

September 27, 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

Dear Administrator Verma,

The undersigned organizations, who represent hundreds of thousands of patients and health care providers, appreciate the opportunity to submit the following comments representing the patient impact of the "Laboratory Date of Service Policy" (DOS) in the Centers for Medicare & Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule for Calendar Year 2020 issued on July 29, 2019.

Our collective organizations are very concerned that CMS is considering reinstating access barriers to timely testing that were effectively eliminated with the Date of Service Rule in the CY 2018 Hospital Outpatient Prospective Payment System Final Rule and we **respectfully request that CMS not finalize the "Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv)" or "Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs" changes discussed in the DOS portion of the above referenced proposed rule due to the harmful impact on patient access to testing and resulting appropriate care.**

It is our hope that the below comments will illustrate why the proposed changes to the DOS Exception would be detrimental to patient care.

**The Hospital Outpatient Prospective Payment System Rule for Calendar Year 2018 (CY 2018 HOPPS Rule) Eliminated Access Barriers Caused by the Date of Service Rule**

Prior to the finalization of the CY2018 HOPPS Rule, patients were experiencing delays in receiving their test results because outdated billing policy had not kept up with the advent of precision medicine and other advances in the diagnostic industry that improve patient diagnosis and treatment decisions. We appreciate that CMS in its FY 2018 HOPPS Final Rule acknowledged this fact that the DOS rule imposed administrative complexities for hospitals and laboratories since our organizations saw the negative impacts on patient care. We heard numerous reports that hospitals were holding test requisitions 14 days before sending a specimen to a laboratory so that the lab could bill Medicare directly and the hospital would not

have to get involved in payment issues with the laboratory and CMS. Prior to the CY 2018 HOPPS Rule change, we encountered cases where doctors were literally putting post-it notes on patient files/ requisitions that said “hold for 14 days,” creating unnecessary delays in patients receiving test results that are needed to identify the appropriate care plan.

Timely access to diagnostics that inform treatment decisions is critical for all patients, especially cancer patients. Clinical guidelines, including many from the National Comprehensive Cancer Network (e.g., NCCN Guidelines Version 6.2019 Non-Small Cell Lung Cancer, NCCN Evidence Blocks and - NCCN Guidelines Version 2.2019 Colon Cancer), recommend advanced diagnostic testing as an important clinical tool to aid in identification of appropriate treatment options or to recommend avoiding those unlikely to provide clinical benefit. A report on biomarker testing practices in community cancer centers cites the former DOS rule (in place prior to the CY2018 HOPPS Rule) in particular as a serious hurdle for appropriate genomic evaluation of non-small cell lung cancer (NSCLC), and these hurdles have consequences: “These challenges can lead to under genotyping, with a recent series reporting as much as 40% and 60% of patients without guideline recommended EGFR and ALK testing, respectively, and 19% receiving cytotoxic chemotherapy before test result review. These factors also lead to under referral to clinical trials of molecularly targeted agents.”<sup>1</sup>

### **Delays in testing lead to delays in care and create undue harm**

Prior to the CY 2018 Date of Service Exemption changes that were implemented in the CY 2018 HOPPS Rule, patients were at risk of undue harm due to delays in biomarker testing, which is the first step to accessing personalized therapies. In lung cancer, as well as many other cancers, patients are able to benefit from targeted therapies to treat their cancer; however, in order to identify the appropriate therapy, it is essential that individuals receive timely comprehensive biomarker testing to identify the most appropriate treatment plan for each unique individual. There is unequivocal evidence that targeted therapies, matched to a specific biomarker, are superior to chemotherapy, in improving survival of advanced-stage lung cancer patients, and therefore it is essential that patients receive timely information from comprehensive biomarker panels before the initiation of treatment.

