

Michigan Office of Administrative Hearings and Rules

Administrative Rules Division (ARD)

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**REGULATORY IMPACT STATEMENT
and COST-BENEFIT ANALYSIS (RIS)**

Agency Information:

Department name:

Health and Human Services

Bureau name:

Public Health Administration

Name of person filling out RIS:

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Rule Set Information:

ARD assigned rule set number:

2022-13 HS

Title of proposed rule set:

Amyotrophic Lateral Sclerosis (ALS) Reporting

Comparison of Rule(s) to Federal/State/Association Standard

1. Compare the proposed rules to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

There are no federal rules or standards for comparison.

A. Are these rules required by state law or federal mandate?

These rules are not required by state law or federal mandate.

B. If these rules exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rules exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

These rules would not exceed any federal standard as there are no federal standards for this proposed rule set.

2. Compare the proposed rules to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

Massachusetts

ALS is considered a reportable disease under Title 105 of the Code of Massachusetts Regulations (CMR), Section 300.192: "Surveillance of Diseases Possibly Linked to Environmental Exposures." The Massachusetts Department of Public Health is authorized to collect medical records and other identifiable information from health care providers and other persons subject to 105 CMR 300.000, and/or prepare data, as detailed in 105 CMR 300.190 and 300.191, on people evaluated for or diagnosed with ALS and other selected environmental related diseases.

Under Massachusetts General Law (MGL) Title 111, Section 24A, all information collected for public health investigations approved by the Commissioner of Public Health is strictly confidential and is not admissible as evidence in any legal proceeding. The statute also states that anyone providing information to a researcher approved by the Commissioner of Public Health shall not be liable for any damages related to that disclosure.

Vermont

As described in Act 149 (2022), the Vermont Department of Health operates a statewide ALS registry. Healthcare providers who diagnose or treat ALS patients must report all individual cases to the Vermont Department of Health.

Maine

Bill LD 2007 requires health care practitioners and facilities to report diagnoses of ALS to the Maine Center for Disease Control and Prevention (Maine CDC) to create and maintain a statewide registry for the surveillance of ALS. It also requires the Maine CDC to annually report on the statewide prevalence and incidence estimates of ALS, including any trends occurring over time in Maine, to better understand the disease.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

The proposed rules for Michigan do not exceed standards in these states.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rules.

There are no laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rules. Currently, MDHHS maintains a list of communicable disease for mandatory reporting from healthcare professionals, MCL 333.5111. The proposed ruleset furthers the list of reportable conditions beyond communicable disease, introducing clear guidelines for MDHHS to direct reporting of ALS by healthcare professionals and health facilities.

A. Explain how the rules have been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

MDHHS staff engaged external parties, such as those representing organizations or individuals that would be required to report under the new rules, as well as other interested parties with an interest in ALS prevention or management. MDHHS met with these external parties on eight occasions through 2022 and 2024 to collect input. MDHHS also met with Massachusetts and Vermont to discuss their state rules and hear about their lessons learned. From these discussions, feedback was collected and reviewed to determine if there was any duplication with other federal, state, and local laws. No duplication resulting from the introduction of the proposed ruleset was identified.

Purpose and Objectives of the Rule(s)

4. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

The proposed rules are meant to improve surveillance methods for ALS. It is expected that the rules will be minimally invasive to reporting providers and facilities. Quarterly, providers would report cases of ALS, through existing electronic health record exchange and health information technology infrastructure, fax, or excel report. To obtain more detail about the diagnosis, providers would either provide the medical records or MDHHS staff would go onsite to collect the required elements. The proposed rules and information collected with increased reporting will improve patient outcomes through quality improvement and public health interventions.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

The proposed rules would expand electronic reporting to all hospitals in Michigan, as well as other healthcare settings and providers outside of the hospital. Reporting will primarily be carried out through electronic reporting to reduce the burden of the rules on providers and healthcare facilities. Additionally, the proposed rules will eliminate the need for individual agreements with healthcare organizations and health information exchanges to be established or updated regularly.

B. Describe the difference between current behavior/practice and desired behavior/practice.

No current regulations exist to mandate the reporting of ALS to the state. The desired practice is for this reporting.

