COLLEGE of AMERICAN PATHOLOGISTS

September 17, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–1753–P
P.O. Box 8010
Baltimore, MD 21244–1850

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

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals (CMS–1753–P), (RIN 0938–AU43)

Dear Administrator Books-LaSure:

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-1753-P for calendar year (CY) 2022. 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. Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges
2. Proposed Change to Packaged Items and Services
3. Laboratory Date of Service Policy
4. Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program

1) Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

Section 2718 of the Public Health Service (PHS) Act requires hospitals each year establish and "make public a list of the hospital's standard charges for items and services provided by the hospital." The PHS Act requires the Secretary of the Department of Health and Human Services to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for penalties. The CMS proposes to amend several hospital price

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transparency policies in order to ensure compliance. The CMS proposes to increase the amount of the penalties for noncompliance through the use of a scaling factor based on hospital bed count, and the CMS proposes to prohibit conduct that creates barriers to accessing the standard charge information.

The CAP believes 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 continues to express concern about requiring laboratories to inform patients about out-of-pocket costs for a service before patients are furnished that service, as any delays in providing that service can cause a significant risk of patient harm. Further, there is significant difficulty in determining the cost of laboratory 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 the CMS in Medicare's Benefit Policy Manual, which contains a surgical/cytopathology exception noting there are additional tests that a pathologist may need to perform after an examination or interpretation, "even though they have not been specifically requested by the treating physician/practitioner.

The pathologist may perform such additional tests under the following circumstances:
• These services are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner;
• The results of the tests are communicated to and are used by the treating physician/practitioner in the treatment of the beneficiary; and
• The pathologist documents in his/her report why additional testing was done."[1]

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.

The agency has stated 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 listed charge differs from the cost to the patient and likely does not accurately represent the patient's 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 that patients understand the information provided, including the fact that that price alone does not determine the value of care or services. Posting prices online often exacerbates patient confusion of health care pricing. ***The CAP maintains that many laboratory services, like emergency services, are typically not shoppable as they are not anticipated and scheduled in advance. Laboratory services should therefore be exempt from being reported on any public list of hospital standard charges***.

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

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In this proposed ruling, CMS states that "noncompliance of posting standard charges does not rise to the level of harm to the public as other violations (such as safety and quality issues) for which HHS imposes a civil monetary penalty (CMP) and therefore should remain at a relatively lower level." The CAP agrees, as any penalty imposed will divert critical direct and indirect resources of staff time and money away from patient care. Penalties will do more harm than good within a health care setting and the agency should promote public pricing as a strategic competitive opportunity for providers rather than mandating compliance. Providers should have the flexibility to create their own public facing pricing and not be burdened with regulatory controls.

If the agency moves forward with its proposal, imposing an increase in the CMP, the agency should use a scaling factor methodology based on a very small percentage of revenue rather than bed count. The percentage of revenue, such as 0.1%, should be much smaller as this penalty may amount to millions of dollars of lost patient care revenues. ***The agency should postpone finalizing any civil monetary penalty until stakeholders can review and propose other alternative methods of price transparency***.

2) Proposed Change to Packaged Items and Services

The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services efficiently and to manage their resources with flexibility. The CAP believes that the packaging of pathology services has been extremely constrictive to the practice of pathology because our services are often billed multiple times on a patient claim to complete the overall pathology service. Each unit of service is separate and distinct laboratory work and provides a unique clinical result used in the treatment the patient.

The CAP continues to hear concerns from stakeholders that the agency's packaging policies are hampering the practice of pathology. Specifically, this occurs when a pathology service is performed more than once for a patient encounter in order to complete a patient diagnosis. This often causes reimbursement shortfalls due to CMS' packaging policy. Additionally, 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.

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 5 (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.

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The CAP urges the agency to exclude pathology services that are billed more than once per patient encounter from being packaged and pay them separately. Additionally, the CAP urges the agency to change the status indicators of all pathology add-on codes from "N" to "Q2", as each unit of service of a pathology service involves separate and distinct laboratory work. A status indicator of "Q2" provides for an APC assignment when the services are separately payable.

