

**21st Century Cures (H.R. 34)
Impact for People with MS**

Section, Title	Category	Summary & Impact on People with MS	Position	National MS Society's Engagement
Sec. 1001. National Institutes of Health (NIH) Innovation Projects	Research Funding	Funds the Precision Medicine Initiative, the BRAIN Initiative, the Cancer Moonshot, and Regenerative Medicine Research. Precision Medicine aims to create a new framework for delivering healthcare where treatment decisions are tailored to the individual, by incorporating genetic information as well as personal environment and lifestyle into healthcare decisionmaking. This will include a million+ person longitudinal research study that public volunteers can participate in, called the "All of Us Research Program." The BRAIN Initiative will revolutionize our understanding of the human brain by exploring how individual cells and complex neural circuits interact in both time and space. This will fill gaps in our current knowledge and provide opportunities for exploring the connections between the brain and the human body. The Cancer Moonshot aims to make a decade's worth of advances in cancer prevention, diagnosis, and treatment in five years. Additional funds will be used to award grants and contracts for clinical research to advance the field of regenerative medicine.	Support	Worked in Coalition (e.g., Ad Hoc Group for Medical Research) for increased funding for the NIH. Lobbied Capitol Hill. Increased funding for the overall NIH budget is a Public Policy Conference issue. Signed on to group letters including ones that specifically supported the NIH Innovations projects.
Sec. 2001. NIH Reauthorization	Research Funding	Authorizes funding levels for the NIH for fiscal years 2018 through 2020. These funding levels still need to be appropriated.	Support	Worked in Coalition (e.g., Ad Hoc Group for Medical Research) for increased funding for the NIH and with the Alliance for a Stronger FDA for increases for the Food and Drug Administration (FDA) budget; Lobbied Capitol Hill; Increased funding for the overall NIH budget is a Public Policy Conference issue; Signed on to group letters.
Sec. 2011. Precision Medicine Initiative	Research Funding	Establishes the Precision Medicine Initiative at NIH.	Support	Signed on to group letters including ones that specifically supported the NIH Innovations projects.
Sec. 2040. Improving Medical Rehabilitation Research at the National Institutes of Health	Research Funding	Directs the NIH to coordinate rehabilitation research at the NIH's Institutes and Centers. Requires a comprehensive plan for coordinating rehabilitation research across the Agency. Widely supported by the rehab researchers and groups, this will be the first update since 1993, helping provide critical evidence supporting the value of rehab therapies for people with physical and cognitive impairments.	Support	The Society is a long-time supporter of the goals of the Disability & Rehab Research Coalition, which has called for updating and improving the coordination of rehab research for over 10 years.
Sec. 2061. National Neurological Conditions Surveillance System	MS Population Data	Provides funding for the Centers for Disease Control and Prevention to implement a national data collection system to track incidence and prevalence of neurological diseases like MS. This new data system could one day lead to a cure for diseases like MS, as information collected will provide a foundation for evaluating and understanding aspects of these diseases on which we currently do not have a good grasp – such as the geography of diagnoses, variances in gender and changes in healthcare practices among patients.	Support	Led the Neurodata Coalition. Lobbied in the House and the Senate for the inclusion of the Advancing Research for Neurological Diseases Act in the 21st Century Cures Act including at the 2015 and 2016 Public Policy Conferences. Submitted letters from the coalition urging legislative language closer to the original, strong House-passed H.R. 292 so that the system is most beneficial to researchers. These efforts were successful, as the language in Sec. 2061 closely aligns with the H.R. 292 language.
Sec. 3022. Real World Evidence	Access to Care / MS Population Data	Requires the FDA to evaluate and establish a framework for using real world evidence (data regarding the usage or the potential benefit/risk of a drug that is captured outside of a clinical trial) to help support the approval of a new indication for a previously approved drug and to help support or satisfy post-approval study requirements.	Support	The Society has supported certain circumstances where companies can share information about a medication that is not included in the product label. We believe it is important that people affected by MS have the most relevant information about treatments so they can work with their healthcare providers to make the most informed treatment decisions. The Society will work directly with the FDA to ensure that the Agency's guidance document and framework, which details the standards for this type of data to be used in the regulatory process, prioritizes FDA's safety and efficacy standards.
Sec. 3033. Accelerated Approval for Regenerative Advanced Therapies	Stem Cells	Permits regenerative medicine products to receive accelerated approval from the FDA. This will ease regulatory tensions that created an environment of uncertainty about the FDA's approval process for human cell and tissue products.	Support	Worked in coalition with the Alliance for Regenerative Medicine and other patient groups. Signed onto letters that opposed the Senate's REGROW language and emphasized the importance of the FDA's safety and efficacy standards. Met with the Bipartisan Policy Center and Senator Kirk's office to improve the legislative language found in the REGROW Act. This effectively resulted in the favorable language found in Sec. 3033.
Sec. 4010. Improving Medicare Local Coverage Determinations	Access to Care	Helps ensure basic procedural fairness in Local Coverage Determinations (LCDs), and thereby provides an important Medicare beneficiary protection that is often lacking in determining what benefits Medicare does (and does not) cover. This section begins to address this complex problem that millions of Medicare beneficiaries have been left without a voice in the determination of what innovative health care services are offered in their region.	Support	Partnered with the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition and Coalition to Preserve Rehab; sent letters of support to Capitol Hill.
Sec. 4013. Telehealth Services in Medicare	Telehealth	Requires the Centers for Medicare and Medicaid Services (CMS) to provide data on the population of Medicare beneficiaries whose care could be improved by the implementation of telehealth services in the Medicare program and the practicality of such implementation. This will create a body of evidence that will be essential to determine whether or not the implementation of telehealth services in Medicare is financially feasible.	Support	Worked in coalition with Health IT Now. The Society supports telehealth implementation in Medicare.

