SafeCare
HEALTHCARE STANDARDS

Standards Development Procedure

Amsterdam

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1 Purpose and Scope

The purpose of this policy is to outline the procedures and processes to be followed in the development of new standards or the revision of existing standards.

The procedures and processes described in this policy apply to all SafeCare standards.

This policy is to be followed by the Standards Development Coordinator and the Standards Development Group.

2 Responsibilities

2.1 The Standards Development Coordinator

It is the responsibility of the Standards Development Coordinator, in consultation with the SafeCare Director, to coordinate the standards development process and to organize and record the proceedings of the Standards Development Group. The Standards Development Coordinator is the chair of the Standards Development Group.

2.2 The Standards Development Group

This Group directs all matters relating to the development or revision of standards, including all steps to be followed in the research, consultation, piloting, and acceptance process, until the standards are finally approved by the SafeCare Director.

2.3 SafeCare Director

It is the responsibility of the SafeCare Director to grant final approval to new or revised standards.

3 Related documents

- QA-GEN-005 Procedure for the functioning of the standards development group
- QA-GEN-005_Annex 1 Composition of the SafeCare standards development group

4 The principles for all SafeCare standards

- There is a clear, rigorous, published and publicly available plan and process for the development and revision of all standards.
- Transparent processes result in the consistent measurement of an organization's performance in meeting individual standards and for the final decisions on overall performance by the organization seeking certification.
- SafeCare standards support organizations in:
    - Creating and sustaining the capacity and efficiency to deliver services to patients.
    - Understanding and managing risk to protect patients, staff, and visitors.
    - Providing person-center care processes in partnership with patients and families.
- SafeCare standards guide organizations in the continuous evaluation and improvement in the quality and safety of services.

5 Procedure for the development or revision of standards

When the development of new standards or revision of existing standards is contemplated, a proposal must be drawn up and submitted to the SafeCare Director for initial approval.

5.1 The proposal for the development of new or revised standards includes the rationale and process for their development or revision.

5.1.1 The aim or rationale for the development of new or revised standards is considered in the proposal and includes:

a) Data and information on *environmental changes* or trends that may impact the content of new standards or changes to existing standards
b) The *market requirements* and the *opportunities* that may arise from developing and instituting a new or revised certification program
c) Changes in *statutory and legal requirements* that would influence the content of specific standards or the addition of standards
d) *Views and requirements of interest groups.* Such stakeholders are to include SafeCare assessors and surveyors, certification partner organization, individual clients, health care professionals or organizations, patients or organizations representing patient groups, relevant governmental agencies, and other relevant stakeholders
e) Compliance data and experiences of users with current standards
f) The knowledge and advice of experts in content areas of standards.

5.1.2 The development or revision proposal includes a documented plan that identifies steps (activities), the resources required and a flow chart or timeline for all the steps. The resources include human and financial and include the costs for Standards Development Group meetings, travel costs, consultant costs, computer programing, pilot testing, and assessor, surveyor, and client training costs.

5.1.3 The development or revision process is posted on the SafeCare website at the beginning of the process according to the overall plan.

5.1.4 The proposal is reviewed by the Standards Development Group prior to sending the proposal to the SafeCare Director for approval.

Related documents

- QA-GEN-019 Procedure on considering rationale for new or revised SafeCare Standards
- QA-GEN-020 Policy on Plan for the Long-Term Development or Revision of Standards

6 Development and review of draft standards

6.1 The development of the content of new or revised draft standards is based on:

a) current available reports of relevant research and scientific inquiry
b) available guidelines from recognized authoritative sources
c) recommendations or published standards from national and international professional organizations such as an MOH, CDC, WHO, etc.
d) recommendations from content or technical advisors or experts, local, national, or international.

6.2 The review of the draft standards is through formal and informal methods

6.2.1 The draft standards are posted on the SafeCare web site with a process to receive comments.

6.2.2 Stakeholders are notified on how to use the SafeCare website for submitting content comments or how to request a copy of the draft standards for comment. Stakeholders include at least the SafeCare Country teams, partner and client organizations, patients and patient advocacy groups, government and regulatory bodies, assessors and surveyors, health care professionals and any other interested parties.

6.2.3 Stakeholders are requested to comment on:

- The clarity of the framework for the new or revised standards
- The clarity of the language of the new or revised standards
- That the new or standards are relevant, understandable, measurable, beneficial, and achievable (RUMBA)

6.2.4 There is a process for the recording, aggregation, analysis and Standards Development Group review and action on all formal and informal comments on the draft standards.

6.2.5 The Standards Development group approves the standards for pilot testing or recommends further development.

Related document

- QA-GEN-021 Procedures for Stakeholder Input into SafeCare

7 Pilot testing of draft new or revised standards

7.1 The newly developed or revised standards and criteria are tested in pilot healthcare facilities and, if needed, are further developed to meet the specific needs of the healthcare facilities. The standards to be pilot tested include:

- New sets of standards related to new certification programs
- New standards for existing certification programs
- Existing standards that have been significantly revised to change their scope or requirements
- Existing standards for which the assessment or survey process or required evidence has been significantly changed.

7.2 Pilot testing steps or processes include the following:

- The Standards Development Group decides how many test sites are needed, and when to pilot the standards and, in collaboration with the executive unit, sets up the process
- The Standards Development Group decides if existing standards or standards that have not been revised are also included in the pilot testing
- Senior assessors and surveyors meet to study the new and/or revised standards and assist with the planning of the pilot testing process
- Prior to pilot testing, meetings of senior assessors and surveyors are held to clarify any doubts regarding the interpretation of standards and criteria and the assessment process
- Pilot sites are identified, and the facilities are invited to be evaluated against the draft standards.

- Following the pilot assessments and surveys of the draft standards, modifications are made as required prior to approval of the new and/or revised standards.

7.3 The pilot test sites, and the participating assessors or surveyors evaluate the pilot testing experience, and the results are reported to the Standards Development Group.

8 There is a formal approval process for all new or revised standards

- The Standards Development Group reviews all data and information from the pilot testing and any other sources of information on the new or revised standard.
- The Standards Development Group votes to recommend the standards for approval to the SafeCare Director, or to continue the development and testing of the new or revised standards.
- The SafeCare Director approves the new or revised standards upon the recommendation of the Standards Development Group.
- There are minutes or a document that records the signature of the SafeCare Director and the date of approval.
- There is an implementation policy for all new or revised standards that includes the publication data, implementation date, phase-in considerations and planned education.
- Communications regarding approved new or revised standards are on the SafeCare web site.

Related documents

- QA-GEN-006_ Implementation procedure for new or revised Standards
- QA-GEN-022_ Policy on Education of Stakeholders on new or revised SafeCare Standards

9 There is a process to collect, analyze and monitor all feedback on SafeCare standards and on the certification programs.

- The process is ongoing and is accessed through the SafeCare web site.
- The SafeCare country directors coordinate the feedback process and respond to questions and complaints when required.

Related Document

- QA-GEN-021 Procedures for Stakeholder input into SafeCare

10 General considerations

- The scope of SafeCare certification standards is for entire facilities and organizations, not individual units, or departments.
- The SafeCare certification standards may be licensed to partner organizations and others through a formal process of approval and monitoring.
- Once the standards have been approved for use, they are not changed substantially for a period of **at least two years**.
- Only the SafeCare Director is empowered to order changes to standards should they be deemed necessary.