



COLLEGE of AMERICAN PATHOLOGISTS

June 25, 2018

Seema Verma
Administrator

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

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.

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; (CMS-1694-P)

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1694-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 is recognized throughout the care continuum and affects many patient encounters.

This letter includes comments regarding the following issues:

1. Requirements for Hospitals to Make Public a List of their Standard Charges via the Internet
2. Promoting Interoperability
3. Chimeric Antigen Receptor (CAR) T-Cell Therapy
4. Revising CMS' Date of Service (DOS) policy in the 2019 inpatient hospital payment regulations

1. Requirements for Hospitals to Make Public a List of their Standard Charges via the Internet

Within this proposed ruling, the Centers for Medicare and Medicaid Services (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 and physician fees for emergency room visits." 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.

In order 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 (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.

With respect to the Agency’s question on page 20549 (“Should health care providers be required to inform patients how much their out-of-pocket costs for a service will be before patients are furnished that service?”), 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 particular 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 not be required to inform patients how much their out-of-pocket costs for a service will be before patients are furnished that service.**

2. 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 which now aligns 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) in order 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 typically, as medical directors 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.
- 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.

Further, CAP supports the CMS proposal to align the PI program for hospitals with the Quality Payment Program (QPP). Pathologists can currently only participate in 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. 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 greater 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. We encourage CMS to propose this pathway in the forthcoming QPP proposed rule. Such a proposal 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.

Additionally, the CAP supports the CMS proposal to reduce the reporting period to 90 days from the current full year. We believe the current full year reporting period is too burdensome for clinicians and that sufficient data on technology use can be collected and evaluated in the shorter and more efficient 90-day reporting period. The 90-day reporting period will also allow physicians the necessary time to test, upgrade, and replace their systems. The CAP strongly urges CMS to shorten the reporting period for the PI category of MIPS to 90 days as well in order to align with the hospital PI program.

Overall, the CAP supports the CMS goals of reducing burden while aligning the QPP and the hospital PI programs. We hope to continue our productive conversations with CMS on more appropriate PI measures for pathologists and ways for pathologists to more fully, and meaningfully, participate in MIPS.

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

Chimeric Antigen Receptor (CAR) T-Cell therapy is an evolving service that is high in cost, and has the potential for volume increases over time that present unique challenges for providers, patients, and the CMS. The resource consumption and clinical characteristics of the patients with a given set of conditions are clinically distinct from others. The CAP has been working with ASH, ASBMT, ASCO, and other stakeholders to develop comments on the CAR-T provisions of the proposed Inpatient Prospective Payment System (IPPS) rule. Our goal is for the CMS to achieve a payment structure that allows physicians to utilize what they feel is the best product for each patient, in the most appropriate care setting. Therefore, the CAP seeks solutions that:

- Create a site-neutral, product-agnostic payment structure
- Remove provider responsibility for managing product costs
- Minimize/remove financial losses for providing CAR-T
- Create flexibility for future products and combination therapies
- Minimize reimbursement disruption for other cellular therapies/HCT

The proposals offered by CMS reflect stakeholder suggestions and would improve the current state to some degree in each of the scenarios. However, the CAP believes CMS's option within the proposed rule to revise MS-DRG 016 for autologous bone marrow transplant along with a New Technology Add-On Payment (NTAP) (if approved) and the revised cost to charge ratio of 1.0 to address charge compression would result in significant losses incurred by hospitals (losses estimated over \$65,000 per patient). The CAP believes this estimated loss is a conservative estimate because the revised MS-DRG 016 does not account for the cost of the ICU stays required to treat the adverse events experienced by the typical CAR-T patient. An equitable Medicare



payment should account for both the cost of the product and the cost of care. CMS' proposal does not do this.

