correct errors as needed to achieve "Green" benchmark status.
- For all active registries in which the Participant is enrolled, a data record will be submitted for each patient eligible for inclusion into that registry. These data records will act as a complete representation of the patient population for each quarter. Sampling of data is not permitted except for select populations in the Chest Pain – MI Registry. (Please review Registry-Specific Requirements section).
- Upon ACCF request, Participant agrees to provide verification that all eligible patient records have been included in their data submission.
- Participant must ensure that data conforms to the registry-specific data elements, definitions and transmission formats as outlined in the registry-specific Core Data Element Documentation (Full Specifications Data Dictionary).
- Participant must submit clinical data using an ACCF-approved software vendor or ACCF's online data collection tool. A current list of approved software vendors can be found on the NCDR website.
- Participant will upload data submissions to ACCF using only systems with current vendor supported operating systems and software patched to current support releases.
- Outdated, expired, or end of life software shall not be used to communicate with ACCF systems and may result in a failure of the Participant's data submissions. Participants should consult with the Participant's IT department to ensure that its systems conform to these requirements.
    - Examples of expired software include but are not limited to:
    - All versions of Internet Explorer

  - Un-patched versions of Windows 11 client or Windows 2022/2025 Server
  - Versions of Windows Server 2012, 2008, and/or Windows 2000
- Participant understands WebNCDR file uploads will not be accepted if the file exceeds 30MB.
- Participant understands any files uploaded in preparation for submission and then left in the upload queue without being submitted will prevent other users within the facility from submitting the same quarter's file. ACCF reserves the right to remove the uploaded file if after 24 hours the uploaded file has not been submitted. This will maintain the site's ability to submit data files.
- Participant understands that ACCF has no role in the relationship between Participant and any ACCF- approved software vendor.

Data Audit:

- ACCF, or a party contracted by ACCF, may audit Participant data for accuracy and completeness by using auditors approved by ACCF. Auditing may involve review of patient medical records and additional supporting documentation remotely or onsite. If a Participant is selected for an audit, the initial audit will be at the expense of the ACCF. Participant is expected to make required documentation available to auditing staff. ACCF may require Participant to submit a remediation plan if data accuracy issues are identified. Additionally, ACCF may withhold submitted data from the national outcomes report until data remediation has been successfully completed by Participant.
- Participant may voluntarily choose to have its data audited. A voluntary audit is paid for by the Participant and can only be conducted by ACCF-approved auditors. Contact the ACCF directly if a voluntary audit is desired.

Use of Data:

- Participant may use the information provided by the NCDR, including the benchmark outcomes reports, quality improvement reports, or any other aggregated data or reports (NCDR-produced reports) for internal purposes only.
- Participant must seek approval from the ACCF prior to sharing NCDR-produced reports to any external party. Contact ACCF for review and approval if you desire to share NCDR-produced reports. Submit all requests through email to ncdr@acc.org.
- ACCF may use NCDR data to provide aggregate summary data to its wholly owned subsidiaries for the purpose of providing Participants with the opportunity to participate in value-added quality improvement services. ACCF will aggregate all NCDR data and reports at the facility level and no patient information will be shared. All such reports shall be provided through a secure login and shall not be used for any purpose other than as described.

Training and Orientation:

Participant's registry staff is expected to complete all aspects of NCDR supplied orientation and training which includes the use of registry start-up checklists and terminology, the QII Learning Center, registry Resource Documents, FAQs, and all other ongoing training and communications which are posted to the registry announcement page on the private (log-in) website. Participant is also expected to do self-learning via registry documents available and adhere to the NCDR target values and definitions provided in the registry-specific Full Specifications Data Dictionary.

Annual Fees:

- Participating facility is required to pay an annual fee for each registry.
- The annual fee covers the period of January 1 through December 31 and does not extend past December 31 for any purpose including submission of patient follow-up data as required by specific registries.
- ACCF will provide the Participant with an invoice of fees via email when annual fees are due. Renewal emails will be sent to both the Executive Sponsor and Registry Site Manager.
- The annual fee is non-refundable even if your participation in the NCDR is terminated for any reason.

