Michigan Office of Administrative Hearings and Rules
Administrative Rules Division (ARD)
MOAHR-Rules@michigan.gov

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:
Talisa Gauthier
Phone number of person filling out RIS:
517-241-0048
E-mail of person filling out RIS:
gauthiert1@michigan.gov

Rule Set Information:
ARD assigned rule set number:
2022-24 HS
Title of proposed rule set:
Chronic Disease 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. The Centers for Disease Control and Prevention collects data from each state regarding chronic diseases without mandate.
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.
Maine:
10 ME Code Rules § 144-253
SUMMARY: These rules and regulations govern the operation of Maine chronic disease surveillance methods of data quality assurance and follow-up investigations. They establish the objectives, responsibilities and duties pertinent to the validation and operation of Maine chronic disease surveillance programs and set forth guidelines for the operation, conduct, and implementation of follow-up investigations.
2.INTRODUCTION
In accordance with 22 MRSA Section 1692-B, the Department of Human Services must be given access to all confidential reports and records filed by physicians, hospitals or other private or public sector organizations, and with all departments, agencies, commissions or boards of the State for the purpose of conducting investigations or evaluating the completeness or quality of data submitted to the Department's disease surveillance programs. The

Department shall follow the data confidentiality requirements of the departments, agencies, commissions or boards of the State providing this information to the extent those requirements are consistent with 22 MRSA Section 1692-B. Upon notification by the Department of Human Services, physicians or hospitals shall provide to the Department any further information requested for the purpose of conducting investigations or evaluating the completeness or quality of data submitted to the Department's disease surveillance programs.
The Maine State Department of Human Services maintains several chronic disease surveillance programs which monitor selected chronic disease rates throughout the state.
The general objectives of these programs include:
Surveillance of specific chronic diseases which may have environmental/ occupational etiologies.
Determination of frequencies and rates of these diseases on a community level with evaluation and analysis of this data and applicable comparisons with state and national data.
Evaluation of factors/etiologies which may effect incidence, prevalence or survivorship of these diseases.
Conducting follow-up investigations, when warranted, in areas where real, verified disease incidence is remarkable, i.e., a potential spatial/temporal disease cluster where investigation may yield fruitful results and lead to the initiation of preventive measures, public health interventions, and/or screening of the population-at-risk to identify undiagnosed cases and assist with the implementation of the intervention efforts.
The Department shall not seek information under these rules if the proposed identification of or contact with patients or health care practitioners would diminish the confidentiality of medical information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation. The Department shall not seek identifying information under these rules without an advisory body approved protocol.

Utah:
Utah Code § 53-2d-901 - Statewide stroke registry
(1) The bureau shall establish and supervise a statewide stroke registry to:
(a) analyze information on the incidence, severity, causes, outcomes, and rehabilitation of stroke;
(b) promote optimal care for stroke patients;
(c) alleviate unnecessary death and disability from stroke;
(d) encourage the efficient and effective continuum of patient care, including prevention, prehospital care, hospital care, and rehabilitative care; and
(e) minimize the overall cost of stroke.
(2) The bureau shall utilize the registry established under Subsection (1) to assess:
(a) the effectiveness of the data collected by the registry; and
(b) the impact of the statewide stroke registry on the provision of stroke care.
(3)
(a) The bureau shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to establish:
(i) the data elements that general acute hospitals shall report to the registry; and
(ii) the time frame and format for reporting.
(b) The data elements described in Subsection (3)(a)(i) shall include consensus metrics consistent with data elements used in nationally recognized data set platforms for stroke care.
(c) The department shall permit a general acute hospital to submit data required under this section through an electronic exchange of clinical health information that meets the standards established by the department under Section 26-1-37.
(4) A general acute hospital shall submit stroke data in accordance with rules established under Subsection (3).
(5) Data collected under this section shall be subject to Title 26, Chapter 3, Health Statistics.
(6) No person may be held civilly liable for providing data to the department in accordance with this section.
Utah Code § 53-2d-903 - Stroke registry advisory committee
(1) There is created within the bureau a stroke registry advisory committee.
(2) The stroke registry advisory committee created in Subsection (1) shall:
(a) be composed of individuals knowledgeable in adult and pediatric stroke care, including physicians, physician assistants, nurses, hospital administrators, emergency medical services personnel, government officials, consumers, and persons affiliated with professional health care associations;

(b) advise the bureau regarding the development and implementation of the stroke registry;
(c) assist the bureau in evaluating the quality and outcomes of the stroke registry; and
(d) review and comment on proposals and rules governing the statewide stroke registry.