3. Laboratory Date of Service (DOS) Policy

In the OPPS final rule for 2021, CMS expanded the Packaging Policy exceptions to include multi-analyte assays with algorithmic analyses (MAAA), using the framework CMS previously established for advanced diagnostic laboratory tests (ADLTs). In response to comments that we and other entities submitted for the 2021 OPPS proposed rule, CMS also indicated that it would consider expanding the Packaging Policy exceptions for pathology testing in subsequent rulemaking.[2] ***The CAP is disappointed that the agency did not propose any changes to the laboratory date of service policy for CY 2022.***

In the CY 2020 rulemaking cycle, CMS stated that a protein-based multi-analyte assay with algorithm analyses (MAAA) that had received ADLT status (CPT code 81538 *Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival*) was eligible for the DOS exception. In the CY 2021 rulemaking cycle, following stakeholder feedback, CMS acknowledged that the clinical use of a subset of protein-based MAAAs was generally not connected to the primary hospital outpatient service and that the tests should be paid excluded from the OPPS packaging policy and paid separately under CLFS. As such, it finalized an exception to add five cancer-related protein MAAAs to the DOS exception. (Impacted codes include 81500, 81503, 81535, 81536, and 81539 with 81538 already excepted from the DoS policy due to its ADLT status).

The CAP appreciates that CMS recognized the clinical use of tests beyond the RNA and DNA tests. In this expansion of the DoS exception last year, 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. These barriers impact not only providers of molecular tests paid under the CLFS but also to molecular tests furnished as technical components of physician pathology procedures, such as in situ hybridization (ISH), flow cytometry, and immunohistochemistry procedures. (Relevant codes include: 88120, 88121, 88184, 88185, 88341, 88342, 88344, 88360, 88361, 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377)

When 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. This can create the same barriers to access and confusion that arise with similar tests paid under the CLFS.

[2] 85 Fed. Reg. 85901 (December 29, 2020)

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As an example, there are molecular pathology tests and physician pathology tests that both target the same molecular marker. For example, ALK for non-small cell lung cancer may be analyzed using molecular methods, immunohistochemistry (IHC), or in situ hybridization (ISH) methods. While testing for the same marker, these tests are handled differently under the date of service rule as it currently stands. The molecular method laboratory test is eligible for the (b)(5) exception and may be billed by the performing laboratory (reported by 81401 *Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat) EML4/ALK (inv(2)) (eg, non-small cell lung cancer), translocation or inversion analysis*)[3], but the physician pathology test (reported by 88374/88377 for ISH or 88360/88361 for IHC) is not eligible and must be furnished under arrangements which hospitals may or may not be willing make or held until 14+ days, leading to unnecessary delays to beneficiary care.

Another dynamic with the date of service rule relates to specialized physician pathology services and the difference in access depending on the site of service selected by the Medicare beneficiary. In one scenario, a patient may receive a specialized physician pathology test (e.g., WATS^{3D} test) in an ambulatory surgical center while a second patient receives the same test in a hospital outpatient clinic. The patient at the ASC would have access to the test while the patient seeking care at the hospital clinic could be denied if the hospital refuses to enter into an arrangement with the laboratory. Patients should not face denials of care based on where the test is performed. This dynamic also places the hospital-based physicians in a difficult predicament if the physicians are prevented from following professional practice guidelines due to an administrative decision to prohibit access to these tests at their facility.

To address this issue, the CAP recommends that CMS issue a regulatory exception to the OPPS Packaging Policy for physician pathology services that meet the current established exception criteria under 414.510(b)(5). By expanding the current exception to include this category of services, CMS would align payment for the TC of the test with the actual provision of that service, ensuring the continued availability of the test to Medicare beneficiaries who receive outpatient services at hospitals.

When granting a Packaging Policy exception to MAAAs for Calendar Year 2021, CMS noted several criteria that justified excepting these tests from the Packaging Policy. First, these tests are unconnected to the primary hospital outpatient service during which the test specimen was collected. Specifically, the tests are not performed in the hospital outpatient department and are instead furnished well after the patient leaves the hospital. Second, rather than informing current treatment, the excepted tests are used to inform future interventions beyond the hospital outpatient encounter in which the test specimen was collected. Finally, as an additional consideration, CMS looked at how an exception might improve beneficiary access to health care services. The same criteria apply to certain physician pathology services, and CMS can apply the same regulatory exception test to identify tests eligible for exception.

