TRANSFORMING HEALTH, *Insightfully*

Program Requirements

PINNACLE Registry®

The Diabetes Collaborative Registry ®

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These Program Requirements set forth terms and conditions for participation in the PINNACLE Registry® and the Diabetes Collaborative Registry® (collectively, the "Registries" and each, a "Registry") and are a part of and incorporated into the Practice Based Registry or Registries Data Collection Agreement (the "Agreement"). Corporation or Practice (both referred to hereinafter as "Practice") acknowledge that Veradigm may modify or amend the Agreement and/or these Program Requirements from time to time with notice to Practice. Such modifications may include, but are not limited to, the addition or removal of data elements and quality measures.

Practice will be bound by any modifications or amendments to the Agreement and/or these Program Requirements unless Practice notifies Veradigm in writing within 30 days of receipt of such notice that a specific modification or amendment is not acceptable to Practice, in which case the Agreement and Practice's participation in the Registries will terminate effective at the end of the 30-day period following Veradigm's receipt of such notice. In addition, during the foregoing pre-termination period, Practice will not have the right to submit further data to the Registries, but the other provisions of this Agreement will apply.

1.0 Institutional Review Board (IRB) Oversight

Practice acknowledges that the Registries are subject to the jurisdiction of an Institutional Review Board ("IRB"). As a result, the Agreement and these Program Requirements, including Practice's responsibilities hereunder, may be amended by Veradigm 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 written 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 Agreement, Practice agrees to comply with these Program Requirements, including the Practice Responsibilities and Obligations outlined below.

2.1 Practice Responsibilities and Obligations

Registry Management:

- Practice must define and provide contact information for the following roles:
    - 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 Practice. If Practice is participating in both Registries, an RPM must be identified for *each* Registry. It can be the same person for both Registries. This individual will act as the primary liaison between Practice and the Registry.

- Privacy Officer—A privacy officer is the person designated by Practice to develop, implement, and oversee the organization's compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

Practice is required to provide a valid and unique email address for all designated users on the registry account management site. This includes all users identified by Practice in the Practice User Administration Profile and Provider Profile page. The email addresses will be used to communicate information related to the Registries.

If Practice wishes to change the Registry Program Manager, a written request on Practice letterhead must be sent via email to registries@veradigm.com. The request must include: 1) the name of the previous RPM; 2) the reason(s) for the change in RPM; and 3) the name and contact information for the new RPM.

Practice is required to maintain an accurate and up-to-date site profile at all times.

Submission of Clinical Data:

- To begin testing and validation of the submission of electronic data, Practice must select an approved data collection method. Current approved data collection methods include: 1) export from an EMR; and 2) collection through system integration.
- Practice must submit at minimum 70 percent of all required data elements for participation in a Registry.
- Upon completion of testing and validation of the submission of electronic data, Practice can begin submitting production data to the Registry. The submitted data will be evaluated by Veradigm for accuracy and completeness by means of electronic data checks, consistency checks, and range checks. Veradigm may provide Practice with additional guidance or requirements to ensure high quality data standards.
- Veradigm reserves the right to disconnect Practice from a Registry if Practice does not treat patients with cardiovascular disease or diabetes. Notification will be provided to the Registry Program Manager before this occurs.
- Veradigm agrees to accept Practice's validated clinical data that are submitted on a timely basis using a data collection method approved by Veradigm. Veradigm reserves the right to reject data submission in its entirety, or to limit the use of Practice data, including new data if data does not meet the Registries' quality standards or conform to the Registries' requirements.
- Veradigm will generate quality assurance and improvement-oriented outcome reports periodically based on Practice's submitted data and distribute those reports to Practice. The reports will include aggregated demographic information and patient outcomes in a format determined by Veradigm, which may be updated from time to time by Veradigm.
- Veradigm reserves the right to revise the data elements collected by the Registry when deemed necessary and will provide Practice with an updated data collection form and data dictionary.