Pennsylvania:
Disease Prevention and Control Law of 1955 (35 P.S. § § 521.1—521.21): 27.31. Reporting cases of cancer.
(a) A hospital, clinical laboratory, or other health care facility providing screening, diagnostic or therapeutic services for cancer to cancer patients shall report each case of cancer to the Department in a format prescribed by the Cancer Registry, Bureau of Health Statistics and Research, within 180 days of the patient's discharge, if an inpatient or, if an outpatient, within 180 days following diagnosis or initiation of treatment.
(b) A health care practitioner providing screening, diagnostic or therapeutic services to cancer patients for cancer shall report each cancer case to the Department in a format prescribed by the Cancer Registry, Bureau of Health Statistics and Research, within 5 work days of diagnosis. Cases directly referred to or previously admitted to a hospital or other health care facility providing screening, diagnostic or therapeutic services to cancer patients in this Commonwealth, and reported by those facilities, are exceptions and do not need to be reported by the health care practitioner.
(c) The Department or its authorized representative shall be afforded physical access to all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes and all other facilities, individuals or agencies providing services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer or medical status of any identified cancer patient.
(d) Reports submitted under this section are confidential and may not be open to public inspection or dissemination. Information for specific research purposes may be released in accordance with procedures established by the Department with the advice of the Pennsylvania Cancer Control, Prevention and Research Advisory Board.
(e) Case reports of cancer shall be sent to the Cancer Registry, Division of Health Statistics, Bureau of Health Statistics and Research, unless otherwise directed by the Department.

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

The rules do not exceed standards in the states referenced above. While Maine offers a similar chronic disease reporting rule structure, both Utah and Pennsylvania offer similar reporting requirements, although for singular disease reporting. The Maine rule describes chronic disease reporting follow-up using clinical data from providers and hospitals for the purpose of determining disease frequencies and rates and understanding data quality. The data elements included in the Maine rule and the ascribed purpose of the rule demonstrate similarities to the proposed chronic disease reporting rule. However, the proposed rule and its reporting requirements will primarily rely on a passive feed of electronic health record data, limiting the burden placed on the provider or health system to report that information manually. Though the Pennsylvania rule describes reporting specifically for cancer cases and does not introduce a chronic disease registry advisory board, it contains similar disease reporting requirements. The Utah rule describes a statewide stroke registry with requirements for reporting stroke cases in a specified time frame and format. It also institutes a stroke registry advisory committee to advise the development and use of a statewide stroke registry, similar to the chronic disease registry advisory board in the proposed chronic disease reporting rule.

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

MCL 333.5111 confers authority to the department to maintain a list of reportable conditions. These rules would not duplicate, overlap, or conflict with any laws, rules, and other legal requirements. Currently, MDHHS maintains a list of communicable disease for mandatory reporting from healthcare professionals. The proposed ruleset furthers the list of reportable conditions beyond communicable disease, introducing clear guidelines for MDHHS to direct reporting of chronic diseases 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 coordinated development of the proposed rules. 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 chronic disease prevention or management. MDHHS met with these external parties on eight occasions through 2022 and 2023 to collect input. 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.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, provide a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules.

There are no applicable federal mandated standards where these rules would be considered more stringent.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, provide either the Michigan statute that specifically authorizes the more stringent rules OR a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules.

MCL 24.232(9) does not apply. There is no applicable federal standard that involves a stricter standard imposed by a Michigan statute for more stringent rules.

Purpose and Objectives of the Rule(s)

6. 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 chronic conditions. It is expected that the rules will be minimally invasive to reporting providers and facilities by primarily leveraging existing electronic health record exchange and health information technology infrastructure in Michigan. 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.

