COLLEGE of AMERICAN PATHOLOGISTS

June 28, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1752–P
P.O. Box 8013
Baltimore, MD 21244–1850.

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

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program. (CMS–1752–P)

Dear Administrator Brooks-LaSure:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the hospital Inpatient Prospective Payment System (IPPS) proposed rule CMS-1752-P for fiscal year 2022. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Pathologists are physicians whose diagnoses drive care decisions made by patients, primary care and specialist physicians, and surgeons. When other physicians need more information about a patient's disease, they often turn to pathologists who provide specific diagnoses for each patient. The pathologist's diagnosis and value are recognized throughout the care continuum and affect many patient encounters.

This letter includes comments regarding the following issues that are divided into two sections:

1. V. Other Decisions and Changes to the IPPS for Operating Systems
   a) L. Market-Based MS-DRG Relative Weight Policy – Proposed Repeal (§ 413,20)
   b) M. Payment Adjustment for CAR T-cell Clinical Trial and expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)
   c) J. Proposed Payments for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 through 413.83)

2. IX. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers
   a) FHIR in support of Digital Quality Measurement in Quality Programs
   b) RFI form related to above: FHIR in support of Digital Quality Measurement in Quality Programs
   c) Electronic case reporting

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d) Electronic Reportable Laboratory Result Reporting Measure

1. a) L. Market-Based MS-DRG Relative Weight Policy – Proposed Repeal (§ 413,20)

In the FY 2021 Inpatient Prospective Payment System (IPPS) final rule the Centers for Medicare and Medicaid Services (CMS) finalized a requirement for a hospital to report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organization payers, by Medicare Severity Diagnostic Related Group (MS-DRG), for cost reporting periods ending on or after January 1, 2021. The agency also finalized the use of this data in a new market-based methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing, beginning in FY 2024. In previously submitted comments the CAP expressed concerns that if the CMS implements its proposed change to a market-based methodology for calculating MS-DRG relative weights, the resultant new relative MS-DRG weight payment methodology may exclude or not adequately capture the professional component of clinical pathology services because of non-uniformity of payment in the commercial market. The CAP urged the CMS not to move forward with its proposed market-based MS-DRG relative weight proposed data collection and potential change in methodology for calculating MS-DRG relative weights.

Within this FY 2022 Inpatient proposed ruling the agency stated that after further consideration of the many contract arrangements that hospitals use to negotiate rates with MA organization payers, the CMS proposes to repeal the market-based data collection requirement and market-based MS-DRG relative weight methodology. **The CAP agrees with CMS' proposals to repeal the market-based hospital data collection requirements and market-based MS-DRG relative weight methodology and urges their finalization.** However, for the same reason, the CAP does not support CMS' alternative proposal to instead maintain the requirement that hospitals report the median payer-specific negotiated charge for MA organizations on the Medicare cost report while delaying the implementation of the market-based MS– DRG relative weight methodology from FY 2024 to a later date.

1. b) M. Payment Adjustment for CAR T-cell Clinical Trial and expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)

CAR T-cell therapy is a cell-based gene therapy. The CAR process genetically engineers a patient's T-cells, resulting in the addition of a CAR that will bind to and attack a certain protein on the patient's cancerous cells. For FY2021, CMS created new MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell Immunotherapy for CAR-T cell therapy cases. To calculate the relative weight, CMS does not use clinical trial cases where the hospital does not have a cost for the CAR-T cell therapy product. Similarly, CMS adjusts payment for clinical trial cases to not pay for the cost of the CAR-T cell therapy product that the hospital did not incur. The FY 2021 payment adjustment is 0.15 (e.g., the full IPPS payment is reduced by 85 percent to account for hospital not incurring the very high cost of the CAR-T cell therapy product).

CMS is proposing not to use FY 2020 MedPAR data to set FY 2022 IPPS rates for circumstances where the FY 2020 data is significantly impacted by the COVID-19 PHE, primarily in that the utilization of inpatient services reflect generally markedly different utilization for certain types of services in FY 2020 than would have been expected in the absence of the PHE.

