COLLEGE of AMERICAN PATHOLOGISTS

September 24, 2018

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–1694–P, P.O. Box 8011
Baltimore, MD 21244–1850

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

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; (CMS–1695–P), (RIN 0938–AT30)

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-1695-P for calendar year (CY) 2019. As the world's largest organization of board-certified pathologists and leader 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 affect many patient encounters.

This letter includes comments regarding the following issues:

1. Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services
2. Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider
3. Policies that Promote Accurate, Appropriate Payments for Stem Cell Transplants
4. Request for Information on Promoting Interoperability and Electronic Health Care Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare-Participating and Medicaid-Participating Providers and Suppliers
5. Chimeric Antigen Receptor (CAR) T-Cell Therapy
6. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

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7. Revising CMS' Date of Service (DOS) Policy for CY 2019 to Exclude FISH Services from Packaging Policies
8. Pathogen Reduced Platelets Payment Rates

1. Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services

The CMS proposes to expand the site-specific physician fee schedule (PFS) payment rate (set based on the PFS Relativity Adjustment to the Outpatient Prospective Payment System (OPPS)) to apply to clinic visit services reported under HCPCS code G0463 for all excepted off-campus provider-based departments (PBDs), in addition to the previously nonexcepted PBDs. This proposal is driven by the Agency's concerns regarding perceived shifts in settings of care and overutilization in the hospital outpatient setting. The CAP does not believe that CMS should finalize this proposal as it could result in inadequate payment rates for services furnished in off-campus PBDs.

In addition to this proposal, the CMS is seeking input on how the Agency can expand the application of Secretary's authority under section 1833(t)(2)(F) of the Social Security Act.

The CAP appreciates and supports CMS' concerns about controlling medically unnecessary or clinically inappropriate increases in the utilization of hospital outpatient services. However, we would urge caution against applying methodologies under the broad language of Social Security Act 1833(t)(2)(F) that are not consistent with the specific methods set forth under the Social Security Act for the OPPS. In general, the CAP is concerned that utilization programs, prior authorization protocols, and other volume control methods that dictate or limit health care provider decision-making may impinge on the practice of medicine and could improperly encumber and curtail medically necessary clinical laboratory and pathology services.

The CMS already has implemented significant tools to manage utilization – especially for the technical components of physician pathology services—through packaging policies and the creation and expansion of comprehensive Ambulatory Payment Classifications (APCs), which CMS has introduced over the past several years.

Still, the CAP emphasizes that the packaging policy of pathology add-on services that bundle all add-on services into the base code APC is extremely restrictive on the provision of pathology services. Specifically, when certain add-on services are performed on a particular patient case multiple times without separate payment, a significant loss is incurred. As a clinical example, CMS' packaging policies do not allow for the appropriate application of immunofluorescence to medical renal biopsies, which account for a significant percentage of the total use of CPT Code 88350. According to the Renal Pathology Society's *Practice Guidelines for the Renal Biopsy*, there are at least 9 antigens that need to be examined with immunofluorescence. These antigens may include: immunoglobulins (primarily IgG, IgM and IgA), complement components (primarily C3, C4, and C1q), albumin, fibrinogen, and kappa and lambda light chains. In cases such as these, it is clear that a loss is incurred when this patient service is provided as CMS' status indicator for CPT code 88350 is equal to "N." The CAP believes that because of CMS' packaging policies, these and other types of pathology services, with status indicators equal to "N," are not reimbursed properly to the laboratory providers, which may hamper patient access to care. **The CAP therefore urges the Agency to**

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change the status indicators of pathology add-on codes from "N" to "Q2," as each unit of service of an add-on pathology service involves separate and distinct laboratory work. A status indicator of "Q2" provides for an APC assignment when the services are separately payable.

