COLLEGE of AMERICAN PATHOLOGISTS

September 24, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–1717–P
P.O. Box 8013
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; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals; (CMS–1717–P), (RIN 0938–AT74)

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-1717-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 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. Potential Revisions to Laboratory Date of Service (DOS) Policy
2. Proposed Recalibration of APC Relative Payment Weights, CPT Code 88307
3. Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges

1) Potential Revisions to Laboratory Date of Service (DOS) Policy

The CAP believes that two of the three policy revisions under consideration by CMS would once again restrict access to precision diagnostic information and timely treatment. The CAP opposes changes to the test results requirement at 42 CFR 414.510(b)(5)(iv) and limiting the laboratory DOS exception at 42 CFR 414.510(b)(5) to Advanced Diagnostic Laboratory Tests (ADLTs). The CAP agrees with CMS' regulatory considerations to exclude blood banks and blood centers from the laboratory DOS Exception at 42 CFR 414.510(b)(5). The CAP also urges CMS to expand the

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exclusions from the laboratory DOS rules to include in situ hybridization, and flow cytometry technical component services. Our comments on these regulatory considerations are discussed in greater detail below:

Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv)

The CAP urges the agency to not implement any new policy in this area at this time, as any potential changes would limit beneficiary access to these important tests, taking a step backwards and creating administrative burden and documentation costs and complexities. Under this proposed change, a test would be considered a hospital service and be excluded from the DOS policy (thus making the hospital responsible for billing for the test through the "under arrangements" regulations) *if the ordering physician determines that the test results are intended to guide treatment during a hospital outpatient encounter, including a future hospital outpatient encounter*. This would change the current policy (see § 414.510(b)(5)(iv)) under which the DOS is the date of test performance to the date of specimen collection. Not only is this proposed change inconsistent with current CMS policy, but it is administratively unworkable because it does not reflect the reality of current clinical practice.

Appropriately, the existing regulation focuses on guiding hospital treatment at the same outpatient encounter because that is clinically comprehensible at the time the test is ordered. By contrast, ordering physicians likely would not feel comfortable predicting whether the results of a given test will be used in a subsequent outpatient encounter for two reasons: first, the physician is ordering the test to determine the next clinical intervention steps of the patient; second, the physician ordering the testing and thus determining the patient's diagnosis may not be the same physician who ultimately treats the patient based on the test results. Therefore, the ability of the ordering physician to make a prediction as to whether the test results will or will not guide treatment management will vary widely based on the type of physician, the type of test, the treatment options available to the patient, and other factors. The "totality of the circumstances" standard and the decisional factors listed in the proposed rule will not assist the physician in making a prediction in many of these circumstances because there will not be sufficient information to make a prediction in the first place. The broad range of clinical scenarios where this policy may have applicability gives strong support against a uniform or one-size-fits-all standard.

This approach would also be inconsistent with CMS policy governing services performed outside the hospital for outpatients. In the CY 2000 OPPS Final Rule, in response to a question about the treatment of diagnostic tests furnished by "outsourced" hospital departments that operate as free-standing providers of outpatient services on hospital grounds, the agency made clear that *"[a] free-standing entity, that is, one that is not provider-based, may bill for services furnished to beneficiaries who do not meet the definition of a hospital outpatient at the time the service is furnished. Our bundling requirements apply to services furnished to a 'hospital outpatient,' as defined in § 410.2, during an 'encounter,' also defined in § 410.2."*[1] The current laboratory DOS policy at § 414.510(b)(5) accords with this standard. There is no policy basis to require hospitals to bill for a service that may be performed weeks after an outpatient encounter.

Requiring a physician to predict future treatment in the hospital outpatient setting would create more administrative complexities than the current DOS policy. It is unclear how CMS would expect the physician to document their prediction as to the future use of every single molecular pathology test or

[1] 65 Fed. Reg. 18434, 18440-41 (Apr. 7, 2000).

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ADLT that they order. The ongoing administrative burden created by this proposed policy is likely to be far more complex than any implementation issues with the recently revised DOS policy. The added burden for physicians may further delay test orders for beneficiaries and incentivize physicians not to use precision diagnostic tests. CMS should not determine the applicability of the DOS policy exception based on the ordering physician's determination of whether the results of a molecular test are intended to guide the treatment provided during a hospital outpatient encounter.

