

**DARTNet Component Patient Safety Organization
Policies and Procedures As Revised November 1, 2015**

Background:

The DARTNet Institute ("DARTNet") is a Missouri not-for-profit corporation that was established for the purpose of improving the use of existing electronic health data, patient reported outcomes and device data to improve the quality and safety of health care and to create a learning health care system. The DARTNet Institute's mission and primary activity is to improve patient safety and the quality of primarily ambulatory health care and treatment by sharing data on quality and safety measures for ambulatory care screening and treatment and developing quality improvement projects based on analysis of these data. Under the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act"), the DARTNet Institute is the "parent organization" and the DARTNet Component-PSO is its "component organization" per 42 C.F.R Part 3.

The DARTNet Component-PSO (DARTNet-PSO) is governed by a Standing Committee of the DARTNet Institute's Board of Directors (the DARTNet Safety Committee). The DARTNet-PSO may also form certain ad hoc advisory groups for specific work areas as needed, examples of potential advisory groups include Chronic Kidney Disease safety and quality, teratogenic medication use in women of childbearing age, quality and safety related to hospital transitions in care. The DARTNet Safety Committee shall review the measures and quality improvement projects and best practices related to ambulatory care in general that will be considered PSWP. Other ad hoc Advisory Committees may develop additional quality measures and send to the DARTNet Safety Committee for review and approval.

Definitions:

- (1) **Bona Fide Contract:** A written contract between a participating healthcare provider and the DARTNet-PSO that is executed in good faith by individuals authorized to execute such contracts.
- (2) **Component Organization:** An entity that: (1) is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization); or (2) is owned, managed, or controlled by one or more legally separate parent organizations. (See 42 C.F.R. §3.20)
- (3) **Component PSO:** A PSO listed by the Secretary that is a component organization.
- (4) **Financial Relationship:** Any direct or indirect ownership or investment relationship between the DARTNet Institute and a participating healthcare provider, shared financial interests or direct or indirect compensation arrangements whether cash or in-kind.
- (5) **Identifiable Patient Safety Work Product:** Patient safety work product ("PSWP") that: (1) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in, or are responsible for, activities that are a subject of the work product; (2) constitutes individually identifiable health information as that term is defined in the HIPAA Privacy Rule at 45 CFR 160.103; or (3) is presented in a form and manner that allows the identification of an individual who in

good faith reported information directly to the DARTNet-PSO or to a provider with the intention of having the information reported to the DARTNet-PSO.

- (6) **Non-Identifiable PSWP:** PSWP that is not identifiable in accordance with the non-identification standards set forth at Sec. 3.212 of the Patient Safety Rule.
- (7) **Participating Clinical Healthcare Organization (healthcare organization):** Healthcare organizations that provide clinical care and have entered into a bona fide contract with the DARTNet-PSO and have agreed to share data as laid out in the contract under the terms of such contract.
- (8) **Patient Safety Act:** The Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41), which amended Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b-21 through 299b-26, and 42 C.F.R. Part 3; Patient Safety and Quality Improvement: Final Rule, all as may be amended from time to time.
- (9) **Patient Safety Activities:** The following activities carried out by or on behalf of the DARTNet-PSO or a participating clinical healthcare organization:
 - (i) efforts to improve patient safety and the quality of health care delivery;
 - (ii) the collection and analysis of PSWP;
 - (iii) the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
 - (iv) the utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
 - (v) the maintenance of procedures to preserve confidentiality with respect to PSWP;
 - (vi) the provision of appropriate security measures with respect to PSWP
 - (vii) the utilization of qualified staff; and
 - (viii) activities related to the operation of a patient safety evaluation system-- the collection, management, or analysis of information for reporting to or by a PSO ("PSES") and to the provision of feedback to participants in a PSES. (*See* 42 C.F.R. §3.20).

(10) PSWP: Except as provided in paragraph (iii) of this definition, PSWP means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)

(i) which could improve patient safety, health care quality, or health care outcomes; and

(A) which are assembled or developed by a participating healthcare organization for reporting to the DARTNet-PSO and are reported to the DARTNet-PSO, which includes information that is documented as within a PSES for reporting to the DARTNet-PSO, and such documentation includes the date the information entered the PSES; or

(B) are developed by the DARTNet-PSO or its subcontractors for the conduct of patient safety or quality improvement activities; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

(iii) PSWP does not include a patient's medical record, billing and discharge information, or any other original patient or provider information still in the control of the healthcare organization; nor does it include information that is collected, maintained, or developed separately, or exists separately, from a PSES. Such separate information or a copy thereof reported to the DARTNet-PSO shall not by reason of its reporting be considered PSWP within the healthcare organization but will be considered PSWP for any such data maintained by the DARTNet-PSO.

(iv) nothing in this policy shall be construed to limit information that is not PSWP and maintained by the clinical healthcare organization from being:

(A) discovered or admitted in a criminal, civil or administrative proceeding in accordance with local or federal law;

(B) reported to a Federal, State, local or Tribal governmental agency for public health or health oversight purposes as required by such governmental agencies; or

(C) maintained as part of a provider's recordkeeping obligation under Federal, State, local or Tribal law. (*See* 42 C.F.R. §3.206).

(11) Patient Safety Evaluation System: The collection, management, or analysis of information for reporting to or by the DARTNet-PSO. (*See* 42 C.F.R. §3.20).