Data Audit:

- Veradigm may audit Practice 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 Practice is selected for an audit, the initial audit will be at the expense of Veradigm. As part of its participation in a Registry, Practice agrees to make required documentation available to auditing staff. Veradigm may require Practice 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 Practice.

Publication of Data:

- Practice 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.
- Practice must seek approval from Veradigm prior to sharing produced reports with 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. Please contact the Registry Support Team at registries@veradigm.com if you desire to share Registry-produced reports.

Release of Physician-Specific Data:

- Physicians may 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 will maintain appropriate policies and procedures to protect data confidentiality in compliance with applicable laws. 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 will maintain appropriate liability insurance or a program of self-insurance for its acts and omissions under this paragraph.

2.2 Registry-Specific Requirements

PINNACLE Registry:

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

Diabetes Collaborative Registry

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

3.0 Partnership with the American College of Cardiology.

Through Veradigm's partnership with the American College of Cardiology Foundation ("ACCF"), Practices may have access to certain benefits. These may include:

- Access to the ACCF's NCDR suite of clinical toolkits to help implement best practice care and address common quality issues including:
  - National quality initiatives (e.g., Door-to-Balloon, Hospital-to-Home, Surviving MI); and
  - Electronic quality improvement toolkits (e.g., checklists, reminders, slide sets, apps).
- Opportunity to submit hypothesis-driven research requests based on analysis of ACCF's NCDR suite of data registries.
- Ability to participate in continuing education programs sponsored by the ACCF.

Practice does not need to be a member of the ACCF to access these benefits. To access specific ACCF tools, register for a free account at https://cvquality.acc.org/Register.

Practice is under no obligation to become active in a specific ACCF initiative or to download or disseminate any ACCF toolkit. The reports and tools provided by the ACCF 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 Practice.

If Practice has any questions regarding the ACCF initiatives or materials, please contact the ACCF at 1-800-257-4737.

4.0 Research Opportunities

4.1 Research Responsibilities and Obligations

From time to time, Veradigm leads projects or collaborates with third parties to explore questions in cardiovascular or diabetes science and care delivery. Veradigm or its partners may present key research opportunities to Practice. Practice may be contacted directly concerning these research opportunities. Relevancy may be based on qualitative or quantitative Practice characteristics. Each research opportunity will be a voluntary, optional item for your Practice's consideration.

To determine whether Practice qualifies for a certain research opportunity Veradigm may share aggregated, de-identified patient counts, identifiable practice demographic information (i.e. practice name, address, phone number) with a third party that is subject to confidentiality obligations. If Practice has sufficient population and could benefit from participation in the study, Practice will be sent enrollment information for that specific study. There is no obligation to participate in any research project with Veradigm. If Practice chooses to opt into a research project, the responsibilities, and obligations (including research protocols) will be clearly outlined in the enrollment materials.

In some instances, Practice data that has been de-identified in accordance with HIPAA may be used for research purposes or for use by Veradigm or third parties. A Limited Data Set, which is a data set that excludes certain direct identifiers specified under HIPAA, may also be generated from Practice data for research purposes or as allowed under HIPAA.

4.2 Research Benefits

In addition to furthering diabetes and cardiovascular science to improve patient outcomes and provide publication opportunities, some of the research opportunities presented to Practice may involve Fair Market Value compensation for Practice's participation in the research opportunity. If Practice chooses to opt in to a research opportunity, the financial and non-financial benefits will be clearly outlined in the enrollment materials and Practice may be asked to sign a confidentiality agreement prior to reviewing a study protocol. A site contract will be required to participate in a research opportunity.

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

Practice acknowledges that Veradigm may receive financial and other support 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, unless noted in a specific study protocol that Practice has opted into. Nothing in the Agreement or these Program Requirements will be construed to require any of Practice's physicians to refer patients or order the products of a Sponsor. Physicians associated with Practice will 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 Practice 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).