COLLEGE of AMERICAN PATHOLOGISTS

June 10, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1808-P
P.O. Box 8013
Baltimore, MD 21244–8013.

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

Re: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements and Other Policy Changes (CMS–1808–P) Docket RIN:0938–AV34

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-1808-P for fiscal year 2025. 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:

1. **Graduate Medical Education, Proposed Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act of 2024 (CAA) 2023**
2. **Proposed Revision to Labor Market Area Delineations and Continuation of the Low Wage Index Hospital Policy**
3. **Proposed Payment Adjustment for Certain Clinical Trial and Expanded Access Use for Immunotherapy Cases**
4. **Proposed Changes to the Calculation of the Inpatient New Technology Add-On Payment (NTAP) for Gene Therapies Indicated for Sickle Cell Disease (SCD)**
5. **Public Health eReporting RFI**

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1. **Graduate Medical Education, Proposed Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act of 2024, (CAA) 2023**

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.

Section 4122 of the CAA, 2023, requires the distribution of an additional 200 Medicare-funded residency positions to train physicians. The provision dedicates at least one-half of the total number of positions to psychiatry or psychiatry subspecialty residencies. The law requires CMS to notify hospitals receiving residency positions under section 4122 by January 31, 2026. CMS is proposing to implement policies that will govern the application and award process in line with the statutory requirements. Additionally, CMS is proposing to the extent slots are available, to focus on health professional shortage areas to help bolster the healthcare workforce in rural and underserved areas. CMS estimates that this additional funding will total approximately $74 million from FY 2026 through FY 2036.

While we understand that it is a statutory requirement that 50 percent of the additional residency positions are dedicated to psychiatry/psychiatry subspecialties, the CAP reminds the agency that specialties such as pathology are experiencing significant workforce shortages that need to be addressed.

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

Physician shortages in specialty care are significant and often overlooked by policy makers. The CAP membership continually reports that in recent years, annual demand for pathologists in the US has far outstripped the number of new pathologists entering the workforce. In 2023, only 30% of pathology practice leaders who were seeking to hire at least one or more pathologists reported that they expected to fill all open positions. The CAP believes that the CMS has not done enough to address the issue of physician shortage in this ruling.

Pathologists drive patient care decisions. When other physicians need more information about a patient's disease, they turn to pathologists to provide specific diagnoses and/or consultations for each patient. Pathologists are tasked to make accurate diagnosis and interpretations from a wide range of patient specimens including but not limited to tissue biopsies, cytology preparations and blood samples as well as data obtained from immunologic, chemical, microbiologic, and molecular testing. The critical importance of timely and accurate pathological diagnosis is recognized throughout the care continuum. Pathologists are also professionally responsible and legally accountable for the laboratory results upon which the majority of patient care relies, and for ensuring compliance with all laboratory, regulatory, and accreditation standards. The influence of pathologists' services on clinical decision-making is thus pervasive and constitutes the critical foundation for appropriate patient care. **The CAP urges the CMS to create opportunities and incentives for the pathologist workforce to expand as needed to meet population growth and**

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ageing.

2. **Proposed Revision to Labor Market Area Delineations and Continuation of Low Wage Index Hospital Policy**

The CAP recognizes that Medicare payments to hospitals (and various other provider types) are adjusted by a wage index intended to account for geographic differences across labor markets. The CMS updates the wage index annually based on hospital cost report data and other inputs and policies. This year, CMS proposes two significant changes that would affect the wage index.

A) Revised Labor Market Delineation – In FY 2025, CMS is proposing to revise the labor market areas used for the wage index based on the most recent core-based statistical area delineations issued by the Office of Management and Budget (OMB) based on 2020 Census data. In the rule CMS stated that using the revised delineations will create a more accurate representation of current geographic variations in wage levels and increase the integrity of the IPPS.

