TRANSFORMING HEALTH, *Insightfully*

Program Requirements

PINNACLE Registry®

The Diabetes Collaborative Registry ®

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This Program Requirement document is for participation in either the PINNACLE Registry® or the Diabetes Collaborative Registry® ("The registries"). Practice acknowledges that either registry may be subject to modification or adjustment by Veradigm. Practice agrees that Veradigm may, from time-to-time, modify or amend the substantive provisions of the Practice Based Registry or Registries Data Collection Agreement and this Program Requirement document related to the manner in which the registries operate, so long as such modifications or amendments are of general applicability to all similarly situated Practices participating in the registries.

Practice will be bound by any modifications or amendments to Practice Based Registry or Registries Data Collection Agreement and this Program Requirement document unless, within thirty (30) days of receipt of such modification or amendment, Practice notifies Veradigm that a specific modification or amendment is not acceptable to it, in which case, the Practice Based Registry or Registries Data Collection Agreement and Practice's participation in the registries will terminate effective at the end of the thirty (30) day period in which Veradigm receives such notice. In addition, during the foregoing pre-termination period, Practice shall not have the right to submit further data to the registries, but the other provisions of this Agreement shall apply.

1.0 Institutional Review Board (IRB) Oversight

The Practice agrees and acknowledges that the registries are subject to the jurisdiction of an Institutional Review Board ("IRB"). As such, the Practice Based Registry or Registries Data Collection Agreement and this Program Requirement document, including Practice's responsibilities hereunder, may be amended by ACCF on notice to Practice conforming to the requirements of the IRB.

Veradigm will disclose the IRB utilized for review and the findings of such review to Practice upon request.

2.0 Program Requirements

The registries were developed to collect and report on standardized, national, clinical cardiovascular and diabetes data in connection with different cardiovascular or diabetes process of care or outcomes. By signing the relevant Practice Based Agreement , your institution agrees to comply with the Participant Responsibilities and Obligations outlined below. These requirements may be updated periodically. Veradigm will notify you when the Program Requirements have been modified.

2.1 Participant Responsibilities and Obligations

Registry Management:

- Each participating institution (Participant) must define and provide contact information for the following roles for each registry
    - Registry Program Manager—The Registry Program Manager (RPM) is the primary point of contact for the registry and will supervise the data collection, confirm the accuracy of the data, and receive the confidential reports on behalf of the Participant. If your institution is participating in both registries you must identify a RPM for each registry. It

can be the same person for both registries. This individual will act as the primary liaison for the registry.

- Privacy Officer—A privacy officer is the individual person designated by the organization to develop, implement, and oversee the organization's compliance with the Health Insurance Portability and Accountability Act (HIPAA) privacy 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 always required to maintain an accurate and up-to-date site profile.

Submission of Clinical Data:

- To begin testing and validation of the submission of electronic data, Practice will select an approved data collection method. Current data collection methods include: Export from an EMR or collection through System Integration.
- Upon completion of testing and validation of the submission of electronic data practice can begin submitting production data to the registry. Such data will be evaluated for data quality upon submission. Veradigm will provide guidance/requirements to ensure high quality data standards.
- Practice understands that its submitted data may be reviewed for accuracy and completeness by Veradigm. Veradigm shall analyze the Practice's submitted data records, by means of electronic data checks, consistency checks and range checks.
- Veradigm reserves the right to remove providers from the registry that do not see patients with cardiovascular disease or diabetes. Notification will be provided to the registry program manager when this occurs.
- Veradigm agrees to accept Practice's clinical data that are submitted on a timely basis. Veradigm reserves the right to reject data submission in its entirety, or to limit the use of such Practice data, including new data if data does not meet the Registries' quality standards or conform to the Registries' requirements . Further, data may only be accepted if submitted using a data collection method approved by Veradigm.
- Veradigm shall generate quality assurance and improvement-oriented outcome reports periodically based on Practice's submitted data and distribute those reports to the Practice. Such reports shall include aggregated demographic, general information and patient outcomes in a format determined by Veradigm and as updated from time to time by Veradigm.
- Veradigm reserves the right to produce, disseminate, and revise the data elements, definitions and formats when deemed necessary.

Data Audit:

- Veradigm may audit Participant data for accuracy and completeness by using auditors approved by Veradigm. 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 Veradigm. As part of its participation in the Registries, Participant agrees to make required documentation available to auditing staff. Veradigm may require Participant to submit a remediation plan if data accuracy issues are identified. Additionally, Veradigm may withhold submitted data from the national outcomes report until data remediation has been successfully completed by Participant.

Publication of Data:

- Participant may use the information provided by Veradigm, including the outcomes reports, quality improvement reports, or any other aggregated data or reports for internal purposes only.
- Participant must seek approval from Veradigm prior to sharing produced reports to any external party.
- If Practice desires to publish or otherwise distribute or use, in whole or in part, any aggregate data or reports provided by Veradigm or produced in connection with or derived from the Registries, with the exception of strictly internal use within the Practice for quality assurance and improvement, Practice must first obtain the prior written consent of Veradigm, which may be granted or withheld in the sole discretion of Veradigm. To the extent Practice is permitted to publish aggregate data, such publication of aggregate data and any related information must be reviewed and approved by Veradigm prior to publication. Contact the registry support team at ncdr@acc.org if you desire to share registry produced reports.

Release of Physician Specific Data:

- Physicians will be asked to sign a data release consent form for any reporting program in which Practice participates to authorize Veradigm to submit physician level data to a third party. The data release consent form will identify the applicable reporting program. The execution of the data release consent form is voluntary and not a requirement of participation in the PINNACLE or Diabetes Collaborative Registry.