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For this reason, CMS' analysis of the payment adjustment for this proposal is based on an update of FY 2019 MedPAR data. Based on the later FY 2019 MedPAR data, CMS proposes a revised adjustment of 0.17. CMS also solicits comments on an alternative approach of using the same FY 2020 data that they would ordinarily use for purposes of FY 2022 rulemaking. CMS notes that the payment adjustment would be 0.25 if it used the latest FY 2020 data.

The CAP is supportive of the steps the CMS is proposing to slightly increase the payment adjustment. However, the reimbursement rate is still insufficient to cover the cost of CAR-T therapy and related services. Current levels are already likely leading to fewer services provided and more limited access to these lifesaving cancer targeted treatments and therefore the CAP urges adoption of the agency's alternative approach of using FY 2020 MedPAR data for FY 2022. **The CAP urges the CMS to finalize its alternative approach of using the FY 2020 data for purposes of establishing the FY 2022 payment amount for the MS-DRG 018, and to recognize that appropriate coverage and reimbursement is necessary for all items and services furnished throughout the continuum of CAR T-cell and related cellular immunotherapy treatments.** Patients eligible to receive CAR-T therapy are extremely ill and the CAP believes that the inpatient setting is still the safest and best setting to treat most patients with these therapies.

Pathologists play a critical role as integral members of the cancer patient management team during CAR T-cell therapy. In addition to playing an integral role in initially diagnosing diseases and monitoring disease persistence and recurrence, pathologists are also directly involved in patient education, care management, and the provision of CAR-T cell therapy clinical services—notably, the harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells.

With its increased use, CAR-T-cell therapy is an expensive evolving service that presents unique challenges for providers, patients, and the CMS. The resource consumption and clinical characteristics of the patients with a given set of conditions are clinically distinct from others. It is also difficult to predict what the costs associated with other future CAR-T therapies will be – there will likely be new or different side effects or additional agents that are co-administered with the therapy with the potential to increase toxicity. The CAP urges the CMS to take these issues into account as the agency updates the new proposed MS-DRG overtime.

For FY 2021, based on the fact that CAR-T cell therapies are extremely resource intensive, CMS grouped these patients before MDC assignment, based on the OR procedure rather than the principle diagnosis, creating a Pre-MDC MS-DRG (Chimeric Antigen Receptor (CAR) T-cell immunotherapy) and reassigned cases reporting ICD-10-PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) or XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3) from Pre-MDC MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy).

For FY 2022 the CMS proposes to classify sixteen new ICD-10-PCS procedure codes as non-O.R. procedures affecting Pre-MDC MS-DRG 018 listed on Table 6B (page 25095) and revise the title for Pre MDC MS-DRG 018 from "Chimeric Antigen Receptor (CAR) T-cell Immunotherapy to "Chimeric

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Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect the cases reporting the administration of non-CAR –T cell therapies and other immunotherapies that would also be assigned to this MS-DRG. **The CAP appreciates that CMS established MS-DRG 018 as a Pre-MDC due to the extensive resources, steps, and processes required of a CAR T-cell administration consistent with the policy of Pre-MDCs that group items or services primarily on resource utilization. However, the CAP believes CMS' proposal to rename Pre-MDC MS-DRG 018 to include the language, "Other Immunotherapies," may be too broad. The CAP recommends CMS to utilize a naming convention, such as cellular immunotherapies, which would capture similar resource-intensive procedures for the DRG.**

Cellular immunotherapies utilize active immune cells that have been enhanced to fight cancer in patients. These therapies include tumor-infiltrating lymphocyte (TIL) therapy, engineered T- Cell receptor (TCR) therapy, CAR T-cell therapy and natural killer (NK) cell therapy. While the CAP appreciates that CMS wants to include non-CAR T-cell therapies in order to increase access to new cellular therapies as requested in previous comments, using the term "other immunotherapies" potentially includes many immunotherapies, such as antibody-based targeted therapies and oncolytic virus therapy, which are not cellular therapies and have very different clinical and resource utilization. Thus, the CMS should use more specific language in the naming of MS-DRG 018 that would more accurately reflect the pre-MDC logic and ICD-10-PCS codes that would be mapped to MS-DRG 018. The CAP looks forward to future collaboration with the agency on these life saving therapies.