Additionally, the administrative aspects of changing the test results requirement may present unforeseeable patient care access, delay, and efficiency issues. The specifics of how hospitals and physicians should implement these changes is also unclear. It is our understanding that increasing physician administrative and documentation burden is contrary to this agency's and the Administration's goals. The CAP is aligned with the American Medical Association and the American Society of Clinical Oncology in opposition to any policy change to this test results requirement. **Therefore, the CAP opposes any changes to the test results requirement at 42 CFR 414.510(b)(5)(iv).**

Limiting the laboratory DOS exception at 42 CFR 414.510(b)(5) to ADLTs

The CAP also opposes removal of molecular pathology tests from the laboratory DOS exception and limiting it only to ADLTs. Under this proposed policy change, the DOS policy would be limited to ADLTs. The CMS justifies the potential elimination of the policy's applicability to molecular pathology tests on the grounds they are "not required by statute to be furnished by a single laboratory, so hospital laboratories and independent laboratories are not prevented from performing molecular pathology testing." CMS further contends that many molecular pathology tests are becoming available by kits and thus can be performed by hospitals. We disagree with this presumption. It is important to remember that the problem that led to CMS finalizing changes to the DOS policy in 2017 was the precise issue of independent laboratories being unable to bill for tests and hospitals being required to bill for them, highlighting the point that these tests are not commonly performed by hospitals. If they were, the hospital would simply perform and bill for the test.

The use of sole source laboratories is not necessarily a leading or even contributing factor to delays in care, nor should only tests provided by these laboratories be afforded an exception. Hospitals do not often use a "single source laboratory" but rather just a few or perhaps a single major reference laboratory to which they are contracted to provide patients access to advanced esoteric testing at the lowest possible cost with fastest available turnaround time. These centralized reference labs will often contract for all testing and refer out any unusual tests that are not performed in house. Performing such tests in house in either a hospital or regional lab is not always practical or cost effective due to lower test volumes, hence the referral to commercial reference labs or other regional labs or specialty-focused esoteric testing labs which can run more frequent set ups of tests in larger batches to reduce costs.

The American Medical Association's Current Procedural Terminology (CPT) includes nearly 800 Category I tests in the molecular pathology sections (Tier 1, Tier 2 and GSP), and we believe there are fewer than 80 FDA approved devices for testing nucleic acid. Excluding platforms, instruments, software, and sole source tests, this leaves about 50 test kits that are available for purchase. However, many of those are redundant (i.e. for the same analyte), therefore, there are no more than 15 -20 unique kits available for molecular testing that might be used by a hospital laboratory. Additionally, the same costs, operational complexities, and other concerns regarding access to care and financial risk arise regardless of whether a kit is used. The focus of any policy should be on the

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timely and accurate provision of results leading to prompt diagnosis and therapeutic intervention. Distinctions based on the existence and use of kits, are largely irrelevant. In addition, even if a hospital has a molecular department and staff, not all molecular testing is performed on site due to cost and expertise limitations. A minority of hospitals have capabilities or expertise to perform certain testing in house. For many hospitals, a large percentage of molecular test orders are sent to other laboratories for interpretation regardless of whether the test is an ADLT, molecular pathology test, or provided by a single laboratory. We have seen nothing to indicate that this situation has changed. **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 hinder the initiation of targeted pharmacotherapies**

The 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 could lead to delayed access to medically necessary care, regardless of whether the services are provided "under arrangements" or not. Both ADLTs and molecular pathology testing do not tie to the primary service or reason for the hospital visit. The CAP supports the DOS policy that allows laboratories to bill Medicare directly for certain laboratory tests excluded from the OPPS packaging policy. The CAP is not able to identify any reason that warrants distinguishing ADLTs from other molecular analyses under a modified policy.

