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September 13, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1717-P — Hospital Outpatient Prospective Payment System, Proposed Rule – Potential Changes to the Laboratory Date of Service Policy

Dear Administrator Verma:

On behalf of the Coalition for 21st Century Medicine (C21), we appreciate the opportunity to comment on the Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule for Calendar Year 2020. We are writing in strong support of maintaining the current laboratory date of service (DOS) policy at 42 CFR 414.510(b)(5), which has dramatically improved beneficiary access to innovative molecular diagnostic tests to guide physicians in selecting appropriate care for complex diseases like cancer, cardiovascular disease, and rheumatoid arthritis.

C21 strongly opposes any revisions to the laboratory DOS policy that would limit beneficiary access to precision diagnostic testing. For this reason, we believe that CMS should not finalize the first two potential revisions in the Proposed Rule: (1) requiring physicians to predict whether test results will inform treatment during a future outpatient encounter and/or (2) limiting the DOS policy to Criterion A Advanced Diagnostic Laboratory Tests (ADLTs). Both of these options would significantly curtail beneficiary access to precision diagnostics and would be highly burdensome to implement just two years after establishing new billing rules. C21 does support the third potential revision, which would allow molecular pathology testing services performed by blood banks to be billed by the hospital.

C21 comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. C21's mission is to improve the quality of healthcare by encouraging research, development, and commercialization of innovative diagnostic technologies that will personalize patient care, improve patient outcomes, and substantially reduce healthcare costs. C21 has worked with CMS and Congress on the laboratory DOS issue since 2005, and we appreciate the agency's efforts in establishing the current policy at § 414.510(b)(5) and its continued attention to these issues.

I. Existing Laboratory DOS Policy Has Improved Beneficiary Access to Precision Testing

C21 worked with the agency and other stakeholders to modernize Medicare’s policies on laboratory billing jurisdiction in order to ameliorate beneficiary access issues that arose from requiring the hospital to bill for precision diagnostic tests performed by an outside laboratory. Over the past eighteen months, the revised DOS policy at § 414.510(b)(5) has improved beneficiary access to precision tests and targeted treatment by removing barriers that once led to delayed and canceled orders. **It is important to note that the agency’s revisions implementing the laboratory DOS policy did not lead to unbundling of payment because these tests are paid separately on the Clinical Laboratory Fee Schedule (CLFS) in the outpatient setting whether billed by the laboratory or the hospital.**

A. C21 Supported DOS Policy in 2018 to Address Access Risks

C21 strongly supported the establishment of the current laboratory DOS policy at § 414.510(b)(5) in the CY 2018 HOPPS Final Rule. The DOS policy prior to 2018 made the DOS the date of specimen collection for tests performed on a specimen collected from a hospital outpatient, unless the test was ordered 14 days or more after the date of the patient’s discharge from the hospital. This policy, combined with the agency’s separate “under arrangements” regulations governing services furnished to hospital patients,¹ required hospitals to bill for tests that they did not perform, and forced laboratories, in turn, to seek payment for testing from hospitals with which they frequently lacked a relationship.

As CMS notes in the Proposed Rule, there was a consensus among stakeholders that these rules limited beneficiary access to precision diagnostic testing. Specifically, as a result of these rules, hospitals were often reluctant to bill Medicare for a test they would not typically or never perform. CMS noted that in some cases, this led hospitals to delay the ordering of tests because of billing complexity and confusion, sometimes waiting until at least 14 days after the patient was discharged from the hospital outpatient department, and in other cases canceling orders. Both delays and cancellations of orders restricted patient access to timely test results and targeted treatment for Medicare Part B beneficiaries, especially compared to enrollees of Medicare Advantage plans and other private payers that allowed laboratories to bill directly for testing.

C21 agreed with CMS and other stakeholders that patients would benefit from the establishment of the DOS policy at § 414.510(b)(5), which generally makes the DOS the date of test performance for a molecular pathology test or Criterion A ADLT performed on a specimen collected from a beneficiary during a hospital outpatient encounter. Specifically, we believed that this new policy would alleviate beneficiary access issues by enabling the performing laboratory, and not the hospital, to bill Medicare directly for these tests. We likewise agreed with the agency that this revision was appropriate to promote greater consistency between the laboratory DOS policy and CMS’ outpatient laboratory packaging policy with respect to those tests that “may have a different pattern of clinical use, which may make them generally less tied

¹ These regulations, found at 42 CFR §§ 410.42 and 411.15(m), generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement with that entity to furnish that particular service to its patients.

to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.”

