



LEGISLATIVE POSITIONS

Medical Devices

Bill Sheet

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| Category | PRN's Position | Bill | Title | Summary | Sponsor | Cosponsors | Status |
|--------------|----------------|--------|---|--|-----------------------------------|------------|---|
| Access | Support | S2025 | Patient Access to ESRD New Innovative Devices Act | A bill to amend title XVIII of the Social Security Act to improve access to innovative new medical devices furnished to individuals with end-stage renal disease under part B of the Medicare program by establishing a new device add-on payment adjustment under such part. | Sen. John Cornyn [R-TX] | 3 B | 06/10/2021 Referred to the Committee on Finance |
| Transparency | Support | HR7192 | Diagnostic Device Advisory Committee Act | To provide for the establishment of a panel on the real world impact of diagnostic medical devices, and for other purposes. | Rep. Kim Schrier [D-WA-8] | 0 | 03/22/2022 Referred to the Subcommittee on Health |
| Transparency | Support | S1508 | A bill to provide for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes | A bill to provide for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes | Sen. Roger Marshall [R-KS] | 2 B | 04/29/2021 Introduced in Senate |
| Access | Monitor | HR5331 | Patient Access to ESRD New Innovative Devices Act | To amend title XVIII of the Social Security Act to improve access to innovative new medical devices furnished to individuals with end stage renal disease under part B of the Medicare program by establishing a new device add-on payment adjustment under such part | Rep. Danny Davis [D-IL-7] | 3 B | 09/22/2021 Introduced in House |
| Access | Monitor | HR6848 | Medicare Demonstration of Coverage for Low Vision Devices Act of 2022 | To provide for a Medicare demonstration project to evaluate the fiscal impact of covering low vision devices as durable medical equipment under part B of the Medicare program. | Rep. Carolyn B. Maloney [D-NY-12] | 27 B | 02/28/2022 Referred to the Subcommittee on Health |
| Access | Monitor | S41 | Ally's Act | A bill to amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and the Patient Protection and Affordable Care Act to require coverage of hearing devices and systems in certain private health insurance plans, and for other purposes | Sen. Shelley Moore Capito [R-WV] | 7 B | 01/25/2021 Introduced in Senate |
| Transparency | Monitor | HR7389 | MVP Act | To amend title XIX of the Social Security Act to codify value-based purchasing arrangements under the Medicaid program and reforms related to price reporting under such arrangements, and for other purposes. | Rep. Kurt Schrader [D-OR-5] | 2 R | 04/05/2022 Referred to the Subcommittee on Health |
| Access | Monitor | HR4809 | Patient Access to ESRD New Innovative Devices Act | To amend title XVIII of the Social Security Act to improve access to innovative new medical devices furnished to individuals with end-stage renal disease under part B of the Medicare program by establishing a new device add-on payment adjustment under such part. | Rep. Danny K. Davis [D-IL-7] | 0 | 07/30/2021 Referred to the Subcommittee on Health |

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| Transparency | Monitor | HR7646 | Emerging Signals Modernization Act of 2022 | To amend the Federal Food, Drug, and Cosmetic Act to notify the public about an emerging signal concerning a medical device in order to reduce or limit the number of patients exposed to a potential risk identified based on such emerging signal, and for other purposes. | Rep. Brett Guthrie [R-KY-2] | 1 D | 05/03/2022 Referred to the House Committee on Energy and Commerce |
| Transparency | Monitor | S3983 | PATCH Act | A bill to amend the Federal Food, Drug, and Cosmetic Act to require, for purposes of ensuring cybersecurity, the inclusion in any premarket submission for a cyber device of information to demonstrate a reasonable assurance of safety and effectiveness throughout the lifecycle of the cyber device, and for other purposes. | Sen. Bill Cassidy [R-LA] | 1 D | 03/31/2022 Referred to the Committee on Health, Education, Labor, and Pensions |
| Access | Support | H.R.6513 | Medical Innovation Acceleration Act of 2022 | To amend the Federal Food, Drug, and Cosmetic Act to exempt from regulation as devices, non-invasive diagnostic devices, and for other purposes. | Rep. Andy Biggs [R-AZ-5] | 0 | 01/31/2022 Referred to the Subcommittee on Health |
| Access | Monitor | S2401 | 21st Century Assistive Technology Act | A bill to reauthorize the Assistive Technology Act of 1998, and for other purposes. | Sen. Bob Casey [D-PA] | 4 B | 08/07/2021 Placed on Senate Legislative Calendar under General Orders |
| Access | Monitor | S3793 | Technology-Enabled Care in the Home (TECH) Act | A bill to amend title XI of the Social Security Act to recommend the Center of Medicare and Medicaid Innovation test the effect of technology-enabled care interventions in the home to coordinate care over time and across settings, improve quality, and lower costs for certain Medicare Advantage beneficiaries, and for other purposes. | Sen. Tim Scott [R-SC] | 1 D | 03/10/2022 Referred to the Committee on Finance |
| Affordability | Monitor | S2257 | Expanding Access to Affordable Prescription Drugs and Medical Devices Act | A bill to provide Federal support for nonprofit generic and essential medicine and device manufacturers to increase the availability of drugs and devices in order to reduce drug or device shortages and drug and device costs. | Sen. Jacky Rosen [D-NV] | 0 | 06/24/2021 Referred to the Committee on Finance |