1. c) J. Proposed Payments for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 through 413.83)

The United States is facing a shortage of between 54,100 and 139,000 physicians by 2033 – a dearth that is almost certain to be exacerbated by rising rates of physician burnout and early retirement due to the COVID-19 pandemic. The physician workforce, much like our population, is aging, with nearly 45 percent of active physicians in the United States being age 55 and older. Access issues persist for patients in both rural and urban underserved communities, and in both primary and specialty care, and it is crucial that we invest in our country's health care infrastructure by helping provide them the physicians they need to improve access to care.

The CAP is pleased that the CMS proposes to implement several provisions of the Consolidated Appropriations Act of 2021, including its requirement for 1,000 new Medicare-funded medical residency positions. Specifically, CMS proposes to, beginning in FY 2023, phase in 200 positions each year for five years. **The CAP supports the increased Medicare funded medical residency positions for all medical specialties to help ease current physician shortages and bolster the foundation of our health care system.** Additionally, CMS proposes to prioritize applications for residency positions in programs serving underserved populations. CMS' proposal includes priorities for underserved populations by measuring severity scores indicating health provider shortages in primary care and mental health providers. The CAP agrees that there are physician shortages, and observes that those shortages are also occurring in specialty areas such as pathology, especially in rural areas.

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The health care system in rural America continues to face a health care crisis. Approximately one-fifth of the US population live in a rural area and by most measures, the health of these residents is significantly worse than the health of those in urban areas.[1] Interestingly:

- Rural residents are more likely to be Medicare or Medicaid beneficiaries and make up over half of rural hospitals' net revenue. [2,3]
- The leading cause of negative margins for small rural hospitals is insufficient payment from private health insurance plans and MA plans. Many private health insurance plans pay less than the cost to deliver care in small rural hospitals, whereas private plan payments at most large hospitals are higher than the cost of delivering services.[4] Rural hospitals cannot easily use profits from the privately insured to cover losses from Medicare and Medicaid patients like larger hospitals do.
- Between 2018 and 2020, 50 rural hospitals closed, representing a 30 percent increase in the number of closures compared to the 3 years prior. Hospital closures are generally preceded by financial losses caused by a combination of decreasing rural population and inadequate payments from health insurers.[5]
- With more than 2,000 rural hospitals across the country approximately 40 percent of them are estimated to be at risk of closing and most of them are small hospitals serving isolated rural communities.[6]

When a rural hospital closes, recruiting and retaining physicians in the local community often becomes increasingly difficult, leading to decreased access to care.[7] Rural hospital closure puts vulnerable populations at increased risk of losing access to health care, worsening health disparities, and negatively impacting the economy of the local area.[8] **The CAP supports the prioritization of residency slots to rural hospitals.**

Within this proposed ruling the CMS proposes to prioritize awarding residency slots based on Health Professional Shortage Areas and the CAP agrees. Physician shortages in specialty care are also significant and are often overlooked by policy makers during this time when primary care is at center stage. The CAP membership continually reports that the pathology workforce is not keeping up with patient growth and population changes and should be addressed in this ruling. Pathologists are physicians whose diagnoses drive care decisions made by patients, primary care and specialist physicians, and surgeons. When other physicians need more information about a patient's disease, they often turn to pathologists who provide specific diagnoses for each patient. The pathologist's diagnosis and value are recognized throughout the care continuum and affect a large portion of patient encounters. The pathologist is also professionally responsible and legally accountable for their laboratory's results, and pathologists assure compliance with all laboratory regulatory and accreditation standards. Pathologists in hospitals and independent laboratories around the country are responsible for developing and/or selecting test methodologies, validating and approving testing for patient use, and expanding the testing capabilities of the communities they serve to meet emergent needs. The influence of these pathology services on clinical decision-making is pervasive and they constitute a critical foundation for appropriate patient care. **The CAP supports prioritization of residency positions based on Health Professional Shortage Areas and urges the agency to consider funding additional medical residency positions in pathology as it is one medical specialty that is often overlooked and experiencing shortages, especially in rural areas**.

