ASHI on the Hill

Histocompatibility NCD Remains in Effect

In the Calendar Year (CY) 2021 Physician Fee Schedule (PFS) Proposed Rule, the Centers for Medicare and Medicaid Services (CMS) proposed to retire a host of National Coverage Determinations (NCDs), including the Histocompatibility NCD (190.1). ASHI submitted formal comments on the proposed rule in fierce opposition to retirement of the Histocompatibility NCD, as this would have left coverage determinations to the discretion of local Medicare Administrative Contractors (MACs) and risked harmful inconsistency in coverage determinations. Fortunately, ASHI's comments were instrumental in persuading CMS from retiring the Histocompatibility NCD when the CY 2021 PFS Final Rule was released. However, CMS left the door open to retiring NCD 190.1 in its CY 2022 PFS Proposed Rule.

This past July, CMS released its CY 2022 PFS Proposed Rule, and, while CMS proposed to retire a number of additional NCDs, it *did not* propose to retire the Histocompatibility NCD. The continuation of the Histocompatibility NCD is a testament to the importance of ASHI's federal advocacy efforts and leadership in shaping policies impacting our labs and patients. To be sure, ASHI will continue monitoring developments closely to address any future threats to the continuity of NCD 190.1.

VALID Act Re-Introduced

ASHI has been closely engaged in the years-long legislative effort to overhaul regulation of laboratory developed tests (LDTs). The current iteration of this legislation, known as the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021, was re-introduced in late June. The newest iteration of this legislation once again proposes to create an LDT regulatory framework under the authority of the Food and Drug Administration (FDA). ASHI remains steadfast in its position that LDTs used in support of transplantation should remain solely under the jurisdiction of CMS, through the Clinical Laboratory Improvement Amendments (CLIA), particularly given the strict oversight regime ensuring clinical and analytical validity that these tests are already subject to.

ASHI has been in dialogue with the House and Senate lead sponsors of the VALID Act advocating that Histocompatibility test used in support of transplantation be exempted from the new FDA regulatory framework in light of the unique regime in place to ensure the accuracy and safety of these tests, including ASHI, UNOS/OPTN, FACT, NMDP, SRTR, and CIBMTR oversight. As these conversations continue and the VALID Act advances through the legislative process, ASHI will continue to provide update on this important advocacy effort.