COLLEGE of AMERICAN PATHOLOGISTS

June 17, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1771-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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation (CMS–1771–P) Docket CMS-2022-0074, Docket RIN: 0938-AU84

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-1771-P for fiscal year 2023. 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:

Section One

a) Proposed Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)
b) MS- DRG 018 Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies

Section Two

a) B. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information
b) C. Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs–Request for Information

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Section One

a) Proposed Payments for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 through 413.83)

Medicare pays hospitals for direct graduate medical education (DGME) and indirect medical education (IME) costs based on the number of full-time equivalent (FTE) residents they train. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare DGME and IME payments the hospital will receive. Statutorily, each resident is counted as a 1.0 full-time equivalent (FTE) trainee while they train within their initial residency period (IRP), not to exceed five years, and 0.5 FTE for additional training in an approved residency program. Prior to 1996, hospitals used the total weighted FTE count to calculate the DGME reimbursement. In response to Congress capping the number of residents for which a hospital can be reimbursed, the CMS developed a "proportional reduction methodology" to ensure that a hospital's adjusted weighted FTE count did not exceed their 1996 cap. However, for each resident above the cap added that is beyond the initial residency period, the hospital's weighted count declines. The hospital is penalized for adding residents in sub-specialty training as opposed to receiving no additional payment that would occur if each additional unweighted resident being added is not counted at all. Effectively, this results in each resident beyond the initial residency period being weighted at less than 0.5 FTE. The CMS indicates in their proposed ruling that the above formula has been applied separately for residents training in primary care and obstetrics/gynecology from residents training in all other specialties. In May 2021, a United States District Court for the District of Columbia held that the proportional reduction method reduced the statutorily mandated weighting factors for hospitals that had a weighted FTE count higher than their 1996 cap, and trained residents beyond their IRP. In effect, the proportional reduction method reduced the statutorily mandated weighting factors to less than their required weights.

CMS' proportional reduction methodology was ruled inconsistent with the statutory requirement that each resident beyond the initial residency period be weighted at 0.5 FTE. In response to the court's decision, CMS is proposing to implement a modified policy applicable to all teaching hospitals, retroactively effective October 1, 2001, because it is unaware of any open or reopenable notice of program reimbursements for the 1997-2001 period where the proportional reduction method caused a provider's payments to be lower than they would be under the proposed new policy.

CMS proposes if the hospital's weighted FTE count is equal to or less than the FTE cap, no adjustment is necessary, if the hospital's weighted FTE count is greater than the FTE cap, CMS will adjust the weighted FTE to make the total weighted FTE count equal the FTE cap. Under the proposed change, hospitals that train residents in excess of their 1996 caps would no longer experience a reduction in their FTE count when they train residents beyond their IRP. **The CAP agrees with CMS' proposed retroactive change to its calculation for the adjusted weighted direct graduate medical education FTE count methodology and urges the CMS to finalize its proposal.**

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, in both primary

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and specialty care, therefore 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. –

Pathologists continue to be on the frontline of the pandemic testing and developing tests for COVID and its variants. The work pathologists formed the foundation of our nation's response to the pandemic. Now more than ever patients and providers are relying on pathologists to mitigate the impact of COVID-19, and screen for and diagnose other diseases like cancer.

The CAP observes that physician shortages are also occurring in specialty areas such as pathology, especially in rural areas. The pathology workforce is not keeping up with patient growth and population changes and should be addressed in future rulings.

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 have been 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 ensuring patients get the most accurate and reproducible results from assays are not only sensitive enough to detect even low levels of disease but specific enough to make the right call in every patient blood test, infectious disease results, or tissue/cancer diagnosis. The influence of these pathology services on clinical decision-making is pervasive and they constitute a critical foundation for appropriate patient care.

b) MS-DRG 018 Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies

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 and Other Immunotherapies for CAR-T cell therapy cases. In some cases, the CAR-T cell or other immunotherapy patients may be part of a clinical trial where the high-cost therapy product is furnished to the hospital at no cost. Beginning with FY 2021, CMS adopted a differential payment for these cases to recognize hospitals' lower costs. CMS also excluded CAR-T cases billed with a clinical trial indicator of less than $373,000 in drug costs—the average sales price of the two CAR-T cell products approved to treat relapsed/refractory diffuse large B-cell lymphoma in drug costs—from the relative weight calculation.