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2. IX. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers

Executive Summary for Section 2:
The CAP believes that before CMS establishes the Fast Healthcare Interoperability Resources (FHIR) standard for digital quality measures (dQMs), it is critical to first ensure that the components necessary to develop and test dQMs are available. This will allow time for providers and health IT vendors who are not well-versed in FHIR to familiarize themselves with the standards. This will also allow time for CMS to determine what resources are needed to support a low-cost, low-burden transition for providers. Given the frequent changes to existing quality reporting programs, the CAP recommends a targeted roll-out of any new requirements focusing on areas where resources are well-developed, with frequent opportunities for feedback and revision as the transition occurs.

2. a) FHIR in support of Digital Quality Measurement in Quality Programs

To support Electronic Health Information (EHI) reuse, digital Quality Measure (dQM) automation, and public health reporting in an interoperable way, data capture standards must not be neglected and high-quality national EHI standards must be available for:

a. **Data capture** via standard structured data elements (DEs) and forms
b. **Data and metadata structures** appropriate for automated Electronic Health Record (EHR) incorporation
c. A coherent **terminology/coding** system for querying, DE aggregation, and analytics

We suggest that to maximize the utility of **data exchange** via FHIR and **data query** (e.g., using SQL or CQL) these standards for capturing data should first be established.

If standards for 1a-c are not addressed, a large amount of transmitted data will not be usable without manual validation, data cleaning, harmonization, and reconciliation with local specifications (e.g., local EHR data dictionaries or the NAACCR data dictionary and selected standards for cancer registries) for similar DEs.

CAP feels that the data standards for 1a-c, the data exchange model (e.g., a FHIR-based API), and the data query model (e.g., CQL, SQL, FHIRPath) must be part of an integrated informatics solution that can be reused regardless of the data exchange use-case, and that can be thoroughly validated for multiple use cases. This is especially true for pathology data because pathology encompasses thousands of potential DEs that need standardization at the time of data capture.
Of the existing structured DEs – even non-standard ones – that are required for the automation of quality measure calculations are not present in EHR systems for a large fraction of patients. Data hidden in narrative text - even if present - are rarely suitable for automating quality measure calculations. The problem is compounded when analyzing narrative text derived from multiple practitioners across multiple source sites. As CMS moves towards digital quality measures, this lack of standardized data elements will be an increasing issue.

The current problems with standard capture of pathology data are:

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a) Currently insufficient USCDI definition for pathology result data particularly structured pathology data.
b) The separation of USCDI pathology reports ("clinical notes") into “pathology” and “laboratory.”
c) Overreliance on LOINC, which does not adequately capture pathology data

We hope to continue working with ONC and CMS to address these issues and promote standard capture and transmission of pathology data.

2. b) RFI form related to above: FHIR in support of Digital Quality Measurement in Quality Programs

Definition of Digital Quality Measures

a. Do you have feedback on the dQM definition?

We have concerns about defining a measure as “a software”. This implies that the measure is capable of independent action, like any software on a computer, which is not the case for existing quality measures. Combined with other changes proposed in this document, this definition suggests a shift in CMS’ thinking to be closer to the ONC model of measures where instruments are stored in and called from a central repository via an app and function independently from a registry. As this does not align with the current structure of measures, we have concerns regarding the burden of shifting the entire CMS measure portfolio to a new type of measure without demonstrated gain in doing so.