Registry-Specific Requirements:

a) For LAAO Registry Participants:
    - The LAAO Registry includes an adverse events adjudication component. This adjudication will be performed by an ACCF contracted Data Analytic Center (DAC). On occasion, the DAC may request additional source documentation (medical records) from the Participant in order to properly adjudicate adverse events.
    - Participant will be required to provide source documentation directly to the DAC.
    - ACCF has signed a Sub-Contractor Business Associate Agreement with the DAC.
    - Participant acknowledges and agrees that to comply with the Center's for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for Percutaneous Left Atrial Appendage (LAA) Closure Therapy, issued on February 8, 2016; the Participant must submit data to a CMS approved registry. Participant further acknowledges that the LAAO Registry is an approved CMS registry. Participant, by participating in the LAAO Registry, hereby consents and authorizes ACCF to transmit Participant's data in the LAAO Registry directly to CMS for purposes of meeting the NCD requirements as such requirements are updated from time to time.
b) For Chest Pain – MI Registry Participants:
    - The Chest Pain – MI Registry includes a sampling option for eligible patient populations, which is outlined in the registry Inclusion Criteria and Submission Populations Guides. Participant must declare whether the data submission for each eligible patient type represents a sample of all patient records (by patient type) eligible for registry inclusion.
    - ACCF has a Performance Achievement Award (the "Award") that recognizes participants meeting award eligibility criteria published on CVQuality.ACC.org. Participant acknowledges that as an eligible site, ACCF will notify Participant of the Participant's Award status on an annual basis. Participant acknowledges that the grant of the Award represents the fulfillment of eligibility criteria and does not represent ACCF's guarantee or endorsement of Participant's services. Participant further agrees that ACCF will publicly recognize the Participant's achievement through media outlets and public reporting. Recognition may include the use of the Participant's name and/or logo and Participant consents to such in connection with the Award.

2.2 Data Retention

Data Access via ACCF Online Data Collection Tools:

The ACCF's online data collection tool will keep and store the data entered by the user for the duration of the registry version while it is active for up to seven years. At such a time that a new data collection tool is active for a new or updated registry version, the following actions will occur for the retiring data collection tool and registry version:

- Applicable to the CathPCI Registry, Chest Pain – MI Registry, Afib Ablation Registry, EP Device Implant Registry, IMPACT Registry, and CV ASC Registry:
    - The retiring version will remain active for 2 quarters to support the data correction and resubmission process.
    - At the start of the 3rd quarter, the tool will no longer support data entry or edits, it will be available as a "read only" portal.
    - Data extracts will be supported for 4 quarters (1 year), at the start of the 5th quarter that functionality and the registry version Data Collection Tool will retire. Participant will no longer have access to raw data for that registry version.
- Applicable when regulatory mandates are in place for a registry, LAAO Registry:
    - The retiring version will remain active for 4 quarters to support the data correction and resubmission process.
    - At the start of the 5th quarter, the tool will no longer support data entry or edits, it will be available as a "read only" portal.
    - Data extracts will be supported for 4 quarters (1 year), at the start of the 5th quarter this functionality and the registry version Data Collection Tool will retire. Participant will no longer have access to raw data for that registry version.

Data Retention Registry Dashboards:

The ACCF's online dashboard for each individual registry will keep and store data following established data retention policies and best practices as follows:

- **Active Registry:**
    - For a period of seven (7) years, data will be accessible for viewing on the dashboard via selection of the quarterly ending timeframe in the filter panel.
- **Inactive (Discontinued) Registry**
  For a period of two (2) years data will be accessible for viewing on the dashboard via selection of the quarterly ending timeframe in the filter panel.
- **Files/Documents: (File Delivery)**
    - **Protected Health Information (PHI) Files:** For a period of seven (7) years, submission files containing PHI will be retained.
    - **ACCF Generated Files:** For a period of two (2) years, ACCF generated files will be retained.