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.

CMS is proposing to adopt these same policies for FY 2023. For FY 2023, CMS estimated that the average costs of cases assigned to MS-DRG 018 that are identified as clinical trial cases ($61,356) were 20 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as

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non-clinical trial cases ($299,460). Accordingly, CMS is proposing to adjust the payment for MS-DRG 018 by applying an adjustor of 0.20 to the full payment amount in those situations where the hospital does not have a cost for the CAR-T or other immunotherapy product. The proposed rule also indicates that this policy will not apply to clinical trial cases where the CAR-T or immunotherapy product was purchased through the normal mechanisms, but the clinical trial was of another product.

CMS did not find any occurrences in the data of this situation but also indicated that it is developing a modifier for hospitals that will allow them to exclude these situations from the policy when they occur. CMS further notes that the policy will apply to expanded access use of immunotherapy—a potential pathway for a patient with an immediately life-threatening or serious disease to gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. While CMS is unaware of any of these situations in the data, it believes a hospital would not have drug costs that are $373,000 or above because “compassionate use” drugs or biologicals are typically provided to the hospital at no cost.

The CAP is supportive of the CMS’s efforts to assess the appropriateness of the therapies assigned to MS–DRG 018, and its continued work with stakeholders to evaluate the resource costs to improve the predictability and stability of hospital payments for these complex, novel cell therapies.

For FY 2022 the CMS’ used FY 2019 data, over the alternate proposal to use FY 2020 data, for several reasons stemming from the Public Health Emergency (PHE). The CAP agreed with the use of the FY 2019 data. For FY 2023 we believe CMS must again carefully analyze what data to use for FY 2023 rate-setting as the PHE has continued well into CY 2021 and FY 2021 data might be reflective of the same issues as FY 2020.

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 MS-DRG 018 overtime.

The CAP looks forward to future collaboration with the agency on these lifesaving therapies.

Section Two

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B. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information

CMS is requesting comment on how CMS can stratify quality measures in hospital reporting programs so clinicians can identify areas to advance health equity; results will be reported privately to clinicians.

Comment is requested on:

- *Overarching goals for measuring disparity that should be considered across CMS quality programs, including the importance of pairing stratified results with overall measure results to evaluate gaps in care among groups of patients attributed to a given healthcare provider and comparison of care for a subgroup of patients across healthcare providers.*

We strongly support the paired approach, as it will yield more meaningful results and encourage CMS to report data both within and across providers. We are pleased that CMS has recognized that the way to maximize the utility of stratification is for CMS to perform uniform calculations across measures rather than to place that responsibility on individual clinicians, payers, or measure developers.

We suggest that CMS consider measures for stratification individually or by specialty rather than a one-size-fits-all approach. That is, there may be value in stratifying some specialties' measures by demographic factors and some by social risk factors. There are also likely to be significant differences in what data is available depending on the sophistication of different providers' EHRs and the level of data collection across the specialty. Non-patient-facing clinicians should not be held responsible for data that they cannot collect.

As part of the stratification of quality measures, CMS must do the following: (1) clearly distinguish between stratification and adjustment (the second IMPACT report details conditions under which stratification and adjustment are appropriate), (2) ensure that all efforts align with NQF's best practices, (3) communicate the implications of stratification, and (4) provide regular opportunities for feedback on stratification including the ability to request that stratification is changed, removed, or added based on available data (part of the proposed rule) and avoid subregulatory actions that could compromise the process. In fact, we suggest implementing a field test period as is implemented for cost measures (for example, clinicians could receive feedback reports showing what their scores would look like stratified with structured opportunities for questions and feedback).