We would also like to highlight remaining areas of vagueness in the definition, including whether end-to-end reporting from one electronic system to another is required for a measure to be considered a dQM. It is not clear whether the intention of dQMs is to eliminate any human interaction with the data between collection and generation of a measure score. CMS also lists “other sources” as an option for where dQMs can come from. It is unclear if they intend to fully define the list of options. Laboratory Information Systems are not currently captured in any of the defined categories and would therefore be “other”. If CMS intends to use the transition to dQMs to impose new requirements on measure composition or data sources, we suggest as much detail and transparency as possible be included in the definition. The existing definition lacks full details. The CAP agrees with AMA’s statement that “realizing the full extent of digital quality measurement requires rethinking electronic health record (EHR) certification.”

b. Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising?

Use of FHIR-based APIs could in theory reduce the burden on providers depending on implementation requirements and support. However, it is not clear that FHIR is sufficiently advanced in all fields to allow widespread use. We also suggest that standardizing data elements and data capture is equally important as data exchange via FHIR APIs. Therefore we recommend a simultaneous consideration of ways to implement standard data capture above and beyond what is currently captured by the USCDI. In particular for pathology, the USCDI remains incomplete and relies too heavily on LOINC.

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Furthermore, it is not clear how CMS intends for FHIR-based technology to be developed; who will be incentivized to develop, test, and maintain software that supports this functionality? We believe it is critical to first ensure that the components necessary to develop and test dQMs are available before focusing on how they will be deployed. This will allow time for providers and health IT vendors who are not well-versed in FHIR to familiarize themselves with the standards. This will also allow time for CMS to determine what resources are needed to support a low-cost, low-burden transition for providers.

Use of FHIR for Current dQMs

a. Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers?

As noted above, a transition to FHIR-based quality reporting could reduce burden on health IT vendors and providers but this is far from certain. In areas where FHIR resources are fully developed and familiar to users, health IT vendors may already have infrastructure in place to support FHIR and the transition would reduce burden. However, it is unlikely that most providers are familiar with FHIR. Given the well-documented concerns about frequent changes to the MIPS program, any transition should be done in the background as much as possible rather than requiring providers to familiarize themselves with new standards or documentation.

In general, we suggest that CMS publish as much guidance about what is expected as soon as possible. Among FHIR's selling points is that it is very structured and there are many resources available. If CMS expects that, for instance, all pathology quality measures will comply with the Diagnostic Report resource and/or other profiles in the US Core IG, CMS should make that clear as soon as possible to allow maximum time for compliance. We also suggest that CMS work with HL7 to ensure that opportunities for comment on IGs prior to balloting are publicized widely if CMS is intending to require them. Given the frequent changes to existing quality reporting programs, we recommend a targeted roll-out of any new requirements focusing on areas where resources are well-developed, with frequent opportunities for feedback and revision as the transition occurs.

b. Would access to near real-time quality measure scores benefit your practice?

While access to near real-time quality measure scores would benefit most practices, this is unrelated to FHIR-based APIs. Current registry infrastructure allows most practices in most registries to see their scores on quality measures for MIPS in near real time as well as comparative and benchmarking data. FHIR-based APIs would not change this functionality.

Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025

a. 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 Implementation Guides suggested for consideration?

This approach is by its nature limited to data that is stored in certified health IT, which does not include significant amounts of data that would be necessary for dQMs. It is possible that in the long

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run this approach would save providers time and burden. However, the benefits in the short term are less clear. The amount of data that is already captured as standardized, interoperable data is unknown; we suggest that before CMS implements requirements for such data to be used for quality measures, assessment of such data be completed and made public. The "interoperable standards" CMS intends to adopt should also be available for public comment before implementation.
As it stands now, the suggested plan does not provide adequate detail for full assessment of the impact on providers. We fully support efforts to reduce burden on providers by moving away from manual chart abstraction but significantly more information about future requirements, timelines, incentives and opportunities for input is required.