Other mechanisms to manage utilization, such as prior authorization, would require a substantial infrastructure to establish fairly and reasonably without unnecessarily burdening patient access. Such managed care mechanisms would require consideration of several factors (patient factors, environmental factors) that may support referral for particular procedures to hospital outpatient departments rather than other settings of care. Before CMS considers the adoption of such mechanisms in the outpatient setting, it should consider how it would address these other factors and whether any potential savings from reduced service utilization or shifts to other settings of care would be offset by beneficiary loss of access as well as increased transaction costs for CMS and providers. Again, the CAP believes that such programs may pose an unnecessary procedural encumbrance upon the practice of medicine with the potential to improperly curb medically necessary testing.

2. Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

In the Proposed Rule, the CMS proposes to limit the expansion of clinical families that would be covered outpatient department services for excepted off-campus PBDs. Specifically, if an excepted off-campus PBD furnishes services after January 1, 2019 that were not part of any clinical family of services for which it furnished services during the baseline period (defined as November 1, 2014 through November 1, 2015), these services would not be considered outpatient department services and would be reimbursed subject to the PFS Relativity Adjustment to the OPPS rate.

The CMS is also seeking comments on alternate methodologies to limit the expansion of excepted services such as a proposal from MedPAC to establish a baseline volume for each excepted off-campus PBD and cap the volume of services (regardless of the clinical families). Any services above that cap for that specific facility would no longer be considered covered outpatient services but would be reimbursed subject to the PFS Relativity Adjustment to the OPPS rate. The CAP opposes such a policy and urges the Agency not to pursue this methodology.

Most physician pathology services are conditionally packaged under the OPPS rules (status Q1 or Q2) and are paid separately only when these services are not furnished with other services to which they are packaged. We assume that when physician pathology services are represented as a new clinical family furnished by an excepted off-campus PBD and are packaged with items and services that are not from new clinical families, CMS would pay the full OPPS rate for these services and would not attempt any adjustment or offset to reflect the portion of the packaged payment that represents a new clinical family. Otherwise, there would be potentially myriad rates that could apply considering all of the various combinations of established and new clinical family services that could be furnished. In addition, given that packaging already provides strong incentives to furnish services only when medically necessary and appropriate and as efficiently as possible, any further reduction in payment for these services would likely penalize providers who perform these services when appropriate and necessary in excepted off-campus PBDs.

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Site specific payment policies are the most appropriate way to pay for any service as they accurately account for the resources used. The CAP opposes the CMS proposal that would expand the site-neutral payment policy to pathology services when these are offered alone and represent a new clinical family offered by excepted off-campus PBDs. When these services are furnished alone, it is critical that the payments reflect the costs required to furnish these services consistent with the cost data used to establish OPPS rates. If these services are paid by applying the PFS Relativity Adjustment, the off-campus PBDs would be receiving only a small fraction of their costs for furnishing these services. Because these services are typically packaged, there already are restraints on the utilization of physician pathology services in off-campus PBDs. Before CMS considers applying the PFS Relativity Adjustment to physician pathology services when offered alone as a new clinical family at excepted off-campus PBDs, the CMS should monitor utilization to see if there is, in fact, any reason to be concerned about excess utilization of these services in this setting. It is vital that changes with this impact are justified with data to ensure that access to care is not unnecessarily hindered.

3. Policies that Promote Accurate, Appropriate Payments for Stem Cell Transplants

A. Comprehensive APC (C-APC) for Autologous Stem Cell Transplant.

The CAP agrees with the AABB's support for the C-APC for allogeneic stem cell transplant, which CMS introduced in CY 2017, and believe that the CMS should pursue a similar strategy for autologous stem cell transplant. A C-APC for autologous stem cell transplant would improve the accuracy of reimbursement and is appropriate because the primary procedure is often furnished on the same date of service as other ancillary, supportive and adjunctive services. For 2019, from the AABB, we understand that the CMS was able to use only 14 single procedure claims out of 379 total claims to set the APC payment rate for autologous stem cell transplant (CPT code 38241). If CMS uses all claims associated with autologous stem cell transplant, it will improve the accuracy of the reimbursement rate for this important service.