(12) Reporting Relationships: Relationships by which a participating healthcare organization has access to information regarding the work and operation of the DARTNet-PSO that is not available to other participating healthcare organization.

(13) Data Sharing Agreement: The agreement between the DARTNet-PSO and each Participating Healthcare Organization to collect data relating to ambulatory care, screening and treatment.

(14) Disclosure: The release, transfer, provision of access to, or divulging in any other manner of PSWP by: (i) an entity or natural person, including a participating healthcare organization and the DARTNet-PSO, holding the PSWP, to another legally separate entity or natural person outside the entity holding the PSWP; or (ii) the DARTNet-PSO to another entity or natural person outside the DARTNet-PSO.

(15) Common Formats: The term common formats is used to describe the technical requirements and reporting specifications that allow participating healthcare organizations to collect and submit standardized information regarding patient safety events to the Agency for Healthcare Research and Quality (AHRQ), or other formats developed by the DARTNet-PSO that allow participating healthcare organizations to collect and submit PSWP to the DARTNet-PSO in a standardized manner that permits valid comparisons of similar cases.

(16) Healthcare Operations: Activities defined at 45 C.F.R. § 164.501, including patient safety activities, for which covered entities, including participating healthcare organizations, are authorized to use and disclose protected health information, in accordance with the HIPAA

Privacy Rule.

(17) Business Associate: A person or entity, including the DARTNet-PSO, which performs or assists a covered entity, including a participating healthcare organization, in the performance of a function or activity involving the use or disclosure of protected health information, as required by the regulations contained at 45 C.F.R. Parts 160 and 164, as amended from time to time (“the HIPAA Privacy Rule”).

Purpose:

To create a component Patient Safety Organization (PSO) in accordance with the Patient Safety Act.

Policy:

The DARTNet Component-PSO is seeking to establish itself as a PSO listed by the Secretary of Health and Human Services ("Secretary") as a component of the DARTNet Institute.

Procedures:

(1) The DARTNet Institute has as its purpose to improve healthcare through the appropriate re-use of existing electronic health data, to improve the collection and use of patient reported outcomes and other ancillary electronic data and advance the systematic use of electronic data to support care processes with a focus on ambulatory care. The DARTNet Institute brings healthcare organizations and providers from across the country together to collaborate on improving the quality and safety of the care they provide by sharing data on quality and safety measures for ambulatory care, screening and treatment.

(2) Under the Patient Safety Act, the DARTNet Institute is the "parent organization" and the DARTNet Component-PSO is its "component organization."

(3) The DARTNet-PSO shall ensure its mission and primary activity is to conduct activities that improve patient safety and the quality of healthcare delivery in participating healthcare providers through patient safety and quality activities.

(4) The DARTNet-PSO shall have appropriately qualified staff, including licensed or certified medical professionals that will work under the direct supervision of the PSO. These staff will include a licensed health professional with a background in patient safety who will serve as the DARTNet-PSO Director. This individual, in conjunction with the DARTNet Safety Committee will determine the qualifications of other DARTNet-PSO staff.

(5) The DARTNet-PSO currently has and will ensure to retain, within each sequential 24-month period thereafter, two or more bona fide contracts, each of a reasonable period of time and with a different participating healthcare organization, for the purpose of receiving and reviewing PSWP.

(6) The DARTNet-PSO is not, and is not a component of: a health insurance issuer, a regulatory agency, an organization that serves as an agent of a regulatory agency, an

accreditation and licensure entity, or an entity that administers a Federal, State, local, or tribal patient safety reporting system to which health care providers are required to report by law or regulation (See 42 CFR §3.102(a)(2)(ii)).

(7) The DARTNet-PSO shall meet the requirements in the Patient Safety Act to fully disclose to the Secretary, within 45 days from the date on which the DARTNet-PSO enters into a bona fide contract with a participating healthcare organization, if applicable, its relationships, and those of its parent organization, with such participating healthcare organization. The DARTNet-PSO shall fully disclose (a) any financial, reporting, or contractual relationship between the DARTNet-PSO and any organization that contracts with the DARTNet-PSO and (b) if applicable, the fact that the DARTNet-PSO is not managed, controlled, and operated independently from any organization that contracts with the entity. The DARTNet-PSO shall use the appropriate forms and narratives outlined in 42 C.F.R. §3.102(b)(2)(ii) for such disclosures.

(8) The DARTNet-PSO shall collect PSWP from participating healthcare organizations in a standardized manner that permits valid comparisons of similar cases among similar providers, in accordance with the DARTNet-PSO Common Format Policy.

(9) The DARTNet-PSO shall utilize PSWP for the purpose of providing direct feedback and assistance to participating healthcare organizations to effectively minimize patient risk and improve quality of care.

(10) The DARTNet-PSO shall maintain PSWP separately from unrelated research or other data activities of the DARTNet Institute, and establish appropriate security measures to maintain the confidentiality of the PSWP.

Related Policies:

- (1) DARTNet-PSO Common Format Policy
- (2) DARTNet-PSO Staffing Policy
- (3) DARTNet-PSO Confidentiality and Privilege of PSWP Policy
- (4) DARTNet-PSO Data Security Policy
- (5) DARTNet-PSO PSES Policy (6)
DARTNet-PSO PSQI Policy
- (7) DARTNet-PSO PSWP Policy
- (8) DARTNet-PSO Conflict of Interest Policy