2.3 NCDR Benefits

- ACCF provides business operation support via telephone and email during ACCF's business hours posted on the NCDR private (log-in) website. Access the "Contact Us" option located on the left navigation bar on the registry home page.
- ACCF provides clinical and quality advisement support via e-mail. All clinical support is delivered on a first-in, first-out basis during ACCF's business hours posted on the NCDR private (log-in) website.
- ACCF provides resources, tools and training to guide and assist Participant's data collection, data interpretation, and data quality activities. These resources include:
    - QII Learning Center with tutorials, educational videos, case scenarios, and other training offerings. Continuing Education credit is available for certain Learning Center courses.
    - Bi-monthly, registry specific webinars
    - Live programs and conferences
    - Resource documents such as User Guides, Quality Tools and Reference Documents, Appropriate Use Criteria Reference Documents, and NCDR Risk Model Documents
    - On-line FAQ databases
- Domestic and International Orientation
- ACCF provides an approved online data collection tool for each registry.
- ACCF provides training materials, expert clinical advisors, and technical support for the ACCF online data collection tool; the Participant is responsible for hardware support.
- ACCF certifies multiple software vendors. Participants may choose to work with any registry specific approved software vendor to transmit patient data to NCDR as an alternative to utilizing the ACCF online data collection tool. Participant is responsible for all third-party vendor tool training and communication.
- Participants have access to the NCDR eReports dashboard for reviewing trends and comparing facility level data.
    - ACCF provides real-time weekly aggregation of submitted data for participants to evaluate performance measures and quality metrics and quarterly national benchmarks on all data, including risk adjusted and risk standardized results.
    - ACCF provides quarterly provider level outcomes reports for members of the ACCF directly utilizing the provider's National Provider Identifier (NPI). ACCF will aggregate registry results for all participating facilities for which a provider is on the medical staff and provide the reports directly to providers through secure acc.org log-in.
    - ACCF provides quarterly outcomes reports for Emergency Medical Services (EMS) directly utilizing an EMS Agency ID Number. ACCF will aggregate registry results for all participating facilities and provide the reports directly to EMS through secure cvquality.acc.org log- in.
- For optimal functionality, particularly for the online data collection tools and eReports, the following are required:
    - Operating System - Microsoft Windows 10 or higher
    - Browser - Currently supported version of Microsoft's Edge
    - Microsoft Excel version 2011 or higher
    - Adobe PDF Reader

- NCDR eReports may work with other systems and versions, but ACCF cannot assure nor support the functionality on systems not listed in this document.

- ACCF will produce, distribute, and periodically revise the data elements, definitions, and formats as clinically indicated.
- ACCF analyzes submitted data for accuracy and completeness using electronic data checks, consistency checks and range checks. ACCF provides real-time feedback results on the data submission status through the Data Quality Reports, which helps the Participant identify and correct data submission issues.

3.0 Quality Improvement Program Requirements

ACCF has developed several quality improvement initiatives (e.g., Reduce the Risk: PCI Bleed, Patient Navigator, Surviving MI) and clinical toolkits to support medical facilities in effectively addressing common problems and pinpointing areas for improvement in cardiovascular care. By signing the NCDR Participant Master Agreement and indicating the commitment of your facility to the *ACC Quality Improvement for Institutions* program, your facility agrees to comply with the Quality Improvement Program Responsibilities and Obligations outlined below. These requirements may be updated periodically. ACCF will notify your facility when the Program Requirements have been modified.

3.1 Quality Improvement Program Responsibilities and Obligations

Annual Fees and Obligations

- Any medical facility that participates in at least one (1) eligible NCDR registry will receive full access to the suite of quality improvement initiatives and clinical toolkits through their NCDR annual fee. The list of initiatives can be found at cvquality.acc.org.
- There is no obligation to become active in a specific initiative or to download or disseminate any toolkit.
- To reduce data collection burden, Participants who are active in specific quality initiatives offered by the ACCF who also participate in one or more registry programs, hereby consent and authorize ACCF to use such registry data, if required, for the specific quality initiative program solely for the purpose of aiding Participant in data collection required of such quality initiatives.