B. Recalculation of Reimbursement Rate for Allogeneic Transplantation of Hematopoietic Progenitor Cells (C-APC 5244)

The CAP supports the concerns of the AABB, America's Blood Centers and the American Red Cross which believe that CMS' proposed 2019 payment rate for allogeneic transplantation of hematopoietic progenitor cells (C-APC 5244) is flawed due to potential errors in the rate-setting process. We are concerned that CMS may have unintentionally left out important packaged costs from the rate-setting calculation, including donor search and cell acquisition costs that were historically reported with revenue code 0819, but which are now reported with the newly released revenue code 0815. Although this revenue code requires a HCPCS code, HCPCS codes are not typically reported and many payers, including CMS, do not edit for it. For the development of the C-APC 5244 payment rate, CMS included all line items of revenue code 0819 irrespective of the presence of a HCPCS code on that line. The CMS should apply the same reasoning to revenue code 0815.

Revenue code 0815 was released for use in 2017, and therefore it appears for the first time in claims used to set reimbursement rates for 2019. It appears that the CMS intended to ensure that the allogeneic C-APC payment rate reflected donor search and acquisition costs when the agency

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established C-APC 5244 and the edit requiring the presence of revenue code 0815 when CPT code 38240 is billed on outpatient claims. While CMS used all 36 single procedure claims for setting the payment rate, the agency only used the revenue code 0815 line item from the 19 claims that had both revenue code 0815 and a HCPCS code report (typically 38204). We encourage CMS to add revenue code 0815 to its packaged revenue code list as a technical rate-setting correction, and recompute the payment rate for C-APC 5244 for CY 2019 using all claims with revenue code 0815. We believe that this will result in a more accurate payment rate that is reflective of all donor search and cell acquisition costs.

If CMS intends to require hospitals to report a HCPCS code with revenue code 0815, we encourage CMS to release detailed instructions to providers and establish a claims edit for the future. If this is the case, we recommend that CMS specify that HCPCS code 38240 is the appropriate code to report.

C. Cost Reporting Instructions for Cost Report Line 0077

Although CMS established cost center 77 to capture donor search and cell acquisition costs as of January 1, 2017, the CAP agrees with AABB's concerns that the Agency has not yet provided any instruction to hospitals regarding how to correctly aggregate donor search and cell acquisition costs to this cost center. It is relatively easy to identify donor expense for unrelated donor cells, which are a purchased service from the National Marrow Donor Program (NMDP) and individual invoices for these services are sent to the hospital. Alternatively, providers work up related donors (i.e., siblings or other family members) in-house, and do not have guidance on how costs should be reclassified from individual departments that treat related donors (i.e., lab, clinics, etc.) and then aggregated in cost center 77.

While section 231.11.1 of Chapter 4 of the Medicare Claims Processing Manual includes information on donor search and cell acquisition charges, there are no specific instructions regarding how a hospital should reclassify to cost center 77 the expense associated with related donor services from the departments that treat related donors. The revenue for these services are typically posted to each individual donor's patient account under typical department revenue codes (e.g., 300 for lab) and held, due to CMS' instructions that they be billed under revenue code 0815 on the recipient's transplant claim. The original related donor charges on individual donor patient accounts can be used by the hospitals at cost reporting. By applying the respective department's Cost-to-Charge-Ratios (CCRs) to the donor charges by department, the resulting calculated expense can be reclassified from those departments to cost center 77. The revenue billed under the departments should be removed, as this was posted on recipient's accounts under revenue code 0815.

We encourage CMS to issue detailed instructions to providers and the Medicare Administrative Contractors so the expenses in cost center 77 will be complete and accurate for both related and unrelated donors. Within these instructions, we believe CMS should specify that "physician pre-procedure donor evaluation services" should not be reported as facility costs on the hospital claim or the hospital's cost report in center 77. Rather, these physician pre-procedure donor evaluation services should be billed in real-time rather than being held until the transplant recipient's claim.

D. Donor Search and Cell Acquisition Payment Policy

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The CAP supports the AABB's concerns that the current Medicare payment policy for stem cell transplant does not adequately cover the costs hospitals incur when providing transplants in either the inpatient or outpatient settings. One significant problem is that CMS includes the cost of the cell acquisition in the MS-DRG and C-APC. We ask that CMS align its transplant policies and appropriately reimburse acquisition costs outside of the MS-DRG and C-APC payments.