Currently, MDHHS receives electronic reports of stroke and hypertension data from six participating hospitals in Michigan through HL7 Admission, Discharge, Transfer (ADT) message data. 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 rule 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.

Currently, MDHHS must establish agreements with the health systems that have agreed to participate and the Michigan Health Information Network, which facilitates the exchange of electronic health information. Establishing these agreements can be a lengthy process for all organizations involved. The desired practice would remove the requirements for establishing individual agreements with each health system. Because chronic disease reporting would utilize information already existing in the electronic health record and data sharing practices, healthcare facilities and providers would have minimal changes to their business or behavior to satisfy the rule's requirements.

C. What is the desired outcome?

The desired outcome directly resulting from the rule's introduction is standardized, statewide reporting of chronic diseases for conditions that have demonstrated a need for near-real time reporting and been approved by the MDHHS director. By instituting the proposed rules, MDHHS will benefit from the ability to monitor chronic disease trends throughout the state using near real-time electronic health information. This data will be invaluable for chronic disease epidemiology and inform MDHHS efforts in chronic disease prevention and patient outcomes for Michigan residents. Additionally, public health agencies, local governments, 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. State and local health departments will have access to identifiable data. The availability of more timely and robust clinical data for chronic disease monitoring will benefit state and local level public health through improved tailoring of programs and services provided to the communities they serve. 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 chronic conditions and health outcomes beyond their patient population. The long-term goal for the reporting and longitudinal collection of clinical data on chronic disease is to improve public health monitoring, program design, and responsiveness for the purpose of preventing chronic diseases, adverse health outcomes, and improving the quality of life of Michigan residents.

7. 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.

Chronic conditions impact the quality of life for millions of Michigan residents. In 2019, more than 60,000 Michigan deaths could be attributed to chronic diseases (MDHHS Vital Records). Additionally, the COVID-19 pandemic demonstrated that chronic conditions could increase the risk of COVID-19 and severe outcomes. Without the frequent chronic disease reporting established by this ruleset, MDHHS is limited in their ability to respond to emerging public health threats.

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 proposing, reviewing, approving, and maintaining a list of reportable chronic diseases. Additionally, the rules' establishment of a Chronic Disease Registry Advisory Board introduces a collection of representatives from chronic disease focused organizations, provider and healthcare organizations, community-based organizations, and the general public that offer unique perspectives to inform the governance of the reportable chronic diseases list.

8. 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 proposed rules is to support effective public health surveillance of chronic diseases throughout Michigan by leveraging an existing source of valuable electronic health information. MDHHS will use the knowledge gained from access to chronic disease electronic health record data for improving the quality of care and quality of life for people living with chronic conditions in Michigan. Chronic disease reporting introduced in this ruleset will largely rely on electronic tools and existing health information exchange mechanisms to reduce burden on reporting requirements from healthcare providers and facilities. The proposed rules will have minimal to no cost for health care providers and will reduce workload in establishing or maintaining data sharing agreements.

9. 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.

10. 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).

The fiscal impact on MDHHS as a result of the proposed rules will be related to organization of the chronic disease registry board and the ongoing system maintenance costs for the chronic disease registry. The following fiscal impact information is based on information currently available (as of August 2023) and may be subject to changes in the future.

The estimated annual cost of organizing the chronic disease registry advisory board meetings is roughly $1,500. The cost to date for development of a chronic disease registry capable of housing electronic health record data is roughly $200,000. The estimated annual cost of maintenance and operations for the chronic disease registry, which will house the information collected, is roughly $655,000. This estimate includes the software, server, and staff time estimates necessary for the maintenance and operation of the chronic disease registry, analysis of the information collected, and coordination of the chronic disease registry advisory board. There will likely be additional costs for each new chronic condition approved for reporting that are not already collected in the chronic disease registry. It is estimated that the onboarding and enhancements required would roughly be $40,000 for each new chronic condition. Future system enhancements or data integrations to the chronic disease registry will also involve additional costs, however, these cannot be estimated without defined project scope or requirements.