B. DOS Policy has Improved Beneficiary Access to Clinically Important Diagnostic Testing Services

Based on our experience over the past eighteen months, CMS’ establishment of the DOS policy at § 414.510(b)(5) has been highly successful in achieving its most important objective – improving beneficiary access to well-informed treatment for complex conditions. Allowing the performing laboratory to bill Medicare for outpatient molecular pathology tests and Criterion A ADLTs has limited delays in ordering precision diagnostic tests and removed administrative burdens in ordering these tests for patients seeking care during a hospital outpatient encounter. This, in turn, has afforded physicians more consistent and timely access to precision diagnostic information to guide clinical decision-making.

Advanced lung cancer is a good example of a rapidly progressive disease where even days-long treatment delays matter. The National Comprehensive Cancer Network (NCCN) guidelines advise tissue or plasma-based broad molecular profiling in the treatment algorithm for Non-Small Cell Lung Cancer (NSCLC).² Many professional society guidelines recommend that testing be performed as soon as possible, to the point of recommending that results be available within ten days of diagnosis.³ Because the molecular profile assists physicians with therapy selection, any delay to the testing process delays the initiation of therapy or leads to the wrong therapy for that patient.

Specifically, society guidelines and peer reviewed publications have acknowledged that many lung cancer patients proceed directly to chemotherapy or immunotherapy when molecular profiling is delayed.⁴ For example, a study of 289 community-based oncologists found that 55% of advanced NSCLC patients who test positive for *EGFR*, *ALK*, *ROS1*, or *BRAF* genomic alterations do not receive targeted therapy because they do not receive results in time for first-line treatment to be started.⁵ Not only do these patients miss out on targeted therapies with response rates two or threefold better than chemotherapy or immunotherapy, but many receive immunotherapy even though they have an EGFR or ALK mutation predictive lack of response to

² NCCN NSCLC Guidelines Version 3, 2017.

³ See Lindeman NI, Cagle PT, Aisner DL et al. Updated Molecular Testing Guideline for the Selection of Lung Cancer Patients for Treatment With Targeted Tyrosine Kinase Inhibitors: Guideline From the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. *J. Mol. Diagn. JMD* 2018; 20(2):129–159.

⁴ Singal G, Miller PG, Agarwala V et al. Association of Patient Characteristics and Tumor Genomics With Clinical Outcomes Among Patients With Non-Small Cell Lung Cancer Using a Clinicogenomic Database. *JAMA* 2019; 321(14):1391–1399; Kim ES, Roy UB, Ersek JL et al. Updates Regarding Biomarker Testing for Non-Small Cell Lung Cancer: Considerations from the National Lung Cancer Roundtable. *J. Thorac. Oncol. Off. Publ. Int. Assoc. Study Lung Cancer* 2019; 14(3):338–342.

⁵ Gierman HJ, Goldfarb S, Labrador M et al. Genomic testing and treatment landscape in patients with advanced non-small cell lung cancer (aNSCLC) using real-world data from community oncology practices. *J. Clin. Oncol.* 2019; 37(15_suppl):1585–1585.

immunotherapy. Only one-half of advanced NSCLC patients live long enough to get to a second line of treatment, thus prescribing the best treatment option in the first line of care is paramount.⁶

Ordering delays of up to 14 days under the previous laboratory DOS policy may have led physicians to make treatment decisions without the results of molecular profiling, with the negative consequences described above. For many patients, the laboratory DOS policy at § 414.510(b)(5) has facilitated rapid, well-informed treatment and treatment.

Recent claims data support the position that changes in the laboratory DOS policy have improved beneficiary access. We conducted an exploratory analysis of trends in the use of molecular tests using relevant claims data from the 5-percent Carrier Standard Analytical Files for the first six calendar months of 2018 and the first six calendar months of 2017. Overall, adjusting for changes in Medicare Part B enrollment and maturity of claims between the 2017 and 2018 files, 36% more Part B beneficiaries received molecular testing during the first six months of 2018 to guide complex care decisions.

