

## CLINICAL PRACTICE GUIDELINES AS LEGAL STANDARDS – A TERRIBLE IDEA

Recent discussions about national health care have included suggestions that doctors who follow federally-chosen guidelines to treat medical conditions should be immune, or presumed to be immune, from lawsuits – even though a preventable error may have harmed or killed a patient.<sup>1</sup>

The ostensible goal of such proposals is to “improve health outcomes”<sup>2</sup> by reducing unwarranted variations in practice. Indeed, experts have said, “Clinical guidelines make sense when practitioners are unclear about appropriate practice and when scientific evidence can provide an answer.” However, “[g]uidelines that are inflexible can harm by leaving insufficient room for clinicians to tailor care to patients’ personal circumstances and medical history. What is best for patients overall, as recommended in guidelines, may be inappropriate for individuals...”<sup>3</sup>

Turning guidelines into legal standards will only fortify this inflexibility, hampering the cause of patient safety while severely weakening patients’ rights.

### WHEN GOVERNMENT GUIDELINES BECOME LEGAL STANDARDS, MEDICAL CARE BECOMES RIGID, INFLEXIBLE AND CONFUSING.

- **Even the best evidence-based guidelines can be flawed or actually harm patients.** It is generally recognized that “guideline developers may err in determining what is best for patients.... [and] scientific evidence “is often lacking, misleading, or misinterpreted.”<sup>4</sup> Even guidelines based on rigorous clinical trials cannot reflect the differences in how illnesses affect every patient and “how they respond to treatments, based on factors such as their genetic makeup, the way their bodies function, and environmental conditions that researchers are only beginning to understand.”<sup>5</sup> As a result, guidelines may be “inferior to other options, ineffective, or even harmful.”<sup>6</sup> And the problem is exacerbated when patients’ needs are not “the only priority in making recommendations,” such as when they are developed to serve the interests of risk managers and those more concerned about liability protection than quality of care.<sup>7</sup>
- **Current bills in Congress would replace clinical decision-making with systems that designate the federal government as the sole arbiter of acceptable medical practice.** Proposed congressional legislation,<sup>8</sup> for example, would empower the U.S. Secretary of Health and Human Services to select and issue guidelines for particular medical conditions even though “knowledgeable, respected professional groups can, and often do, come down on opposite sides on a particular treatment issue.”<sup>9</sup> Given how loudly medical lobbies complain that the government should not be meddling in health care, it is safe to assume that this will, among other things, likely lead to a “loss of confidence in the guideline itself.”<sup>10</sup>

- **There may be good clinical reasons to vary from the government’s “one size fits all” recommendation for a patient, yet establishing guidelines as legal standards will prevent any flexibility.**<sup>11</sup> Since guidelines are written for “average patients,” they cannot encompass the huge variation in how patients present. Yet providers would have little choice but to follow a designated guideline – even one the provider knows is obsolete or outdated.<sup>12</sup>
- **Guidelines can contradict each other.** It is estimated that more than 1,400 sets of clinical practice guidelines exist today. While some standards, such as those in anesthesia, are “simple and clearly defined,” others, such as those in obstetrical cases, are complicated and can be contradictory.<sup>13</sup> Conflicting guidelines from different professional bodies can confuse and frustrate practitioners.<sup>14</sup>
- **When guidelines are contradictory, courts will need to get involved.** “Accepting that there will almost certainly be multiple guidelines for many conditions, courts will have to engage in a process of deciding, when guidelines conflict on a material point, which one to treat as authoritative, or more authoritative.”<sup>15</sup>

## **IT IS UNFAIR FOR PATIENTS’ CASES TO SOLELY BE JUDGED BY STANDARDS WRITTEN BY MEDICAL SOCIETIES THAT WOULD EXCULPATE THEIR PHYSICIANS.**

- **Conflicts of interest and specialty bias in the development of guidelines, already a well-recognized problem,**<sup>16</sup> will escalate knowing they are written to exonerate fellow physicians. These proposals contemplate that guidelines will be written by medical and specialty societies, which are inherently biased in their views about liability. Such societies, particularly the American College of Obstetricians and Gynecologists (ACOG), have been aggressive leaders in the medical lobbies’ push for liability limits in the last few years and remain committed to that goal.<sup>17</sup>
- **The one-sided nature of most proposals raises fundamental issues of fairness and constitutionality.** Most proposals would allow physicians to take advantage of guidelines to immunize themselves from liability but would prevent or make it very difficult for patients to use those same guidelines to prove negligence. This “raises disturbing questions of fairness and of validity under the U.S. Constitution’s Fifth and Fourteenth Amendments’ due process and equal protection mandates, and under state constitutional principles as well.”<sup>18</sup>

## **THIS IDEA HAS BEEN TRIED BEFORE AND FAILED EVERY TIME.**

**Only a few states have attempted to develop and use certain guidelines as legal standards beginning and ending in the 1990s; no programs were renewed.**<sup>19</sup>

- **Maine.** In the 1990s, Maine established a program that allowed doctors in four specialties – anesthesiology, emergency medicine, obstetrics/gynecology and radiology – to participate in a program allowing use of guidelines as exculpatory evidence in lawsuits.<sup>20</sup> Other specialties were encouraged to take advantage of this program but did not. The program expired, and the Maine Bureau of Insurance concluded that “the medical demonstration project had no measurable effect on medical professional liability claims, claims settlement costs, or malpractice premiums.”<sup>21</sup>

- **Other states.** In 1996, Florida began a demonstration project for cesarean deliveries but reportedly “garnered relatively little support among physicians – only 20% of physicians eligible to participate chose to do so. The project ended in 1998. Three other states (Kentucky, Maryland, and Minnesota) adopted test projects in the 1990s, though none of the projects is fully operational today (the Maryland and Minnesota projects have fully expired).”<sup>22</sup>

## NOTES

<sup>1</sup> See, e.g., H.R. 2300, H.R. 2603, H.R. 2653 (114th Congress).

