

Rule speeds approvals for ‘breakthrough’ devices, other commercially covered services

Senior Counsel [Alan J. Sedley](#) was recently interviewed Part B News to discuss a new final rule that allows items and services to gain approval for Medicare reimbursement more quickly than in the past, particularly medical devices that clear a specific FDA hurdle.

From the Article:

Alan J. Sedley, senior counsel with the Nelson Hardiman firm in Los Angeles, notes that “breakthrough” technology was originally “the primary focal point” of the rule, as suggested by then-President Trump’s Oct. 3, 2019. Executive Order, which called for regulations to be written so that “innovative products are brought to market faster, and so that such products, including breakthrough medical devices and advances in telehealth services and similar technologies.” The MCIT part of the rule is seen as a boon to device manufacturers and to medical organizations whose patients could benefit from new avenues of treatment.

[Full Interview](#)