We then engaged the Moran Company to conduct a more detailed analysis (attached as [Appendix A](#)) which confirms the positive impact of the current DOS rule on beneficiary access to precision diagnostics in the outpatient setting. Importantly these findings demonstrate provider familiarity and adoption of the new billing policies, notwithstanding enforcement discretion issued by CMS. Using the 5-percent Carrier Standard Analytic Files for calendar years 2017 and 2018, the Moran Company compared the utilization of molecular tests that are excluded from OPSS packaging as designated by the OPSS Status Indicator “A” and found overall that 55% more beneficiaries benefitted from molecular testing in 2018 versus 2017 in the 30-days following an outpatient discharge. This higher rate of growth among molecular testing following an outpatient discharge (55% vs 36%) suggests that beneficiary access may have been impeded by the prior DOS policy as contemplated by CMS in the 2018 HOPPS Final Rule.

Notably, in the Moran Company’s analysis, the proportion of molecular testing laboratory claims with the same diagnosis and a DOS between 1 and 13 days following the outpatient discharge grew by 15% from 2017 to 2018. By contrast, the proportion of same-diagnosis molecular testing claims with the same DOS or a DOS 14-30 days following the outpatient claim declined by 13% and 2% respectively (Table 1a).⁷

⁶ Davies J, Patel M, Gridelli C et al. Real-world treatment patterns for patients receiving second-line and third-line treatment for advanced non-small cell lung cancer: A systematic review of recently published studies. *PloS One* 2017; 12(4):e0175679.

⁷ The proportion listed in Table 1a for 14-30 day same-diagnosis claims is the same for 2018 as for 2017 because of rounding. The proportion for 2018 represents a 2% decrease from the proportion for 2017.

Table 1a. Proportion of All Molecular Pathology Lab Claims Billed in Timeframe

	Proportion of Lab Claims with Same Diagnosis Linked to an Outpatient Procedure			Proportion of Total Lab Claims Linked to an Outpatient Procedure		
	2017	2018	% Change	2017	2018	% Change
Same Day	39%	34%	-13%	30%	22%	-26%
1-13 Days	38%	44%	15%	41%	46%	12%
Between 14 and 30 Days	22%	22%	-2%	29%	32%	10%

The Moran Company’s findings show even more dramatic changes in the adoption of lung cancer molecular diagnostics, a clinical area in which considerable importance is placed on early access to molecular testing results for the reasons discussed above. The proportion of molecular testing claims for lung cancer with the same diagnosis as the outpatient claim and with a DOS between 1 and 13 days following the OPSS discharge grew by 37%. Same-diagnosis molecular testing for lung cancer with the same DOS and a DOS 14-30 days following the outpatient claim declined by 39% and 1% respectively (Table 1b).⁸

Table 1b. Proportion of Lung Cancer Lab Claims and Diagnoses Billed in Timeframe

	Proportion of Lung Cancer Lab Claims Linked to an Outpatient Procedure with the Same Diagnosis			Proportion of Total Lung Cancer Lab Claims Linked to an Outpatient Procedure		
	2017	2018	% Change	2017	2018	% Change
Same Day	39%	24%	-39%	39%	23%	-40%
1-13 Days	42%	57%	37%	41%	57%	41%
Between 14 and 30 Days	19%	19%	-1%	21%	19%	-6%

These data support the policy position that under the prior DOS policy, patients may have encountered barriers to access for precision medicine diagnostics in the 1-13 day window. It highlights that even in light of the CMS enforcement discretion, the new DOS exception is being implemented by the provider community, physicians are likely are receiving more timely diagnostic information, and patients are receiving timelier and better-informed treatment for complex conditions. These results are aligned with feedback that C21 has received from patients and clinicians. CMS should carefully consider these findings and their positive implications for patient care before concluding that the 2018 changes in the DOS policy should be reversed after only 18 months in effect and less than a full year of claims data.

^{8 8} The proportion listed in Table 1b for 14-30 day same-diagnosis lung cancer claims is the same for 2018 as for 2017 because of rounding. The proportion for 2018 represents a 1% decrease from the proportion for 2017.

