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

March 28, 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
38	Policies and Procedures	Mergers and Acquisitions	Revise the email address in the third paragraph to read: sig@ncqa.org	**CO**	**3/28/22**
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**
46	PT 1, Element B	Data source	Add "documented process" and "materials" as data sources.	**CL**	**3/28/22**

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46	PT 1, Element B	Scope of review	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.	**CL**	**3/28/22**
47	PT 1, Element C	Data source	Remove "documented process" as a data source.	**CL**	**3/28/22**
47	PT 1, Element C	Scope of review	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.	**CL**	**3/28/22**
2-1	Appendix 2- Delegation Guidelines	Definitions	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.	**CL**	**3/28/22**
2-4	Appendix 2	How NCQA Evaluates Delegation—Delegation oversight—De facto delegation	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.	**CL**	**3/28/22**

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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**
	SPO 1		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.		**11/22/21**

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<table>
<tr><th colspan="6">Previously Posted Updates</th></tr>
<tr><th>Page</th><th>Standard/Element</th><th>Head/Subhead</th><th>Update</th><th>Type of Update</th><th>IRT Release Date</th></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>
<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</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></table></td><td>PC</td><td>11/22/21</td></tr>
</table>

Previously Posted Updates					
Page	**Standard/Element**	**Head/Subhead**	**Update**	**Type of Update**	**IRT Release Date**
			(continued table below)		

	Visual Verification									
E	Dispensing Process	1	0.5	0	1	0.5	0	1	0.5	0
F	Dispensing Report	NA	NA	NA	1	NA	0	1	NA	0
G	Dispensing Visual Verification	NA	NA	NA	1	0.5	0	1	0.5	0
H	Shipping Process	1	0.5	0	1	0.5	0	1	0.5	0
I	Shipping Visual Verification	NA	NA	NA	1	0.5	0	1	0.5	0
J	Unusable Medications Process	1	NA	0	1	NA	0	1	NA	0
K	Recalled Medications Site Reporting	NA	NA	NA	1	NA	0	1	NA	0

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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>
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