NCQA Corrections, Clarifications and Policy Changes to the 2022 Specialty Pharmacy Standards and Guidelines

November 14, 2022

This document includes the corrections, clarifications and policy changes to the 2022 SP standards and guidelines. NCQA has identified the appropriate page number in the printed publication and the standard and head—subhead for each update. Updates have been incorporated into the Interactive Review Tool (IRT). NCQA operational definitions for correction, clarification and policy changes are as follows:

- A ***correction (CO)*** is a change made to rectify an error in the standards and guidelines.
- A ***clarification (CL)*** is additional information that explains an existing requirement.
- A ***policy change (PC)*** is a modification of an existing requirement.

An organization undergoing a survey under the 2022 SP standards and guidelines must implement corrections and policy changes within 90 calendar days of the IRT release date, unless otherwise specified. The 90-calendar-day advance notice does not apply to clarifications or FAQs, because they are not changes to existing requirements.

Page	Standard/Element	Head/Subhead	Update	Type of Update	IRT Release Date
15	Policies and Procedures—Section 1: Eligibility and the Application Process	Eligibility for Accreditation	Add the following new subhead and text at the end of "Eligibility for Accreditation." **Eligibility for international organizations** NCQA standards evaluate performance of U.S. health care organizations and their U.S. operations only. Organizations that apply for and participate in an NCQA Survey must agree to comply with all applicable U.S. federal, state and other applicable laws, and must agree that the use of NCQA products and services shall for all purposes be governed, interpreted, construed and enforced solely and exclusively in accordance with U.S. laws and regulations, without regard to conflicts of law provisions thereof. NCQA limits evaluation to organizations that operate in and outside the United States, and limits award of NCQA status to an organization's U.S. operations. Organizations that do not operate in the United States (i.e., conduct all activities in the U.S., including in states and territories; conduct operations for U.S. members and clients) or have members, patients or clients in the United States are not eligible for NCQA Specialty Pharmacy Accreditation. NCQA does not evaluate operations of organizations that do not operate in the United States, or that do not have U.S. members, patients or clients. When determining eligibility of an organization with both U.S. and foreign operations, NCQA applies the following criteria: 1. The applicant organization must be the accountable (responsible) entity for performing NCQA-reviewed functions, and must describe how it meets NCQA's definition of an accreditable, certifiable or eligible entity. A parent, holding or shell company may not be eligible to apply.	**CL**	**11/14/22**

Page	Standard/Element	Head/Subhead	Update	Type of Update	IRT Release Date
			2. The applicant organization must be a U.S. company, or be owned by a U.S. company, and provide services in the United States. An applicant organization that is not a U.S. company, but is owned by a U.S. company, must be domiciled in the United States by holding a business license or registration in at least one U.S. state or territory. The organization must submit evidence to reflect incorporation, registration or licensure to satisfy this criterion. 3. To be listed on NCQA's public report card, the applicant organization must have a United States address for a facility, business office or administrative location. NCQA does not allow organizations to list an address of a personal residence or U.S. statutory agent unless the organization conducts NCQA-reviewed functions from the address. 4. If any function to be reviewed is performed outside the United States, the organization must have the capability to complete the onsite survey (and/or any tour) virtually, and to present all required files electronically. Because NCQA does not travel outside the country for onsite reviews, the applicant organization must coordinate a virtual review to satisfy onsite requirements, which may include staff interviews or site tours, as described in NCQA standards. All virtual reviews must be conducted in English or with English translations for the NCQA survey team. 5. The applicant organization must meet all other eligibility criteria specified in the preceding section. Any organization with U.S. and foreign operations that meets the criteria above may apply for an NCQA Survey, and may include functions performed outside the United States in its NCQA Survey.		

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Note: *Revisions to the 2022 SPO standards are reflected in the web-based and IRT versions of the standards and guidelines. NCQA will not republish the e-pub to reflect the following changes; consequently, no page numbers are included.*

