



September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1678-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1678-P

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule for CY 2018 (CMS-1678-P)

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1678-P for calendar year (CY) 2018 for the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. 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 is recognized throughout the care continuum and affects many patient encounters.

Our comments in this letter focus on:

- Potential Revisions to the Medicare Part B Laboratory Date of Service (DOS) Policy
- Analysis of Packaging of Pathology Services in the OPPS, Comment Solicitation on Packaging of Items and Services Under the OPPS
- Proposed Calculation of Single Procedure APC Criteria-Based Costs - Blood and Blood Products, Methodology, and Specific Blood Products Payment Rates
- Proposed OPPS APC – Specific Policies, Blood Driven Hematopoietic Cell Harvesting
- Request for Information and Public Comments

The Potential Revisions to the Medicare Part B Laboratory Date of Service (DOS) Policy

In the interest of furthering prompt and effective diagnosis and treatment, the CAP supports the modifications to current the DOS policy to allow laboratories to bill Medicare directly for certain laboratory tests excluded from the OPPS packaging policy. While the CAP is pleased the CMS is considering modifications to the DOS policy that encourage access to new and evolving testing, the CAP is not able to identify any reason that warrants distinguishing ADLTs from other molecular analyses under a modified policy. **Of the options CMS presents, the CAP therefore, recommends the agency finalize an exception to the DOS policy that is not limited to ADLTs, but also covers other molecular pathology tests.**



As you know, the tests provided by advanced diagnostic laboratories are not necessarily ADLTs under the law, although likely provided by a sole source laboratory. Limiting an exception to ADLTs, therefore, will not encompass all tests provided by advanced diagnostic laboratories. Beyond sole source testing, any modification to the current DOS rule should encompass all molecular pathology testing. Molecular pathology testing is no longer an exception, but is widely acknowledged as both medically beneficial and cost-effective for many patients. **By their nature, ADLTs and molecular pathology testing are appropriately separable from the hospital stay that preceded the test, and should have a DOS that is the date of performance rather than the date of collection.** To continue to handle them otherwise potentially leads to delayed access to medically necessary care, regardless of whether the services are provided “under arrangements” or not. **To avoid any ambiguity, the date of performance should more specifically be the date of final report.**

Molecular Pathology Testing - As CMS suggests, ADLTs and other molecular pathology tests are relatively new and rapidly evolving, and can have a different pattern of clinical use than traditional laboratory tests. In their current state, molecular pathology tests are widespread and medically beneficial and appropriate for many patients. CMS developed the current DOS policy before molecular pathology was commonplace and significant advances in precision medicine had occurred. At that time, a policy could apply greater uniformity to the provision of clinical laboratory tests provided in the hospital setting as part of the hospital service. This is no longer the case. Molecular pathology testing has evolved so much since the DOS policy was developed that the intent of the rule is not consistent with how molecular diagnostics are used in the clinical management of patients. Molecular pathology testing allows patients and their doctors to make more informed decisions about treatment based on a patient’s unique molecular profile. Molecular pathology testing now generates many actionable results and routinely guides therapy including influencing targeted therapy for some cancer treatments ordered consistent with accepted standards of care. **Modifying the hospital-service related DOS-bundling policy to exclude these tests therefore, furthers CMS’s goal of promoting personalized medicine.**

Continued rapid emergence of new molecular testing is expected. This expansion will only serve to exacerbate the problems that arise under the current DOS rule related to molecular pathology testing if not modified. Typically, molecular pathology testing does not tie to the primary service or reason for the hospital visit. **As their evolution continues, bundling molecular pathology services with hospital services is not consistent with how these tests are used clinically and encourages workarounds of the current 14 day rule which leads to increased complexity in the marketplace in the delivery of these services.**