Limiting the DOS policy to the conditions for ADLT designation would significantly curtail which tests could be billed by the performing laboratory in a manner that is inconsistent with the beneficiary access objectives of the policy. As a result, many Medicare fee-for-service beneficiaries who need a sole-source molecular pathology test may face access constraints because these tests are not eligible for an ADLT status. Limiting the DOS exception to ADLTs does not 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. 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. Retaining the exclusion of molecular tests from the current DOS policy, therefore, furthers CMS's goal of promoting personalized medicine. **The CAP urges the agency to retain the exception to the laboratory DOS policy that covers molecular pathology tests.** Additionally, **to avoid any ambiguity, the date of performance should more specifically be the date of final report.** Continued rapid emergence of new molecular testing is expected. This expansion will only serve to exacerbate problems that would result from a change in current policy.

Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception at 42 CFR 414.510(b)(5)

The CAP agrees with the CMS' proposed policy change where hospitals would be required to bill for molecular pathology tests that may be performed by blood banks or blood centers. The CAP agrees that this step would ensure beneficiary access to timely specialized molecular testing performed by blood banks. This makes sense from a policy perspective because blood banks and blood centers are not enrolled Medicare providers and do not currently bill Medicare as laboratories and lack the

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infrastructure, resources and expertise in their finance/billing departments to engage in direct third-party billing for laboratory services. In general, they do not currently obtain information, such as patients' insurance information, discharge information, or ICD-10 code(s), which would be necessary for determining if the hospital or the blood center should bill for testing. Blood centers are facing significant financial challenges and do not have the resources to absorb potential burdens resulting from the applicability of the laboratory DOS policy exception. Thus, requiring blood centers to comply with the laboratory DOS policy exception would create considerable burdens and has the potential to cause delays and jeopardize Medicare beneficiaries' access to care. We believe that requiring hospitals to identify which molecular tests performed by blood centers are subject to the DOS policy exception would create an undue burden on Medicare beneficiaries. The CAP supports the CMS' proposal to exclude blood banks and blood centers from the laboratory DOS policy exception at 42 C.F.R. 414,510(b)(5) and we are aligned with the American Association of Blood Banks and the American Red Cross on this issue. **We urge CMS to finalize the proposal to exclude from the laboratory DOS policy exception blood banks and blood centers and to clarify that all molecular testing performed by blood banks and blood centers is excluded from the policy exception.**

<u>Expand the exclusions from the laboratory DOS rules to include in situ hybridization, and flow cytometry technical component services</u>

In finalizing CY 2018 policy changes, CMS recognized that the Medicare billing and payment rules for molecular diagnostic tests at the time created significant administrative barriers to ordering tests to guide the treatment of Medicare beneficiaries. It is important for the agency to appreciate that these barriers impact not only providers of molecular tests paid under the Clinical Laboratory Fee Schedule (CLFS) but also to molecular tests furnished as technical components of physician pathology services, such as in situ hybridization (ISH), and flow cytometry services.[2] When surgical specimens are obtained in a hospital setting and referred for physician pathology services, the technical components are commonly performed by the hospital pathology laboratory where the specimen was collected. However, this is not universally the case, especially where these tests may be run together with other molecular tests on the same samples. When such specimens are sent to outside laboratories to perform physician pathology services, the same dynamics and concerns arise that also arise with tests paid under the CLFS – the laboratory that initially collected the specimen may have no relationship with the laboratory performing the testing. Thus, there are similar access issues and confusion as with similar tests paid under the CLFS.

As an example, there are molecular pathology tests and physician pathology tests that both target the same molecular marker – ALK for non-small cell lung cancer. While testing for the same marker, these tests are handled differently under the date of service rule as it currently stands. The clinical laboratory test is eligible for the (b)(5) exception and may be billed by the performing laboratory, but the physician pathology test is not eligible and must be furnished under arrangements or held till 14+ days, leading to unnecessary delays to beneficiary care.

Tests on tissue samples acquired from patients during inpatient and outpatient visits 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

[2] Relevant codes include: 88120, 88121, 88184, 88185, 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377.

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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.

As outlined above, the CAP supports the direct billing of molecular pathology tests and ADLTs, as both types of tests and other diagnostic modalities are often used to provide critically important diagnostic information to inform follow-up patient treatment plans. Molecular pathology, ADLTs, ISH, and flow cytometry services are often used in combination, and with other pathology services, to provide the proper and best patient care. For example, molecular pathology tests and ADLTs may be used in combination due to limitations in platform capabilities right now. In the case of NGS testing for lung, not all 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.