In addition, delays in biomarker testing may not only impact the right treatment selection, but in fact, may lead to a patient getting matched to the **wrong** treatment. It is now well-documented that Non-Small Cell Lung Cancer (NSCLC) patients with a driver mutation who receive an immune checkpoint inhibitor (ICI) **before they received a targeted therapy** show a much higher incidence of severe immune-related adverse events. This has been reported in patients with EGFR mutations receiving osimertinib after an ICI<sup>2</sup>; and in patients with oncogenic alterations in ALK, ROS1, or MET receiving crizotinib after an ICI<sup>3</sup>.

The existing CY 2018 Date of Service Exemption has removed access barriers and is good for patients.

**The proposed CY 2020 HOPPS Rule will reinstate access barriers**

We are very concerned that CMS is considering policy proposals that would reinstitute barriers for Medicare beneficiaries effectively limiting or eliminating access to advanced diagnostics in a timely manner. We cannot reinforce more how meaningful the CY 2018 DOS exception is for our patient communities, and we encourage CMS to maintain it.

Our organizations are most concerned with potential impacts of the proposed physician certification component of the proposed rule and the proposed limitation of the Laboratory DOS Exception to Advanced Diagnostic Laboratory Tests (ADLTs). Requiring physicians to certify whether or not the results of a test would be used to guide hospital treatment at a subsequent encounter would not only create additional administrative burdens for providers and hospital systems, thereby creating or contributing to delays in testing, but it also is unclear to us exactly how a physician would be able to make such determination with any degree of certainty. Given that very few tests have been granted ADLT status and that the ADLT eligibility requirements, including to be sole-sourced, based on an algorithm, and unique, are unattainable for most molecular pathology tests, we are concerned with the proposal to limit the Laboratory DOS Exception to ADLTs as this would not capture many of the tests used for cancer patients, meaning that there would once again be delays in testing for many cancers which would create undue harm.

Going forward, we encourage CMS to continue to evaluate the impact of the Laboratory DOS Exception at least annually to ensure that access barriers do not continue to exist and that patients are able to access the test of their and their physician's choosing to ensure timely and accurate results. We also recommend that CMS take the necessary time to acquire meaningful data on the patient impact of the CY 2018 revisions to the DOS rule – which have been in place for less than 2 years – prior to implementing any additional changes to thoroughly understand the impact of these systematic changes.

In closing, our undersigned organizations ask CMS to **not limit beneficiary access to timely and appropriate molecular pathology testing by not finalizing the above-referenced proposed changes to the DOS policy.** Our organizations were very thankful that CMS listened to stakeholder concerns in 2017 and were very pleased to see that the CY 2018 final rule protected patients from unnecessary delays in testing. We are thankful for the opportunity to comment on the proposed changes to the Laboratory Date of Service Policy in the proposed rule and we truly hope that CMS once again will listen to the concerns of the broad stakeholder community, and especially to the patient advocacy community as it did in 2017.

If you have any questions or would like to engage in further dialogue please contact Kristen Santiago, Senior Director of Public Policy Initiatives, LUNGeivity Foundation at 240-454-3105 or [ksantiago@lungevity.org](mailto:ksantiago@lungevity.org).

Thank you for your attention to this very important matter.

Sincerely,

LUNGeivity Foundation

## **REFERENCES:**

1. Gutierrez ME, Choi K, Lanman RB, et al. Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities. *Clin Lung Cancer* 2017.
2. Schoenfeld AJ, Arbour KC, Rizvi H, et al. Severe immune-related adverse events are common with sequential PD-(L)1 blockade and osimertinib. *Annals of oncology : official journal of the European Society for Medical Oncology* 2019;30:839-844.
3. Lin JJ, Chin E, Yeap BY, et al. Increased Hepatotoxicity Associated with Sequential Immune Checkpoint Inhibitor and Crizotinib Therapy in Patients with Non-Small Cell Lung Cancer. *Journal of thoracic oncology : official publication of the International Association for the Study of Lung Cancer* 2019;14:135-140.