In terms of specific Implementation Guides, we do not believe the resources available for pathology are ready to be used for dQMs. Many diagnostic FHIR resources such as the "Diagnostic Report" event are overly broad, encompassing not just pathology but radiology and in some cases other diagnostic modalities such as gastroenterology and cardiology. The lack of specificity for pathology makes the resources less user-friendly to providers and results in large sections of the resource that would be left blank by users. A Quality Measure Implementation Guide already exists in FHIR; we suggest modification and/or expansion of this IG as it may already be familiar to some users.

b. How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

As above, we would support transparency on the part of CMS regarding development of data standards for "non-EHR" digital data. Non-standardized data presents a unique challenge to the efforts outlined in this RFI. Given the significant experience of the CAP with non-standardized data, which includes most pathology data, we recommend caution in applying existing standards and approaches to non-standard data.

Non-standardized data takes many forms and it is unlikely that any one approach will cover all forms. While it is critical to maximize inclusion of PGHD and other non-standardized data in quality measures, the CAP suggests a full evaluation of the current state of such data prior to imposing a data standardization approach. We suggest CMS gather input from those who already generate and use such data on what standards would be appropriate and how they should be deployed. While we support the idea behind CMS's idea of "developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability", steps must be taken to ascertain the current state of data before guidelines can be developed. We also suggest that any guidelines or requirements are developed in conjunction with stakeholders and specific to the non-standardized data in question, rather than attempting to produce new standards that cover all current non-standardized data or to fit data into existing standards.

c. What are possible approaches for testing data quality and validity?

Testing data quality and validity will be essential as CMS attempts to reduce provider burden by automating more data extraction. We know from experience that natural language processing requires a significant input of time at the outset to ensure accuracy of data extraction. CMS should consider how organizations will be incentivized to expend the resources needed to validate NLP

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extraction of data from PGHD; this burden should not fall on patients but it is not clear who is expected to shoulder it. In general, data quality and validity checks are a heavy lift requiring specialized expertise and should not be undertaken by organizations without the authority to do so. If it is the expectation of CMS that measure developers create, implement, refine and maintain the NLP associated with quality measures, additional assistance such as access to contractors with subject matter expertise, expedited or provisional approval of such measures or incentives to health IT vendors to work with measure developers should be considered.

d. *What functionalities, described in Section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?*

As noted regarding the definition of dQMs as "a software", we have serious concerns about the idea of quality measures as free-standing tools that accomplish the functions described in this RFI. This idea of a measure aligns more closely with the model ONC describes in some registry implementation guides, where "Instruments" are stored in a separate repository outside of a clinical data registry and are populated by data from the EHR before the "results" are submitted to a registry. This would fundamentally shift the role of registries as well as the role and function of measures themselves. Considerably more information would be needed before this concept could be seriously considered for quality measures such as those used in the MIPS program.

Of specific concern are two areas: first, even given standard instruments or measures as tools, variation in implementation is a significant possibility. Obtaining standard scores from all users is a major goal of quality measures as tools. However, use by varying groups including hospitals, individual clinicians, payors and more, without oversight from a measure authority, could lead to scores that cannot be compared between entities especially given that these tools are expected to deploy advanced analytics such as NLP. If individual or entity users are able to modify the NLP of the tool, comparisons between scores are nullified; if they are not, however, it is likely that the measure would not work in all circumstances. In the experience of the CAP, who has been using NLP to extract data for quality measures, proper use of NLP requires ongoing maintenance and updating. By removing a centralized measure calculation body such as a registry, the chances that different stakeholders will implement the measure differently are increased. As the AMA notes, "vendors, practices, health systems, and consultants perform their own mapping, which leads to data inconsistencies and is a reason why no two EHRs can reliably calculate comparable results."