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Sec. 5007. Fairness in Medicaid Supplemental Needs Trusts	Disability Rights and Access to Care	Corrects an oversight in law and would promote independence, financial security and access to long-term services and supports by allowing capable individuals with disabilities to create their own special needs trusts.	Support	Worked in coalition with the Consortium for Citizens with Disabilities; sent letters of support to Capitol Hill.
Division B - Helping Families in Mental Health Crisis	Mental Health	Strengthens federal coordination of mental health resources, increases reporting on equality of mental health, advances integrated service delivery, supports the mental health workforce, increases early access to mental health services, promotes suicide prevention, and enacts meaningful reforms to the criminal justice system.	Support	Worked in coalition with the Mental Health Liaison Group. Joined letters in Nov. and Dec. 2016 urging both the House and the Senate to pass mental health reform as part of the 21st Century Cures Act.
Sec. 16005. Delay of Implementation of Medicare Fee Schedule Adjustments for Wheelchair Accessories and Seating Systems when Used in Conjunction with Complex Rehabilitation Technology (CRT) Wheelchairs	Access to Care	Delays application of Medicare competitive bid pricing used with Complex Rehabilitation Technology (CRT) accessories used with Group 3 power wheelchairs (such as tilt-and-recline systems and specialized seat cushions), protecting access to these fundamental components of wheelchairs that keep people with advanced MS healthy and independent.	Support	Partnered with disability organizations and wheelchair supplier and manufacturer associations. Lobbied the House and Senate for continued protection of power and manual CRT and related accessories. Access to CRT generally was a 2014 and 2015 Public Policy Conference issue. Sent letters of support to Capitol Hill and met with the Centers for Medicare and Medicaid Services (CMS).
Sec. 16007. Extension of the Transition to New Payment Rates for Durable Medical Equipment (DME) Under the Medicare Program	Access to Care	Retroactively extends the transition period for the second part of competitive bidding-derived cuts from June 30, 2016 to December 31, 2016, allowing Durable Medical Equipment (DME) providers in rural areas to continue to provide DME to beneficiaries in their communities while a more comprehensive, long-term solution is sought. Also calls for a study to help quantify the impact of DME policies on providers of these vital devices.	Support	Partnered with the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition; sent letters of support to Capitol Hill.
Sec. 16008. Requirements in Determining Adjustments Using Information from Competitive Bidding Programs	Access to Care	Directs the Secretary of Health and Human Services to take into account, when determining adjustments in the use of competitively bid prices in Durable Medical Equipment (DME), the average travel time and cost associated with furnishing items as well as the resulting number of suppliers in the area. This language will help ensure that suppliers of medical equipment are able to provide the items that patients need.	Support	Partnered with the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition; sent letters of support to Capitol Hill.