Sole Source Testing – CMS posits that the circumstances may be different for molecular pathology tests not required to be furnished by a single laboratory, however after considerable discussion among a wide range of expert pathologists, we were unable to identify any credible foundation for such a difference. Therefore, **rather than pursuing this assumption which lacks supportive evidence, we believe that the focus of a revised policy should instead be on what serves the patient best, rather than a distinction based on how many laboratories provide a given test.** The use of sole source laboratories is not necessarily a leading or even contributing factor to delays in care, nor should only tests be provided by these laboratories be afforded an exception. A minority of hospitals will have capabilities or expertise to perform certain testing in house. Many hospitals are likely to send a test out of the hospital for interpretation regardless of whether the test is an ADLT, molecular pathology test or provided by a single laboratory. **What matters most to the patient is not whether the test is an ADLT, a molecular pathology test or provided by a single laboratory, but whether it is timely and accurate, absent incentives for delay that can delay the initiation of targeted pharmacotherapies**



CMS also raises the issue of “kits” for certain molecular pathology tests that a hospital can purchase, allowing the hospital to perform the tests. CMS posits these molecular pathology tests may not present the same concerns of delayed access to medically necessary care as ADLTs, which must be performed by a single laboratory. **The same costs, operational complexities and other concerns regarding access to care and financial risk arise under the current rule regardless of whether a kit is used.** As with sole source testing above, the focus of any policy should be on the timely and accurate provision of results leading to prompt diagnosis and therapeutic intervention. **Distinctions based on the existence and use of kits, are therefore, like distinctions based on sole-source provision, largely irrelevant for similar reasons.**

Complexities of the Current Rule – The current DOS rule forces hospitals to bill Medicare for services not furnished as part of the patient’s hospital stay/visit and potentially for tests they do not perform. This presents billing challenges and administrative complexities and encourages creative work-arounds that may not provide the same timeliness or level of testing, to avoid services being included in the hospital stay or visit. **To alter the existing DOS policy so that the date of molecular pathology testing is the date of performance (the date of the final report) realigns incentives around the prompt and efficiency delivery of patient diagnosis and consequent care. It also increases consistency with the DOS policy for other diagnostic services for beneficiaries and would therefore be less burdensome to administer.** However, to handle ADLTs differently from molecular pathology testing in general under a revised DOS policy would merely serve to create additional complexity and undermine the intended reduction in administrative burden.

Access to Testing –CMS is especially interested in comments regarding how the current DOS policy and “under arrangements” provisions may affect access to care for Medicare beneficiaries. Indeed, the current DOS policy provides perverse incentives to delay care. Worse than operational implications are delays in care. **The intricacy of the current rule’s administrative complexities and its resulting incentives may indeed limit access to testing to avoid being captured under the DOS policy.** The access issues that arise under the current policy can lead to delays in diagnosis contributing to reduced efficacy of treatments, or to follow up therapy including medically appropriate targeted pharmacotherapies and other therapeutic interventions being started later than would have been the case absent the rule. In extreme circumstances, medically necessary molecular testing may even be forgone to avoid financial risk of non-payment. Removing the financial risk that arises from the current DOS rule realigns interests, helps ensure proper timing in determining which molecular test is most warranted, and enhances coordination of care between the ordering physician (typically the oncologist), the hospital, and the laboratory.

Recommendation: Revising the current rule so that the DOS for all molecular testing is the date of performance (date of final report) rather than the date of collection, to improve the consistency with Medicare policy for billing of other diagnostic services for beneficiaries. Most importantly, this will improve timeliness and integration of services, and ultimately, patient care.