C. What is the desired outcome?

The desired outcome directly resulting from the rule's introduction is standardized, statewide reporting of ALS. By instituting the proposed rules, MDHHS will benefit from the ability to monitor ALS trends throughout the state. This data will be invaluable for chronic disease epidemiology and inform MDHHS and partner efforts in ALS disease prevention and patient outcomes for Michigan residents. Additionally, public health agencies, local governments, academia, and community-based organizations can utilize the resulting aggregated and deidentified reports on chronic diseases throughout Michigan to develop more robust community health needs assessments to inform their work. The State health department will have access to identifiable data. There will likely be added value in the information collected as a result of the proposed rule for healthcare providers and facilities in improving their understanding of the burden of this chronic condition and health outcomes beyond their patient population. The long-term goal for the reporting and longitudinal collection of clinical data on ALS is to improve public health monitoring, program design, and responsiveness for the purpose of preventing disease and adverse health outcomes and improving the quality of life of Michigan residents.

5. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

ALS is a debilitating disease without a known cause or cure. There is well-researched and supported evidence in the role of environmental effects on the development of the disease. Without a mandated reporting of cases to the state, it is unknown how many, who, and where in Michigan ALS is occurring. In the absence of the rules, cases of ALS will not be reported. If cases are not reported, clusters may not be apparent and potential environmental causes cannot be identified.

A. What is the rationale for changing the rules instead of leaving them as currently written?

This is a new rule set. Although MDHHS has the authority to collect information on diseases, infections, and disabilities among the Michigan population, these rules would clearly define the process for submitting data to the state and what data elements are required.

6. Describe how the proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

The intended outcome of the rules is to support effective public health surveillance of ALS throughout Michigan. It is estimated that there will be 200 new ALS cases diagnosed in Michigan each year, primarily from five ALS clinics. Therefore, the burden will not be large for the majority of providers in the state. MDHHS will use the knowledge gained from access to these cases for improving the quality of care and quality of life for people living with ALS in Michigan.

7. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

This is a new rule set.

Fiscal Impact on the Agency

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursements rates, etc. over and above what is currently expended for that function. It does not include more intangible costs for benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

8. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

Costs of creating and maintaining an ALS registry will rely on the state of Michigan and MDHHS. The fiscal impact is small in amount compared to other chronic or communicable diseases followed by the state that are currently reportable, since the frequency of ALS is approximately 8.8 per 100,000 population. There are five ALS clinics in Michigan that see the majority of these cases and will have reporting responsibilities. MDHHS will also need to hire 4.25 FTE for data collection, data abstraction, data analysis, evaluation and management (1.0 data analyst, 2.0 FTE case abstractors, 1.0 project coordinator, 0.25 FTE manager, \$650,000). Software and server costs for the data collection would be approximately \$150,000. Travel to sites for case abstraction would be \$5,000.

9. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

There have been no agency appropriations made or a funding source provided for any expenditures associated with the proposed rules. When available, MDHHS has applied for federal support but has not been successful thus far.

10. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

The fiscal and administrative burdens will be minimal as a result of the proposed rules. The only potential costs associated with the proposed rules would be for healthcare facilities to submit data for the limited number of cases they see through a data sharing health information exchange, fax or excel reporting. Such costs would be limited to staff time required for uploading or sending reportable information on ALS cases to MDHHS. This rule is necessary for the data to be collected in one location and analyzed as a whole to understand the burden of disease in the state. Right now the data is housed at individual medical facilities.

A. Despite the identified burden(s), identify how the requirements in the rules are still needed and reasonable compared to the burdens.

The proposed rules are necessary to ensure the most timely and accurate information on ALS is available to public health officials for investigation and prevention. This rule is suitable for achieving that goal as it largely relies on existing data sharing and health information standards that have been introduced in the past, such as the Health Information Technology for Economic and Clinical Health Act (HITECH) and Trusted Exchange Framework and Common Agreement (TEFCA). For the majority of healthcare facilities and providers throughout the state, we anticipate that the reporting burden will be minimal.

Impact on Other State or Local Governmental Units

11. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

The proposed rules will not impact the revenues to state or local governmental units, nor will it cause cost increases or reductions for other state or local governmental units.