C. C21 Members Have Implemented Current DOS Policy

C21 member laboratories are some of the nation's largest providers of precision medicine diagnostics, and have been successful in working with providers to obtain the necessary information to bill for molecular pathology tests. We expect other independent laboratories are able to obtain this information when tests are ordered by non-hospital providers and the laboratory has always been responsible for billing. C21 stands ready to serve as a resource to CMS and is committed to continuing to work with the agency and other stakeholders to identify workable solutions to ensure an efficient transition to the DOS policy at § 414.510(b)(5).

Moreover, it is our understanding that the hospitals whose physicians order our members' testing likewise support the DOS policy at § 414.510(b)(5). Because our members' tests are unique, and are not performed by hospitals (and with respect to member tests with ADLT designation are prohibited by statute from being performed by hospitals), hospitals consider it to be administratively burdensome to be required to bill Medicare for our tests when performed on specimens collected during the outpatient encounter. For these hospitals, the DOS policy has lessened the administrative burden rather than increasing it, and more importantly, has expedited patient and physician access to critical clinical information. Additionally, where hospitals have made the investments needed to perform non-sole source high complexity testing at their own laboratories, they continue to be able to bill for those tests under the current DOS policy and under arrangements regulations.

II. C21 Strongly Opposes Revisions to DOS Policy that Would Limit Beneficiary Access

Given the positive impact of the revised DOS policy in improving beneficiary access to precision diagnostic testing, C21 is concerned about any potential revisions that would limit beneficiary access to these tests and create administrative complexities. We believe that the first two options would undercut access to precision diagnostic information and timely targeted treatment without addressing a program operating need.

A. Requiring Physicians to Determine Future Use of Test Results is Inconsistent and Unworkable

Under the first potential revision offered in the Proposed Rule, a test would be considered a hospital service and be excluded from the DOS policy at § 414.510(b)(5) (thus making the hospital responsible for billing for the test through the under arrangement regulations) if the ordering physician determines that the test results are intended to guide treatment during *either* the current or some future yet-to-occur hospital outpatient encounter. This would change the existing § 414.510(b)(5)(iv), under which the DOS is the date of test performance if the test does not guide treatment during the outpatient encounter at which the specimen was collected.

C21 believes that this potential revision does not reflect the reality of clinical practice, is inconsistent with other CMS OPSS payment policy, administratively unworkable, and places physicians in an untenable decision-making position. The current regulation focuses on tests that are used to guide hospital treatment at the same outpatient encounter – a situation that is

clinically foreseeable at the time the test is ordered. By contrast, ordering physicians cannot be expected to reasonably predict whether the results of a given test will be used in a subsequent outpatient encounter for two clear reasons. First, the very reason they are **ordering** the testing is to determine the next clinical interventional steps to take for the patient. If the physician knew how and where they would be treating the patient at the time they ordered the test, they would not be ordering the test to begin with. Second, the physician ordering the testing may not be the only physician treating the patient based on the results. Patients with complex or chronic conditions, like cancer, often have multidisciplinary care teams coordinating various aspects of the patient's treatment plan, and it is impossible for the ordering physician to predict the treatment preferences of the entire care team.

The ability of the ordering physician to make a prediction about use of test results will vary widely based on the type and number of physicians, the type of test, the treatment options available to the patient, and other factors. For example, in lung cancer the work-up and diagnosis of a patient with a pulmonary lesion is performed by a pulmonologist. However, the treatment of lung cancer is performed by an oncologist or thoracic surgeon and the treatment varies by location, size, and stage of the cancer. Some patients may require surgical intervention in the inpatient setting, while many others proceed to chemotherapy in a community oncology setting. The "totality of the circumstances" standard and the decisional factors listed in the Proposed Rule will not assist the ordering pulmonologist in making a prediction in many of these circumstances, because there will not be the requisite information to make a prediction in the first place, nor is the pulmonologist likely to have the same training and consider the same factors as the clinician who actually makes the treatment decision. The broad range of clinical situations and its implications for the predictability of the future use of test results strongly counsels against the imposition of the one-size-fits-all standard under consideration.

Additionally, this ordering physician prediction-based approach would also be inconsistent with longstanding CMS policy governing services performed outside the hospital for outpatients. In the CY 2000 HOPPS 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.***"⁹ 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.