Conclusion of the CAP’s Comments on Initial Revisions to the Medicare Part B Laboratory Date of Service (DOS) Policy

Given the current challenges outlined above, the CAP supports CMS in modifying the current rule at 42 C.F.R. § 414.510(b) to establish that in the case of a molecular pathology test or ADLT that meets the criteria of Section 1834A(d)(5)(a), **the DOS must be the date the test was performed (the date of final report)** if the specified criteria are met. Such modification would allow laboratories to bill



Medicare directly for ADLTs and other molecular pathology tests that meet the criteria of applicable law, when the specimen is collected during a hospital outpatient procedure and the test is ordered after the patient is discharged from the hospital outpatient department. As noted above, the CAP recommends the agency not limit this modification to ADLTs, but include all molecular testing meeting the specified criteria. **The CAP would also urge an exception apply when the specimen is collected during a hospital outpatient procedure regardless of whether the test is ordered during or after the hospital outpatient procedure, rather than just to those instances in which a test is ordered after the patient is discharged. The logical basis for any such exception is not whether the intent of testing was determined after hospital discharge, but rather whether the clinical care being directed by the results of the testing are not related to the hospital stay or visit, whether inpatient or outpatient.** Therefore, limiting this exception to tests ordered after hospital discharge, would be illogical, and its impact operationally and clinically perverse.

In no event should any exception created only apply to ADLTs meeting applicable criteria as CMS has put forth as an option. That “this exception would not cover molecular pathology tests” is too limiting to address the issues that potentially delay patients’ receipt of results of testing and create burdens for laboratories and hospitals, and would in fact increase operational complexity without benefiting patient care.

We thank CMS for its commitment to continuing to review its DOS policy with the goal of ensuring improved patient care and appropriate recognition of hospital and post-hospital care. We urge CMS to fulfill its goal by adopting modifications to the current dated DOS rule that remedy its unintended consequences as recommended above.

Analysis of Packaging of Pathology Services in the OPPS, Comment Solicitation on Packaging of Items and Services Under the OPPS

Within this CY 2018 CMS’ OPPS ruling the CMS informed us that a stakeholder expressed concern with conditional packaging of pathology services, particularly when payment is limited to the single highest paying code, regardless of the number of services provided or specimens tested. The CAP shares this concern, and agrees with the Agency’s decision not to propose the creation of any pathology composite APC or other additional composite APCs for the stakeholder’s requested services.

While we applaud the Agency’s decision not to create a composite APC for pathology or for any other clinical services, the CAP too continues to hear concerns from stakeholders that the Agency’s packaging policies are hampering the practice of pathology. Specifically, the packaging policy of pathology add-on services that bundle all add-on services into the base code APC is extremely restrictive on the very nature of providing pathology services. These add-on services have a status indicator of “N”, where the payment is packaged into payment for other services, and therefore, there is no separate APC payment.

This proposed ruling also requests feedback on common clinical scenarios involving currently packaged HCPCS codes for which stakeholders believe packaged payment is not appropriate under the OPPS. 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 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 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.

The Proposed Calculation of Single Procedure APC Criteria-Based Costs - Blood and Blood Products, Methodology, and Specific Blood Products Payment Rates

The CAP appreciates that CMS' proposal to establish payment rates for blood and blood products using CMS' blood-specific CCR methodology. These distinct payments recognize the important 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 critical blood safety measures provided by non-profit blood centers. **We urge CMS to finalize its policy of providing separate APC payments for blood products in 2018 and future years.**

As hospitals and blood centers face economic challenges, it is important that Medicare and other payers establish appropriate payment policies and adequate reimbursement rates for blood products. This will help ensure that patients continue to have access to safe, clinically effective blood components. The CAP commends CMS for proposing to increase reimbursement for several blood products, including but not limited to platelets (e.g., P9019). However, the CAP is concerned about CMS' proposal to reduce reimbursement rates for many other blood products.

As the CAP and others in the transfusion medicine community have previously indicated, APC payment rates for blood products lag behind their actual costs and fail to account for safety advances in a timely manner. These payments typically are below the amounts hospitals pay blood centers for individual products and do not provide for additional hospital overhead costs. For instance, the CAP is concerned that CMS' proposed payment rates for cryoprecipitate (P9012) and solvent/detergent treated pooled frozen plasma (P9023) are inadequate and do not cover the costs of the products. As another example, the CAP encourages CMS to reevaluate its proposed payment rate for CMV-negative leukoreduced pheresis platelets (P9055), to ensure that reimbursement is adequate in all regions throughout the country. The proposed payment rate is too low and reflects wide regional variation of utilization. In addition, the CAP recommends that CMS reassess the proposed payment reduction for leukoreduced apheresis platelets (P9035)..