B) Low wage Index Hospital Policy - Under the FY 2020 IPPS/LTCH PPS final rule, CMS finalized a temporary policy to address wage index disparities affecting low-wage index hospitals, many of which are rural hospitals. This policy increased wage indexes for hospitals with a wage index below the 25th percentile by half the difference between the hospital's wage index and the 25th percentile wage index. This temporary policy started in FY 2020; the data collected was significantly impacted due to the COVID-19 public health emergency (PHE) As a result the agency considers the first three years of data collected not usable. Instead, that agency wants to reset by using data starting with FY 2024 which was the first full year of data following the end of the PHE, giving CMS four years of usable data to evaluate the program, as originally intended. Accordingly, CMS proposes to continue the low-wage hospital policy for at least three years beginning in FY 2025. **The CAP supports these proposals to update the wage index and urges the CMS to finalize these changes.**

3. **Proposed Payment Adjustment for Certain Clinical Trial and Expanded Access Use for Immunotherapy Cases**

Beginning in 2021, CMS created a new MS-DRG to capture hospitals cases that includes procedures for CAR T-cell therapies. MS-DRG 018 has a relative weight that is reflective of the typical costs of providing CAR T-cell therapies in the inpatient setting. However, the agency recognized that clinical trial cases, of which there are many, would distort the weight of MS-DRG 018 because of the high cost of the CAR T-cell product. Therefore, the agency must account for cases of CAR T-cell therapy when the product is provided within a clinical trial. As a result, in 2025, CMS proposes to continue to exclude clinical trial cases, which do not include the cost of the CAR T-cell product itself, from the calculation of the relative weight from MS-DRG 018. This ensures that the relative weight of the MS-DRG is not artificially lowered and remains reflective of the true cost of providing CAR T-cell therapy. As we have commented in the past, the CAP believes that with its increased use, CAR-T cell therapy is an expensive evolving service that presents unique challenges for providers, patients, and the CMS. **We agree with the CMS proposal to continue to exclude CAR-T clinical trial cases from the calculation of the relative weight of the MS-DRG 018 and urge the CMS to finalize this proposal. Additionally, the CAP urges the CMS to continue to take issues such as the use of CAR-T in clinical trials into account as the agency updates the**

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MS-DRG 018. The CAP looks forward to future collaboration with the CMS on these lifesaving therapies.

4. Proposed Changes to the Calculation of the Inpatient New Technology Add-On Payment (NTAP) for Gene Therapies Indicated for Sickle Cell Disease (SCD)

In this rule, the CMS proposed increasing the NTAP percentage from 65 percent to 75 percent of the estimated costs of the new technology for gene therapies indicated and used for the treatment of sickle cell disease beginning in FY 2025 and ending at the conclusion of the newness period of the therapy. CMS notes that further facilitating access to these gene therapies for Medicare beneficiaries with SCD may have the potential to simultaneously improve the health of impacted Medicare beneficiaries and potentially lead to long-term savings in the Medicare program. The agency also notes that some gene therapies that treat SCD are among the costliest treatments to date and is concerned about a hospital's ability to sustain a potential financial loss to provide access to such treatments. This proposed change would be consistent with the maximum amount for qualified infectious disease products that otherwise qualify for NTAP.

Additionally, the agency also seeks comment on whether it should make this proposed 75 percent add-on payment percentage available only to applicants that meet certain additional criteria, such as attesting to offering and/or participating in outcome-based pricing arrangements with purchasers (without regard to whether the specific purchaser availed itself of the outcome-based arrangements) or otherwise engaging in behaviors that promote access to these therapies at lower cost.

The CAP supports the proposed increase the NTAP percentage from 65 to 75 percent of the estimated costs of the new technology for gene therapies indicated and used in the treatment of sickle cell disease and urges the agency to finalize this proposal. The CAP does not support making this proposed increase contingent on applicants meeting additional criteria or engaging in behaviors that promote access to these therapies at a lower cost. The agency has already acknowledged that these gene therapies for SCD have the potential to improve the health of the impacted beneficiary, leading to long-term savings in the Medicare program; adding additional criteria would likely reduce access to these therapies.

5. Public Health eReporting RFI

- Should CMS shift to numerator/denominator reporting requirements for current and future measures in the Public Health and Clinical Data Exchange objective? If so, should CMS prioritize only certain measures for numerator/denominator reporting?
    - In addition to the burden created by switching to numerator/denominator reporting, we caution against any shifts that could muddy the distinction between Promoting Interoperability measures and Quality measures. The PI category is intended to drive increased interoperability and it is difficult to see how numerator/denominator reporting would achieve that objective.
- Should CMS create a new measure for each new type of data or use case added to the Public Health and Clinical Data Exchange objective? What are the risks of including too many measures under the objective?