In summary, the CAP requests that CMS exclude the technical component of the physician pathology codes for tests that fit under the criteria currently laid out under 415.510(b)(5).

[3] This code is on list of laboratory tests subject to date of service exception (Link)

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Relevant codes include: 88120, 88121, 88184, 88185, 88341, 88342, 88344, 88360, 88361, 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377.

4) Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program

CMS acknowledges the persistent and often growing inequity in health care access and outcomes and proposes modifications to CMS programs to begin to address the health equity gap. Specifically, CMS is beginning by increasing reporting of health disparities based on social risk factors to increase the actionable data available to hospitals and clinicians. The CAP supports the broad goal of improving health equity and is in general agreement with the definition of health equity proposed by CMS. However, we caution against actions that increase burden on providers and patients without clear benefit, particularly when such actions touch on potentially complex and delicate subjects for patients such as disability status and gender identity.

The CAP supports the inclusion of the anti-racism Improvement Activity (IA) suggested by CMS, and the modifications to other IAs to increase health equity. We also support additional policies aimed at reducing the burden on small practices, particularly small practices in underserved communities. Going forward, the CAP encourages CMS to ensure that health equity is considered in all aspects of the program. While health outcomes are critical to measuring any program or care provided, an exclusive focus on outcomes imposes a risk of ignoring potential levers for improvement by missing key actionable steps in the process. We support policies that ensure that health disparities are addressed across the care continuum.

CMS also considers two potential future initiatives: stratification of quality measures results by race and ethnicity and improving demographic data collection. For the former, CMS acknowledges that while self-reported race and ethnicity data is the gold standard, large amounts of this data are not currently collected. The CAP understands the need to stratify quality measure results and is supportive of the goal broadly. However, it is not clear that the current imputation methods described by CMS provide sufficiently granular data to stratify measures in a meaningful way. CMS states that the indirect estimation method “is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.” The utility of these methods for stratifying results of quality measures that are by definition attributable to an individual clinician and often measured at the individual patient level remains unclear. We recommend caution in the application of imputed race and ethnicity data to most MIPS measures due to the different levels of measurement: imputed data can only be attributed to groups while measures are often at the patient or encounter level. We also recommend careful consideration of the meaning of stratified results to avoid overinterpreting such results or incorrect attribution to individual clinicians.

Regarding improving demographic data collection, the CAP understands the need for such initiatives and is broadly supportive of them. Importantly, the CAP encourages CMS to harmonize with existing projects and standards to avoid duplicative effort or potentially conflicting standards. The CAP especially highlights work already underway at the Office of the National Coordinator for Health Information Technology (ONC) such as Project US@. While this does not directly address race or ethnicity, it does represent a step forward in standardizing collection of some demographic data and should be included in any future CMS initiatives. Similarly, the Gravity Project has submitted

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prospective data elements for inclusion in USCDI version 2. Creating a new set of standards would be unnecessary and confusing.

Importantly, we ask that CMS consider the burden and benefit of adding any mandatory data elements to be collected in Quality Payment Program (QPP) measures. Not all clinicians have access to the full EHR data on a patient and therefore may not collect demographic data elements. If the benefit of collecting them is significant, the CAP recommends that CMS engage with electronic health technology vendors, particularly those used by diagnostic specialties who typically do not collect demographic data from patients, to understand what is feasible. Given the breadth of available social determinants of health, the potential to add numerous required data elements, and therefore significant burden on clinicians, cannot be overlooked. The CAP suggests that CMS rigorously investigate and make public the proposed use cases for any new mandatory data elements prior to requiring them to avoid unnecessary burden on patients and providers. These efforts have the potential to improve data collection but also make quality measure collection increasingly complicated and burdensome; the risks and benefits must be clearly outlined. Similarly, the interpretation of measures in light of any new data elements should be clearly spelled out, as noted with respect to stratification of measure results by race and ethnicity.

The CAP stands ready to support improvement of health equity in diagnostic medicine by working with CMS and other federal partners to collect meaningful data on social determinants of health and to utilize such data to benefit patients, families, and other stakeholders.

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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 Maurine Dennis (202) 354-7136 / mdennis@cap.org.

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