

S. 1253, “Patient Access to Disposable Medical Technology Act of 2015”

Current Law:

The Medicare Supplementary Medical Insurance Program (Part B) currently covers a wide variety of durable medical equipment (DME) if they are medically necessary and are ordered by a physician or qualified non-physician practitioner.

Durable medical equipment (DME) is equipment that (1) can withstand repeated use, (2) has an expected life of at least three years (effective for items classified as DME after January 1, 2012), (3) is used to serve a medical purpose, (4) generally is not useful in the absence of an illness or injury, and (5) is appropriate for use in the home. DME also includes the drugs necessary for the proper function of certain DME, and supplies, such as surgical dressings, used in conjunction with the DME.

Historically, Medicare has paid for most DME on the basis of fee schedules. Medicare pays 80 percent of the lesser of the amount charged or the fee schedule amount, while the beneficiary is responsible for the remaining 20 percent, plus any unmet deductible. Outside of competitive bidding areas (explained below), DME suppliers who do not agree to accept the Medicare fee schedule amounts as payment in full for all services furnished to Medicare beneficiaries, may bill the beneficiary for amounts greater than the Medicare fee schedule amounts in addition to 20 percent coinsurance, plus any unmet deductible.

Fee schedule amounts are updated each year by a measure of price inflation. However, studies by federal agencies have shown that Medicare pays above-market prices for certain items of DME. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA, [P.L. 108-173](#)) established a Medicare competitive acquisition program (i.e., competitive bidding) under which prices for selected DME sold in specified areas are determined not by a fee schedule but by the bids of winning suppliers. Prices for DME established through competitive bidding thus far have been lower than prices established through fee schedules. Certain items of DME are excluded from the competitive bidding program including items that are furnished by a hospital to its own patients during admission or upon discharge, and if furnished by a physician to her own patients as part of the physician’s professional services (e.g., wheelchairs and braces).

Some items of DME are paid for by Medicare on a lump-sum basis, such as certain inexpensive and routinely purchased items (e.g. canes and crutches). Other items are rented for a period of medical need, but not to exceed a specified limit; DME items included in the “capped rental” payment category may be rented for up to 13 months, at which point the title to the equipment is transferred to the beneficiary.

S. 1253, as modified:

This bill amends Medicare to provide a new benefit category for disposable negative pressure wound therapy (NPWT), called an applicable disposable device, which is defined as an integrated system comprising a non-manual vacuum pump, a receptacle for collecting exudate and dressings for the purpose of wound therapy, that is a substitute for and used in lieu of a durable NPWT that would otherwise be covered.

The Secretary, through notice and comment rulemaking, would establish the payment methodology for disposable NPWT. For those services furnished between January 1, 2017, and December 31, 2021, payment would be based on 90 percent of the total payment of what the durable equivalent would be, taking into account prices determined by the competitive bidding program and factoring in the length of time for use of the disposable NPWT.

For services furnished on or after January 1, 2022, the Secretary may establish a new payment methodology, so long as the payment rate established does not exceed a percentage of the total payment for the durable equivalent. In addition, in determining this new payment rate, the Secretary shall take into account information gathered through a Government Accountability Office (GAO) report on pricing (from both public and private payers), utilization, and other data gathered from manufacturers and suppliers. There will be a 3-year transition period whereby payment for services may not decrease from the payment of the previous year by more than 10 percent in 2022, 10 percent in 2023, and 10 percent in 2024. Because disposable NPWT may be used as a substitute for durable medical equipment, several provisions of section 1834(a) relating to DME, and the requirements relating to use in the patient's home in section 1861(n) would apply to disposable NPWT.

In the absence of a national or local coverage determination regarding a disposable NPWT device, applicable coverage determinations for durable NPWT would apply to disposable NPWT.

Traditional coinsurance of 20 percent for Medicare beneficiaries will continue to apply for disposable NPWT.

Not later than 18 months after enactment, the GAO would submit a report on the value of disposable devices and the role of disposable devices as substitutes for durable medical equipment, along with recommendations for any legislation and administrative actions, as appropriate. Not later than four years after enactment, the GAO would submit a report on the impact of coverage of, and payment for disposable NPWT as established by this bill. The report will include the impact on utilization and program and beneficiary spending as a result of this bill, and would also contain recommendations for any legislation and administrative actions, as appropriate.