

ASHI on the Hill

ASHI continues its advocacy and engagement to help shape policies impacting our members. The following is an update on pertinent legislative and regulatory developments at the federal level.

HHS Signals FDA Lacks Authority to Regulate LDTs

ASHI has steadfastly advocated for continued regulation of laboratory developed tests (LDTs) used in support of transplantation by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA). FDA has historically asserted authority over LDTs, and, during the pandemic, FDA has required LDTs used to detect SARS-CoV-2 to obtain emergency use authorization. On August 19, 2020, the Department of Health and Human Services (HHS) [announced](#) that the Food and Drug Administration (FDA) will not require premarket review of LDTs absent notice-and-comment rulemaking. The announcement notes that “those opting to use LDTs in their laboratories without FDA premarket review or authorization may do so. . .absent approval, clearance or authorization and would remain subject to regulation by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and its implementing regulations at 42 C.F.R. pt. 493.” This announcement is potentially significant, as it suggests the Administration is taking the position that FDA does not have the authority to regulate LDTs as it has long asserted, leaving CMS as the sole authority under CLIA.

As you are aware, Congress has been engaged in a years-long effort to develop a legislative framework for the regulation of LDTs. ASHI has been closely engaged in this effort, including with President Medhat Askar, MD, PhD previously testifying on ASHI’s behalf during a Capitol Hill roundtable with Congressional staff, FDA officials, and key stakeholders. ASHI is engaging in dialogue with these key players to determine the implications of this announcement on the future landscape for LDT regulation and remains committed to ensuring HLA labs’ ability to provide timely determinations of donor-specific histocompatibility is preserved.

Regulatory Action

After weeks of delay, CMS released both its 2021 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center (OPPS) [Proposed Rule](#) and Physician Fee Schedule (PFS) [Proposed Rule](#).

ASHI has been closely tracking developments surrounding the Medicare Part B Laboratory Date of Service (DOS) Policy in previous OPPS rulemakings. In the 2021 OPPS proposed rule, the only change CMS is proposing to make to the Laboratory DOS policy is to exclude cancer-related protein-based Multianalyte Assays with Algorithmic Analyses from the OPPS packaging policy, meaning the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5).

The PFS proposed rule provides an overview of Medicare payment for Clinical Diagnostic Laboratory Tests under the Clinical Laboratory Fee Schedule (CLFS), as directed under the Protecting Access to Medicare Act (PAMA) and the CLFS final rule that implemented PAMA. The proposed rule discusses the ASHI-supported statutory changes made by the Further

Consolidated Appropriations Act, 2020 (H.R. 1865), which included the LAB Act, as well as the changes required under the recently-enacted CARES Act (H.R. 748).

Additionally, the PFS proposed rule solicits comments on payment for specimen collection for COVID-19 Clinical Diagnostic Tests. CMS previously established that Medicare will pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients. To identify specimen collection for COVID–19 testing specifically, CMS established two new level II HCPCS codes (Code G2023 and G2024) for independent laboratories to use when billing Medicare for the nominal specimen collection fee for COVID–19 testing for the duration of the COVID-19 Public Health Emergency (PHE). This specimen collection fee policy was established for the duration of the PHE for the COVID-19 pandemic, and CMS is now requesting comments on whether the agency should delete HCPCS Codes G2023 and G2024 once the COVID-19 PHE ends. Specifically, CMS is seeking public input on why these codes, and their corresponding payment amounts, which are higher than the nominal fees for specimen collection for other conditions, would be necessary or useful outside of the context of the PHE.

Public comments on the 2021 OPPTS and PFS proposed rules are due by **October 5, 2020**.

State of the Next Round of COVID-19 Relief Legislation

In late July, Senate Republicans unveiled their proposal for the next comprehensive COVID-19 relief package - the Health, Economic Assistance, Liability Protection and Schools (HEALS) Act. You will recall that the Democrat-controlled House of Representatives passed its \$3 trillion opening offer for the next round of comprehensive COVID-19 relief legislation – the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act – back in May. While Congressional leaders and White House officials held multiple rounds of negotiations over the size and scope of the next COVID-19 relief package, no compromise was reached before lawmakers returned to their districts and states for the August recess. While members could be called back on 24 hours’ notice to vote on compromise legislation, talks currently remain stalled.