COLLEGE of AMERICAN PATHOLOGISTS

June 24, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1716–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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; (CMS–1716–P)

Dear Administrator, Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1716-P for calendar year (CY) 2020. 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 is recognized throughout the care continuum and affects many patient encounters.

**This letter includes comments regarding the following issues:**

1. Interoperability Between Hospital Electronic Health Records (EHRs) and Laboratory Information Systems (LIS) and Clinical Data Registries
2. Proposed Revision of the Calculation of the Inpatient Hospital New Technology Add-On Payment
3. Chimeric Antigen Receptor (CAR) T-Cell Therapies/Kymriah and Yescarta

**1. Interoperability Between Hospital Electronic Health Records (EHRs) and Laboratory Information Systems (LIS) and Clinical Data Registries**

Pathologists participating in the Merit-based Incentive Payment System (MIPS) need to report performance on quality measures. As CMS eliminates claims-based measures, pathologists become disadvantaged in the program because it is difficult or impossible to access data from hospitals' EHRs and Laboratory Information Systems (LIS). Pathologists need access to hospital-owned data to support their ongoing participation in MIPS. As pathologists working in and supporting hospitals, we should have access to our patient's data in the hospital's EHR and LIS. However, in many cases, this does not occur or is made extremely difficult. For example, a large number of pathologists that use the CAP's clinical data registry, the Pathologists Quality Registry, to report quality measures do not receive any data from their hospitals.



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Data from hospitals includes critical information such as laboratory tests and utilization, turnaround times, blood product utilization, cancer diagnostic workups, etc. Without such data elements, these measures cannot be fully calculated and scored. Although hospitals claim that they cannot share the data for privacy and security purposes, CMS has indicated that there are no regulations that impede hospitals from doing so. In addition, each hospital sets its own legal requirements for accessing data, so this becomes a significant resource issue for pathologists, registries, and the hospitals themselves (since multiple specialties presumably approach the hospitals for data). The lack of data availability from hospitals is a significant resource problem for the system as a whole (nobody wins), and a particular problem for pathologists.

Since this is a serious issue for hospital-based clinicians, we encourage both the Office of the National Coordinator (ONC) and CMS to come up with potential solutions to help improve the flow of information between hospital EHRs, LISs, and registries. However, the CAP also supports that hospitals, physicians, and laboratories be held harmless from unintended data breaches that may result from improved and increased interoperability. As such, we support the ONC's Information Blocking exception *Promoting Security of EHI (§ 171.203)* to the Information Blocking provision as proposed in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule. The CAP supports ONC's efforts to promote the security of Electronic Health Information (EHI), as long as hospitals do not inappropriately deny access to their data based on the false premise that such transfer of data somehow violates the Health Insurance Portability and Accountability Act of 1996 (HIPAA). To resolve this seeming conflict, the CAP urges the CMS and ONC to develop a hold harmless provision available to both owners and users of these data (hospitals, physicians, laboratories, etc.) for purposes of MIPS reporting, which will remove this obstacle to improved and increased interoperability.

**2. Proposed Changes to the Calculation of the Inpatient Hospital New Technology Add-On Payment**

The CMS also seeks comment on its proposal to modify the current inpatient hospital new technology add-on payment (NTAP) to increase the amount of the maximum add-on payment amount to 65 percent. Therefore, if the costs of a discharge involving a new technology exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare would make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology, or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. The CAP agrees with the agency that, in many cases, the current maximum add-on payment amount no longer provides enough incentive for the use of new technology. We also believe it is appropriate to modify the current payment mechanism to increase the amount of the maximum add-on payment to at least 65%. However, the CAP believes that the increase to 65% is insufficient to encourage hospitals to adopt new technologies. The CAP therefore recommends the payment amount percentage be 80% and that there may be instances where the payment amount needs to exceed 80%, to account for new medical services and technologies that inflict significant costs upon providers. In addition, public comment should be allowed on new medical services and technologies that would receive new technology add-on payment amounts above 80%.

**3. Chimeric Antigen Receptor (CAR) T-Cell Therapies/Kymriah and Yescarta**

Pathologists play a critical role as integral members of the cancer patient management team during Chimeric Antigen Receptor (CAR) T-Cell therapy. In addition to contributions in initially diagnosing diseases and monitoring disease persistence and recurrence, pathologists are also directly involved



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in 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. In CMS' proposed rule, CMS seeks comments on payment related components for CAR-T therapy and the CAP provides the following comment to improve and secure patient care.

Within this inpatient proposed ruling, the agency states it should collect more clinical and cost data before considering assignment of a new MS-DRG to these therapies, and the CAP agrees. The CAP agrees with the CMS that it is premature to create a new MS-DRG specifically for cases involving CAR T cell therapy for FY 2020, and recommends that the agency finalize its proposal not to modify the current MS-DRG assignment for cases reporting CAR-T cell therapies (MS-DRG 016 Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy) for FY2020, collect further data as more claims become available, and continue new technology add-on payments for discharges through FY2020.

Additionally, during the data collection period, the CAP urges the exclusion of clinical trial cases in the calculation of the MS-DRG as their costs vary widely because of the differing billing and charging practices, and they often disproportionately represent only the costs associated with delivery of these therapies. Clinical trial claims data is not representative of the average cost of the case for CAR-T or any other services.

In the proposed rule, CMS also seeks comment on a payment alternative for CAR-T cases that could include eliminating the cost to charge ratio (CCR) in calculating the new technology add-on payment for the two currently approved FDA therapies by making a uniform add-on payment that equals the proposed maximum add-on payment that is 65 percent of the cost of the technology. For these services, the CAP agrees with the agency's payment alternative to increase the amount of the new technology add-on payment. However, for these CAR-T therapies and other new technologies, the new technology add-on payment should be 80% to assist and encouraging these very costly life-saving services.

In light of the unique experience with billing, pricing, and payment for cases involving CAR T-cell therapies to Medicare patients, CMS seeks comment on whether to utilize a specific CCR for ICD–10–PCS procedure codes used to report the performance of procedures involving the use of CAR T-cell therapies. CMS offers an example of a CCR of 1.0, when determining outlier payments, when determining the new technology add-on payments, and when determining payments to IPPS-excluded cancer hospitals for CAR T-cell therapies. Since hospitals would be unlikely to set charges different from the costs for the products and services associated with CAR-T therapy, the CAP recommends a CCR of 1.0 for determining outlier payments and when determining payments to IPPS-excluded cancer hospitals for CAR T-cell therapies. This payment alternative should result in a higher outlier payment, higher new technology add-on payment, or the determination of higher costs for IPPS-excluded cancer hospital cases. The CAP believes a CCR of 1.0 for CAR T-cell therapies will provide for fair and adequate reimbursement for the new technology add-on payment.

Lastly, the agency asked whether a disproportionate share hospital (DSH) and an indirect medical education (IME) adjustment should be made for cases assigned to any new MS-DRG for CAR-T cell therapy as they are very costly infrequent services at this time that can lead to very high additional payments for CAR-T cell therapy cases. The CAP believes these important adjustments are beneficial essentially to all patient care and medical training. The elimination of these add-on payments for CAR-T services entirely would be unwise and the CAP recommends that some level of



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assistance should still be provided to hospitals that rely upon DSH and IME payment to successfully treat the underserved populations and train sorely needed physicians.

Thank you again for the opportunity to comment on this proposed policy. CAP welcomes the opportunity to work with CMS to address these important issues that affect the medical care of beneficiaries. The College of American Pathologists appreciates the opportunity to comment on issues and your consideration of these comments. Please direct questions to; Todd Klemp (202) 354-7105 / tklemp@cap.org.

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