It is anticipated that the proposed rule will introduce potential savings to MDHHS as well. There may be savings from reduced staff time for carrying out data sharing agreements with participating healthcare providers and as a result of improving the efficiency of lengthy data analyses and investigations, such as maternal mortality reviews, that would be aided by access to timely chronic disease data. It is possible that the data collected in the chronic disease registry as a result of the ruleset will likely improve the strength of grant applications submitted by MDHHS programs, resulting in opportunities for additional funding. There are also anticipated savings in the event of a communicable disease outbreak, such as COVID-19 and Legionella, or other emerging public health threat, such as climate change. The access to timely chronic disease data will provide an advantage in emergency response and resource allocation. It would also the reduce burden on public health and the public to collect comorbidity data, likely resulting in cost savings.

11. 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.

12. 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 or providers that are not engaged in data sharing through the statewide health information exchange. Such costs would be limited to staff time which may include hiring a staff person who would be required for uploading or sending reportable information on a chronic disease to MDHHS. Despite the minimal costs, the rules are necessary and suitable to accomplish their purpose, i.e., to improve patient outcomes through quality improvement and public health interventions based on the information provided by the facilities and health care professionals.

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 chronic diseases is available to public health officials and 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

13. 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 may impact minimally a decrease in revenues due to the possible costs of staff performing the reporting duty. There is a conservate cost increase of $200 to $210 a week to state or local governmenal units, e.g. health departments for staffing costs in either hiring or adding responsibilities for existing staff to provide the reporting.

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

If a local governmental units does not provide healthcare services to Michigan residents, 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 rule. For governmental units that fall into this category, there will only be minimal costs resulting from reporting chronic disease 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.

15. 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

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

The proposed rules may assist rural areas in requiring local facilities and providers to provide data on its area residents to identify chronic diseases and report for consistent statewide data and the health of all Michigan residents.

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 chronic disease information as described in the rule.

Environmental Impact

17. 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

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

The proposed rules cannot exempt small businesses without compromising the intended outcomes of the rules. Instead of exempting them, an electronic tool will be added to assist in reporting. The information collected from healthcare facilities or providers that are deemed small businesses is critical for developing an accurate estimate of the chronic disease burden throughout the state.

19. 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 will not have a disproportionate impact on small businesses as MDHHS will ensure that there are minimal costs associated with reporting chronic disease information and that it can be uploaded, sent, or shared electronically to reduce any undue burden.

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

An estimated number of healthcare facilities deemed to be small businesses is unavailable. However, the proposed rules are not expected to have additional impacts on small businesses.

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.

MDHHS did not establish separate compliance or reporting requirements for small businesses. All healthcare facilities and providers will be required to comply with the proposed rules, large and small.

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 reporting requirements for small businesses. The reporting requirements will be standardized across all healthcare facilities and providers, large and small.

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 these rules.

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

The proposed rules will not result in a disproportionate impact on small businesses as a result of their size or geographic location.

21. 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.

22. 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, 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 approved chronic conditions manually or through another identified method. This may have a minimal fiscal impact on the business as a result of staff time, including the possibility of hiring a staff person, who is required to prepare and report chronic disease information to MDHHS.

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

There are no anticipated identified costs associated with legal, consulting, or accounting services, for small businesses to comply with the proposed rules.

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

There are no anticipated costs to small businesses that would result in economic harm or adversely affect competition.

25. 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 chronic disease 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 require chronic disease 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.

26. 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 will result in inconsistency in data in identifying trends for chronic diseases statewide.

27. 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; however, the rule development was coordinated with healthcare and physician organizations.

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)

28. 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 chronic disease information for approved conditions where the provider or healthcare facility is not connected to a health information exchange for automated electronic reporting. For businesses that are required to report the required information manually, it is estimated that depending on the number of patients and the chronic condition being reported, somewhere between 1 and 2 hours of staff time per month 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. 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. MDHHS will ensure compliance costs are minimal and don't 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.

See May 2022 State Occupational Employment and Wage Estimates - Michigan

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

The businesses that will be impacted by the proposed rules are facilities, such as hospitals, clinics, urgent cares, healthcare providers, and health information exchanges. Costs to the businesses will be limited to staff time to fulfill reporting requirements as described in the proposed rule for those where an existing electronic health record data source cannot be drawn upon. Healthcare facilities may benefit from the proposed rule as it could introduce savings in staff time required to execute data sharing agreements with MDHHS for chronic diseases surveillance or data validation follow up.

