COLLEGE of AMERICAN PATHOLOGISTS

July 10, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health and Human Services
Attention: CMS–1735–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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals; (CMS–1735–P)

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the hospital Inpatient Prospective Payment System (IPPS) proposed rule CMS-1735-P for fiscal year 2021. 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. J. Market-Based MS-DRG Relative Weight Proposed Data Collection and Potential Change in Methodology for Calculating MS-DRG Relative Weights
2. Chimeric Antigen Receptor (CAR) T-Cell Therapies

1. Market-Based MS-DRG Relative Weight Proposed Data Collection and Potential Change in Methodology for Calculating MS-DRG Relative Weights

In response to recent executive orders on price transparency, traditional Medicare, and the Medicare Advantage (MA) program, the CMS proposes to collect MA and third-party payer MS-DRG data and utilize it to calculate new relative MS-DRG weights. The data would be collected by requiring hospitals to report the median payer-specific negotiated rates for inpatient services, by MS-DRG, for MA organizations and third-party payers on the Medicare cost report. The agency notes that hospitals will be required to make this information public in accordance with the Hospital Price Transparency Final Rule. The CMS argues that these proposals will achieve the agency's goals of reducing Medicare's reliance on the hospital chargemaster and "support the development of a relative market-based payment methodology under the IPPS."

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The CAP has previously commented that while we support providing patients with access to appropriate price information prior to services, we have serious concerns about price transparency requirements that risk patient harm and/or that are administratively and practically difficult to implement.[1] With the CMS's current proposal to use MA and third-party payer price information to rework the payment methodology under the IPPS, we now have further concerns. Negotiated rates take into account a number of unique circumstances between a private payer and a hospital and simply are not relevant for fixing fee-for-service Medicare reimbursement. Specifically, the CMS recognizes and includes a hospital payment for the professional component of clinical pathology ("PC of CP") services, while payments for these services by the payers whose rates are proposed to serve as the basis for revised MS-DRG rates are typically separately billed and paid apart from the DRG payment. **The CAP is therefore very concerned 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 PC of CP services.**

Medicare currently includes payment for PC of CP services for hospital inpatients in the fixed amount that Medicare pays to the hospital for each patient under Medicare Part A. Medicare pays each hospital based on each patient's diagnosis related group or DRG. A payment amount is assigned to each DRG, which is intended to cover a variety of services that may be received by the patient, including professional component services of clinical pathology services. Hospitals are then to compensate pathologists for such services at fair market value for such services.

The CAP's "Policy on Pathologist Professional Component Billing for Clinical Pathology Services" describes the nature and type of professional services provided by the physician director of a clinical laboratory. Among those services, pathologists in their capacity as physician medical directors of clinical laboratories provide valuable and necessary medical services for all patients for which they assume medical responsibility and legal liability. Pathologists as directors of hospital laboratories spend a significant amount of time and effort in fulfilling their responsibility to the patient and to their fellow practitioners for quality laboratory services. The pathologist is professionally responsible and legally accountable for laboratory results. To prepare for this responsibility, the pathologist must complete a lengthy medical residency program. Moreover, Federal certification standards and The Joint Commission standards require certain professional, organizational and administrative services be provided in the clinical laboratory to assure quality laboratory services to patients. A pathologist as a physician medical director of a hospital clinical laboratory provides professional services in:

- Assuring that tests, examinations, and procedures are properly performed, recorded and reported;
- Interacting with members of the medical staff regarding issues of laboratory operations, quality, and test availability;
- Designing protocols and establishing parameters for performance of clinical testing;
- Recommending appropriate follow-up diagnostic testing;
- Supervising laboratory technicians and advising technicians regarding aberrant results;
- Selecting, evaluating, and validating test methodologies;
- Directing, performing, and evaluating quality assurance and control procedures;
- Evaluating clinical laboratory data and establishing a process for review of test results prior to issuance of patient reports;

[1] https://documents.cap.org/documents/CAP-CMS-9915-P-Comments.pdf

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- Assuring the hospital laboratory's compliance with state licensure laws, Medicare conditions, The Joint Commission standards, the College of American Pathologists Laboratory Accreditation Program and federal certification standards.