12. Discuss any program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the rules.

For local governmental units that do not provide healthcare services to Michigan residents, then the proposed rules will not impose any additional program, service, duty, or responsibility on them. If a local governmental unit, such as local health department, provides healthcare services, then they would need to follow the reporting requirements introduced in the rules. For governmental units that fall into this category, there will only be minimal costs resulting from reporting ALS information, whether that information is uploaded, sent, or shared electronically with MDHHS.

A. Describe any actions that governmental units must take to be in compliance with the rules. This section should include items such as record keeping and reporting requirements or changing operational practices.

For local governmental units that provide healthcare to residents, such as local health departments, they should already maintain medical records for each patient and visit. If they are not connected to a health information exchange or lack a mechanism for automatic data sharing, they will be required to upload or send a data file with the required information to MDHHS. No other compliance costs are anticipated beyond any minimal costs associated with reporting the required chronic disease information.

13. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rules.

There are no appropriations or funding sources identified for additional expenditures associated with the proposed rules.

Rural Impact

14. In general, what impact will the rules have on rural areas?

The proposed rules may assist rural areas by requiring local facilities and providers to share data on residents to identify ALS. Consistent statewide reporting of data will help to protect the health of all Michigan residents. The rules may also raise awareness of ALS cases in rural areas and thus ensure they receive the specialized care they need.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

Healthcare facilities and providers located in rural areas will be required to report ALS information as described in the rule.

Environmental Impact

15. Do the proposed rules have any impact on the environment? If yes, please explain.

The proposed rules will have no impact on the environment.

Small Business Impact Statement

16. Describe whether and how the agency considered exempting small businesses from the proposed rules.

The information collected from healthcare facilities or providers that are deemed small businesses is critical for developing an accurate estimate of the ALS burden throughout the state. The agency did not consider exempting small businesses from the proposed rules without compromising the intended outcomes of the rules.

17. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

The proposed rules may have a disproportionate impact on small businesses, as smaller businesses may have limited staff who will be required to report the ALS information. However, the MDHHS has provided secure options for the transmission of data from the business to MDHHS to reduce any undue burden. The data can be uploaded, sent (mail or fax), or shared electronically as other health care data are to reduce any undue burden. MDHHS will also have staff to assist with reporting, if needed.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

The American Medical Association indicates that about 54% of all practicing physicians work in small practices of 10 or fewer physicians. In Michigan, there are approximately 2,500 family practice physicians which would suggest that at about 1,900 physicians (54% of 3,500) would meet the definition of small businesses. The probable effect would be that facilities will have the option to report the information themselves, which would require staff time, or they can utilize MDHHS staff to assist with the data reporting.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules after projecting the required reporting, record-keeping, and other administrative costs.

The agency did not establish differing compliance or reporting requirements. All businesses, large or small, are needed to report in order to have valid data regarding ALS. As indicated in Answer 17, MDHHS can assist smaller businesses with reporting if needed.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

MDHHS did not consolidate or simplify the compliance and reporting requirements for small businesses. All healthcare facilities and providers will be required to comply with the proposed rules. The skills necessary to comply with the reporting requirement include identification of proper data, ability to upload and perform data entry on the data for reporting purposes to MDHHS, and ability to understand data submission and work with MDHHS in the event the facility is unable to upload or otherwise provide the data with assistance.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rules.

MDHHS did not establish performance standards to replace design or operation standards required by the proposed rules. The reporting requirements will be standardized across all healthcare facilities and providers.

18. Identify any disproportionate impact the proposed rules may have on small businesses because of their size or geographic location.

Staffing issues may be impacted with the additional requirement of small practices to report the ALS data. The impact is not anticipated to take up an inordinate amount of time as smaller practices have fewer patients than its urban counterparts, which may have more data input required due to higher patient levels.

19. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rules.

If a small business is not connected with the statewide health information exchange and an automatic data sharing method cannot be identified, then there may be minimal costs imposed on the business to meet the rule's reporting requirements. However, these costs would likely be limited to staff time for organizing and sending the chronic disease information to MDHHS. This would involve a percentage of time the business has its staff working on the reporting requirement, e.g. general office assistant with an average salary of \$22.10 an hour (Department of Labor statistics: <https://www.bls.gov/ooh/office-and-administrative-support/secretaries-and-administrative-assistants.htm#:~:text=%2446%2C010%20per%20year,%2422.12%20per%20hour>). No direct costs are anticipated to be incurred by small businesses for compliance with these rules.

20. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

For small businesses that are connected to the statewide health information exchange and can comply with the rules through automated data sharing, then there will be minimal to no administrative costs imposed on the business. Facilities or healthcare providers that are not connected to the health information exchange will be required to report ALS cases manually or through another identified method. This may have a minimal fiscal impact on the business as a result of staff time required to prepare and report chronic disease information to MDHHS.

21. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

No direct legal, consulting or accounting costs are anticipated to be incurred by small businesses for compliance with these rules.

22. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

No direct costs are anticipated to be incurred by small businesses for compliance with these rules that would result in economic harm.

23. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

While there may be no anticipated fiscal costs as a result of exempting small businesses or imposing lesser standards on them, the result would be at the cost of gaps in ALS data throughout the state, particularly in regions where there are more small businesses that provide healthcare services as opposed to larger businesses or health systems. Compliance with reporting the required ALS information is not anticipated to be unduly burdensome and offering an exemption or lesser standards to small businesses would likely compromise the intended goal of the rules.

24. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

The impact on the public interest in exempting or setting lesser standards for compliance on small businesses would be inconsistency in data in identifying trends for ALS statewide, thus reducing the department's ability to identify trends in ALS cases and reducing the ability to intervene and prevent future cases.

25. Describe whether and how the agency has involved small businesses in the development of the proposed rules.

The rules were not developed with involvement from small businesses.

A. If small businesses were involved in the development of the rules, please identify the business(es).

The rules were not developed with involvement from small businesses.

Cost-Benefit Analysis of Rules (independent of statutory impact)**26. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.**

The only anticipated compliance costs as a result of the proposed rules are related to staff time to report ALS cases where the provider or healthcare facility is not connected to a health information exchange for automated electronic reporting and submitting medical records. For businesses that are required to report the required information manually, it is estimated that depending on the number of ALS patients, somewhere between 1 and 2 hours of staff time per ALS report will be expended to gather and report the required information to MDHHS. While the staff member responsible for reporting the information to MDHHS may depend on the type of healthcare facility, we anticipate that medical secretaries, assistants, administrators, or receptionists will likely be gathering and reporting the information required. Based on these estimates and the US Bureau of Labor Statistics estimates for 2022 Michigan wages, it is anticipated that the annual costs to a business might range between \$200 and \$500 per ALS case. MDHHS will ensure compliance costs are minimal and do not exceed staff time costs for manual disease reporting or data quality investigation. For businesses that are connected to a health information exchange where automated reporting to MDHHS is possible, there would be no compliance costs associated with the proposed rules. MDHHS will also have staff to assist in the abstraction of medical information from patient charts and can travel to the clinics to do this work, if needed. See May 2022 State Occupational Employment and Wage Estimates - Michigan, https://www.bls.gov/oes/current/oes_mi.htm#29-0000.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rules.

It is expected that the five ALS clinics in Michigan would be most affected and bear the majority of the costs of reporting and filing mandated reporting of ALS cases. University of Michigan ALS Center of Excellence and Pranger ALS Clinic (Ann Arbor), Henry Ford Harry J. Hoenselaar ALS Clinic (Detroit), Bronson Neuroscience Center/ALS Clinic (Kalamazoo) and Hauenstein Neuroscience Center (Grand Rapids). However other hospitals, clinics, and healthcare providers may be impacted as well. In 2023, there were 177 hospitals, 43,820 licensed physicians, 7,591 licensed physician assistants, and 195,883 licensed nurses in Michigan. The healthcare facilities may benefit from insights derived from the data shared with MDHHS for quality improvement activities.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

There are no additional costs anticipated for compliance with the rules if a healthcare facility is reporting the required information electronically through a health information exchange. As noted above, for businesses that are required to report the required information manually, it is estimated that somewhere between 1 and 2 hours of staff time per ALS case will be necessary to gather and report the required information to MDHHS. While the staff member responsible for reporting the information to MDHHS may depend on the type of healthcare facility, we anticipate that medical secretaries, assistants, administrators, or receptionists will likely be gathering and reporting the information required. It is anticipated that the annual costs to a healthcare facility might range between \$200 and \$500 per ALS case.

