



Public Comments on the Minnesota Department of Health Proposed Quality Reporting Rule 4654.100 – 4654.0800

DEFINITIONS:

Complete Submission - Page 1, lines 21 – 22 – The words “in a format that allows for further review and verification of the data’s accuracy” implies authorizing MDH access to any and all information of the patient and the doctor. There seems to be no limit to what these words could be used to illicit on demand from practitioners about patients and medical decisions. *These words should be stricken.*

Physician Clinic - Page 2, line 11-12 – the phrase “ten full time equivalent employees” appears to be an arbitrary number. Nothing in law allows MDH to set this limit. What if there are 11 FTEs? Will the clinics then have to report from all their separate locations, vastly increasing the administrative burden? M.S. 62Q 1.(a)(2) requires MDH to “avoid increasing the administrative burden on health care providers.” *Thus, this requirement should be stricken.*

Publicly reported measure – page 2, line 15 – the definition is insufficient because it does not follow the legal definition. A measure cannot simply be a measure that the commissioner adopts. The measures must be evidence-based and the evidence must be made available. *The definition should clarify the need for evidence-based criteria and require the citation of the evidence.*

Material error (page 1, lines 28-30). This definition is unclear. What does it mean when it says “significantly changes the results of the analysis of quality measures”? It is important to have a thorough definition or the interpretation can be broad and arbitrary. This need for a clear definition is important. In 4654.0400, the term is stated four times. Despite the fact that a clinic can challenge the commissioner, the commissioner’s decision is final. With no real definition of “material error” the clinic is exposed to the potential of abuse and arbitrary and capricious decisions on the part of the Commissioner.

CRITERIA

Recommendation Process Flawed and Potentially Political – On page 6, line 4, the commissioner lists six criteria for changing the imposed quality measures. These criteria represent very ambiguous judgments, preferences and value systems. Criteria C is

especially disturbing. At the same time the Department is attempting to standardize care across all shapes, sizes and personalities of patients, they are suggesting that care varies by age, gender, socioeconomic status and race/ethnicity. We disagree. Doctors practice person-based medicine, not age-based medicine, gender-based medicine, SES-based medicine or race-based medicine.

Criteria D does not reference the M.S. 62U.02 requirement for the measure to be evidence-based. National consensus decisions have nothing to do with whether a certain procedure is evidence-based. In fact, the evidence base related to what works for one person may be different from what works for the next person and the next and the next, hence the upcoming move to personalized medicine and genomic medicine. Criteria E underscores the fact that MDH knows that the measures they choose or the measures others suggest may NOT be valid or reliable. These allowances for changing the measures are broad, arbitrary and potentially political. *They should be stricken.*

Variations

We believe that this entire process will hurt the smaller clinics. Only the larger clinics, with sufficient staff to deal with the added bureaucratic burdens of this rule will be able to ask for variations, making the rule discriminatory toward the smaller clinics. In addition, the variations allow for discrepancy in the uniformity required by law. *There should be no variations allowed.*

APPENDICES:

“Patient Identification Methodology” Undefined – Nothing in M.S. 62U, the proposed rule, or the appendices defines this term which is listed three times in the Appendix A. Instead, M.S. 62U.02 Subd. 1 requires that the measures include uniform definitions. Without definition, MDH can modify, expand, or change the methodology without the public or the legislature knowing. The rule is enforced as law, and law should be clear and not subject to arbitrary and undisclosed processes and changes by the health department. *This term and the process should be defined in detail and its legality assessed prior to approving the proposed rule.*

Methodology not in Compliance with Statute. “Methodology for Including Patients” – Appendix E. This is not a definition of “patient identification methodology.” The proposed rule not only fails to define this methodology, it appears to be very unclear about this methodology in the data submission section. The rule of law requires clear definitions and wording to prevent arbitrary definitions and penalties. How can the Department even hope to compare “apples to apples” if the methodology is not clearly stated and uniform?

M.S. 62U.02 requires that the measures “include *uniform* definitions, measures, and forms for submission of data.” The methodology in Appendix E is not uniform, allowing clinics to pick and choose patients which may or may not be uniform to every other clinic picking and choosing patients. Or they are required to include their entire patient

population, which is not uniform to another clinic's population or selected set of patients. Furthermore Appendix E (2)(a)(v) states that physician clinics must keep documentation of their methodology, clarifying the wide variety of methodologies that will be used. Yet MDH purports that through this proposed rule they can report on physician "quality" on the basis of uniformity. We disagree. *The rule should not be approved until the methodology is standardized, uniform and publicly available.*

"Physician clinics must submit data by primary payor type" – This statement is made three times, yet there is nothing in law to require that physicians divide their patients by payor prior to reporting. Notably the hospitals are not required to divide their patients by payor prior to reporting. Again, M.S. 62Q 1.(a)(2) requires MDH to "avoid increasing the administrative burden on health care providers." *Thus this requirement should be stricken.*

No Evidence Citations - M.S. 62U.02 requires that "Quality measures must be based on medical evidence." No where in the rule or the Appendices are there citations for the evidence of these measures. Even the statement, "Measure specifications can be found on the Minnesota Department of Health website <http://www.health.state.mn.us/healthreform>" is incomprehensible. If there are evidence citations there, they proved impossible to locate.