Similarly, the CAP requests that CMS reevaluate the proposed payment rate for pooled pathogen reduced plasma (P9070), as the proposed reimbursement rate does not reflect the cost of the product. The CAP recognizes that the code was introduced in 2016, and therefore the hospital cost data is limited. The information reported to CMS may not accurately reflect the use of the product due to potentially erroneous coding and limitations of blood bank information systems, which may have delayed the implementation of proper coding for the product.

Proposed OPPIs APC – Specific Policies, Blood Driven Hematopoietic Cell Harvesting

The CAP commends CMS for using the logic finalized in the CY 2017 hospital outpatient payment rule to update the payment rate for allogeneic transplantation of hematopoietic progenitor cells per



donor (CPT code 38240). Although the CAP encourages CMS to continue using this logic to calculate the payment rate for code 38240, we are concerned that the proposed payment rate for 2018 is artificially low due to potential miscoding or underreporting by facilities. The low payment rate is especially problematic since donor costs continue to rise. We encourage CMS to ensure that payment rates are adequate so that patients continue to have access to allogeneic transplantation of hematopoietic progenitor cells in the hospital outpatient setting.

Additionally, the CAP appreciates CMS' attempt to create uniformity in status indicators among a family of codes. However, 38205 is a code that applies to harvesting cells from a donor for intended use in a patient, in this case a Medicare beneficiary. CMS' billing guidance instructs facilities to hold donor charges and submit them on the patient's transplant bill. Therefore, CMS' proposal to change the status indicator for 38205 from "B" to "S" could accidentally encourage facilities to incorrectly submit for payment at the time of donor cell harvest. **Thus, we encourage CMS to maintain the status indicator of "B" for code 38205.**

Request for Information and Public Comments

The CAP encourages CMS to reduce unnecessary burdens for clinicians and providers by revising the HCPCS p-code descriptors for blood products.

In the proposed rule updating hospital outpatient payment policies for FY 2017, CMS solicited feedback regarding the current set of HCPCS p-codes for blood and blood products. We believe that this extensive undertaking has the potential to result in a code set that provides patients with increased access to new technologies and new blood products that protect the public's health and improve clinical outcomes. In addition, a revised code set can achieve more consistent and accurate billing practices for blood products.

The CAP urges CMS to continue its examination of the p-codes for blood products by convening stakeholders for a public meeting or collaborative workshop prior to establishing, finalizing, or implementing a thoroughly revised code set for blood products. We believe that the code set should align with current clinical practice, manufacturers' needs, and the introduction of new products. In addition, we encourage CMS consider the following specific recommendations:

- (1) Retain unique HCPCS codes for each different blood product based on processing method, since these methods result in blood products that are distinguishable and used for distinct purposes.
- (2) Establish a mechanism to immediately begin billing for a new blood product or a new technology that is not captured by existing p-codes by establishing a "not otherwise classified" code for blood products. In 2013, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) recommended that the Department of Health and Human Services take steps "to improve mechanisms to recover actual costs, including costs of new safety measures." We believe that the establishment of a "not otherwise classified" code for blood products is an important step that is consistent with this recommendation.
- (3) Revise the consistency and uniformity of the descriptors used for blood products, change the order of the products in the code set to ensure that codes involving the same category of blood (i.e., plasma, platelets, and red blood cells) are listed in consecutive order, and modify the descriptors and codes for certain products to reflect current clinical practice and manufacturing processes.



COLLEGE of AMERICAN PATHOLOGISTS

The CAP welcomes the opportunity to work closely with CMS on a collaborative effort to revise the HCPCS code set for blood products.

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