HL7® International

September 13, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-1850

Submitted electronically to:
http://www.regulations.gov

RE: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (CMS-1751-P)

Dear Administrator Brooks-LaSure:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on the Proposed Rule "Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (CMS-1751-P)."
HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

Overall, we applaud the Administration's effort through this Proposed Rule to advance interoperability, accessibility, quality, affordability, empowerment and innovation. HL7 comments in particular, offer input and guidance on the move fully to digital quality measurement in the CMS quality reporting and value-based purchasing (VBP) programs by 2025 and the related RFI to gather planning input. We believe these steps will support a more efficient, effective and holistic health care system. Also, given the RFI highlights the use of HL7 FHIR® for current Electronic Clinical Quality Measures (eCQMs) and alignment of CMS eCQMs with the FHIR standard and support quality measurement via application programming interfaces (APIs), we offer our perspectives and reaffirm HL7's commitment to work individually and in tandem with our federal government partners on these critical issues.

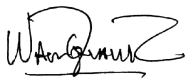
In addition to the perspectives of our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include:

- Clinical Quality Information (CQI); and
- Clinical Decision Support.

Should you have any questions about the attached, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to HHS.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International



Walter G. Suarez, MD, MPH
Board of Directors, Chair
Health Level Seven International

RFI: Advancing Digital Quality Measurement and the Use of HL7 Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs

Below are HL7's comments on the RFI within section IV.A.1.c entitled "Advancing Digital Quality Measurement and the Use of HL7 Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs."

Proposed Rule Language	*HL7 Comments*
Section XIV. Advancing to Digital Quality Measurement and the Use of Fast Health Interoperability Resources (FHIR) in Outpatient Quality Programs – Request for Information B. Definition of Digital Quality Measures and D. Changes Under Consideration to Advance Digital Quality Measurement: Potential Actions in Four Areas to Transition to Digital Quality Measures by 2025 D.2. Redesigning Quality Measures to be Self-Contained Tools We are considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s); and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the	The IPPS proposed rule defined digital quality measures (dQMs) as "Digital Quality Measures (dQMs) are quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems. A dQM includes a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources." HL7 responded that the definition was too broad and difficult to interpret. Given that there is no clear definition in this OPPS document, we repeat our suggested definition provided as a response to the IPPS document, a definition we still support: ○ Digital quality measures (dQMs) are quality measures expressed in a digital format using highly standardized language and data definitions that enable sharing of the fully specified measure electronically between systems. ○ A dQM uses electronically available data from multiple sources that enable assessment, processing by a quality assessor ,which may be represented by software. They are standardized and intended to use data captured in the course of a patient's health experience and include sufficient metadata to indicate who/what captures the data, the time of capture, and additional metadata as required. The dQM does not only standardize the data captured, but also standardizes the logic expression (which some reference as a phenotype). ○ To further distinguish a dQM from an eCQM, the eCQM has been understood as having an expectation that the data and processing entirely exist in the EHR and claims (billing) data.

Proposed Rule Language	*HL7 Comments*
software solution for dQMs should do the following: · Have the flexibility to support calculation of single or multiple quality measure(s).	Key characteristics of dQMs: o dQMs use a standards-based interoperability format including machine interpretable measure logic (e.g., CQL) and data model (e.g., FHIR, OMOP, QDM) Incorporate data concepts/terms (e.g., value sets) required to fully execute the measure o dQMs may utilize a broad array of data from multiple electronic sources including, but not limited to, EHRs, registries, case management systems, HIEs, wearable devices and administrative claims. o Electronic clinical quality measures (eCQMs) use data derived from electronic medical records and are a subset of dQMs. A measure can be digital even if the electronic data it uses are generated through manual processes. Key potential benefits of dQMs include: o The digital format, standardized language and quality assurance processes used to author dQMs mitigate the potential for faulty interpretation of paper-based specifications and errors associated with manually coding narrative measure descriptions. dQMs reference standard data collected in the normal course of care and perform many of the measure calculation functions that previously required additional processes. dQMs use of standardized data can improve accuracy and allow for more rigorous data validation to occur at different levels of the data collection process. o dQMs can be designed to generate clinically relevant patient-specific quality insights based on available clinical data at the point-of-care. This is not the case with current measures which generally provide information about what is best for an "average" patient and often are not implemented to generate timely, actionable information.
D.2. Redesigning Quality Measures to be Self-Contained Tools • Perform three functions – o Obtain data via automated queries from a broad set of digital data sources (initially	This section addresses the same content as noted in the IPPS document. The functions listed are similar to the statement in the IPPS document that referenced "self-contained tools." Our response is similar with some additions: **#1** - The definition of "automated queries" is potentially ambiguous, especially with the previous language about "self-contained tools." A query designed to retrieve data with minimal-to-no human

