

**Michigan Office of Administrative Hearings and Rules
Administrative Rules Division (ARD)**

611 W. Ottawa Street
Lansing, MI 48909
Phone: 517-335-8658 Fax: 517-335-9512

REQUEST FOR RULEMAKING (RFR)

1. Department:

Health and Human Services

2. Bureau:

Bureau Of Epidemiology And Population Health

3. Promulgation type:

Full Process

4. Title of proposed rule set:

Amyotrophic Lateral Sclerosis (ALS) Reporting

5. Rule numbers or rule set range of numbers:

R 330.101 - R 330.120

6. Estimated time frame:

6 months

Name of person filling out RFR:

Mary Brennan

E-mail of person filling out RFR:

BrennanM@michigan.gov

Phone number of person filling out RFR:

517-242-9634

Address of person filling out RFR:

333 S. Grand Avenue, 5th Floor, Lansing, MI 48909

7. Describe the general purpose of these rules, including any problems the changes are intended to address.

These new rules would establish requirements for reporting ALS to the Michigan Department of Health and Human Services. ALS is a progressive, degenerative, neurological disease. The onset of ALS is typically later in life, peaking between 50 and 75 years of age. The majority of patients with ALS die within 2-5 years of diagnosis. In general, it is believed that the ALS incidence is 2/100,000, so assuming a population size in Michigan of 10 million, that is 200 new cases per year; however, the University of Michigan ALS clinic has been seeing more cases and estimates 300 new cases per year. It is hard to determine the number of missed cases, especially given the lack of ALS clinics in Northern Michigan. The state has the authority under the Public Health Code to obtain, upon request, medical records to investigate, monitor, prevent, and control diseases dangerous to public health. Many of the diseases that are currently reportable to the state have treatments or known prevention strategies, but ALS patients and families have nothing that makes any significant difference. All ALS patients eventually die. The cost of the care for one ALS patient has been estimated at nearly \$200,000 per year in some cases, so the prevention of the development of ALS in one life in Michigan would have an economic impact. These rules would establish a statewide ALS case registry based on data collection of patients with ALS, identified by neurologists, hospitals, ALS clinics, and vital records. The ALS case registry would provide data for public health surveillance and provide researchers with standardized and comprehensive data aimed at identifying risk factors and prevention strategies.

8. Please cite the specific promulgation authority for the rules (i.e. department director, commission, board, etc.).

The Department Director.

A. Please list all applicable statutory references (MCLs, Executive Orders, etc.).

By authority conferred on the department of health and human services by sections 2221, 2226, and 2233 of the public health code, 1978 PA 368, MCL 333.2221, 333.2226, and 333.2233, and Executive Reorganization Order No. 2015-1, MCL 400.227.

B. Are the rules mandated by any applicable constitutional or statutory provision? If so, please explain.

The proposed rules are not mandated by any applicable constitutional or statutory provision.

9. Please describe the extent to which the rules conflict with or duplicate similar rules, compliance requirements, or other standards adopted at the state, regional, or federal level.

The rules do not conflict with or duplicate other rules, compliance requirements, or other standards adopted at the state, regional, or federal level.

10. Is the subject matter of the rules currently contained in any guideline, handbook, manual, instructional bulletin, form with instructions, or operational memoranda?

The subject matter of the proposed rules is contained in guidelines, manuals, forms, and operational memoranda.

11. Are the rules listed on the department's annual regulatory plan as rules to be processed for the current year?

The rules are listed on the current year annual regulatory plan.

12. Will the proposed rules be promulgated under Section 44 of the Administrative Procedures Act, 1969 PA 306, MCL 24.244, or under the full rulemaking process?

Full Process

13. Please describe the extent to which the rules exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.

The rules do not conflict with or duplicate other rules, compliance requirements, or other standards adopted at the state, regional, or federal level.

14. Do the rules incorporate the recommendations received from the public regarding any complaints or comments regarding the rules? If yes, please explain.

Clinicians from the University of Michigan ALS clinic contacted the department and requested the development of an ALS case registry and to make ALS a reportable condition. There are currently two ALS registries in the United States: 1. National registry that is a passive data system and is insufficient for Michigan surveillance and 2. Massachusetts Arego Paul Cellucci Registry, which is an active surveillance system based on mandatory reporting of ALS. The U of M team felt that the abstraction process detailed in Massachusetts is sufficient and collects appropriate secondary data use elements. The elements collected in Massachusetts allow determination of the number of ALS cases in the state, identify any gaps in care, identify underserved areas, assess for hotspots, and understand if the number of cases are increasing over time (which is what U of M is seeing in their clinics). The U of M team has stressed the importance of making ALS reportable to their patients and their families. In addition, the ALS registry and reporting has the full support of all 4 ALS clinics and their staff in Michigan.

15. If amending an existing rule set, please provide the date of the last evaluation of the rules and the degree, if any, to which technology, economic conditions, or other factors have changed the regulatory activity covered by the rules since the last evaluation.

This is a new rule set.

16. Are there any changes or developments since implementation that demonstrate there is no continued need for the rules, or any portion of the rules?

This is a new rule set.

17. Is there an applicable decision record (as defined in MCL 24.203(6) and required by MCL 24.239(2))? If so, please attach the decision record.

No