How will practitioners or the public know if the Department is in compliance with Minnesota law unless there are actual citations for the measures that can be looked up, verified, and any exemptions noted?

There should be no assumptions that the measurements adopted by MDH or created by Minnesota Community Measurement, Joint Commission, CMS or any other listed entity are actually "evidence-based." As the Institutes of Medicine noted in *Patient Safety: Achieving a New Standard for Care*,

"There are gaps and inconsistencies in the medical literature supporting one practice versus another, as well as biases based on the perspective of the authors, who may be specialists, general practitioners, payers, marketers, or public health officials." (IOM, 2004, pg 158)

The real question is "whose evidence?". *Thus all measures required by the rule must include evidence citations within the rule for ready public access and easy assessment.*

Overreaching Measures – The measures on Diabetes, OVC, Asthma are collecting data on patient behavior, rather than physician actions. The Diabetes and OVC measure collects data on the patient's daily use of Aspirin and tobacco use and the Asthma measure collects data about the home of the child (i.e. whether the child's environment is tobacco free). *These should be stricken from the rule.*

APPENDIX E

Submission Specification Overreach – In Appendix E, the Department is overreaching in their collection of data. Nothing in M.S. 62U.02 authorizes MDH to require annual registration. Nothing in M.S. 62U.02 requires that clinics to report the data electronically, to obtain an electronic login user ID or a password. In addition, nothing in M.S. 62U.02 requires that the individual making the submission be annually registered. In addition, nothing in M.S. 62U.02 requires a provider to describe the “health care services provided by the physician clinics” and for clinics to provide the NPI or the board certifications of all clinical staff. Many of the “clinical staff” may not even fit into the 62J.03 subd 8 definition of “health plan company.” *These requirements should be stricken from the rule.*

Research without Consent – The State of Minnesota requires that patient consent be obtained for research using medical records (M.S.144.295). All external researchers must seek consent for access. This quality reporting and measurement process is research being conducted on patients treated in Minnesota. This is a violation of their legal rights. This private data on patients will be sent to MDH for the purpose of instituting financial bonuses or penalties potentially impact the kind of care physicians give and patients receive. Drs. Michael A Rie, M.D. and W. Andrew Kofke M.D. writing in CSA Bulletin discussed the improper use of patients for quality improvement research (“The Elephant in the Closet – Clandestine Population Based Experimentation Under the Guise of Cost Containment”). In addition, Dr. Rie wrote in [Medscape General Medicine](#)

To the Editor,

I enjoyed reading [Dr. Loewy's article](#)[1] on the abuses of EBM [evidence-based medicine].

As we all understand, EBM has produced some great success in many areas of clinical medicine. I share Dr. Loewy's cautions and doubts, and have been working on this problem in a more concrete way to bring to public attention the abuses of the quality improvement revolution at the level of medical ethics in the law and policy of finitude in financial healthcare resources. When cost containment impinges on the ethical integrity of healthcare professionals, the rule of law requires the courts to step in to protect that integrity. That day may already be upon the healthcare sector of this nation.[1]

The crossover of research ethics into quality improvement activities is the third generation of the Nuremberg Code of Ethics in American medicine recently introduced into American common case law. We recently covered the evolution of the code in a paper published earlier this year in *Critical Care Medicine*. [2] The mentioned AHRQ [Agency for Healthcare Research and Quality] report from the Hastings Center Task Force [3] was published, and there was a commentary about it from an editorial from NIH [National Institutes of Health] in the May issue of *Annals of Internal Medicine*. [4] This is a developing theme for medicine and the law, and should be covered in Medscape as the issues make their way into Congress and the courts.

Yours truly,

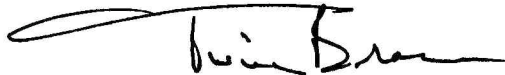
The rule should thus require that data not be transmitted to MDH without patient consent.

Data Submission Template – The Department’s data submission template, noted in Appendix E, must be included with the rule. The public has no idea what this data collection tool is and what data will be collected on individuals or from their private record. The Commissioner could arbitrarily change the template collecting more and more data without the public being aware of the collection. *The rule should not be approved until MDH produces and incorporates the data submission tool into the rule.*

EXPEDITED RULEMAKING

The legislature provides MDH with the option for expedited rulemaking. We believe MDH chose expedited rulemaking to avoid a public hearing over this proposed rule. We are very concerned that MDH plans to make it law by rule that changes to the quality measures list will be done under expedited rulemaking (p. 6, line 2). The law, and now the proposed rule, are unconstitutional takings and unethical use of private medical data for the purpose of controlling the practice of medicine, tying the hands of doctors, imposing financial conflicts of interests between patients and doctors, and standardizing treatment on very non-standardized patients.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Twila Brase". The signature is fluid and cursive, with a long horizontal stroke at the beginning.

Twila Brase
President