Data Confidentiality:

- Practice shall maintain appropriate procedures to protect data confidentiality in compliance with applicable law. Practice will be solely responsible for any and all its acts or omissions that may affect the privacy or security of data it furnishes hereunder. Practice shall maintain appropriate liability insurance or a program of self-insurance for its acts and omissions under this paragraph.

Practice of Medicine:

- The reports and tools provided by the ACCF or Veradigm are for quality assurance and improvement only and are not intended to direct clinical decision making as to the care of individual patients of Practice. Practice represents and warrants that Practice and the physicians affiliated with Practice are solely responsible for clinical decision-making and the exercise of sound medical judgment in the care and treatment of patients of the Practice.

2.2 Registry-Specific Requirements:

2.2.1 PINNACLE Registry

- Participants are required to report on at least 10 measures from the PINNACLE Registry in order to participate in the Registry. The current list of measures can be found here.

2.2.2 Diabetes Collaborative Registry Participants:

- Participants are required to report on at least 6 measures from the Diabetes Collaborative Registry in order to participate in the Registry. The current list of measures can be found here.

3.0 Quality Improvement Program Requirements

Through Veradigm' s partnership with the American College of Cardiology Foundation (ACCF) eligible Registry participants are able to access variety of products and tools to assist participants in their quality improvement efforts. :

- Clinical data registries (PINNACLE and the Diabetes Collaborative Registry)
- National quality initiatives (e.g., Door-to-Balloon, Hospital-to-Home, Surviving MI)
- Electronic quality improvement toolkits (e.g., checklists, reminders, slide sets, apps)

Eligible NCDR registries include the following:

- PINNACLE Registry
- Diabetes Collaborative Registry

By signing the Practice Based Registries Master Agreement and indicating the commitment of your institution to the *ACC Quality Improvement for Institutions* program, your institution agrees to comply with the Quality Improvement Program Responsibilities and Obligations outlined herein. These requirements may be updated periodically. ACCF or Veradigm will notify your institution when the Program Requirements have been modified.

There is no obligation to become active in a specific initiative or to download or disseminate any particular toolkit.

3.1 Quality Improvement Program Responsibilities and Obligations

Annual Fees and Obligations

- Any Participant that participates in at least one (1) eligible NCDR Registry will receive full access to the suite of quality improvement initiatives and clinical toolkit. This exclusive content includes but is not limited to:
  - Door-to-Balloon (quality initiative)
  - Hospital-to-Home (quality initiative)
  - Surviving MI (quality initiative)
  - Quality Improvement 101 (toolkit)
- Hospitals, facilities, or other organizations that do not currently participate in at least one (1) eligible NCDR Registry but wish to access the full suite of quality improvement initiatives and clinical toolkits, may purchase an annual subscription.

- There is no obligation to become active in a specific initiative or to download or disseminate any particular toolkit.
- In an effort 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.

Program Management

- Each participating institution must designate a Program Manager and provide contact information for that individual. The Program Manager is the primary point of contact for the ACC quality initiatives and toolkits offered through the *ACC Quality Improvement for Institutions* Program.

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 the hospital setting and designed to save staff time and energy by providing ready-to-go, off-the-shelf programs and tools.

ACC 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
- Guidance for conducting a Maintenance of Certification (MOC) Part IV project

ACC toolkits provide:

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

As ACC continues to develop additional hospital products and services, ACC will offer Participants the opportunity to test or use these products and services. Examples of future products and services include:

- Appropriate use criteria tools
- Risk model calculators
- Maintenance of certification (MOC) Part IV opportunities

4.0 Research Opportunities

From time to time, Veradigm leads projects or collaborates with outside research organizations to explore questions in cardiovascular or diabetes science and care delivery. Veradigm will present key research opportunities to Participants. Relevancy may be based on qualitative or quantitative Practice

characteristics. Each research opportunity will be a voluntary, optional item for your institution's consideration.

4.1 Research Responsibilities and Obligations

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

4.2 Research Benefits

In addition to furthering diabetes and cardiovascular science to improve patient outcomes, provide publication opportunities, some of the research opportunities may involve Fair Market Value compensation for your institution's role in the study, similar to clinical research conducted by clinical or academic research organizations. If your institution chooses to opt in to a research project, the financial and non-financial benefits will be clearly outlined in the enrollment materials and you may be asked to sign a Confidentiality Agreement prior to reviewing a study protocol.

5.0 Sponsorship, Information to Sponsors, and No Obligation to Refer

Practice acknowledges that Veradigm will receive financial and other support for the operation of the Registries from third parties, including but not limited to pharmaceutical manufacturers ("Sponsors"). Practice hereby consents to the provision by Veradigm to Sponsors of information derived from information provided by Practice, to the extent required by Veradigm' s agreements with Sponsors, provided that Veradigm will not furnish information that identifies any individual patient or Practice or any physician affiliated with a Practice. Nothing in this Agreement shall be construed to require any provider with the Practice to refer patients or order the products of a Sponsor. Providers associated with Practice shall at all times use their individual medical judgment in the best interests of patients of the Practice in the selection of products or services for patients. Neither Participant nor Veradigm will knowingly or intentionally conduct itself in such a manner as to violate the prohibition against fraud and abuse in connection with the Medicare and Medicaid programs (42 U.S.C. § 1320a-7b) or the physician self-referral law, commonly known as Stark II (42 U.S.C. § 1395nn)].