

#### **Program Summary**

NCQA's Data Aggregator Validation program validates electronic clinical data collected and shared with vendors and health care organizations that undergo an audit for reporting NCQA's HEDIS<sup>®1</sup> measures. This program validates that data provided from the original source accurately reflect data reported for use as standard supplemental data and other use cases. Validated data streams are eligible for use as standard supplemental data for only the duration of their validation cycle. Validated data may be shared through the validation cycle as frequently as determined by the organization and their clients.

#### **Program Goals**

- Ensure that data integrity is maintained from ingestion at the primary source (e.g., EMR/EHR) through transmission to vendors and health care organizations.
- Ensure that organizations accurately, consistently and appropriately follow the HL7 C-CDA R2.1 Implementation Guide (IG) or the US Core Implementation Guide STU3 (v3.1.1 R4) (FHIR® IG).
- Minimize the audit burden on vendors and health care organizations that receive and use data for reporting HEDIS measures (no additional primary source verification [PSV]).

#### **Data Aggregator Validation for Measure Reporting**

The final validated output of the program is a CCD that complies with HL7 C-CDA R2.1 or FHIR output that complies with U.S. Core Implementation Guide STU3 (v3.1.1 R4). To support standard supplemental data for HEDIS reporting, **only validated and conformed outbound files from validated sources may be shared.** Data from ingestion sites or clusters that failed validation may not be shared as standard supplemental data. These data are considered nonstandard supplemental data, and must be audited accordingly. If the Responsible Party cannot resolve uncertainty between validated and non-validated data, the validation status may not be recognized.

Organizations must use validated and conformed outbound files for HEDIS reporting, and must complete Section 5 of the HEDIS Roadmap, as with all supplemental data. The Roadmap must explain the process for transferring data from the Responsible Party in an outbound file to the organization. No documentation is required from the validated entity unless it processes the validated CCD or FHIR.

#### If the Responsible Party:

- Processes the validated CCD (e.g., into a vendor file layout): Refer to Auditors may perform SSV, below.
- Shares validated data formatted using FHIR standards: These files cannot be processed to another
  data standard for data exchange, because it compromises the validation status. For example,
  mapping validated data from U.S. Core to the NCQA HEDIS Core IG is permitted, but mapping
  validated data from U.S. Core to a flat file format is not permitted. Where mapping to the same data
  standard is performed, refer to <u>Auditors may perform SSV</u>.

<sup>&</sup>lt;sup>1</sup>HEDIS<sup>®</sup> is a registered trademark of the National Committee for Quality Assurance (NCQA).



- *Processes in the approved way:* Follow the criteria below, if applicable, which will be reviewed by a HEDIS Compliance Auditor:
  - Document mapping.
  - o Document extract-transfer load (ETL) processes.
  - o Maintain an original copy of the validated and conformed file (e.g., CCD, FHIR).
  - Auditors may perform SSV by examining processed data back to the validated and conformed files. SSV does not include PSV back to the original source on these data sources. PSV may not be performed.

When exchanging data, the validated Responsible party must produce an outbound file. There must be separation between the Responsible Party (e.g., health system) and an entity using the data as standard supplemental (e.g., health plan). A Responsible Party may share outbound files with certified measure vendors to run through their measure logic.

#### **Auditor Requirements**

Only Data Aggregator Validation-validated data streams in the conformed CCD or FHIR format are accepted as standard supplemental data. Auditors **do not** conduct PSV back to the original source on these data sources.

For data from an NCQA-Validated Responsible Party, the auditor must:

- Receive completed Roadmap documentation from the organization receiving the data (e.g., the health plan). The Roadmap must explain the process for transferring data from the Responsible Party in an outbound file to the organization.
  - No documentation is required from the validated entity unless it processes the validated CCD or FHIR, as outlined in <u>Data Aggregator Validation for Measure Reporting</u>.
- Receive the final validation report of validated data cases and clusters, and the date when they were validated.
- Refer to <u>NCQA's Data Aggregator Validation directory</u> to ensure that the NCQA validated entity is approved to share validated data.
  - o Organizations with a "Validated Data Steam" Evaluation Product with a validated status and expiration date may share data and contribute to reducing audit burden.
  - o Organizations with a "Certified Data Partner" Evaluation Product may not share data.

Data from ingestion sites or clusters that failed validation may not be shared as standard supplemental data. These data are considered nonstandard supplemental data, and must be audited, per the HEDIS Health Plan Audit manual.



#### **Program Questions**

Refer to Appendix B for program definitions.

Send all inquiries through PCS via My NCQA. Select the "Product/Program Type" as "HEDIS Audit"; select the "General Content Area" as "Data Aggregator Validation Program."

To purchase the Data Aggregator Validation Program manual (this is not required), you can find it here: NCQA > Data Aggregator Validation - HEDIS & Quality Measurement.



#### **APPENDIX A**

#### DATA AGGREGATOR VALIDATION PROGRAM IMPLEMENTATION GUIDES

#### Overview

NCQA works with organizations to ensure their data output adheres to the HL7 C-CDA R2.1 IG in the June 2020 errata package, available on the <u>HL7 C-CDA product page</u>, or in the US Core Implementation Guide STU3 (v3.1.1 R4), available in the HL7 FHIR Implementation Guide Registry.

#### Resources

- An <u>online navigation tool</u> allows searches of C-CDA by description, template OID or conformance number.
- Find specific CDA examples developed and approved by the HL7 Structure Documents Work Group at HL7 C-CDA Example Search.
- The CCD includes a nullFlavor of No Information (NI) at the section level if a section has no pertinent information.
  - A non-relevant section may include this nullFlavor. The HL7 SDWG approved this approach after publication of C-CDA R1.1; the <u>ONC Cures validator</u> supports this change.
- Find FHIR introductory materials and an executive summary here.
- Find the ONC FHIR fact sheets <u>here</u>.



### **APPENDIX B DEFINITIONS**

cluster	A group of similar ingestion sites or provider portals, by EMR type and care setting, that contribute to a data stream.
data partner	An organization that supports responsible parties for validation of the data stream by meeting one or more program standard. Data partners do not conduct PSV, but may support PSV efforts for responsible parties. Findings from a data partner's validation apply only if they contribute to the Responsible Party's data stream validation. They are not valid outside the Data Aggregator Validation program.
DSL	Data submission log. Organization ingestion sites and provider portals that are being considered for validation. Includes site name, EHR product, care setting and other fields to help determine clusters.
ingestion site	Unique data source where clinical services were rendered (e.g., provider, practice, hospital) contributing to a cluster. An ingestion site may have one or many submitters.
outbound file	The chosen file format for validation. The required outbound file format is CCD XML or FHIR JSON. There must be a physical outbound file produced by the responsible party to the end user.
provider portal	A platform hosted by a responsible party where providers enter data that cannot be transmitted via electronic transfer. Each provider (e.g., ingestion site) that uses the portal is identified separately on the DSL, along with the ingestion site's characteristics.
	Note: A portal may not be the responsible party's only ingestion site for validation.
responsible party	The organization seeking validation of the data stream, contractually obligated to conduct PSV and validation of the data stream and for identifying and alerting NCQA to changes that could impact validity or usability.
standard	Specific process and documentation requirements (e.g., PSD 1.0, ODI 2.0) that must be met to ensure accuracy and integrity of the data stream.
submitter	A provider office or care location (e.g., child entity) submitting data to the data aggregator through the same workflow for an ingestion site (e.g., parent entity).
validated data stream	One or more validated clusters that have processed through and passed all Data Aggregator Validation standards, including PSV. The data stream can be used as