ASHI on the Hill

What is Happening in Washington?

President Biden has laid out a bold plan to rebuild U.S. infrastructure. The $2.25 trillion American Jobs Plan is the Administration's top domestic priority, along with a companion $1.8 trillion American Families Plan which focusses on "human infrastructure" by addressing childcare, education, and health care, among other items. It is now up to Congress to work to develop legislation making this plan a reality, and we expect infrastructure legislation to be the primary item on the Congressional agenda this year.

President Biden unveiled his Fiscal Year (FY) 2022 Budget Proposal on May 28th, formally kicking off the FY 2022 appropriations process. Notably, the President's budget requests $78 million for the Organ Transplantation and the Blood Stem Cell Transplantation Program, which would represent level funding compared to the FY 2021 enacted level. With many Administration officials having already testified before Congressional committees to discuss the budget, House and Senate Appropriations Committees now turn to drafting their spending bills. House Appropriations Committee Chairwoman Rosa DeLauro (D-CT) has indicated House appropriators will seek to develop and pass all twelve of their annual spending bills in June and July. The House and Senate will need to agree on funding legislation in advance of September 30th – the end of the current fiscal year – or otherwise pass a temporary continuing resolution to keep the government funded.

Laboratory Developed Test (LDT) Regulation

ASHI continues to fiercely pursue opportunities to advocate that jurisdiction over LDT regulation remain with the Center for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA). The Clinical Laboratory Improvement Advisory Committee (CLIAC) provides advice and guidance to federal agencies pertaining to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of CLIA standards. In mid-April, CLIAC held a public meeting which included discussion of "Clinical Laboratory Perspectives on Laboratory Developed Tests". ASHI prepared and submitted written comments expressing ASHI's position that FDA regulation of LDTs performed in high complexity laboratories under CLIA that are accredited by ASHI is neither warranted nor feasible. ASHI indicated FDA regulation is not warranted since all of these tests are subject to applicable CLIA and ASHI standards and are performed in high complexity laboratories with very strict requirements for staff credentials, continuing education and maintenance of competency; equipment qualification and maintenance; quality control of reagents; and testing facility standards. Additionally, Dr. Medhat Askar provided oral comments during the public comment period on ASHI's behalf. His remarks were well-received by the Committee and had a meaningful impact on the Committee's discussion of LDT regulation following the public comment period.

Finally, Senator Rand Paul (R-KY) introduced the Verified Innovative Testing in American Laboratories (VITAL) Act, which would cement regulation of LDTs under CLIA and clarify that FDA does not have jurisdiction to regulate these tests.

Clinical Laboratory Test Reimbursement

Working to ensure appropriate Medicare reimbursement continues to be a priority for ASHI. As you are aware, Congress has directed the Medicare Payment Advisory Commission (MedPAC) to (i) review the methodology CMS has implemented for the private payer-based Clinical Laboratory Fee Schedule rates; and (ii) report on the least burdensome data collection process

that results in a representative sample of all laboratory market segments. In advance of the June 2021 release of its Congressionally-mandated report on Protecting Access to Medicare Act (PAMA) payment collection methodology, MedPAC held a public meeting, including a session on "Mandated report: Assessing the impact of recent changes to Medicare's clinical laboratory fee schedule payment rates". Notably, MedPAC revealed it engaged a 3rd party contractor (RTI international) to examine potential collection methodologies for a survey to collect a representative and valid sample of payment data from independent, hospital outpatient, and physician office labs. RTI did find that this type of survey would be feasible and would reduce reporting burden on labs. RTI also found this would increase Medicare spending by 10-15 percent over current rates that are based on over representation of independent labs. RTI's report will be published in MedPAC's June report, which ASHI will be carefully reviewing as it continues its advocacy on this important issue.