PREVIOUSLY POSTED UPDATES					
Page	**Standard/Element**	**Head/Subhead**	**Update**	**Type of Update**	**IRT Release Date**
14	Policies and Procedures—Section 2: Accreditation Scoring and Status Requirements	Standards that require onsite survey (virtual)	Revise the bullets under SPO 1 to read: • SPO 1: Pharmaceutical Chain of Custody: – Element C: Inventory Management Site Reporting. – Element D: Inventory Management Visual Verification. – Element F: Dispensing Report. – Element G: Dispensing Visual Verification. – Element I: Shipping Visual Verification. – Element K: Recalled Medications Site Reporting.	**CL**	**11/22/21**
14	Policies and Procedures—Section 2: Accreditation Scoring and Status Requirements	Standards that require review of reports by site	Revise the bullets under SPO 1 to read: • SPO 1: Pharmaceutical Chain of Custody: – Element C: Inventory Management Site Reporting. – Element F: Dispensing Report. – Element K: Recalled Medications Site Reporting.	**CL**	**11/22/21**
23	Policies and Procedures—Section 2: Accreditation Scoring and Status Requirements	Must-Pass Elements and Corrective Action Plan	Revise the third bullet for designated must-pass elements to read: • SPO 1: Pharmaceutical Chain of Custody, Elements B, H.	**CL**	**11/22/21**
38	Policies and Procedures	Mergers and Acquisitions	Revise the email address in the third paragraph to read: sig@ncqa.org	**CO**	**3/28/22**
39	Policies and Procedures—Section 5: Additional Information	Notifying NCQA of Reportable Events	Add new second and third paragraphs to read: Reporting obligations are effective upon issuance of the notice of sanctions, issuance of a fine or request for corrective action. The notification requirement is not paused as a result of any appeal or negotiations with the applicable regulatory authority. All Reportable Events must be submitted through My NCQA (https://my.ncqa.org).	**CL**	**7/25/22**

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Page	**Standard/Element**	**Head/Subhead**	**Update**	**Type of Update**	**IRT Release Date**
39	Policies and Procedures—Section 5: Additional Information	Notifying NCQA of Reportable Events—Annual Attestation of Compliance With Reportable Events	Revise the information in this section to read: On an annual basis, the organization must also complete an attestation signed by an officer or other authorized signatory of the organization, affirming that it has notified NCQA of all Reportable Events specified in NCQA's Policies and Procedures. Failure to comply with Reportable Events submission or annual attestation requirements may result in suspension or revocation of Accreditation status. Annually, NCQA sends an email reminder to the designated Accreditation contact to complete the annual attestation on My NCQA (https://my.ncqa.org). The attestation must be completed within 30 days of the email notification.	**CL**	**7/25/22**
40	Policies and Procedures—Section 5: Additional Information		Add the following new section head and text between "Notifying NCQA of Reportable Events" and "Discretionary Survey." **Interrater Reliability** NCQA strives for consistency in the Accreditation/Certification process and across all surveys. NCQA defines "interrater reliability" (IRR) as the extent to which two or more independent surveyors produce similar results when assessing whether the same requirement is met—the level of confidence that similarly trained individuals would be likely to produce similar scores on the same standards for the same product when the same evidence is evaluated. To support consistency, NCQA will continue to clarify standards and educate surveyors. Organizations preparing for survey should also review all applicable standards, including changes between standards years and related NCQA corrections, clarifications, and policy changes, as well as FAQs, focusing on the standards' intent, scored elements and factors, explanations, and type of evidence (data sources) required to demonstrate that a requirement is met.	**CL**	**7/25/22**

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Page	**Standard/Element**	**Head/Subhead**	**Update**	**Type of Update**	**IRT Release Date**
			Reporting IRR Issues to NCQA Report suspected IRR issues to NCQA during the following survey stages: • When the organization responds to initial issues (following the conference call with the surveyor and ASC). • During the organization review and comment stage (during the post-survey review process). • During a Reconsideration (after the survey is completed). Issues may be reported in the survey tool (IRT) or by submitting a case to My NCQA (https://my.ncqa.org). To protect the integrity of the Accreditation process, NCQA does not accept materials in an IRR report that did not exist at the time of the original completed survey tool submission. As a reminder, file review results may not be disputed or appealed once the onsite survey is complete, whether completed in-person or virtually. If you suspect an IRR issue related to a file review element, the issue should be reported during the onsite survey. NCQA performs an expedited review of reported IRR concerns on non-file review elements to ensure timely and accurate Accreditation/ Certification decisions. Based on review of a potential issue, NCQA may: 1. *If NCQA's scoring was inconsistent for non-file review elements,* issue a one-time exception for scoring of the standard, and require a Corrective Action Plan (CAP). NCQA reserves the right to determine if scoring was inconsistent. 2. *If no inconsistency is found,* maintain the standard score. NCQA analyzes IRR information to identify opportunities to clarify requirements or enhance surveyor education.		
42	Policies and Procedures—Section 5: Additional Information	Suspending Accreditation	Revise the first sentence under the "Grounds for immediate suspension" subhead to read: Grounds for recommending suspension of Accreditation status include, but are not limited to:	**CL**	**7/25/22**

