COLLEGE of AMERICAN PATHOLOGISTS

October 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–1736–P
P.O. Box 8013
Baltimore, MD 21244–1850

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

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician- Owned Hospitals (CMS–1736–P), (RIN 0938–AU12)

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs proposed rule CMS-1736-P for calendar year (CY) 2021. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP services 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 make them a critical member of the patient's health care team.

This letter includes comments regarding the following issues:

1. Proposed Revision to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs
2. Status Indicator Assignment for CAR-T Category III CPT Codes 0537T – 0539T

1) Proposed Revision to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs

The CMS proposes to exclude cancer-related protein-based Multianalyte Assays with Algorithmic Analysis (MAAAs), which are generally not performed in the hospital outpatient setting, from the Hospital OPPS packaging policy and add them to laboratory DOS provisions instead. MAAAs would then be reimbursed under the Clinical Laboratory Fee Schedule (CLFS) rather than the Hospital OPPS. Such tests would have to meet the DOS requirements with the testing lab directly billing Medicare for the tests. **The CAP supports this proposal and asked that it be finalized for CY 2021.**

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2) Status Indicator Assignment for CAR-T Category III CPT Codes 0537T – 0539T

For CY2021, the CMS has proposed not to change the status indicators for category III CPT codes 0537T–0539T from "B" to a "Q1" status as requested and recommended last year by the American Society of Hematology and the CMS Advisory Panel on Hospital Outpatient Payment. Changing the status indicators from "B" to "Q1" would allow these patient services to be eligible for payment on the condition that no other procedures or visits were provided on the same claim. Providers could then report these services in a manner consistent with normal practice. Currently, providers are not able to report codes 0537T-0539T because their Medicare Status indicator is "B" which requires CMS to reject the claim upon receipt. CMS has released specific coding and billing guidance to providers instructing them to hold any outpatient claims with codes 0537T-0539T until the infusion code 0540T is reported on the patient's inpatient claim. This allows these outpatient services to be counted towards the patient's total covered billed charges, and therefore significantly deviating from standard coding and billing practice. By assigning a payable status indicator, CMS will enable hospitals to bill and be paid appropriately for the services they provide during each step of the CAR-T process, regardless of when or where the service is provided. Streamlining the coding and billing of new services and instructing providers on how to code and bill correctly is critical for providers to be paid appropriately both today and in the future. **The CAP urges the CMS to change the status indicators for category III CPT codes 0537T–0539T from "B" to a "Q1" status.**

The CAP also requests that CMS work with the Healthcare Common Procedure Coding System (HCPCS) group to modify the description of the two CAR-T Q codes, Q2041 and Q2042, to separate the cell collection and cell processing services from the product itself. This will allow these physician services to be reported consistent with coding and billing practices and will make the data available to the agency as it sets future payment rates.

The CAP understands that the CMS has not changed the status indicator for the CPT codes because the descriptions of the two CAR-T Q codes Q2041 and Q2042, both include leukaphresis and other dose preparation services." The agency believes that reimbursement for these physician services is provided through the Q codes and therefore is not needed through CPT codes 0537T-0539T. However, neither the providers nor the manufacturers consider the cell collection and processing services (represented by codes 0537T-0539T) to be part of the manufacturing process for CAR-T, and consequently, the manufacturers do not reimburse physicians for these services from the payment provided when either Q code is billed. The CAP asks that CMS identify the specific statutory language in the Public Health Services Act that is guiding these coding and billing decisions.

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The College of American Pathologists is pleased to have the opportunity to comment on issues and appreciates your consideration of these comments. Please direct questions on these comments to; Todd Klemp (202) 354-7105 / tklemp@cap.org.

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