4. Request for Information on Promoting Interoperability and Electronic Health Care Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare-Participating and Medicaid-Participating Providers and Suppliers

Pathologists' Contributions to Promoting Interoperability

The CAP appreciates that CMS acknowledges the importance of interoperability and health information exchange by changing the name of the Advancing Care Information performance category of the Merit-Based Incentive Payment System (MIPS) to the Promoting Interoperability (PI) performance category in the 2019 Inpatient Prospective Payment System (IPPS) proposed rule. The CAP supports the alignment of the PI category of MIPS with the Medicare and Medicaid's Promoting Interoperability (PI) Program, formally known as the "Meaningful Use" (MU) program. The CAP encourages alignment across the MIPS Promoting Interoperability performance category and PI Program, including efforts that would streamline the requirements across healthcare settings.

The CAP appreciates CMS identifying the need to address Health Information Technology (HIT) adoption and interoperability among providers that were not eligible for the Medicare and Medicaid Electronic Health Record (EHR) Incentives program, including pathologists. Pathology was one of the earliest specialties to embrace HIT. Pathologists and their laboratories have long relied on laboratory information systems (LIS) to support the work of analyzing patient specimens and generating test results, and it is with LIS that EHR or enterprise-wide clinical information systems exchange laboratory and pathology data. As such, pathologists, as medical directors, typically have significant and extensive responsibility and involvement in EHR through LIS.

Previously, as part of the MU program, pathologists were granted automatic relief based on their Provider Enrollment, Chain and Ownership System (PECOS) specialty code. For MIPS, most pathologists as non-patient facing clinicians are not required to participate in the PI category. Through these exemptions, the CAP believes that CMS has noted pathologists' inability to attest to or report on many of the MU and PI measures as these require face-to-face interaction with patients. Several of the previous MU measures and the current PI measures were developed with patient-facing physicians in mind and have the following overlapping themes that render these measures inappropriate for pathologists:

- The measures are written from the perspective of the ordering provider, not the physician receiving the order and performing or directing the activities ordered (e.g. pathologist/radiologist.)
- Pathologists engage in the activities covered by the measures but maintain and transmit the information relevant to that measure in LISs, which have greater relevant clinical functionality to pathologists than EHRs.
- The measures are outside the control of the pathologist.

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- The activities referenced by the measures are outside the scope of pathologists' usual practice and interaction with patients.
- The pathologist is dependent on another clinician for the information.

Another hindrance is that LISs are not Certified EHR Technology (CEHRT). The CAP is actively working to finding a pathway for LISs to become certified. This would in the long term allow possible participation in the PI category but more importantly would allow pathologists to earn MIPS bonus points associated with using CEHRT and show their value in Alternative Payment Models (APMs).

Further, CAP supports the CMS proposal to align the PI program for hospitals with the Quality Payment Program (QPP). Pathologists can currently participate in only two of the four categories of MIPS. This means that 85% of the MIPS final score for pathologists is based on quality measures which places a disproportionate amount of weight on that category for these eligible clinicians (EC). While we appreciate the recognition of the non-applicability of the PI category to pathologists by CMS, the CAP is continuing to explore alternatives for pathologists to engage and more fully participate in the QPP. One possible solution would be to allow hospital-based eligible clinicians such as pathologists to earn points in the PI category of MIPS through their hospital's participation in the PI program, for example, if more than 50% of the Medicare Part B payments for that EC are generated at a particular facility. This would be similar to eligible clinicians' use of facility-based measurement in MIPS beginning in CY 2019. Laboratory testing and pathology diagnostic information are without question a key influence on health care decision making. Thus, allowing a pathway for hospital-based pathologists to earn points for supporting hospitals that meet PI program requirements would recognize the important role pathologists play in diagnosis and management of patient health care. It would support hospital-based MIPS eligible pathologists' efforts in promoting the electronic exchange of health information across LIS and hospital EHRs, while ensuring their participation in the PI category is not administratively burdensome.