3.2 Quality Improvement Program Benefits

The suite of quality improvement initiatives and clinical toolkits are offered as optional benefits and are conveniently located on a single website. Participants are free to pick and choose among the programs and tools that best fit their unique needs. These online assets are intended to inspire and accelerate quality improvement in a hospital or other medical facility setting and designed to save staff time and energy by providing ready- to-go, off-the-shelf programs and tools.

ACCF quality initiatives provide:

- Success metrics – performance objectives for addressing a quality improvement opportunity
- Assessments – to identify specific areas for improvement
- Toolkits – resources (e.g., checklists, protocols) for improvement
- Webinars – presentations on the evidence, strategies, and lessons learned
- Online collaborative tools – best practice sharing by experts and participants
- MIPS high weighted activity credit for participation in the Patient Navigator Program and the Reduce the Risk: PCI Bleed campaigns

ACCF toolkits provide:

- Worksheets
- Checklists
- Webinars
- Slide decks for individual and team-based learning
- Case studies illustrating the use of a tool/toolkit in specific settings

As ACCF continues to develop additional products and services, ACCF will offer Participants the opportunity to test or use these products and services.

4.0 ACCF Accreditation Services

ACCF Accreditation Services allows medical facilities that are accredited, or that have purchased the accreditation services, to use the facility's registry data to meet specific accreditation requirements. Therefore, the Participant, by participating in one or more registry programs, hereby consents and authorizes ACCF to use registry data for applicable accreditation programs. Each medical facility which purchases accreditation services must enter into an Accreditation/ Certification Services Agreement with ACCF.

5.0 Research Opportunities

From time to time, ACCF leads projects or collaborates with outside research organizations to explore questions in cardiovascular science and care delivery. ACCF will present key research opportunities to medical facilities. Each research opportunity will be a voluntary, optional item for a facility's consideration.

5.1 Research Responsibilities and Obligations

There is no obligation to participate in any research project with the ACCF. If a facility chooses to opt into a research project, the responsibilities and obligations (including research protocols) will be clearly outlined in the enrollment materials.

5.2 Research Benefits

In addition to furthering cardiovascular science to improve patient outcomes, some of the research opportunities may involve financial compensation for the facility's role in the study, similar to clinical trials run by clinical or academic research organizations. If a facility chooses to opt into a research project, the financial and non-financial benefits will be clearly outlined in the enrollment materials.

6.0 NCDR Participation Promotion Kit

ACCF has developed an NCDR participation promotion kit to support participants in communicating their participation in the *ACCF Quality Improvement for Institutions* program internally and externally. The promotion kit includes a sample press release, sample articles, social media messages, a digital seal for use on your webpage, and other tips and ideas your institution can use to promote your quality improvement efforts to your patients and the community. By signing the NCDR Participant Master Agreement and indicating the commitment of your facility to the *ACCF Quality Improvement for Institutions* program, your facility agrees to comply with the appropriate use of the kit.

7.0 eReports Health Systems

ACCF has developed an eReports Health Systems dashboard for systems to obtain a multi-facility view of NCDR data for comparative purposes and to monitor the quality of data submissions from participant facilities. By signing the Corporate Level NCDR Participant Master Agreement and subscribing to eReports Health Systems, the health system agrees to comply with the responsibilities listed below.

Use of Materials/Publication of Data

- The health system has the right to create and use reports, analyses or other materials (Materials) from the eReports Health Systems dashboard for internal purposes only.
- The health system must seek prior written approval from the ACCF prior to sharing Materials with any external party. Contact ACCF for review and approval if the health systems wish to publish any Materials. Submit all requests through email to ncdr@acc.org

Annual Fees

The health system is required to pay an initial registration fee and annual subscription fee for eReports Health Systems dashboard.

- ACCF will provide health system with an invoice of fees via email when annual fees are due.
- The annual fee is non-refundable even if the health system's subscription to eReports Health Systems dashboard is terminated for any reason.