

ASHI on the Hill

As we race towards the end of 2020 and begin preparations to tackle federal policy priorities important to ASHI membership in the new year, the following is an overview of pertinent regulatory developments, as well as an overview of the federal policy landscape in 2021.

Regulatory Action

In the 2021 Physician Fee Schedule [Proposed Rule](#), CMS proposed to retire the National Coverage Determination (NCD) for Histocompatibility testing (190.1). CMS is proposing to remove a total of nine different NCDs. If this proposal is finalized, the impact would be that Histocompatibility testing would no longer automatically be covered, but rather, local Medicare Administrative Contractors (MACs) would determine coverage for Histocompatibility testing. ASHI has submitted formal comment strongly opposing finalization of this proposal, advocating that the Histocompatibility NCD should rather be updated and expanded.

ASHI commented that removal of the Histocompatibility testing NCD would be inconsistent with, and contrary to, the Administration's efforts to improve kidney care and increase treatment options through increased transplant rates. Further, removing the Histocompatibility NCD poses serious risk of inconsistencies in coverage determinations, which is not in the best interest of beneficiaries. CMS correctly acknowledges that positive advancements have taken place in the field of Histocompatibility testing; however, ASHI emphasized that continuing uninterrupted coverage for current critical applications is critical.

The 2021 Physician Fee Schedule Final Rule is expected to be published in December.

Looking Ahead to 2021

With the November elections in the rearview, a flurry of activity is underway as President-elect Biden works to build out his administration, and Congress selects its leadership and organizes committees for the 117th Congress. These preparations are occurring in the midst of a lame duck (where some lawmakers will not return in 2021 due to retirement or losing their re-elections, etc.) session of Congress, where major priorities include working to avert a government shutdown by passing appropriations legislation before December 11th, as well as negotiating an additional round of COVID-19 relief legislation.

An important aspect of President-elect Biden's transition is vetting potential cabinet appointees, which his transition team is currently working through. ASHI is closely monitoring discussions surrounding potential appointees for agencies overseeing laboratory testing regulation and reimbursement, including the Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS). ASHI is also closely monitoring the outlook for the jurisdictional dispute over laboratory developed test (LDT) regulation between CMS and the Food and Drug Administration (FDA), in light of the Trump Administration's assertion that FDA does not possess this jurisdictional authority it has long claimed.

In the Congressional realm, ASHI seeks to build on its past legislative successes in the 117th Congress. Party leadership elections have occurred in the House and Senate, but leadership of a number of key committees with jurisdiction over ASHI priority areas remain yet to be determined.

For example, with Senator Lamar Alexander's (R-TN) retirement, the top Republican position on the Senate Health, Education, Labor, and Pensions (HELP) committee –which has broad healthcare jurisdiction – will be open. Additionally, there will be a new top Republican on the Senate Finance Committee, which has jurisdiction over the Medicare program, after Senator Chuck Grassley (R-IA) reached his term limit as chairman. Finally, there will be a new top Republican on the House Energy and Commerce Committee, which has vast healthcare jurisdiction, after the retirement of Rep. Greg Walden (R-OR). Democratic leadership on these committees is expected to remain the same as it was in the current Congress. Notably, it is not yet clear which party will control the U.S. Senate, with two Georgia runoff elections set to determine control of the chamber on January 5th. The results of those elections will determine whether the top Senators on these committees will be chairs or ranking members. Whatever the outcome, we are working to ensure that ASHI is well positioned to advance its priorities in the 117th Congress, including ensuring LDT regulation remains within CMS' jurisdiction, addressing reimbursement cuts resulting from Protecting Access to Medicare Act (PAMA) implementation, and exploring policies to promote the ability of PhD's to bill Medicare for interpretive services under the Physician Fee Schedule.

ASHI looks forward to finishing 2020 strong and continuing its advocacy engagement in 2021 and beyond to help shape policies impacting our members.