

## ASHI on the Hill

With the near end of 2021 comes the action-packed conclusion of the first session of the 117<sup>th</sup> Congress. Indeed, Congress is charged with passing a short-term spending bill to keep the federal government funded, addressing the federal debt limit, passing its annual defense bill that has passed every year for the past 60 years, as well continuing progress on the Democratic social spending legislation – the *Build Back Better Act*. Layered on top of these pressing issues are looming Medicare cuts resulting from scheduled expiration of the Medicare sequester moratorium originally enacted in the *CARES Act*, statutory Pay-As-You-Go reductions resulting from passage of the *American Rescue Plan Act* earlier this year, as well as expiration of a 3.75% payment adjustment Congress provided at the end of 2020.

While many of these issues may very well spill over into the new year, clinical labs will face an additional hurdle in 2022 by way of the currently-scheduled resumption of Protecting Access to Medicare Act (PAMA)-induced cuts to the Clinical Laboratory Fee Schedule (CLFS) and an additional round of private payer data reporting. You will recall that Congress delayed previously scheduled CLFS cuts and private payer data reporting in 2021 as part of the CARES Act. Barring Congressional action, laboratory test reimbursement cuts of up to 15% will resume in January of 2022, and it will be very important that applicable labs report on data collected during January 1, 2019 and June 30, 2019 to determine 2023 to 2025 CLFS rates. Under reporting due to flawed PAMA implementation was a challenge with previous reporting, and ASHI has been advocating for remediation of this methodology and educating on the need for fuller lab participation to help ensure appropriate reimbursement.

Additionally, we expect 2022 to bring the next chapter of the longstanding jurisdictional dispute between the Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration (FDA) over the regulation of laboratory-developed tests (LDTs). In November, the Department of Health and Human Services withdrew the Trump-era policy directing FDA not to enforce premarket review requirements for LDTs. We expect this policy shift to provide momentum for Congress to address LDT regulation legislatively in 2022. As you are aware, multiple iterations of the Verifying Accurate Leading-edge IVCT Development (VALID) Act have been introduced, and ASHI has been engaged with the bill's sponsors advocating for sole jurisdiction of LDTs used in support of transplantation under CMS. Congress is expected to take up FDA user fee reauthorization legislation in 2022, and we expect the strongest push to enact the VALID Act to occur concurrently with this effort.

In summary, we expect 2022 to be an especially consequential year for ASHI labs in light of these relevant federal policy developments. Rest assured that ASHI will continue to have a seat at the table and fiercely advocate for favorable policy outcomes for our member labs.