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 month 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.

29. 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 do not introduce any compliance costs on individuals. The information required for reporting a chronic condition is information already collected and documented by providers. There are no anticipated additional costs required for reporting this information.

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

In 2023, there are 177 hospitals, 43,820 licensed physicians, 7,591 licensed physician assistants, and 195,883 licensed nurses in Michigan.

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

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

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

Chronic diseases have a large economic impact and according to the Centers for Disease Control and Prevention, they are the leading driver of the $4.1 trillion spent annually on national healthcare costs, as of 2021. Cost reductions may arise as a result of the proposed rules and the value added to public health information to more effectively target and reduce chronic disease burden throughout the state, both to the businesses providing care and the patients seeking care.

31. 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.

The proposed rules will support improved public health data to more accurately quantify the chronic disease burden throughout the state and develop interventions that help improve health outcomes of Michigan residents.

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

The proposed rules are unlikely to impact business growth or job creation in Michigan.

33. 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.

There are no identified individuals or businesses that would be disproportionately affected by the proposed rules.

34. 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 rules were not developed with involvement from small businesses; however, the rule development was coordinated with healthcare and physician organizations. Participants included:MDHHS, Michigan Health Information Network (MiHIN), Michigan State Medical Society (MSMS), Michigan Health and Hospital Association (MHA), Henry Ford Health, Hurley Medical Center, Michigan Medicine, Wayne State University, Genesee County Health Department, Great Lakes Inter-Tribal Epidemiology Center (GLITEC), Michigan State Alliance of YMCAs, and the American Heart Association (AHA).

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. Further information was also obtained through
LARA BPL Active License Counts
MHA Hospitals
'Uses of Electronic Health Records for Public Health Surveillance to Advance Public Health'
'Leveraging Electronic Health Record Data for Timely Chronic Disease Surveillance: The Multi-State EHR-Based Network for Disease Surveillance'

See: LARA BPL Active License Counts
MHA Hospitals
May 2022 State Occupational Employment and Wage Estimates - Michigan

There are 177 hospitals in Michigan. Costs associated with clerical assistance in reporting the information to the Department and using the Bureau of Labor Statistics 2022, using a conservative 10 hours a week with the reporting, at an average salary of $20 an hour, the hospitals can expect to spend $200 a week for healthcare support workers assistance in the process. For physicians offices and healthcare facilities support workers, at an average salary of $21 an hour and at the conservative 10 hours a week, those offices and facilities can anticipate a cost of $210 a week for the worker assistance.

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.

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 proposed rules would support statewide collection of electronic health record information on chronic diseases. There are a number of articles citing the benefits of utilizing electronic health record data to advance chronic disease surveillance and examples of successful models across the United States.

LARA BPL Active License Counts
MHA Hospitals
'Uses of Electronic Health Records for Public Health Surveillance to Advance Public Health'
'Leveraging Electronic Health Record Data for Timely Chronic Disease Surveillance: The Multi-State EHR-Based Network for Disease Surveillance'

Alternative to Regulation

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

No reasonable alternatives to the proposed rules were identified that would achieve the goal of statewide reporting from all healthcare facilities and providers. The only alternative to obtain chronic disease data as proposed in the rule would be through individual data sharing agreements that introduce additional administrative and agency burden.

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

No statutory amendments are necessary at this time.

36. 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.

Other states and local health departments, such as Indiana, Washington, and Louisiana, utilize a shared surveillance network, known as MENDS, for monitoring chronic disease data. While each public health entity maintains their authority for surveillance in using the network, the collection of the data requires data sharing agreements with each of their contributing partners. This approach is effective for smaller public health jurisdictions but the execution and maintenance of individual agreements with health systems or health data contributors is cumbersome at a statewide level and has the potential to limit or interrupt the reporting of chronic disease data without a standard, statewide approach.

37. 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

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

The proposed rules establish a Chronic Disease Registry Advisory Board, which will be convened following the approval of the rules and whose protocols will be created after the initial convening.