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Page	**Standard/Element**	**Head/Subhead**	**Update**	**Type of Update**	**IRT Release Date**
42	Policies and Procedures—Section 5: Additional Information	Suspending Accreditation	Add the following as a new sixth bullet under the "Grounds for immediate suspension" subhead: • Failure to comply with Reportable Events submission or annual attestation completion requirements.	**CL**	**7/25/22**
42	Policies and Procedures—Section 5: Additional Information	Revoking Accreditation	Revise the sixth bullet under "Grounds for revocation" to read: • The organization violates other published NCQA policies, including failure to submit Reportable Events or completion of annual attestation.	**CL**	**7/25/22**
4-3	Appendix 4—Glossary		Add the following as a new definition: **interrater reliability:** The extent to which two or more independent surveyors produce similar results when assessing whether the same requirement is met—the level of confidence that similarly trained individuals would be likely to produce similar scores on the same standards for the same product when the same evidence is evaluated.	**CL**	**7/25/22**
45	PT 1, Element A	Factor 4: Obtaining consumer input on program content	Revise the first sentence to read: Feedback from patients, prescribers, consumer organizations or patient advocacy organizations provide valuable information to maximize the program's effectiveness. The program description outlines the organization's process for including input from patients, prescribers or other consumer groups in the ongoing development of its patient programs and associated materials.	**CL**	**3/28/22**
45	PT 1, Element A	Examples	Add bullets to the example to read: ***Factor 2:*** **Exclusion criteria** • Contraindications • Off-label uses that may determine exclusion criteria for the patient program. • MedB prescriptions. • Oncology practice prescriptions. • White-bagged scripts or categories that do not require follow-up reassessments.	**CL**	**3/28/22**