Information Blocking

Both the American Medical Association's (AMA) and the Office of the National Coordinator's (ONC) own reports to Congress have identified that health IT vendors engage in information blocking—activities that interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.[1] Health IT vendors continue to block information through financial, technical, and contractual means. Through the QPP, CMS already requires physicians to attest they will not engage in information blocking activities. However, to resolve information blocking problems, vendors must be held accountable as well.

The CAP believes that EHR vendors continue to create barriers to access patient information. These barriers interfere with and materially discourage physician and patient access to information. The CAP's experience through its Qualified Clinical Data Registry (QCDR) known as the Pathologists Quality Registry (PQR) has been that some EHR vendors make it difficult for the transfer of patient information to clinical data registries. While some EHR vendors have negotiated with physicians and third-party software companies, other EHR vendors tack on large fees to send data from the EHR to clinical data registries or to even connect to a health information exchange (HIE). For instance, Cerner and Epic charge fees of $30,000 and $20,000 (respectively) for sending data abstraction from their EHR to clinical data registries, and Allscripts charges $1,000 to $1,500 per clinician for

[1] Office of the National Coordinator for Health Information Technology, Report to Congress: Report on Health Information Blocking, Washington, DC: Department of Health and Human Services, (April 2015), Available at https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf, Accessed June 2018.

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reporting under the MIPS Program.[2] The AMA is also aware of vendors requiring physicians to purchase intermediary software systems, owned by the EHR vendor, just to enable data exchange. While certified EHR vendors are required to acknowledge the existence of fees, they are not required to publish the actual dollar amount, or even list a range of costs. In the spirit of transparency, and to better inform health IT consumers, we urge CMS and ONC to establish a method to collect, list, and publicize actual fees EHR vendors charge customers.

Essentially, "fitting a round peg into a slightly round hole" allows vendors to assert they are conforming to a standard while still stretching the standard's flexibility to fit their own business needs—effectively curbing data access, use, and exchange. The CAP is concerned that, without the appropriate transparency, testing, and assurances, EHR vendors will extend current interoperability issues into their next generation products. Furthermore, clinicians have little influence or capability to fix these interoperability issues and should not be held liable for issues outside their control. **Therefore, we urge CMS to establish "hold harmless" exceptions for physicians and hospitals when EHRs are suspected of or found to be information blockers.**

Overall, the CAP supports the CMS goals of reducing burden while aligning the QPP and the hospital PI programs. We hope that the CMS continues to examine the burden of data collection and regulatory compliance on physicians and the impact it has on their ability to provide higher quality patient care. CMS should explore fundamental issues of data blocking that continue to hinder interoperability and identify appropriate methods to address them. The CAP looks forward to continued productive conversations with CMS on more appropriate PI measures for pathologists and ways for pathologists to more fully, and meaningfully, participate in MIPS.

5. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

Within this proposed ruling, the CMS mentions its concern that challenges continue to exist for patients due to insufficient price transparency, and that such challenges "include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals, and patients being surprised by facility fees, physician fees for emergency department visits, or by fees for provider and supplier services that the beneficiary might consider to be a part of an episode of care involving a hospitalization but that are not services furnished by the hospital." In general, out-of-network billing occurs in situations wherein patients cannot access in-network physicians in the private insurance market. Accordingly, this scenario is of concern in the health insurance exchanges for Qualified Health Plans (QHPs), but it is not germane to the Medicare program where balance billing is prohibited. We therefore are unclear of the context for the CMS discussion on "out-of-network bills" in this rule-making.

To remedy the problem of inadequate insurance networks for the health insurance exchanges, CMS should assess whether health plan networks with in-network hospitals have actually contracted with facility and hospital-based physician specialties at that hospital. QHPs should not be legally allowed to claim compliance with State or Federal network adequacy standards when the plan represents to regulators that it has an in-network hospital but does not undertake the obligation to contract with the specialties of emergency medicine, anesthesiology, radiology and radiation oncology, pathology, and other hospitalists at such facility. With respect to this issue, current American Medical Association

[2] Letter from the Physician Clinical Registry Coalition to James A. Cannatti III, J.D., Senior Counselor for Health Information Technology, Office of Inspector General, U.S. Department of Health and Human Services, Kathryn Marchesini, J.D., Chief Privacy Officer Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services, (February 8, 2018), Available at https://www.registrycoalition.net/wp-content/uploads/2018/02/PCRC-Letter-re-Information-Blocking-by-Electronic-Health-Record-Vendors-D0765240-2.pdf, Accessed June 2018.

