

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

November 22, 2021

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.

Standard/Element	Head/Subhead	Update	Type of Update	IRT Release Date
Policies and Procedures—Section 2: Accreditation Scoring and Status Requirements	Standards that require onsite survey (virtual)	<p>Revised the bullets under SPO 1 to read:</p> <ul style="list-style-type: none"><li>• SPO 1: Pharmaceutical Chain of Custody:<ul style="list-style-type: none"><li>– Element C: Inventory Management Site Reporting.</li><li>– Element D: Inventory Management Visual Verification.</li><li>– Element F: Dispensing Report.</li><li>– Element G: Dispensing Visual Verification.</li><li>– Element I: Shipping Visual Verification.</li><li>– Element K: Recalled Medications Site Reporting.</li></ul></li></ul>	CL	11/22/21
Policies and Procedures—Section 2: Accreditation Scoring and Status Requirements	Standards that require review of reports by site	<p>Revised the bullets under SPO 1 to read:</p> <ul style="list-style-type: none"><li>• SPO 1: Pharmaceutical Chain of Custody:<ul style="list-style-type: none"><li>– Element C: Inventory Management Site Reporting.</li><li>– Element F: Dispensing Report.</li><li>– Element K: Recalled Medications Site Reporting.</li></ul></li></ul>	CL	11/22/21

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Standard/Element	Head/Subhead	Update	Type of Update	IRT Release Date				
Policies and Procedures—Section 2: Accreditation Scoring and Status Requirements	Must-Pass Elements and Corrective Action Plan	Revised the 3rd 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, please refer to the separate “2022 SPO 1 Standards” document posted at the following link: <a href="https://www.ncqa.org/programs/health-plans/policy-accreditation-and-certification/policy-updates">https://www.ncqa.org/programs/health-plans/policy-accreditation-and-certification/policy-updates</a> .		11/22/21				
SPO 2, Element B	Scope of Review	Revised 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.	CL	11/22/21				
SPO 2, Element B	Look-back period	Revise the look-back period for First and Renewal Surveys to read:  <i>For First Surveys and Renewal Surveys:</i> On the date of the site visit.	CO	11/22/21				
SPO 2, Element B	Scoring	Revised the Partially Met and Not Met scoring language to read:  <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="text-align: center;">Partially Met</td> <td style="text-align: center;">Not Met</td> </tr> <tr> <td style="text-align: center;">Any site meets 2-3 factors</td> <td style="text-align: center;">Any site meets 0-1 factors</td> </tr> </table>	Partially Met	Not Met	Any site meets 2-3 factors	Any site meets 0-1 factors	PC	11/22/21
Partially Met	Not Met							
Any site meets 2-3 factors	Any site meets 0-1 factors							
SPO 3, Element A	Look-back period	Revised the look-back period for all surveys to read:  <i>For All Surveys:</i> 6 months.	CO	11/22/21				
SPO 3, Element A	Scope of Review	Removed “documented process” and revised the scope of review to read:  <i>For All Surveys:</i> NCQA reviews the organization’s service continuity plan.	PC	11/22/21				
Appendix 1	Element Points for 2022	Revised the scoring for SPO 1 to read:	PC	11/22/21				

**Key = CO—Correction, CL—Clarification, PC—Policy Change**

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		INTERIM SURVEY			FIRST SURVEY			RENEWAL SURVEY					
		Partially Met	Not Met		Partially Met	Not Met		Partially Met	Not Met				
<b>SPO 1: Pharmaceutical Chain of Custody</b>													
A	Procurement and Processing	1	NA	0	1	NA	0	1	NA	0			
B	Inventory Management Process	1	0.5	0	1	0.5	0	1	0.5	0			
C	Inventory Management Site Reporting	NA	NA	NA	1	0.5	0	1	0.5	0			
D	Inventory Management Visual Verification	NA	NA	NA	1	0.5	0	1	0.5	0			
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			

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		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											
Appendix 3	Table 1: 2022 Specialty Pharmacy Standards for MAC Survey	Revise the Element titles in the rows as follows:										CL	11/22/21										
<b>SPO 1: Pharmaceutical Chain of Custody</b>																							
A   Procurement and Processing																							
B   Inventory Management Process																							
C   Inventory Management Site Reporting																							
D   Inventory Management Visual Verification																							
F   Dispensing Report																							
G   Dispensing Visual Verification																							
H   Shipping Process																							
I   Shipping Visual Verification																							
K   Recalled Medications Site Reporting																							

Note: Revisions to the 2022 SPO standards are reflected in the Web-based and IRT versions of the 2022 SP Standards and Guidelines. NCQA will not be re-publishing the 2022 SP Standards and Guidelines E-Pub to reflect these changes; subsequently, no page numbers are included.