ISH, and flow cytometry, technical component services are equally utilized and vital within outpatient and inpatient hospital care in the same ways that molecular and ADLTs are, for clinical guidance of essential clinical decisions in a timely fashion to determine the best course of care. These technical component services, associated with CPT codes 88120, 88121, 88184, 88185, 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377, have unique clinical utilization distinct from conventional laboratory tests. Laboratories use these services in combination with other molecular tests as well as independently, to provide critical patient results that inform and guide treatment and patient care**. The CAP urges the CMS to expand the exclusions from the OPPS packaging policy to include in situ hybridization, and flow cytometry, technical component services in the definition of molecular services provided in both the outpatient or inpatient hospital settings: CPT codes 88120, 88121, 88184, 88185, 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377.**

2) Recalibration of APC Relative Payment Weights, CPT Code 88307

In this proposed rule, CMS proposes to move surgical pathology tissue exam by pathologist (CPT code 88307) to APC 5672 "Level 2 Pathology" from APC 5673 "Level 3 Pathology". This service includes complex Level V surgical pathology specimens and CMS's proposed change represents a 46 percent decrease in the payment amount. The CAP believes the data leading to this change in APC level must be flawed. OPPs charge-based cost data were neither designed nor intended to be an accurate estimate of service/procedure level costs at the CPT code level. The hospital charge-based cost data used for OPPS rate-setting allow CMS to estimate costs for purposes of grouping a number of services or procedures (multiple distinct codes) into appropriate clinically and economically homogeneous APCs. These data do not identify actual costs for specific procedures. The costs associated with an 88307 service is greater than six times the cost of an APC 5672 "Level 2 Pathology" service, based on physician fee schedule technical component cost differences. This proposed reassignment creates a resource cost rank order anomaly with other physician services and the technical costs will not be fully recovered from each unit of service. We believe the unique complexity of specimens associated with these services require a level 3 pathology APC. **The CAP urges the CMS to maintain the assignment of APC 5673 for CPT code 88307.**

3) Requirements for Hospitals to Make Public a List of Their Standard Charges

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This proposed rule emphasizes that as "health care costs continue to rise, health care affordability has become an area of intense focus." The agency specifically highlights the lack of transparency in health care pricing and that it is the agency's belief that transparency in health care pricing is "critical to enabling patients to become active consumers so that they can lead the drive towards value." Similarly, many provider groups, including the CAP, have acknowledged that a lack of information about the cost of health care services can be an impediment to transparency and patient empowerment. To that point, the CAP agrees with the AMA that when scheduling services for patients, providers should be transparent about their own anticipated charges, and insurers should be transparent about the amount of those charges they will cover. However, the CAP has expressed concern about requiring pathologists to inform patients about out-of-pocket costs for a service before patients are furnished that service, as there is significant risk for patient harm from any delays. Further, there is significant difficulty in determining the cost of pathology services in advance of services conducted by the pathologist. 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 costs. In fact, this reality is reflected by CMS in Medicare's Benefit Policy Manual with a surgical/cytopathology exception that notes there are additional tests a pathologist may need to perform after an examination or interpretation, "even though they have not been specifically requested by the treating physician/practitioner."[3]

Pathologists understand how access to price information prior to services may be useful for patients, but the CAP opposes adding additional administrative requirements on physicians that interfere with or impair the patient's medical diagnosis and care.

Noting concerns that commenters have expressed in earlier responses to CMS, the agency states that they believe the "public posting of hospital standard charge information will be useful to health care consumers who need to obtain items and services from a hospital." The CAP would again stress that while recent efforts to increase access to charge information are well-intentioned (including, as listed in the proposed rule, many efforts undertaken by states, insurers, and self-funded employers), pricing data posted online by hospitals is often incomprehensible and unusable by patients. Even where a patient can determine the appropriate item from the chargemaster, which must now be posted online by the hospital, that charge differs from the cost to the patient and likely does not accurately represent patient out-of-pocket costs. Further, any efforts to increase the availability of price information for patients would have to be accompanied with significant education efforts to ensure patients understand the information provided, including the fact that that price alone does not determine the value of care or services.

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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 or Elizabeth Fassbender, (202) 354-7125, efassbe@cap.org.

[3] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

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