



National ALS Registry Update June, 2010

The ALS Association is the leading organization championing the establishment of a national ALS patient registry that will identify cases of ALS in the United States and collect information that will advance research into the cause, treatment and cure for Lou Gehrig's Disease. Significant progress has been achieved to date including the following:

Congress Enacts the ALS Registry Act, Appropriates \$16 Million for ALS Registry

Thanks to the outreach of people with ALS and ALS Association advocates across the country, The ALS Association has partnered with Congress to enact the ALS Registry Act (Public Law 110-373). Signed into law in October, 2008 the legislation provides the Centers for Disease Control and Prevention (CDC) with the authorization and guidance necessary to create a national ALS registry. At the same time, The Association has worked with Congress to secure nearly \$16 million in funding for the Registry over the past five years (FY 2006- FY 2010), including \$6 million in FY 2010. This funding has enabled the CDC to conduct four pilot projects to determine the most effective and efficient ways to accurately identify ALS cases in the United States and to share information. It also has enabled the Agency to take the first steps towards enrolling patients in the Registry as discussed below. Importantly, because The ALS Association pursued funding for the Registry even before enactment of the ALS Registry Act, the CDC will be able to implement the National ALS Registry much sooner than otherwise would have been possible.

Creating the Registry: Pilot Project Results, Identifying Cases

Pilot Projects

Over a nearly three year period, the CDC sponsored four pilot projects in order to create the building blocks for the Registry. The pilots were conducted in Georgia, Minnesota, and South Carolina and at the Kaiser Permanente HMO network. The projects evaluated several different strategies to identify ALS cases, learning how to overcome the significant challenges of effectively and efficiently ascertaining cases of ALS, a disease that progresses rapidly, is not easily diagnosed and often is misdiagnosed or confused with other diseases ranging from Multiple Sclerosis to Parkinson's disease

to Lyme disease. The projects also examined challenges associated with obtaining data, such as privacy and confidentiality laws, regulations and policies, as well as the limitations of administrative databases and medical records, which in addition to potentially including incorrect diagnoses also include administrative errors in the coding of ALS cases. Results from the projects have been presented to the CDC and are guiding the next steps in creating the Registry.

How to Identify ALS Cases: National Databases (Medicare, Medicaid, VA, National Death Index)

Using data learned from the projects, the CDC has created an algorithm that will enable the Agency to accurately identify approximately 80-85% of ALS cases in the United States by examining large national administrative databases, such as those maintained by Medicare, Medicaid, the Veterans Administration and the CDC's National Death Index.

The effectiveness of these databases in identifying cases is relatively unique to ALS and is made possible because of changes The Association has championed at Medicare, Social Security and the VA. For example, because the 24-month Medicare waiting period is waived for people with ALS, many more people with the disease are enrolled in the program and therefore can be identified through Medicare records. Similarly, regulations implemented by the VA in 2008 to make ALS a service connected disease also will significantly help to identify an increasing number of cases through VA records.

Once an ALS case is identified via this method, it will be included in the National ALS Registry.

How to Identify ALS Cases: Web Portal, Self-Registration

In order to identify the remaining 15-20% of cases, the CDC is launching an on-line web portal that will allow people with ALS to self-enroll in the Registry via a secure website. The first phase of the portal (www.cdc.gov/als) was unveiled in October 2009 and currently includes general information about ALS and answers to frequently asked questions. Self registration is expected to begin in late 2010 after the Agency has obtained approval from the Office of Management and Budget (OMB), which can take 9-12 months and is required by law to comply with privacy and data collection laws. CDC submitted the Registry for OMB approval in January 2010. A notice of the submission is available here: <http://edocket.access.gpo.gov/2010/pdf/2010-1718.pdf>.

Once operational, the web portal will utilize a combination of strategies, including those learned from the pilot projects, to verify true cases of ALS and to avoid duplication of individuals already enrolled in the Registry. The web portal ultimately is expected to allow any person with ALS to access the site to enroll in the Registry or confirm that they already are enrolled.

As with other elements of the Registry, The ALS Association is partnering with the CDC in the design of the web portal. We have submitted formal comments, available here, https://ssl.capwiz.com/alsa/attachments/07_27_09_ALS_Assoc_Comments.pdf. that also include recommendations on how the web portal and the Registry can provide people with ALS with additional information about ALS research, including clinical trials, as well as how they may obtain needed care, services and information. In addition, The Association is preparing to actively assist people with ALS across the country in enrolling in the Registry.

Identifying Gaps: Targeted State Based Registry Projects

Although the National ALS Registry is expected to identify that vast majority of ALS cases utilizing the online web portal and National databases, the CDC/ATSDR anticipates that gaps may exist in the data collected, particularly in urban and rural underserved areas of the country. Therefore, the Agency is partnering with three states (Florida, New Jersey and Texas) to create state registry projects. These projects are designed to obtain more detailed information about how to identify additional ALS cases. The CDC is not duplicating state registry projects in all 50 states. Rather, data collected in these states will be used to identify gaps in the National Registry and to develop strategies to improve the operation of the National Registry so that it identifies as many people with ALS as possible throughout the country, including those in underserved areas.

Next Steps

The ALS Association is working closely with the CDC to take the steps that are necessary to fully implement the Registry as soon as possible. Several vital activities will be taking place in the coming months as the Registry is implemented. A timeline of activities is available here:

[https://ssl.capwiz.com/alsa/attachments/National ALS Registry Timeline May 2010 .pdf](https://ssl.capwiz.com/alsa/attachments/National%20ALS%20Registry%20Timeline%20May%202010.pdf).

Enrolling in the Registry

Although self enrollment in the ALS Registry has not yet begun, The ALS Association is working with the CDC to ensure that as many people with ALS as possible enroll in the Registry once self enrollment is available. Therefore, we urge all people with ALS to sign-up as ALS Advocates via our website here: <http://capwiz.com/alsa/mlm/signup/>. By selecting ALS Registry when signing-up, advocates will be notified as soon as the self enrollment phase of the web portal becomes operational and they also will receive detailed instructions on how people with ALS can enroll.

Congressional Funding Needed

The ALS Association is working with Congress to appropriate \$10 million in funding in FY 2011 to continue the Registry and enable this important research project to move forward. Funding in FY 2011 also is needed to begin to realize the promise of the Registry as an engine that will drive research forward, helping to generate vital data that will advance our understanding of the disease, its causes and how it can be diagnosed and treated.

On March 19, 2010, Representatives Eliot Engel (D-NY) and Peter King (R-NY) sent a letter to the House Appropriations Committee urging the Committee to appropriate \$10 million in funding for the Registry in 2011. The letter was signed by nearly 40 U.S. Representatives.

The ALS Association will provide additional information about the ALS Registry as it becomes available. If you have any questions, please contact us at advocacy@alsa-national.org or toll-free at 1-877-444-ALSA.