

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

The CAH must develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven quality assessment and performance improvement (QAPI) program. The CAH must maintain and demonstrate evidence of the effectiveness of its QAPI program.

(a) *Definitions.* For the purposes of this section—

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.

Error means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems; and

Medical error means an error that occurs in the delivery of healthcare services.

(b) *Standard: QAPI Program Design and scope.* The CAH's QAPI program must:

(1) Be appropriate for the complexity of the CAH's organization and services provided.

(2) Be ongoing and comprehensive.

(3) Involve all departments of the CAH and services (including those services furnished under contract or arrangement).

(4) Use objective measures to evaluate its organizational processes, functions and services.

(5) Address outcome indicators related to improved health outcomes and the prevention and reduction of medical errors, adverse events, CAH-acquired conditions, and transitions of care, including readmissions.

(c) *Standard: Governance and leadership.* The CAH's governing body or responsible individual is ultimately responsible for the CAH's QAPI program and is responsible and accountable for ensuring that the QAPI program meets the requirements of paragraph (b) of this section.

(d) *Standard: Program activities.* For each of the areas listed in paragraph (b) of this section, the CAH must:

(1) Focus on measures related to improved health outcomes that are shown

to be predictive of desired patient outcomes.

(2) Use the measures to analyze and track its performance.

(3) Set priorities for performance improvement, considering either high-volume, high-risk services, or problem-prone areas.

(e) *Standard: Program data collection and analysis.* The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.

(f) *Standard: Unified and integrated QAPI program for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated QAPI program is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

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