Second, by establishing measures as free-standing tools, CMS is disincentivizing use of registries and relegating them to a secondary role as simply data storage units. This not only goes against the policies stated in MACRA, but also increases burden on providers and reduces opportunities for quality improvement. As noted above, registries already provide the "near real-time quality measure score" CMS is considering. By removing the role of registries in quality measure calculation, CMS would force providers to find another way to get those scores. What's more, in the absence of registries, information such as national averages and resources such as tool kits to promote quality improvement would no longer be available. Registries have played a key role in creation and implementation of specialty-specific quality measures that promote reporting by providers in many areas. Many of these measures would likely vanish without registries, thus reducing the opportunities for improvement for smaller specialties. Furthermore, by making measures free-standing tools, CMS incentivizes providers to operate independently rather than strive to meet standards set by their

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peers. CMS has recently increased the amount of comparative data that Qualified Registries (QR) and Qualified Clinical Data Registries (QCDRs) are expected to provide their users; establishing measures as free-standing tools moves in the opposite direction.

e. How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

We do not believe sufficient information is available to determine whether this approach would result in increased engagement with measure development. Most clinicians are likely not familiar with FHIR, so it is possible that implementing new standards could increase the perceived burden on clinicians of measure development if they feel they need to learn a new system. While FHIR in theory would make resources more widely available by standardizing access methods, it is not clear whether use of tools for quality improvement, public health or research would immediately increase. We suggest a pilot project, funded by or conducted by CMS, to determine what additional resources are needed to ensure providers understand the new strategy. This would promote engagement in tool development and use.

f. Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?

There are a number of policy considerations for aggregation of data from multiple sources. The experience of the CAP with obtaining data from hospitals suggests it will be a difficult process. Currently there is no incentive for hospitals to provide data to clinical data registries; it is difficult to see what incentive could be generated or what requirement could be put in place. If data aggregation remains voluntary or includes governmental programs only, its usefulness, will be limited and aggregation could end up more of a burden than a help. As with other suggested policies, we recommend careful consideration of what stakeholders will be responsible for what aspects of aggregation of data to ensure burden does not fall disproportionately on clinicians. Many pathologists work with multiple hospitals and in on our experience, it is incredibly time-consuming for them to navigate the bureaucracy of the hospitals trying to access data.

g. Do you have feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

While we support the idea of standardizing policies and processes for data aggregation and measure score calculation by third party aggregators, it is not clear whether CMS intends to bring other aggregators up to the level of Qualified Clinical Data Registries (QCDRs), or whether CMS intends to impose additional requirements and expectations on all aggregators including QCDRs. In theory, aggregation of data from multiple sources is beneficial for all involved but in practice, we do not believe CMS should define who QCDRs must aggregate data from, due to system-specific requirements of each QCDR. We also do not support addition of requirements to QCDRs, which already comply with strict rules regarding measure implementation, data collection and auditing, and feedback provided to users.

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h. What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

Initial priority areas should be limited to areas where an environmental scan to assess the state of structured data has already been done or can be done easily. Areas where the state of data is unknown, or where most data is not structured cannot be the first priority, as it is not yet clear that dQMs will function as expected or that they are appropriate for all settings. As with other CMS programs, dQMs should be rolled out in as a pilot project to ensure that providers are not penalized for being early adopters of new technology but are incentivized to improve quality using new methodologies and are given opportunities to provide feedback.

In terms of specific resources to be created, we encourage transparency in expectations first and foremost. As previously noted, a large number of resources exist around FHIR; if CMS expects that a specialty or clinician comply with certain requirements, the exact guides and resources should be clearly stated, and stakeholders given the chance to provide feedback. As much specificity around the definition of a dQM as possible should be established quickly.

We support AMA's comments on this section, particularly the idea that CMS should "incent the use of standardized semantic content from recognized developers."

i. We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

CMS is considering implementing standard measures across all programs and payors if possible. In their words "(t)his common portfolio would require alignment of: (1) measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements." We support the idea of aligning measure concepts/specifications including individual data elements across government programs and payors. However, the idea of limiting data elements to standardized, interoperable elements is concerning. It is based on the assumption that all parts of all measures will be able to be expressed as standardized data elements; in practice this has not been demonstrated for very many measures. The limited number of eCQMs are not sufficient to conclude that all data elements in all measures can be defined in this way. While CMS does acknowledge that this would be an ongoing effort in partnership with other interested parties, the basic assumption may be flawed.