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<tr><td>46</td><td>PT 1, Element B</td><td>Data source</td><td>Add “documented process” and “materials” as data sources.</td><td>CL</td><td>3/28/22</td></tr>
<tr><td>46</td><td>PT 1, Element B</td><td>Scope of review</td><td>Add the following as the second bullet:
For All Surveys: NCQA also reviews reports or materials that demonstrate that the senior-level licensed pharmacist is certified or has specialized training related to the program’s subject matter.</td><td>CL</td><td>3/28/22</td></tr>
<tr><td>47</td><td>PT 1, Element C</td><td>Data source</td><td>Remove “documented process” as a data source.</td><td>CL</td><td>3/28/22</td></tr>
<tr><td>47</td><td>PT 1, Element C</td><td>Scope of review</td><td>Remove the following bullet:
Evidence that at least a pharmacist and an appropriate clinician provided recommendations for program updates at least once during the look-back period.</td><td>CL</td><td>3/28/22</td></tr>
<tr><td></td><td>SPO 1</td><td></td><td>For updates to the SPO 1 standards, refer to the separate “2022 SPO 1 Standards” document posted at the following link:
https://www.ncqa.org/programs/health-plans/policy-accreditation-and-certification/policy-updates.</td><td></td><td>11/22/21</td></tr>
<tr><td>135</td><td>SPO 2, Element B</td><td>Scoring</td><td>Revise the Partially Met and Not Met scoring language to read:<table><tr><th>Partially Met</th><th>Not Met</th></tr><tr><td>Any site meets 2-3 factors</td><td>Any site meets 0-1 factors</td></tr></table></td><td>PC</td><td>11/22/21</td></tr>
<tr><td>136</td><td>SPO 2, Element B</td><td>Scope of review</td><td>Revise the scope of review for First and Renewal Surveys to read:
NCQA conducts a site visit of factors 1–4 for sites selected for live survey in SPO 1, Element C: Inventory Management Implementation. NCQA names selected sites 15 days prior to the visit.</td><td>CL</td><td>11/22/21</td></tr>
<tr><td>136</td><td>SPO 2, Element B</td><td>Look-back period</td><td>Revise the look-back period for First and Renewal Surveys to read:
For First Surveys and Renewal Surveys: On the date of the site visit.</td><td>CO</td><td>11/22/21</td></tr>
<tr><td>137</td><td>SPO 3, Element A</td><td>Look-back period</td><td>Revise the look-back period for all surveys to read:
For All Surveys: 6 months.</td><td>CO</td><td>11/22/21</td></tr>
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<tr><td>137</td><td>SPO 3, Element A</td><td>Scope of review</td><td>Remove “documented process” and revised the scope of review to read:
For All Surveys: NCQA reviews the organization’s service continuity plan.</td><td>PC</td><td>11/22/21</td></tr>
<tr><td>1-3</td><td>Appendix 1</td><td>Element Points for 2022</td><td>Revise the scoring for SPO 1 to read:
<table>
<tr><th colspan="2" rowspan="2"></th><th colspan="3">INTERIM SURVEY</th><th colspan="3">FIRST SURVEY</th><th colspan="3">RENEWAL SURVEY</th></tr>
<tr><th>Met</th><th>Partially Met</th><th>Not Met</th><th>Met</th><th>Partially Met</th><th>Not Met</th><th>Met</th><th>Partially Met</th><th>Not Met</th></tr>
<tr><td colspan="11">SPO 1: Pharmaceutical Chain of Custody</td></tr>
<tr><td>A</td><td>Procurement and Processing</td><td>1</td><td>NA</td><td>0</td><td>1</td><td>NA</td><td>0</td><td>1</td><td>NA</td><td>0</td></tr>
<tr><td>B</td><td>Inventory Management Process</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td></tr>
<tr><td>C</td><td>Inventory Management Site Reporting</td><td>NA</td><td>NA</td><td>NA</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td></tr>
<tr><td>D</td><td>Inventory Management Visual Verification</td><td>NA</td><td>NA</td><td>NA</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td></tr>
<tr><td>E</td><td>Dispensing Process</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td></tr>
<tr><td>F</td><td>Dispensing Report</td><td>NA</td><td>NA</td><td>NA</td><td>1</td><td>NA</td><td>0</td><td>1</td><td>NA</td><td>0</td></tr>
<tr><td>G</td><td>Dispensing Visual Verification</td><td>NA</td><td>NA</td><td>NA</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td></tr>
<tr><td>H</td><td>Shipping Process</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td></tr>
</table></td><td>PC</td><td>11/22/21</td></tr>
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<tr><td></td><td></td><td></td><td>
<table>
<tr><td>I</td><td>Shipping Visual Verification</td><td>NA</td><td>NA</td><td>NA</td><td>1</td><td>0.5</td><td>0</td><td>1</td><td>0.5</td><td>0</td></tr>
<tr><td>J</td><td>Unusable Medications Process</td><td>1</td><td>NA</td><td>0</td><td>1</td><td>NA</td><td>0</td><td>1</td><td>NA</td><td>0</td></tr>
<tr><td>K</td><td>Recalled Medications Site Reporting</td><td>NA</td><td>NA</td><td>NA</td><td>1</td><td>NA</td><td>0</td><td>1</td><td>NA</td><td>0</td></tr>
</table>
</td><td></td><td></td></tr>
<tr><td>2-1</td><td>Appendix 2- Delegation Guidelines</td><td>Definitions</td><td>Add the following as a new definition:
Previously unidentified delegate
A contracted delegate identified during a survey that was not initially reported by the organization in the NCQA delegation worksheet.</td><td>CL</td><td>3/28/22</td></tr>
<tr><td>2-4</td><td>Appendix 2</td><td>How NCQA Evaluates Delegation—Delegation oversight—De facto delegation</td><td>Revise the following subhead and first paragraph to read:
Previously unidentified delegates and de facto delegation
If NCQA identifies previously unidentified delegates or de facto delegation at any point after selecting the delegates (including during the offsite survey), NCQA reserves the right to review oversight of the previously unidentified delegates or de facto delegates by selecting them at random to include up to two delegates in addition to the four originally selected.</td><td>CL</td><td>3/28/22</td></tr>
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<tr><td>3-6</td><td>Appendix 3</td><td>Table 1: 2022 Specialty Pharmacy Standards for MAC Survey</td><td>Revise the element titles in the rows as follows:
<table>
<tr><th colspan="2">SPO 1: Pharmaceutical Chain of Custody</th></tr>
<tr><td>A</td><td>Procurement and Processing</td></tr>
<tr><td>B</td><td>Inventory Management Process</td></tr>
<tr><td>C</td><td>Inventory Management Site Reporting</td></tr>
<tr><td>D</td><td>Inventory Management Visual Verification</td></tr>
<tr><td>F</td><td>Dispensing Report</td></tr>
<tr><td>G</td><td>Dispensing Visual Verification</td></tr>
<tr><td>H</td><td>Shipping Process</td></tr>
<tr><td>I</td><td>Shipping Visual Verification</td></tr>
<tr><td>K</td><td>Recalled Medications Site Reporting</td></tr>
</table></td><td>CL</td><td>11/22/21</td></tr>
</table>