Finally, 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 the physician would be required to document their prediction as to the future use of every single molecular pathology test or ADLT that they order. They would also be required to communicate their decision to the hospital and to the performing laboratory to ensure that the correct entity bills for the test. This will require physicians to navigate two sets of bureaucracies and respond to queries and concerns from both hospitals and laboratories regarding their prediction of test

⁹ 65 Fed. Reg. 18434, 18440-41 (Apr. 7, 2000).

use. CMS will have no ability to adjudicate this policy to determine whether to pay claims that are submitted electronically based upon the laboratory collecting the physician's prediction. We believe that this ongoing administrative burden on physicians is likely to be far more complex than any implementation issues with the revised DOS policy at § 414.510(b)(5).

B. Limiting DOS Policy to Criterion A ADLTs Would Restrict Access to Sole-Source Molecular Pathology Tests

Under the second potential revision offered by CMS, the DOS policy at § 414.510(b)(5) would be limited to Criterion A ADLTs. The Proposed Rule justifies the potential elimination of the policy's applicability to molecular pathology tests based on a number of putative distinctions between molecular pathology tests and ADLTs that are inapplicable to a wide range of molecular pathology tests and do not take into account the access issues faced by the large number of unique, sole-source molecular pathology tests.

The Proposed Rule takes the position that molecular pathology tests do not face the same access issues as ADLTs in part on the grounds that such tests 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." The generalization that molecular pathology tests can be performed by hospital laboratories is unreflective of the wide diversity of that group of tests. CMS defines a molecular pathology test to include all "[t]ests that analyze nucleic acids,"¹⁰ and includes 307 tests on its list of "Laboratory Test Codes Subject to Date of Service Exception." Although only five of the listed tests are Criterion A ADLTs, dozens of them are molecular pathology tests that are *not* ADLTs, but *are* sole-source tests for very specific clinical indications. These tests are never performed in a hospital laboratory. Hospitals have no incentive to learn to perform an esoteric precision diagnostic assay for a tiny subset of its patients. The Proposed Rule provides no examples or evidence to demonstrate that hospitals are actually performing these sole-source molecular pathology assays.

Contrary to the Proposed Rule, of the hundreds of molecular pathology test codes, very few have been approved as kits by the FDA. One of the problems the current DOS policy sought to address was that these tests are not commonly performed by hospitals so the hospitals did not work to bill for the tests. If the hospital were performing these tests, they would simply bill for the test. We have seen nothing to indicate that this situation has changed in the past two years.

Nor is it likely that a hospital laboratory will "establish an arrangement with an independent laboratory to perform the[se] test[s]." The beneficiary access issues prior to the enactment of § 414.510(b)(5) were directly related to hospitals' unwillingness to enter into arrangements with precision medicine laboratories to perform sole source tests, or to devote resources to billing for them. One particular difficulty that hospitals faced in billing for sole-source tests prior to the establishment of the current laboratory DOS policy at § 414.510(b)(5) was that the hospitals were often located in jurisdictions where the local Medicare Administrative Contractors (MACs) lacked familiarity with the assays. This led to denials even where the test was covered by a different MAC that had jurisdiction over the sole provider of the test.

¹⁰ 81 Fed. Reg. 41036, 41057 (Jun. 23, 2016).

Limiting the DOS policy to 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. To date, the agency has only approved five ADLTs under Criterion A. By statutory and regulatory definition, *not all sole-source molecular pathology tests on the fee schedule would be afforded the opportunity to protect beneficiary access through ADLT designation*. Many innovative precision diagnostic tests *are not eligible to* be approved as ADLTs despite being sole-source assays. Part (1) of the ADLT definition at 42 CFR § 414.502 requires that a Criterion A ADLT use an “empirically derived algorithm” and provide “new clinical diagnostic information that cannot be obtained from any other test or combination of tests.” The requirement of an empirically-derived algorithm would exclude sole-source Genomic Sequencing Procedures (GSPs) from the DOS policy if this option is finalized. The requirement to provide new clinical diagnostic information could limit sole source tests in competitive markets from being approved as ADLTs and falling under the protections of the DOS policy.