The CAP recommends that CMS finalize its proposal to assign CAR-T cases to MS-DRG 016 for the next two to three years while data is collected and further analyzed before determining how to proceed with future CAR-T specific MS-DRGs. In addition, the CAP recommends a separate CAR-T product payment and CMS use the proposed concept of a CCR of 1.0 to ensure adequate reimbursement is provided to both PPS-hospitals and PPS-Exempt hospitals. For PPS hospitals, CMS can implement a CCR of 1.0 using a separate, add-on payment for CAR-T, based on ASP or actual acquisition cost. This will ensure that the agency can clearly identify the hospital's cost of acquiring the therapy and reimburse for it accordingly.

We are confident future claims will show that MS-DRG does not accurately reflect the costs of the complex care required by these patients. Despite the limitations of revised MS-DRG 016, the CAP is confident the alternate option of reimbursing for the revised MS-DRG and the CAR-T product separately will create a sustainable payment model that will protect patient access to CAR-T therapy and can be applied to other similar innovative therapies. We urge CMS to adopt this approach.

The payment option the CAP recommends above does not require the application of a NTAP payment. However, we recommend that CMS grant the application for a NTAP payment in the event that CMS does not implement the alternate payment option we have outlined. This payment will help institutions address financial losses associated with CAR-T therapy in the short-term and allow CMS and stakeholders to develop a sustainable long-term solution.

Our recommendations above would allow CMS to pay for the cost of care under MS-DRG 016 with its current outlier policy in place and to pay for the product cost separately as a pass-through at actual acquisition or invoice cost. It would have the added benefit of being site neutral, eliminating financial incentives to treat patients in settings that may not be medically appropriate. This recommendation would also apply a consistent payment rate across CAR-T centers. CMS would also be able to adjust payment for the product on a quarterly basis when ASP changes rather than having to wait years to adjust MS-DRG payment. We recognize that reimbursing for the product as a pass-through will require the agency to use its adjustment authority.¹ Given the innovative nature of therapy, we believe using this authority is warranted.

While the revised MS-DRG 016 may still fall short of covering the cost of care at this time, it is likely that within the next few years CMS would have the data justification, through claims and cost reports, to adjust the payment rate or create a new MS-DRG for CAR-T, so that these lifesaving therapies are appropriately reimbursed.

In addition, the CAP recommends that the CMS leave payment methodologies for these services open for further comment and revision as they, technologically and procedurally, will likely evolve from their current form.

4. Revise CMS' Date of Service (DOS) policy in the 2019 inpatient hospital payment regulations

The CAP would like to urge the agency to revise its Date of Service (DOS) policy in the 2019 inpatient hospital payment regulations. Specifically, the CAP urges CMS to:

¹ Social Security Act §1886(d)(5)(I)(i): "The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate."



- A. Apply all of the recent revisions to Hospital Outpatient Prospective Payment System laboratory date of service policy to hospital inpatients
- B. Include FISH technical component services as exclusions from packaging policies

A. Apply all of the recent revisions to Hospital Outpatient Prospective Payment System laboratory date of service policy to hospital inpatients

The CAP appreciates the improvements to Medicare’s laboratory DOS policy in Medicare’s Outpatient Prospective Payment System (OPPS) rulings to date. However, these improvements did not address hospital inpatients and payments for some tests are still problematic.

The CMS and other commenters recognize that these tests have a different pattern of clinical use than the more conventional laboratory tests. Regardless of the location or date of the testing, the services performed during an inpatient or outpatient encounter are typically unrelated to those driven by molecular testing. For example, if blood is drawn at the same time a cancer patient receives chemotherapy during an outpatient encounter (e.g., for the purposes of determining potential metastasis or minimal residual disease), the results of testing completed on that specimen will inform treatment during a future, not the current, encounter.

