



COLLEGE of AMERICAN PATHOLOGISTS

September 6, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1656-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1656-P

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Proposed Rule for CY 2017 (CMS-1656-P)

Dear Acting Administrator Slavitt:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule for calendar year (CY) 2017 for the Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems, published in the *Federal Register* on July 14, 2016 (81 Fed. Reg. 45,604). The CAP is a national medical specialty society representing over 17,000 physicians who practice anatomic and/or clinical pathology. The CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals, and federal and state health facilities.

Our comments in this letter focus on the following subjects included in the proposed rule:

- 1) Proposed Changes to Packaged Items and Services; Proposed Clinical Diagnostic Laboratory Test Packaging Policy
- 2) Proposed Updates Affecting OPPS; Blood and Blood Products

1) Proposed Changes to Packaged Items and Services; Proposed Clinical Diagnostic Laboratory Test Packaging Policy

For CY 2017, the CMS proposes to discontinue the unrelated laboratory test exception (and the “L1” modifier), and therefore package any and all laboratory tests if they appear on a claim with other hospital outpatient services. The CAP opposes this additional packaging of laboratory tests. The CAP is very concerned that the rapid pace of these changes exceeds both the hospitals’ and laboratories’ adaptive capacity and the Agency’s ability to accurately model and sufficiently explain the impact of either past or current proposals. Although the CMS regulatory impact analyses indicated this proposal to package unrelated laboratory tests into OPPS payment would add 0.03 percent in payment to facilities, this packaging is likely to result in unintended and unanticipated consequences in particular clinical settings. Also, the CAP is concerned that the rapidity with which new policies are being adopted and the lack of full detailed impact analyses published in the OPPS rulings leaves inadequate time to identify and address implementation issues. **For these reasons,**



the CAP urges the CMS to not finalize the proposed 2017 packaging of unrelated laboratory tests.

As the CMS moves to a payment system that bundles more services together and accounts less for individual patient complexity, the CAP urges the Agency to take a fresh look at the overall adequacy of OPPS payments to hospitals and laboratories. The CAP is concerned that the burden of these changes may fall disproportionately on the providers of care for more complex patients.

2) Proposed Updates Affecting OPPS; Blood and Blood Products

The CAP comments in this section support the comments of the American Association of Blood Banks (AABB). For CY 2017, the CMS proposes to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the C-APCs. The CAP urges the Agency not to implement this proposal and continue to provide separate payments for blood products in the outpatient setting. These distinct payments recognize the particular role blood and individual blood products play in caring for a wide range of patients. They also are needed to account for the increasing cost of blood products associated with critical blood safety measures provided by non-profit blood centers. **We urge the CMS to maintain its policy of providing separate APC payments for blood products in 2016 and future years.**

The CMS is also proposing a number of reductions and modifications to the ambulatory payment classification (APC) payment rates for blood products, transfusion, apheresis and stem cell procedures, transfusion laboratory services, and to the comprehensive APC for hematopoietic stem cell transplants. The CAP comments on these payment rates are in support of and agree with the comments of the AABB.

- The CAP, the AABB and others in the transfusion medicine community have commented to the CMS that APC payment rates for blood products lag behind their actual costs. These payments typically are below the amounts hospitals pay blood centers for individual products and do not provide for hospital overhead costs. Therefore, we request that the CMS consider potential alternative methodologies for setting APC payment rates for blood products, seeking input from affected stakeholders. The CAP would welcome the opportunity to work with the CMS and other interested parties to determine the most appropriate payment methodology and to allow for timely implementation of blood safety measures and availability of patient-appropriate blood products.
- The CAP commends the CMS for proposing to increase payment rates for some blood products for FY 2017. However, the CAP provides comment on the payment rates proposed for the following products and services:
 - The proposed 64% reduction in reimbursement for HCPCS code P9010 (Whole blood for transfusion) is substantial and should be reevaluated for its payment methodology.
 - The CAP is concerned with the CMS' proposal to substantially reduce the payment rates for the following HCPCS codes; 36513 (Apheresis platelets), 38210 (T-cell depletion of harvest), 38211 (Tumor cell depletion of harvest), 38212 (Rbc depletion of harvest), 38213 (Platelet depletion of harvest), 38214 (Volume depletion of harvest), 38215 (Harvest stem cell concentrate), 38230 (Bone marrow harvest allogenic) and



38241 (Transplnt autol hct/donor). The CAP believes the CMS may have used incomplete and misleading data to justify the proposed significant reductions in the payment rates for these services, since the services are low volume, heterogeneous and are mostly used for bundled procedures. In addition, these codes are often used in multiple claims, and are therefore subject to discounts from rate setting. The CAP urges the CMS to reconsider the methodology used as well as the proposed payment rates for these procedures, as well as other codes used for transfusion, apheresis and stem cell procedures since the proposed reimbursement rates are inadequate and will not cover providers' costs.

- The reduced reimbursement of the majority of transfusion laboratory services should be reevaluated by the CMS. However, the CAP appreciates the CMS' proposal to increase the payment rates for transfusion laboratory services assigned to HCPCS codes 86902 (Blood type antigen donor ea), 86905 (Blood typing rbc antigens), 86930 (Frozen blood prep), and 86971 (Rbc pretx incubat w/enzymes).
- The CAP agrees with the CMS for proposing modifications aimed at improving reimbursement for hematopoietic stem cell transplants (HCT). We believe that establishing a rate that recognizes the cost of cell acquisition will help ensure that patients have access to life-saving bone marrow and cord blood transplants.
- The CAP also supports the creation of a new Comprehensive Ambulatory Payment Classification (C-APC) 5244 (Level 4 Blood Product Exchange and Related Services). However, we are concerned that the proposed payment rate of \$15,267 for CY 2017 is artificially low because it was determined using a low volume of total claims, including claims that are incomplete and should be excluded. Consistent with the CMS Billing Guidance, we believe that the CMS should exclude from the calculation claims with CPT code 38240 but without revenue code 0819 charges, because the donor search and cell acquisition costs are missing. Rather, we encourage the CMS to calculate the payment rate using only correctly coded CPT 38240 claims with revenue code 0819 charges.
- In addition, the CAP concurs with the AABB that the CMS should clarify its proposal to create a new cost center line, 112.50, to record acquisition costs related to HCT. We appreciate the CMS for recognizing that it should collect acquisition costs separate from other transplant related costs. However, selecting line 112.50 has implications for the inpatient setting. We ask the CMS to confirm that changes reported to cost center line 112.50 will be calculated during the rate-setting process.

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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 either; Maurine Dennis (202) 354-7136 / mdennis@cap.org or Todd Klemp (202) 354-7105 / tklemp@cap.org.

Sent via Electronic Submission to <http://www.regulations.gov>