September 27, 2019

Submitted Electronically

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

RE: CMS-1717-P

Dear Administrator Verma:

On behalf of the Colorado BioScience Association (CBSA), thank you for the opportunity to provide comments on the CY 2020 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule that was issued on July 29, 2019. Specifically, we are writing to oppose proposed changes to the current Laboratory Date of Service (DOS) Policy that would restrict patient access to testing results and delay appropriate treatment.

CBSA represents over 720 life sciences organizations including biotechnology, medical device, diagnostic, pharmaceutical, ag bio, and digital health companies, as well as research institutions and service providers across the state of Colorado. From concept to commercialization, our members drive health innovations, products, and services that improve and save lives. Colorado is the center of bioscience for the Rocky Mountain Region, directly employing 30,000 people and spinning out an average of 20 new bioscience companies each year. The industry here is largely comprised of small, early-stage companies that play a crucial role in the development of new diagnostic testing and targeted treatments that are leading to improved patient outcomes and reduced health care costs.

Following the release of the CY 2020 HOPPS Proposed Rule in July, CBSA conducted outreach to industry stakeholders and experts within our diagnostic community to provide a thoughtful review of the proposed changes to the laboratory DOS policy. We have strong concerns that the proposed revisions would significantly limit patient access to clinically important diagnostic testing information.

As a result of the Laboratory Date of Service Rule in the CY 2018 HOPPS Final Rule, our members have reported significant improvements in patient access to timely precision diagnostic information. By allowing laboratories to bill Medicare directly for these tests (rather than bundling with the hospital service if ordered within 14 days of discharge), the current policy gives patients quicker access to biomarker testing results that will help guide their treatment plan. There have been reports that prior to the 2018 Rule, hospitals would often wait 14 days

before sending a specimen to a laboratory so the lab could bill Medicare directly and the hospital would not have to handle payment issues. For many patients, time to treatment is critical so creating unnecessary delays and barriers to clinically relevant information only makes it harder for patients to make an informed decision about whether a targeted therapy is appropriate.

CBSA is concerned that the proposed revisions will undo the progress that was made in the CY 2018 HOPPS Final Rule. We oppose two of the three potential changes to the current laboratory DOS exception at § 414.510(b)(5).

Under the first potential revision, a test "would be considered a hospital service unless the ordering physician determines that the test does not guide treatment during a hospital outpatient encounter."[1] This potential change would not only create more administrative burdens for physicians, but it would be extremely challenging to implement as it would base billing for the test on the ordering physician's ability to predict future treatment and site of care. At the time the test is ordered, the physician will not know whether the test results are going to inform treatment at a future hospital outpatient encounter. Requiring physicians to make this determination without critical pieces of information is not feasible.

CBSA also opposes the second proposed revision to the laboratory DOS exception at § 414.510(b)(5), which would limit the DOS exception to Advanced Diagnostic Laboratory Tests (ADLTs). We object to this change because it fails to account for the molecular pathology tests that are sole-source assays performed by small laboratories, but not eligible for ADLT designation. In particular, sole-source molecular pathology tests that are non-algorithmic Genomic Sequencing Procedures or those that the agency determines do not provide "new clinical diagnostic information that cannot be obtained from any other test or combination of tests"[2] would no longer qualify for the DOS exception. That means the patients who need those tests will once again experience inappropriate and potentially life-altering delays to treatment.

CBSA applauds CMS for continuing to evaluate the current laboratory DOS policy, but we hope the agency will consider the unintended consequences of the proposed changes outlined in this letter. We urge CMS not to finalize Option 1 or Option 2.

Thank you for your consideration. If you have any questions, please contact Emily Roberts, Vice President at Eroberts@cobioscience.com.

Sincerely,

Jennifer Jones Paton

Jennifer Jones Paton
President and Chief Executive Officer
Colorado BioScience Association

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[1] CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule, 84 Fed. Reg. 154 (August 9, 2019).
[2] 42 CFR § 414.502(1)(iii).