Proposed Rule Language	*HL7 Comments*
from EHRs, and in the future from claims, PRO, and PGHD); o Calculate the measure score according to measure logic; and o Generate measure score report(s).	manipulation is reasonable, but such queries must take into account the fact the local data capture terminology is local and the queries will always use standard terminologies. Therefore, some tooling will be needed to enable transformation of local data to identify the data required by the query. Further, queries should use FHIR-based standards such as Quality Improvement Core (QI-Core) and other specific Implementation Guide data (e.g., mCode, Occupational Data for Health (ODH), Gender Harmony, Social Determinants of Health (SDOH) as well as Patient Reported Outcomes (PRO) and Patient Generated Health Data (PGHD), especially data from wearable devices). The "automated" nature of these queries should use the HL7 Clinical Quality Language (CQL) standard. FHIR-based APIs should apply to non-EHR data as well as EHR data. Note, some process data exists in administrative systems (e.g., appointment scheduling information, billing and coverage information, and resource availability, all of which is beneficial in addition to clinical data. Also, obtaining all data required for a future dQM will likely require queries to retrieve data from multiple data capture systems. While Health Information Exchanges (HIEs) may be helpful in this regard, standards are still maturing especially for wearable device data and adoption for implementation will take some time. Such data are essential for direct clinical care as well as quality measurement and clinical decision support. However, all data expected in the three functions listed require access to more than one repository and aggregation of results by a third party organization or app. Such aggregation will come with patient identification, privacy and security concerns that must be addressed to achieve success. Also note that some data collection requires new workflows and processes, specifically Social Determinants of Health (SDOH). For SDOH, we suggest that there is variability with respect to how race and ethnicity is recorded (I.e., how a self-identifies). E.g., there is no priority/hierarchy for documenting mixed-race. The variability will make stratification complicated. Example, some vendors report alphabetically but that is not necessarily the order a patient believes appropriate. Other vendors may report in the order in which the patient chooses the options. We recommend that: o CMS collects the data o Collect the data in a way consistent with the way the census collects the data - established by the CDC and the census bureau o Enable multiple races to be reported

Proposed Rule Language	*HL7 Comments*
	#2 - Expecting the automated query to retrieve data (with the caveats noted above). However, expectation that the query will calculate the measure score according to the measure logic recasts the dQM as software (I.e., fully executable code). The quality community has defined the measure as a specification that can be executed in any number of ways. Recasting dQM as software (I.e., fully executable code) ties it to a single platform which limits capabilities and may introduce burden. There is no clear way for a measure developer to produce this type of "self-contained tool." The statement suggests a SMART-app but that is problematic which can result in vendor lock-in and additional care practitioner and administrative burden. **#3** - Similar to the response to measure calculation, generation of measure score report(s) is overreach. We agree with the expectation identified in the IPPS document that common policies for data retrieval by third parties for aggregation will improve common reporting strategies from providers and limit rework and burden. Further, HL7 a*grees with a common portfolio of Federal program measures to streamline the support from a standards perspective. We agree that measure concepts, specifications and data elements should be aligned across Federal and private sector measures.*
D.2. Redesigning Quality Measures to be Self-Contained Tools • Be compatible with any data source systems that implement standard interoperability requirements.	HL7 encourages CMS to establish a platform for real-world testing and consider establishing a process whereby functionality can be certified. Incorporate detailed certification requirements that assess all necessary FHIR-based functionality to support current measures and CDS capabilities. It is important to encourage data collectors and data aggregators to support more than just MUST SUPPORT functionality to build upon our current capabilities. CMS should assure such capability before moving forward with complex requirements for broadly reaching programs.
• Be tested and updated independently of the data source systems.	CMS should review and participate in the HL7 and Observational Health Data Sciences and Informatics (OHSDI) activities to coordinate work with FHIR and Observational Medical Outcomes Partnership (OMOP) to express queries including expressions called phenotypes that align relatively closely with CQL-based libraries. OMOP datasets may be a good way to evaluate aggregate data sets once FHIR bulk data has matured and is widely available.
E. Solicitation of Comments As noted previously, we seek input on the future development of the following:	

Proposed Rule Language	*HL7 Comments*
• Definition of Digital Quality Measures. We are seeking feedback on the following as described in section XIV.2. of the preamble of this proposed rule: o Do you have feedback on the potential future dQM definition? ▪ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.	
· Use of FHIR for Current eCQMs. We are seeking feedback on the following as described in section XIV.3. of the preamble of this proposed rule: o Would a transition to FHIR-based quality reporting reduce burden on health IT vendors and providers? Please explain. o Would access to near real-time quality measure scores benefit your practice? How so? o What parts of the current CMS Quality Reporting Data Architecture (QRDA) IGs cause the most burden (please explain the primary drivers of burden)? o In what ways could CMS FHIR Reporting IG be modified to reduce burden on providers and vendors?	HL7 agrees with transition to FHIR-based eCQMs and retiring the Quality Data Model (QDM). For several years, HL7 has been publishing QDM to Quality Improvement Core (QI-Core) with QI-Core as the FHIR IG to address needs for quality measurement and clinical decision support. HL7 has further tested FHIR-based measures in Connectathons for the past 4 years using the FHIR Quality Measure Implementation Guide (QMIG) and the FHIR Data Exchange for Quality Measures (DEQM) Implementation Guide. The two IGs replace and expand on measure capabilities of the Health Quality Data Format (HQMF) and Quality Reporting Document Architecture (QRDA), respectively. Further DEQM replaces both QRDA Category I and QRDA Category III. By aligning data retrieval with the same information model used to exchange clinical and administrative data for routine care-related interoperability, measures using QMIG (with QI-Core as the data model) and data reporting using DEQM (with QI-Core as the data model), the burden associated with HQMF and QRDA is significantly reduced.

Proposed Rule Language	*HL7 Comments*
· Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025. o We are seeking feedback on the following as described in section XIV.4.a. of the preamble of this proposed rule: ▪ Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR IGs suggested for consideration? ▪ How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data? ▪ What are possible approaches for testing data quality and validity?	With respect to testing data quality and validity, HL7 recommends CMS should further participate in the HL7-OHDSI activities as noted above. OHDSI has a robust community that evaluates OMOP phenotypic expressions for syntax errors using automated fabricated data, and further the community evaluates the phenotypic expressions with real-world data to identify false positive and false negative results to improve and yield a highly valid, reliable, and re-usable expression. Aligning the quality community with this effort may streamline the measure development and testing process especially as measures move to PGHD and other non-standardized data.