27. Estimate the actual statewide compliance costs of the proposed rules on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

The proposed rules will not introduce any compliance costs to individuals. The reporting responsibility is placed solely on the healthcare facilities and providers to report the required ALS information to MDHHS in an acceptable format.

A. How many and what category of individuals will be affected by the rules?

Only businesses providing healthcare services to patients will be required to report information to MDHHS. Individuals will not be impacted by the proposed rules.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

Reporting of ALS cases will not impact the healthcare providers or patients directly as this information is already documented in patient records and EHRs. The information will be collected electronically to ensure limited impact or burden.

28. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

If preventable factors are identified as a result of an ALS mandatory reportable registry, and mitigation efforts are performed, a cost reduction in terms of lives saved, or savings in health care costs incurred by ALS patients, their families, Medicare, Medicaid, or private insurance companies, is expected.

29. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

Primary direct benefits are that the proposed rules will support improved public health data to more accurately quantify the ALS burden throughout the state. Secondary indirect benefits are that by identifying ALS patients across the state, not just at the five main clinics, they may be able to gain earlier access to specialized ALS care via direct care or virtual physician visits. Patients who are diagnosed more quickly have measurable extension of life and overall improved quality of life through proper physical and occupational therapy.

30. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.

No impact on business growth and job creation is expected with the adoption of these rules. This rule will not eliminate jobs.

31. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

The medical field will be affected by these rules as a result of their industrial sector, or segment of the public they serve (patients), business size or geographic location, both urban and rural.

32. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of the proposed rules and a cost-benefit analysis of the proposed rules.

The proposed rules and regulatory impact statement were developed with consideration of MCL 333.5111 and the anticipated results of the proposed rules to improve health outcomes through public health interventions and to reduce healthcare costs posed to individuals, federal, and state agencies.

The number of hospitals was obtained from Michigan Health and Hospital Association website and the number of healthcare providers in Michigan was obtained from the Michigan Department of Licensing and Regulatory Affairs website. The salary or wage estimates for staff time required for manual reporting were based on the Bureau of Labor Statistics 2022 Michigan estimates.

MDHHS staff reviewed literature on the cost of ALS in the United States, including a literature review that was published in 2023 titled 'Epidemiology and economic burden of amyotrophic lateral sclerosis in the United States: a literature review'. They estimated the total national costs are likely to be approximately \$1.02 billion USD. The article concluded there is a variability in identified prevalence estimated and under-recognition of costs and a need for population-based data. This proposed rule would assist with this by informing disease burden across Michigan and support equitable healthcare resource planning.

Hyperlinks to the websites used to compile the RIS are below this box:

LARA BPL Active License Counts

MHA Hospitals

May 2022 State Occupational Employment and Wage Estimates - Michigan

<https://link.springer.com/article/10.1007/s10198-021-01328-7?fromPaywallRec=true>

<https://www.tandfonline.com/doi/full/10.1080/21678421.2023.2165947#abstract>

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., that demonstrate a need for the proposed rules.

Per the state of Michigan Epidemiology team's meetings with the states of Massachusetts, Vermont and the Centers for Disease Control and Prevention. The Department's experiences with birth defects, maternal mortality, and other data registries and case abstraction projects aided with the estimation of costs for this rule.

Alternative to Regulation

33. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

No reasonable alternatives to the proposed rules would achieve the expected goal of reporting all cases of ALS within Michigan.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

No statutory amendments are expected to be needed to adopt these rules.

34. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

No private market-based systems are utilized by the states of Massachusetts, Maine or Vermont in their development or maintenance of a mandatory registry for ALS. In Michigan, this would require the execution and maintenance of individual agreements with health systems or health data contributors which is cumbersome at a statewide level and has the potential to limit or interrupt the reporting of ALS data without a standard, statewide approach. If a private market-based mechanism was tried, not all providers may be willing to voluntarily participate, thus reports would be incomplete.

35. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rules. This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

No other alternatives were considered to incorporate into the rules. The proposed ruleset was developed with input from stakeholders to ensure that the reporting requirements were not overly burdensome to fulfill their purpose.

Additional Information

36. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rules, if applicable.

Policy, job aids, and website updates are being reviewed for best methods of instructions for complying with the rules.