We recognize CMS' interest in reducing the number of measures, both within individual program and across programs. However, CMS should not use standardization of data elements and alignment across programs as a mechanism to winnow out measures. Furthermore, CMS should be clear about the role of various parties in this process. That is, if dQMs are intended to be self-contained tools, the responsibility of ensuring that the tools function equally well on all platforms should not fall entirely on the measure developers, but on vendors as well if they intend to use these free-standing software packages. We are in agreement with AMA on this point.

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CMS should also consider the statutory requirements of various programs as they seek to align measures. Measures that have value in the Agency for Healthcare Research and Quality's Clinical Decision Support Initiative may not satisfy the requirements of the Merit-Based Incentive Payment System and vice-versa. As noted previously, we do not support this alignment initiative as a mechanism to remove measures from programs simply to reduce the number of measures. We support a gradual rollout, starting with CMS's proposal to "identify which existing measures could be used or evolved to be used as dQMs". We also suggest concurrent identification of priority areas where new measures for an aligned measure set need to be developed and further suggest that CMS prioritize working with established measure developers and subject matter experts to address those gaps.

2. c) Electronic case reporting

CMS proposes making the Electronic Case Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022. We support improving electronic case reporting; however, we are concerned about the burden this proposal would have on reporting entities. As such, the CAP would outline two issues that should be considered before moving forward with such a proposal – (1) federal versus state mandatory reporting and (2) Interfaces. A federal baseline for reporting emerging pathogens would be useful, but state public health agencies would also need to be mandated to accept federally required data. Funding to modernize state systems to accept this data needs to be considered. In addition, altering existing interfaces, generating new interfaces, and altering databases to handle the data requirements have significant financial cost that require funding given the financial difficulty for healthcare organizations and clinical laboratories to comply with such a mandate, especially in the aftermath of the pandemic. We support the agency's intention to standardize data and give public health officials access to "comprehensive and nearly real-time data to inform decision making in their response during a pandemic but suggest the agency consider implementation of standardized data captured models before requiring this as a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program for 2022.

2. d) Electronic Reportable Laboratory Result Reporting Measure

CMS proposes making the Electronic Reportable Laboratory Result Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022. CMS outlines the current reporting mechanism, which are APHL AIMS platform, HIEs, and other mechanisms for hospital laboratories, as feasible for implementing this requirement. However, during the current pandemic, hospital clinical laboratories cited problems collecting required data elements for reporting electronically to public health agencies. Electronic submission of laboratory results to public health agencies is not currently mandated at the federal level, and states vary on whether electronic submission is required and on the format of the electronic submission. Each interface with an EHR or with an individual state's public health agency is costly ($40,000 to $70,000 on average per interface), and each change made to an interface also has associated cost. Further complicating the

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matter is the variability by state as to who is required to do the reporting, and this will also need to be clarified if it is going to be standardized at a national level. To alleviate reporting burdens on clinical laboratories and state public health agencies, the CAP advocates for national standardized reporting requirements and formats in which clinical laboratories would be required to report only to the state in which the laboratory is located, and the same national standards could be used by state public health agencies to report data on out-of-state patients to the state public health agency of the patient's residency. Some states report to outside states, but many do not. We believe there is too much variability and obstacles in the current reporting structure to make this a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program for 2022.

Thank you again for the opportunity to comment on these proposed policies. The CAP welcomes the opportunity to work with the CMS to address these important issues that affect the medical care of beneficiaries. Please direct questions concerning section V. Other Decisions and Changes to the IPPS for Operating Systems to; Todd Klemp (202) 354-7105 / tklemp@cap.org and for questions on section IX. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers to Loveleen Singh at lsingh@cap.org / 202-354-7133.

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