For these tests, the process of seeking payment from the hospital has long proven burdensome for clinical laboratories, hospitals, treating physicians and Medicare beneficiaries and may have negatively impacted patient care, particularly in the cancer setting where large genomic sequencing panels are increasingly used and timely access to test results can impact the treatments patients receive. The Agency stated in its OPPS Final ruling for 2018 that “adding the laboratory DOS exception for hospital inpatients would have policy and rate setting implications under the IPPS diagnosis related group (DRG) payment.” However, close examination of the Medicare program policy documents show a strong history of excluding pathology technical components from the inpatient DRG bundled payment. In fact, agency policy has dictated that such costs were not included in the DRGs for all hospitals utilizing independent laboratories, and in particular these diagnostic services could not, by virtue of their recent emergence, be included in the data on which any prospective payments are based. Furthermore, there has never been a specific adjustment in the DRGs for technical component services.

Laboratory tests ordered for hospital inpatients do not have the specific CPT code tests listed on the inpatient claim. As a result, the hospital and CMS cannot easily track patients who have received these tests using claims data, or evaluate how advanced testing contributes to cancer care and other advanced treatments, or evaluate the total cost of care. If laboratories could directly bill Medicare for molecular pathology tests and advanced diagnostic laboratory tests (ADLTs) in the inpatient setting, consistency across places of service, tracking capabilities and patient outcomes could be enhanced.

The CMS and all stakeholders recognize that molecular pathology tests and ADLTs have unique clinical utilization distinct from conventional laboratory tests. As molecular technologies continue to advance, the CAP believes their utility will continue to differ significantly. Molecular testing allows patients and their physicians to make actionable medical decisions based on genomic information. The information and the treatment decisions gleaned from molecular testing are relevant to future patient care, but generally do not impact patient management during the hospital visit. Additionally it is an administrative burden on hospitals that collect specimens, and laboratories that furnish and bill for ADLTs and molecular pathology tests, to track tests ordered for hospital outpatients in a way that is inconsistent with those performed on specimens obtained from hospital inpatients. Reimbursement policy for these services should be consistent across places of service and consistency between the



DOS for hospital inpatients and hospital outpatients is important for evaluating data on patient outcomes.

Many hospitals do not perform these types of more technologically advanced laboratory tests in-house. Hospitals therefore, upon receipt of a physician's orders, instead send patient specimens to independent and/or specialized laboratories for testing, regardless of the place of service.

Restricting the DOS policy to only outpatients:

- Restricts patient access to tests and reduces efficacy of treatment plans due to hospitals delaying or foregoing patient testing to avoid financial risk
- Discourages hospitals from utilizing advanced tests because billing for tests not performed by hospitals can create administrative and financial complexities
- Presents confusion among clinical laboratories and hospitals as to who and when each is responsible for billing of laboratory services
- Hampers the access of beneficiaries to these results

Thus, regardless of the place of service, a revised DOS policy that allows the performing laboratory to bill directly for molecular pathology tests and ADLTs, rather than receiving payment from the hospital, would reduce administrative and billing complexity for hospitals, clinical laboratories, treating physicians and Medicare beneficiaries, while promoting timely access to patient testing.

Tests on tissue samples acquired from patients during hospital stays are critically important for determining future treatment planning and responsible patient care. The CAP and the AMA, along with other stakeholders, believe that molecular pathology testing has rapidly evolved over the past five years, whereas they are performed as a separate set of services in the targeting of treatment and patient care management. Therefore, it is more appropriate that all laboratories performing molecular pathology testing bill Medicare directly. The AMA has recognized this fact and unanimously passed recent policy at its November 2017 House of Delegates meeting that reads:

Elimination of Laboratory 14-Day Rules Under Medicare D-330.903

Our AMA will actively lobby the federal government to change laboratory Date of Service rules under Medicare such that complex diagnostic laboratory services performed on pathologic specimens collected from a hospital procedure be paid separately from inpatient and outpatient bundled payments

The CAP is eager to work with CMS to ensure that all patients have access to this testing and the personalized medical information it provides. **We urge CMS to allow laboratories to directly bill Medicare for molecular pathology tests and ADLTs in the inpatient setting.**

B. Include FISH services as exclusions 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 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 OPSS packaging policy to include FISH technical component services in the definition of molecular services provided in inpatient hospital settings: CPT codes 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377.**

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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 Klemm (202) 354-7105 / tklemm@cap.org.