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  - In order to avoid exacerbating workplace burnout, we advocate for ways to reduce burden as much as possible while achieving quality and public health objectives. In this case the value of increasing the burden is unclear. We would need to understand what benefits CMS and hospitals would derive from shifting to numerator/denominator reporting before being able to judge if there is sufficient benefit to the increased burden.
  - With respect to the risks, in addition to the aforementioned burden, too many measures dilute the value of any single measure, both in terms of points and in terms of the ability of facilities to identify areas of improvement. Also unclear whether these would all be required measure or optional measures. Currently there are 5 required and 2 optional measures under this objective (all attestation only). Increasing the number could add confusion as well.
- Alternatively, should CMS explore ways to group data types and use cases under a more limited set of Public Health and Clinical Data Exchange objective measures?
  - Clinical laboratories may have problems collecting the required data elements if requirements are expanded to include reporting of laboratory results with some new data elements that have not historically been required and may not be in many information systems currently. Some required data elements are not tracked in many if not all information systems (e.g., FDA Unique Device Identifier, the actual zip code of the ordering provider). In addition, several data elements lack enough clarity with conflicting information regarding required vs. optional items for reporting.
  - Clarify and specify minimum necessary. The Office of Civil Rights (OCR) should release a clarification that public health usage covers the exchange of personal information as part of laboratory orders and results, and that these data fall within the minimum necessary standard.
- What potential benefit versus burden trade-offs CMS should consider? How should CMS account for varying levels of public health readiness and capacity for expanding conditions reported electronically, such as in rural areas?
  - A: Regarding the potential benefit versus burden trade-off, our position is the same as in the response to the questions above “Should CMS create a new measure for each new type of data or use case added to the Public Health and Clinical Data Exchange objective?”
  - With respect to varying levels of readiness, we suggest that new measures be optional (bonus points only) at least at the beginning, and for an extended period of time and with additional incentives for CAHs/rural hospitals.
- Q: What additional levers besides the Medicare Promoting Interoperability Program should CMS explore to improve the completeness of reporting to public health? How should CMS work with other partners to incentivize or require reporting?
  - Allocate government funding explicitly for the purpose of making such reporting feasible. This could include grants to help hospitals, laboratories, and public health authorities upgrade their systems. Priority for federal funding should be inverse to any resource capability of the laboratory so that financially weaker laboratories are eligible for the most federal resources.
- How can the Medicare Promoting Interoperability Program balance robust Public Health and Clinical Data Exchange objective requirements with our desire to reduce burden on eligible hospitals and CAHs?
  - Align incentives to encourage standards usage. Currently, payment programs such as Promoting Interoperability provide financial incentives for using certified EHR

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technology to achieve certain functions. One measure within the Promoting Interoperability program is to electronically submit laboratory results to public health agencies. However, there is not an associated standard of use, or a data completeness requirement, as part of the measure. Centers for Medicare and Medicaid Services (CMS) could incentivize the use of ONC-identified standards, such as using the USCDI demographic data set when exchanging laboratory orders and results, within Promoting Interoperability or other payment programs. Incentives should be available for all stakeholders, including laboratories and public health, in order to ensure resources are available for needed system upgrades.
    - Ensure that laboratories are not penalized if they don't get the correct or full demographic data in the test order. The responsibility for collecting the correct demographic data lies with the ordering physician, and the ordering physician must ensure that data is collected and exchanged accurately and in its totality.
- How can new technical approaches to data exchange with PHAs, such as the use of FHIR APIs, reduce burden for health care providers? What are potential barriers to achieving burden reduction as these new approaches are implemented?
    - Moving to FHIR-based laboratory data exchange would be costly in that it would require replacement of existing interfaces. Additionally, FHIR is not ready for laboratories, as FHIR does not yet cover the full set of laboratory use cases needed for reporting to PHAs.

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 regarding our first four items to: Maurine Dennis (202) 354 – 7136 / mdennis@cap.org or Todd Klemp (202) 354-7105 / tklemp@cap.org. Questions about item 5. Public Health eReporting RFI should be directed to Andrew Northup (202-354-7128 / anorthu@cap.org

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