STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Administrative Rule Chapter, Title and Number
Med 18

3. Subject
Informed consent

4. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

5. Chapter 20, Stats. Appropriations Affected

6. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget
☐ Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

8. Would Implementation and Compliance Costs Be Greater Than $20 million?
☐ Yes ☒ No

9. Policy Problem Addressed by the Rule
This proposed rule is a result of recent legislation. 2013 Wisconsin Act 111changed the standard regarding doctors informing patients of their health care options by removing the reasonable patient standard and replacing it with the reasonable physician standard. The reasonable physician standard requires doctors to disclose only the information that a reasonable physician in the same or similar medical specialty would know and disclose under the circumstances. As a result of the legislation doctors must obtain informed consent from their patients by advising them of reasonable alternate medical modes of treatment and the benefits and risks of those treatments in a manner consistent with the reasonable physician standard. The proposed rule will update Wis. Admin. Code s. Med 18 to reflect these changes.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.
The Rule was posted on the Department and Professional Services website for 14 days in order to solicit comments from businesses, associations representing of Safety businesses, local governmental units and individuals that may be affected by the rule. No comments were received.

11. Identify the local governmental units that participated in the development of this EIA.
No local governmental units participated in the development of this EIA.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
This proposed rule will not have a significant impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
Physicians will advise their patients their patients in a manner of alternate modes of treatment in a manner that is consistent with current law. There is no alternative to implementing the proposed rule due to the changes being necessitated by passage of legislation.

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14. Long Range Implications of Implementing the Rule

Physicians consistently advising patients of reasonable alternate medical modes of treatment will result in physicians upholding their duty to inform patients in accordance with s. 448.30, Stats.

15. Compare With Approaches Being Used by Federal Government

Several federal agencies, including but not limited to the Food and Drug Administration, have rules protecting human subjects participating in investigative trials. Investigators are required to obtain informed consent of each person that will participate in experimental studies, 21 CFR 50.20, including experiments involving drugs for human use found in 21 CFR 312.60. Obtaining informed consent from participants in the investigatory research is not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois: Illinois does not have a comparable statute or rule.

Iowa: Iowa statutes create a presumption that informed consent was given if it is documented in writing. "A consent in writing to any medical or surgical procedure or course of procedure in patient care which meets the requirements of this section shall create a presumption that informed consent was given." IOWA CODE § 147.137.

Michigan: Michigan's statute has comparable language which is directed towards physicians who are treating breast cancer patients. Physicians are required to inform patients verbally and in writing about alternative modes of treatment of cancer. The statute sets forth the reasonable physician standards. "A physician's duty to inform a patient under this section does not require disclosure of information beyond what a reasonably well-qualified physician licensed under this article would know." MCLS §333.17013 (6).

Minnesota: Minnesota does not have comparable statute or rule.

17. Contact Name	18. Contact Phone Number
Shawn Leatherwood	608-261-4438

This document can be made available in alternate formats to individuals with disabilities upon request.

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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No