Laboratory medical directors are critical to the analysis of laboratory trends and utilization to prevent overuse and inappropriate use of laboratory tests. They also are educators to physicians and patients regarding test results and interpretations. The significance of these services has warranted their payment under both the CMS and American Medical Association (AMA) practices and guidelines. Payment for these services is also consistent with the results of recent litigation. For the CMS to change the MS-DRG payment methodology in a way that would implicitly fail to recognize the appropriate reimbursement for these services would prove detrimental to patients, as such services may not be paid other than by billing individual patients for them, as is presently the case for other payers whose hospital payments are proposed to be used as the basis for Medicare hospital payments.

Under Part A, Medicare provides reimbursement for, among other medically necessary services, "professional services which are rendered for the general benefit to patients in a hospital or skilled nursing facility" (Vol. 48 of the Federal Register, at page 8904). The professional component of clinical pathology services is a prototypical example of the services described by Medicare as provided for the general benefit of all patients.

The CAP urges 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. This proposed use of privately negotiated rates will not further the CMS' goal of paying market rates that reflect the cost of delivering care, and could in particular do more harm in potentially excluding the professional component of clinical pathology. Further, this proposal jeopardizes private contractual arrangements which could threaten the financial viability of hospital laboratories, hospitals, and the physician's practices employed by hospitals. Negotiated rates take into account a number of unique circumstances between a private payer and a hospital and simply are not relevant for changing fee-for-service Medicare reimbursement. Hindering access to high-quality pathology services through reduced rates or failing to pay for pathology and laboratory services adversely affects patient diagnosis, treatment, and outcome. Now more than ever, during this national health crisis, patients and their treating physicians recognize their reliance on the expertise of pathologists as the directors of clinical laboratories and the availability of appropriate testing that their professional work assures.

2. Chimeric Antigen Receptor (CAR) T-Cell Therapies

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. The CMS' proposal modifies its relative weight methodology and creates a new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), which would have a proposed relative weight of 37.1412 that better reflects the high cost of the therapy. Specifically, the CMS proposes that clinical trial claims that group to the proposed new MS-DRG 018 would not be included when calculating the average cost used to calculate the relative weight for this new MS-DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. The CMS also proposes to discontinue new technology add-on payments for the two CAR T products currently

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available. The CAP expresses its appreciation with the agency's creation of a new MS-DRG for CAR-T therapy that solidifies a payment methodology that provides coverage and reimbursement certainty for these critical services.

The CAP is supportive of the steps the CMS is proposing to help ensure that physicians and institutions are being reimbursed for the care provided by excluding clinical trial cases and claims with pharmacy charges less than $373,000 when calculating the weight of this new proposed MS-DRG. However, the CAP remains concerned that more and better data is needed to determine an appropriate weight for the new MS-DRG.

Analyses performed by the American Society of Hematology (ASH) and the American Society for Clinical Oncology (ASCO) indicate the reimbursement rate is still insufficient to cover the cost of CAR-T therapy and related services, leaving providers with a financial loss. According to ASCO, the proposed reimbursement rates for FY2021 will result in a financial loss to providers of approximately $180,000 per patient case. This level of reimbursement is unacceptable and will likely result in fewer services provided and more limited access to these life-saving cancer targeted treatments. **The CAP urges the CMS to reconsider its payment methodology and increase the reimbursement for CAR-T cell therapies.** 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. The CAP urges the CMS to continue to analyze claims and recognize the significant costs of these patients when admitted to the hospital.

Pathologists play a critical role as integral members of the cancer patient management team during CAR T-Cell therapy. In addition to contributions 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 a high cost 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 that may increase toxicity. The CAP urges the CMS to take these issues into account as the agency updates the new proposed MS-DRG overtime.

Thank you again for the opportunity to comment on this proposed policy. 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 to; Todd Klemp (202) 354-7105 / tklemp@cap.org or Elizabeth Fassbender (202) 354-7125 / efassbe@cap.org.

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