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(AMA) Policy on Network Adequacy (H-285.908.11) states: "Our AMA advocates that health plans should be required to document to regulators that they have met requisite standards of network adequacy including facility and hospital-based physician specialties, (i.e., radiology, pathology, emergency medicine, anesthesiologists and hospitalists) at in-network facilities, and ensure in-network adequacy is both timely and geographically accessible."

We note that CMS finalized policy that relies on State reviews for network adequacy in States in which a Federally-Facilitated Exchange (FFE) is operating, provided the State has a sufficient network adequacy review process, rather than performing a time and distance evaluation. In States without the authority or means to conduct sufficient network adequacy reviews, CMS would rely on an issuer's accreditation (commercial or Medicaid) from an HHS-recognized accrediting entity (i.e., the National Committee for Quality Assurance (NCQA), URAC (formerly the Utilization Review Accreditation Commission), and Accreditation Association for Ambulatory Health Care (AAAHC)). Unaccredited issuers would be required to submit an access plan as part of the Qualified Health Plan (QHP) Application that demonstrates that the issuer has standards and procedures in place to maintain an adequate network consistent with the National Association of Insurance Commissioners' (NAIC) Health Benefit Plan Network Access and Adequacy Model Act.

The network adequacy standards established as part of the NCQA Health Plan Accreditation (HPA) program, the Accreditation Association for Ambulatory Health Care (AAAHC) QHP Accreditation program, and the URAC Accreditation for Marketplace Plans, do not ensure access to in-network pathologists; rather, the standards simply ask if there are sufficient numbers of practitioners available to its members.

The CAP believes patient notification of cost prior to the performance of a health care service jeopardizes patient care by requiring a potential delay in the performance of a pathology service for a patient. For example, some surgical specimens require prompt analysis to be reported to a surgical team while the patient is under anesthesia and undergoing a surgical or diagnostic procedure. This analysis cannot be delayed without the potential for patient harm. In the case of anatomic pathology, which involves the diagnosis of tissue specimens (i.e. biopsies), a pathologist cannot predict the type or number of specimens or anticipate what separate studies may be necessary. The type of specimen or complexity of the analysis is often not known in advance of the initial microscopic analysis conducted by the pathologist, making it impossible to provide a reliable estimate of charges or cost. Quite simply, ethical and legal standards of care do not allow for the performance of these services to be delayed by insurance considerations, as such could be detrimental to quality and to the actual performance of the service. Furthermore, in the case of the private insurance market, only health insurance carriers can calculate the actual out-of-pocket cost of a health care service based on the unique provisions of the health insurance policy and the patient's contribution to the deductible. Health care providers do not have the information to make such assessments prior to the service. It is for all these reasons that the requirement for prior notification of cost was rejected by both the National Association of Insurance Commissioners (NAIC) and the National Conference of Insurance Legislators (NCOIL) in their consideration of model state legislation on this issue. **The CAP recommends that health care providers <u>not</u> be required to inform patients how much their out-of-pocket costs for a service will be before patients are furnished that service.**

6. Chimeric Antigen Receptor (CAR) T-Cell Therapy

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We support the August 20, 2018 HOP Panel's recommendation to change the status indicators for the new Category III CAR-T CPT codes from "B" to "S," and to cross-walk these codes to the stem cell transplant APCs. While CAR-T is not stem cell transplant, we believe that the assignment of these services to these APCs resembles CMS' decision to assign CAR-T therapy to autologous stem cell transplant MS-DRG 016.