- *Principles to consider for prioritization of measures for disparity reporting, including prioritizing stratification for: Valid clinical quality measures; measures with established disparities in care; measures that have adequate sample size and representation among healthcare providers; and, measures that consider access and appropriateness of care.*

We suggest that CMS prioritize measures with known disparities in care, outcome measures, and measures that consider access and appropriateness. This is the best mix of measures that maximize positive outcomes while also reducing the risk of providers reducing access for high-risk or marginalized patients. We caution that measures with known disparities in care should be judged carefully—that is, the disparity must be actionable, not just the quality action of the measure.

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We also suggest that prioritizing outcome measures should attribute the action to the most appropriate clinician. There is a risk of suggesting that clinicians who are not interacting with patients or who are downstream of the initial encounter have control over the risk factors.

We also agree that while stratifying measures across programs may be an eventual goal, measure context is key. In the short term, acknowledging the current state of data is essential.

- *Principles to be considered for the selection of social risk factors and demographic data for use measuring disparities, include the importance of identifying new social risk factor and demographic variables to use to stratify measures. We also seek comment on the use of imputed and area-based social risk and demographic indicators for measure stratification when patient reported data are unavailable.*

Social risk factors and demographics are distinct. Stratifying measures by one or the other will likely reveal different distributions across clinicians. Not all measures will be appropriate for stratification by both or either. Moreover, pathologists and other non-patient-facing clinicians should not be held responsible for reporting based on the presence or absence of demographic or social risk factor data, as they are not in a position to affect initial collection of such data.

In addition, CMS should also prioritize increasing collection and standardization of patient-reported data using available levers such as funding to community health practices, critical access hospitals, and other providers serving medically underserved populations. CMS should establish a process by which new social risk factors can be submitted for consideration of stratification, including which measures or types of measures they would be applicable to, and a process by which such suggestions are validated (for example, this process would establish the necessary data to support inclusion of a factor in a measure or measure type). CMS should also establish a process by which clinicians can suggest measures to be stratified if they feel their results are not representative of the care they provide.

- *Preferred ways that meaningful differences in disparity results can be identified or should be considered.*

The point of risk stratifying is to provide actionable results: consequently, we favor whichever approach provides the most relevant feedback and suggest that CMS measure action in the subsequent years. That is, we suggest that CMS measure whether disparities have improved as per the stratification.

We agree that each program will have to choose an approach that makes sense for the metrics in question but there should be some general principles such as how to interpret results—for example, if different approaches yield different levels of disparities in the same population, the various methodologies should be reconsidered.

- *Guiding principles for the use and application of the results of disparity measurement such as providing confidential reporting initially*

We strongly support confidential reporting first, especially for a new process with the sensitivity around race and ethnicity. If/when results are reported publicly, it must be with a lot of context. Furthermore, if/when sufficient data that accurately represents the current state of disparities within

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and across groups becomes available, and CMS proposes that stratified measure results be used to adjust payment, it will be critical that clinicians with a higher-than-average proportion of patients with social risk factors do not have their payment adjusted downward due to their case mix. In fact, CMS should consider a bonus structure similar to the complex patient bonus currently in use to benefit clinicians who not only improve performance on quality metrics but also close health equity gaps.

We suggest that CMS provide clinicians a chance to give feedback on both the factors chosen for stratification and the approaches to identifying differences. We also suggest that CMS consider data-driven ways to ensure that results are consistent across clinicians, programs, settings, etc. Ideally, CMS would have confidential reporting for at least two years to ensure that results are consistent and accurate and to address any issues raised in the first year. Moreover, CMS should provide webinars, surveys, and opportunities for review and comment, similar to the Cost measure field testing, to ensure that clinicians understand their results and how to address them and know when and how results will be publicly reported.

C. Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs–Request for Information

- Refined potential future Definition of dQMs. We are seeking feedback on the following as described in section IX.C.2. of the preamble of this proposed rule:
    - *Do you have feedback on the potential refined definition of digital quality measures (dQMs)?*

The CAP is concerned by the definition of digital quality measures (dQMs) because of the implications it has related to clinical registries. The updated definition states that dQMs are "self-contained measure specifications and code packages." This term could be interpreted as software that functions completely independent of any other software. Establishing dQMs as free-standing software disincentivizes the use of clinical data registries, which perform many functions beyond storing the specifications and codes for quality measures. Consequently, the CAP is concerned that the value of clinical registries will be depreciated based on CMS' clarified definition of dQMs as an essentially independent, calculative tool. Clinical registries are an important piece of the healthcare ecosystem. It is not clear how data would be stored in an accessible repository independently of registries. More importantly, registries provide essential data organization and management functions, standardize data collection and calculation, and offer feedback and quality improvement assistance to clinicians. These features are not an inherent function of dQMs as free-standing software.

Additionally, Laboratory Information Systems (LIS) are not considered certified electronic health record technology (CEHRT) because they do not meet the required criteria (drug to drug interactions, electronic prescribing, etc.). Therefore, clinical quality measures (CQM), which all CAP pathology measures are, can only be calculated outside of CEHRT as opposed to electronic clinical quality measures (eCQMs).

Lastly, most anatomic pathology data is free-form, narrative text which cannot be completely and accurately captured by LOINC. Therefore, some level of manual intervention is required for data abstraction/quality measurement compared to other types of clinical data for electronic clinical quality measures. While pathology continues to advance in data standardization, the current state of

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pathology data limits the ability to create fully digital measures to only a subset of pathology procedures.

- *Do you have feedback on potential considerations or challenges related to non-EHR data sources?*

The CAP supports CMS' decision to widen the list of acceptable data sources to include "clinical registries". However, the "meat" of anatomic pathology data is free-form, narrative text. Current semantic standards such as LOINC do not completely and accurately capture pathology data in the narrative text. Therefore, pathology data cannot be transmitted and end-to-end reported in its native state. At the moment, reporting of pathology CQMs requires initial set up with human intervention.

Lastly, the CAP understands the importance and supports standardized data. However, the current CMS' guidelines and requirements for standardized data should not be "one-size fits all".

- Data Standardization Activities to Leverage and Advance Standards for Digital Data. We are seeking feedback on the following as described in section IX.C.3 of the preamble of this proposed rule:
  - *Do you have feedback on the specific implementation guides we are considering, additional FHIR implementation guides we should consider, or other data and reporting components where standardization should be considered to advance data standardization for a learning health system?*

The CAP is not able to provide sufficient feedback on this section because the FHIR implementation guides do not apply to the CQMs of which pathology measures are comprised because LISs are not considered CEHRT.

- Approaches to Achieve FHIR eCQM Reporting. We are seeking feedback on the following as described in section IX.C.4. of the preamble of this proposed rule:
  - *Are there additional venues to engage with implementors during the transition to digital quality measurement?*

The CAP supports CMS engagement with other implementors, specifically non-patient facing specialty organizations such as the CAP, to identify ways to better capture non-standardized data in preparation for transition to dQMs and FHIR.

- *What data flow options should we consider for FHIR-based eCQM reporting, including retrieving data from EHRs via FHIR APIs and other mechanisms?*

The CAP is not able to provide feedback on data flow options for FHIR-based eCQM reporting because LISs are not considered CEHRT.

- *Are there other critical considerations during the transition?*

The CAP has outlined several critical considerations related to the standardization of data and transition to FHIR eCQM reporting in the sections above.

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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 one to; Todd Klemp (202) 354-7105 / tklemp@cap.org and for questions on section 2 to Colleen Skau at CSKAU@cap.org / 202-354-7142.

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