<sup>2</sup> See, Steven H. Woolf et al., “Potential benefits, limitations, and harms of clinical guidelines,” 318 *BMJ* 527 (February 1999), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1114973/>.

<sup>3</sup> *Ibid.*

<sup>4</sup> *Ibid.*

<sup>5</sup> See, Maxwell Mehlman, “Professional Power and the Standard of Care in Medicine,” 44 *Ariz. St. L.J.* 1165 (2012), <http://ssrn.com/abstract=2205485>.

<sup>6</sup> See, Steven H. Woolf et al., “Potential benefits, limitations, and harms of clinical guidelines,” 318 *BMJ* 527 (February 1999), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1114973/>.

<sup>7</sup> *Ibid.*

<sup>8</sup> See, e.g., H.R. 2300, H.R. 2603, H.R. 2653 (114th Congress).

<sup>9</sup> Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” 26 *Journal of Health Politics, Policy and Law* 327 (April 2001), <http://archive.ahrq.gov/research/findings/evidence-based-reports/jh ppl/roff.pdf>.

<sup>10</sup> *Ibid.*

<sup>11</sup> See, e.g., Terrence M. Shaneyfelt and Robert M. Centor, “Reassessment of Clinical Practice Guidelines: Go Gently Into That Good Night,” 301 *JAMA* 868, 868–69 (2009), <https://medicosdigitall.files.wordpress.com/2007/06/reassessment-of-clinical-practice-guidelines.pdf>.

<sup>12</sup> See, Steven H. Woolf et al., “Potential benefits, limitations, and harms of clinical guidelines,” 318 *BMJ* 527 (February 1999), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1114973/>.

<sup>13</sup> Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” 26 *Journal of Health Politics, Policy and Law* 327 (April 2001), <http://archive.ahrq.gov/research/findings/evidence-based-reports/jh ppl/roff.pdf>.

<sup>14</sup> See, Steven H. Woolf et al., “Potential benefits, limitations, and harms of clinical guidelines,” 318 *BMJ* 527 (February 1999), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1114973/>.

<sup>15</sup> Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” 26 *Journal of Health Politics, Policy and Law* 327 (April 2001), <http://archive.ahrq.gov/research/findings/evidence-based-reports/jh ppl/roff.pdf>.

<sup>16</sup> Institute of Medicine, *Knowing What Works in Health Care: A Roadmap for the Nation* (2008), <https://www.iom.edu/Reports/2008/Knowing-What-Works-in-Health-Care-A-Roadmap-for-the-Nation.aspx>.

<sup>17</sup> See, e.g., “American Congress of Obstetricians and Gynecologists 2015 Legislative Priorities,” <http://www.acog.org/Advocacy/ACOG-Legislative-Priorities> (viewed June 13, 2015). See also, Peggy Peck, “Coalition includes ACOG: specialty societies push tort reform,” 29 *OB/GYN News* 1 (March 2004), <http://www.thefreelibrary.com/Coalition+includes+ACOG%3A+specialty+societies+push+tort+reform.-a0114521526>. (One-million-dollar donors include the Society of Thoracic Surgeons, the American Association of Neurological Surgeons/Congress of Neurological Surgeons, the American College of Emergency Physicians, the American College of Surgeons and the American Academy of Orthopedic Surgeons. The American College of Cardiology has pledged \$500,000, the North American Spine Society has pledged \$100,000 and the American College of Obstetricians and Gynecologists and the American Academy of Dermatology have joined and agreed to donate undisclosed amounts.)

<sup>18</sup> Arnold J. Rosoff, “Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines,” 26 *Journal of Health Politics, Policy and Law* 327 (April 2001), <http://archive.ahrq.gov/research/findings/evidence-based-reports/jh ppl/roff.pdf>.

<sup>19</sup> See, e.g., FLA. STAT. § 408.02(9)(e) (1999); 24 ME. REV. STAT. tit. 24, § 2975 (repealed in 1999 with expiration).

<sup>20</sup> See, Linda L. LeCraw, “Use of Clinical Practice Guidelines in Medical Malpractice Litigation,” 3 *J. Oncol Pract.* 254 (September 2007), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2793844>.

<sup>21</sup> *Ibid.* (citing Me Bureau of Ins and Bd of Lic in Med, Medical Liability Demonstration Project 2 and 5, 2000).

<sup>22</sup> *Ibid.* (citing Fla Agency for Health Care Admin: Practice Guidelines as Affirmative Defense: The Cesarean Demonstration Project Report, 1998; 5. Md Code Ann Health-General §§ 19-1601 to 19-1606 (1993); Minn Stat § 62J 34 (1993)).