The potential revision also would not protect any tests that are FDA-approved or cleared such as FoundationOne CDx, which is covered under a National Coverage Determination (NCD) and designated as an ADLT under Criterion B. There is no reason why a sole-source test that is FDA-cleared or approved should be excluded from the laboratory DOS policy while Laboratory Developed Tests are included. Other elements of the ADLT definition could exclude other sole source tests from the DOS policy at § 414.510(b)(5) if this option is finalized.

Lastly, limiting the DOS policy to Criterion A ADLTs would impose a substantial administrative burden on CMS, laboratories, and hospitals. For instance, if CMS finalizes the limitation of the DOS policy to Criterion A ADLTs in November, there would not be a quarterly ADLT application and approval cycle before the revision would take effect in January 2020. If a laboratory with a sole-source molecular pathology test applied for ADLT designation in January 2020 and was approved in March 2020, the laboratory would have to bill Medicare for the test in December 2019, the hospital in January and February 2020, and the laboratory again beginning in March 2020. If the laboratory later lost ADLT status because new tests on the market were determined to provide the same clinical diagnostic information, the laboratory would no longer be able to bill for the test. This potential fluctuation in billing jurisdiction is certainly more burdensome than a straightforward rule that sets date of service at the date of performance.

III. Support Hospitals Billing for Blood Bank Tests

C21 supports requiring hospitals to bill for molecular pathology tests performed by blood banks, and agrees with the agency that this step would facilitate beneficiary access to testing performed by blood banks. From a policy standpoint this makes sense because blood banks are not enrolled Medicare providers. We agree with the agency that “blood banks and centers perform molecular pathology testing for patients to enable hospitals to prevent adverse conditions associated with blood transfusions, rather than perform[ing] molecular pathology testing for diagnostic purposes.”

We would note that this approach would be consistent with existing CMS policy. The Medicare Manual already states that “codes for procedures, services, blood products[,] auto-transfusions...codes such as whole blood, various red blood cell products, platelets, plasma, and cryoprecipitate,” along with “[o]ther codes for tests primarily associated with the provision of

blood products” are “not clinical laboratory tests and are therefore never subject to [clinical laboratory] fee schedule limitations.”¹¹ The Manual notes that this is because “[s]uch tests identify various characteristics of blood products, but are not diagnostic in nature.” Arguably, this Manual guidance already excludes molecular pathology tests performed by blood banks and blood centers from the DOS policy at § 414.510(b)(5), as paragraph (b)(5), like the rest of § 414.510, applies only to the date of service for “a clinical laboratory test.” However, we agree with stakeholders and the agency that it would be appropriate to clarify that molecular pathology testing performed by blood banks and blood centers must be billed by the hospital.

IV. Conclusion

C21 strongly supports maintaining the current laboratory DOS policy at § 414.510(b)(5), which has significantly improved Medicare beneficiary access to valuable precision diagnostic tests that assist physicians in making well-informed treatment decisions. We firmly oppose any revisions to the DOS policy that would re-impose administrative burdens and undercut beneficiary access to personalized treatment. We agree with the agency’s statement that it should proceed with caution as it relates to modifying this policy due to potentially negative implications for beneficiaries with complex and chronic conditions. However, making inclusion in the DOS policy contingent on either a physician’s subjective prediction of future clinical decisions or a test’s designation as an ADLT would significantly limit beneficiary access and be difficult to implement.

Given that the Proposed Rule did not solicit comment on any other options, the agency should not finalize any other changes to the laboratory DOS policy for CY 2020 (aside from requiring hospitals to bill for blood bank tests, which we support). C21 thus respectfully encourages the agency to maintain the existing laboratory DOS policy and explore in future rulemakings potential changes through the under arrangements regulations to resolve any lingering implementation issues.

Thank you for considering our comments. Please contact me at hmurphy@c21cm.org or (916) 835-5117 should you have any questions or if we can provide you with further information.

Sincerely,



Hannah Murphy
Executive Director
Coalition for 21st Century Medicine

Enclosures

¹¹ Medicare Claims Processing Manual, chapter 16, section 100.2.

