

April 21, 2014

HLB Files Complaint To Rein-In MAC Authority

On April 18, 2014, Hooper, Lundy & Bookman, PC, filed a lawsuit on behalf of the California Clinical Laboratory Association (CCLA) and a Medicare beneficiary (Jane Doe) against the U.S. Department of Health & Human Services, to try to stop Medicare Administrative Contractors (MACs) from continuing to develop and apply Medicare Local Coverage Determinations (LCDs) that deprive Medicare beneficiaries throughout the country of critically necessary clinical laboratory services.

“This is an issue that transcends clinical laboratory testing,” said HLB attorney Patric Hooper, lead attorney for the plaintiffs. “This case challenges the authority of private contractors to unilaterally develop Medicare coverage policy,” explained Mr. Hooper.

Not only are both Medicare Part A and Part B coverage policies impacted by the MACs, but the same policies are often used by private insurers to make coverage determinations in the private health insurance market, so private pay patients are also affected by these policies, Mr. Hooper noted.

At issue in the present case is Medicare coverage for various clinical laboratory tests, including advanced laboratory testing that enables ordering physicians to use personalized rather than “one-size-fits-all” treatment and medication protocols based on population averages. When weighed against the costs of treating complications and other side effects that may not be ideal for a particular patient, the costs of the tests are considered both economical and quality-of-life enhancing.

“With the rate of speed at which health care reform is moving in other sectors, it is time to catch up with respect to innovative, patient-centered care from a clinical perspective,” said Mr. Hooper. While not all laboratories support the litigation route, Hooper believes court intervention is the best way to protect Medicare patients’ continuing access to these valuable laboratory tests.

The complaint, which was filed in federal court in Washington D.C., asserts that

- Congress has unlawfully delegated regulatory power to the MACs;

- MACs have implemented Medicare policy without following required federal rulemaking requirements;
- MACs have developed LCDs based on criteria they are not permitted to consider;
- HHS has eliminated any meaningful opportunity for laboratories to administratively appeal the application of LCDs and has not established a required mediation process;
- HHS has not developed an effective plan to evaluate the appropriateness of adopting new LCDs nationally, as noted recently by the Office of Inspector General.

“By limiting Medicare coverage of testing through arbitrary LCDs, the MACs are effectively preventing clinical labs from promoting progress in patient care nationally,” said Mr. Hooper. The MACs have simply overstepped their authority, as has Congress, and HHS has not fulfilled its promises to beneficiaries. ”

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