We also reiterate the request made by the CAP and other public presenters at the May 2018 HCPCS meeting to remove clinical services from the definition of the CAR-T product Q-codes, Q2040, and Q2041, so that the codes' descriptions reflect only the drug. This will allow providers to accurately report services furnished to patients and will ensure that CMS receives accurate data. We believe status indicator "S" for separately payable procedures is appropriate, since these codes represent new services. By assigning a payable status indicator, CMS will enable hospitals to bill and be paid appropriately for the services that they provide during each step of the CAR-T process, regardless of when or where the service is rendered.

7. Revise CMS' Date of Service (DOS) policy for CY 2019 to Exclude FISH technical component services from Packaging Policies

The CAP would like to urge the agency to revise its Date of Service (DOS) policy for CY2019 to exclude FISH services from packaging policies.

The CAP supports the direct billing of molecular pathology tests, ADLTs and Fluorescence In Situ Hybridization (FISH) on tissue samples acquired from patients during inpatient and outpatient visits as they are critically important for determining follow-up treatment plans and responsible patient care. The goal is to have all test results in hand prior to the oncologist (or other physicians) making the treatment decision to explore the best quality and value based options for the patients. This supports the Agency's programmatic objectives of providing appropriate use, high value, and personalized patient care.

Molecular pathology, ADLTs, and FISH tests are often used in combination, and with other pathology services to provide critically important diagnostic information. For example, molecular pathology tests and ADLTs (NGS tests) may be used in combination due to limitations in platform capabilities right now. In the case of NGS testing for lung, not all tests or laboratories have the robust capabilities to find translocation genes such as ALK and ROS1 so they would use a combination of the NGS and the fluorescence in situ hybridization (FISH) assays. Excluding one would limit capabilities, as well as create unmanageable scenarios within laboratories, to provide comprehensive, guideline-based results in a cohesive and timely manner.

FISH technical component services are equally utilized and vital within outpatient and inpatient hospital care in the same ways that molecular and ADLTs are: for timely clinical guidance of essential clinical decisions to determine the best course of care. FISH technical component services, associated with CPT codes 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377, have unique clinical utilization distinct from conventional laboratory tests. Laboratories use FISH in combination with other molecular tests as well as independently, to provide critical patient results that inform and guide treatment and patient care**. CAP urges the CMS to expand the exclusions from the OPPS packaging policy to include FISH technical component services in the**

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definition of molecular services: CPT codes 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377.

8. Pathogen-Reduced Platelets Payment Rate

The CMS proposes to calculate the payment rate for services described by HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit) in CY 2019 and in subsequent years using claims payment history, however the CAP believes that if the CMS uses the claims data proposed, the resulting payment rate will be seriously flawed and undervalued. The proposal does not use CMS' standard methodology used by the OPPS for codes with at least 2 years of claims history, but considers claims from codes P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), Q9987 (Pathogen(s) test for platelets) and Q9988 (Platelets, pheresis, pathogen-reduced, each unit). Like the CMS, the CAP is concerned that there has been confusion among the provider community of what HCPCS codes P9072, Q9987, and Q9988 describe. The descriptors for HCPCS codes P9072 and Q9988 changed in 2017 and Q9987 was added effective 7/1/2017, therefore at this time, two years of clear claims data are not for public review, nor would they be clean claims usable to the Agency. A review of CMS' HCPCs 2017 files reveals no listings of HCPCS codes P9073, Q9987, or Q9988. Further, it is possible that erroneous claims data from four high-volume hospitals, which collectively submitted 1,267 of the 2,772 total claims for Medicare outpatient pathogen reduced platelet units in 2017, resulted in CMS establishing an incorrect and artificially low reimbursement rate for pathogen reduced platelets for 2019. **Given the provider confusion and lack of public transparency with these HCPCS codes, the CAP recommends for CY 2019 HCPCS code P9072 continue to be cross-walked to P9037 (Platelets, pheresis, leukocytes reduced, irradiated, each unit).**

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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; Elizabeth Fassbender (202) 354-7125/efassbe@cap.org, Todd Klemp (202) 354-7105 / tklemp@cap.org, and Loveleen Singh (202) 354-7133/lsingh@cap.org

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