Appendix A

Moran Report

Memorandum (September 12, 2019)

To: Coalition for 21st Century Medicine

From: Gina Baxter and Caitlin Sheetz

Subject: Molecular Pathology Labs After an Outpatient Procedure, 2017-2018

We were tasked with examining the frequency and timing of molecular pathology laboratory services that were paid separately under the Clinical Lab Fee Schedule (CLFS) following an outpatient procedure. Beginning in 2018, CMS established an exception to the laboratory date of service (DOS) policy for molecular pathology tests. The exception excluded these tests from Outpatient Prospective Payment System (OPPS) packaging by making the DOS the date the test was performed, if certain conditions are met. We examined molecular labs billed on the same day, between 1 and 13 days, and 14 to 30 days after an outpatient stay to determine how lab billing patterns may have changed from 2017 to 2018. We performed the same analysis on a limited set of lung cancer molecular labs and diagnoses as you identified. The balance of this memo highlights our findings and analysis methodology.

Highlights

- Overall, the use of molecular pathology labs following an outpatient procedure grew significantly year over year.
 - From 2017 to 2018 the number of claims with the same diagnosis as the outpatient procedure grew by 40% from 20,159 to 28,296.
 - The number of total molecular claims with or without the same diagnosis code following an outpatient procedure grew by 55% from 43,012 to 66,637.
- The timeframes in which providers bill molecular pathology labs following an outpatient procedure have shifted from 2017 to 2018.
- Most notably, the proportion of lab claims billed the same day as an outpatient procedure has dropped while the proportion of those billed 1 – 13 days following an outpatient procedure have markedly increased between 2017 and 2018.
 - The proportion of claims with the same diagnosis code as the outpatient procedure billed on the same day dropped by 13% while the proportion of claims billed 1-13 days following the procedure increased by 15%.
 - The proportion of total lab claims (i.e. same and different diagnoses) billed on the same day fell by 26% with corresponding increases in the proportion of those billed 1-13 days and 14-30 days later, 12% and 10% respectively.

- Similar, yet more dramatic, shifts occurred between 2017 and 2018 when analyzing only lung cancer molecular labs and diagnoses of interest, which overall grew by 27%.
 - The proportion of labs with the same diagnosis as the outpatient procedure billed on the same day fell by 39% with corresponding increases in the proportion billed 1-13 days later with an increase of 37%.
 - The proportion of total cancer lab claims billed on the same day fell by 40% while those billed 1-13 days later increased by 41%.

Results

Table 1a. Proportion of All Molecular Pathology Lab Claims Billed in Timeframe

	Proportion of Lab Claims with Same Diagnosis Linked to an Outpatient Procedure			Proportion of Total Lab Claims Linked to an Outpatient Procedure		
	2017	2018	% Change	2017	2018	% Change
Same Day	39%	34%	-13%	30%	22%	-26%
1-13 Days	38%	44%	15%	41%	46%	12%
Between 14 and 30 Days	22%	22%	-2%	29%	32%	10%

Table 1b. Proportion of Lung Cancer Lab Claims and Diagnoses Billed in Timeframe

	Proportion of Lung Cancer Lab Claims Linked to an Outpatient Procedure with the Same Diagnosis			Proportion of Total Lung Cancer Lab Claims Linked to an Outpatient Procedure		
	2017	2018	% Change	2017	2018	% Change
Same Day	39%	24%	-39%	39%	23%	-40%
1-13 Days	42%	57%	37%	41%	57%	41%
Between 14 and 30 Days	19%	19%	-1%	21%	19%	-6%

Methodology

- We first identified the list of molecular pathology laboratory procedures excluded from OPSS packaging as designated by the OPSS Status Indicator "A" and paid under the CLFS in the 2017 and 2018 5% Carrier Standard Analytic File (SAF).
- Using the date of the lab service and the unique patient identifier, we then examined the 2016-2017, and the 2017-2018 Outpatient SAFs for any outpatient stay that occurred at most 365 days prior to the lab procedure with the same diagnosis code.
- If multiple applicable outpatient procedures fell within the 30-day window, then the outpatient procedure closest to the lab procedure's date was kept for further analysis.
- With the linkage of labs-to-outpatient discharge found, we then tabulated (by HCPCS) the rate of occurrence of the lab on the same day, in the 1-13-day window, and in the 14-to-30-day window after outpatient discharge.

- The same analysis as described in the previous bullet was also grouped by the diagnosis code associated on the linked claims.
- Finally, we analyzed a client-provided subset of HCPCS and diagnosis codes for lung cancer.