Testimony regarding SB 96 —Proponent

Kansas disclosure of unanticipated medical outcomes and medical errors act

January 26, 2016

To Senator Jeff King (Chairman) and the Senate Judiciary Committee:

My mother and I are the authors of SB 96, which would require the disclosure of harmful medical errors and unanticipated medical outcomes to patients. This bill is based on four principles that describe rights and responsibilities:

1) Patients have the right to know about unanticipated outcomes of their care and medical errors that have occurred during their care.

Patients expect to be informed of errors that occur during their care. [1, 2] The organizations and individuals who deliver health care have an obligation to act in the best interest of the patent, and many membership organizations have stated in their codes of ethics that their members have a duty to treat patients with honesty and integrity. [3, 4, 5] However, when an obligation exists only in a code of ethics, it is easy to dismiss in the real day-to-day world. A recent study of the attitudes of US physicians on the topic of attitudes and behavior related to patient communication found that only two-thirds agreed with the statement "Physicians should disclose all significant medical errors to affected patients." [6]

This bill will establish unambiguously that the responsibility to the patient supersedes all other factors when an issue of disclosure arises. The content of the disclosure required by this bill reflects the best-practice recommendations by Mastroianni et al. [7]

2) Health care workers and administrators of health care institutions have the responsibility to have timely and authentic conversations with patients (and their families or representative, as appropriate) about unanticipated outcomes and medical errors.

Conversations should be not only authentic and comprehensive, but timely. The survey by Mastroianni et al. [7] found timeframes for disclosure in other states ranging from 24 hours to 7 days. The bill as drafted allows 7 days (section 3(i)), but we welcome shortening this requirement.

Disclosure is not a one-time event. It will often consist of a series of conversations as the medical team learns more about the event. Initially it may not be clear whether or not an error was made. These conversations should begin early. Risk managers should not act as a gatekeeper in deciding whether to discuss a situation with a patient, but rather as a resource for disclosure conversations.

3) Patients who have been harmed due to medical errors have the right to be treated fairly and compensated appropriately.

To help ensure that patients who have experienced a medical error are treated fairly and compensated appropriately, this bill requires health institutions to inform injured patients of their right to seek legal council if the institution makes an offer of financial compensation (section 3(m)). Offers of financial compensation following disclosure have been promoted as a way to quickly compensate injured patients and avoid malpractice lawsuits. These settlements can be a good solution for both parties, but there is a danger that patients will be persuaded to settle for far less than the amount necessary to cover future medical expenses, replace lost income, and compensate for pain and suffering. Therefore, this bill follows the recommendation of Gabriel Teninbaum [8] by creating a six month waiting period between the offer of a settlement and acceptance of that settlement if a patient chooses not to consult an attorney.

4) Health care institutions have the responsibility to establish procedures for disclosure of unanticipated outcomes and medical errors to patients and their families.

Section 3(c) of this bill sets forth a requirement for medical care facilities to design and implement a disclosure policy.

Unanticipated outcomes and medical errors will occur in even the best of medical care facilities. Therefore, it is to the benefit of both patients and medical care facilities that procedures for disclosure are established so that the responsibilities of health care providers, expectations of administrators of the medical facility, and timelines for action are clear.

The magnitude of medical harm

Medical harm is a public health concern. The effects of harm range from being a minor inconvenience to causing a patient's death. One study of Medicare beneficiaries estimated that 13.5% of Medicare patients experienced adverse events of a serious nature during their hospital stay—with 1.5% experiencing an event that contributed to their death. [9] I have provided a chart that compares estimated death rates from medical harm to the officially reported "top ten" causes of death in the US.

Your opportunity to take a stand for patients in Kansas

My mother and I recognize that the culture of healthcare does not automatically change with the passage of a law. Real change takes leadership within healthcare organizations. But this bill is the catalyst for that change. Without it, the status quo will continue, and patients will continue to confront the Wall of Silence. The culture of "deny and defend" is well entrenched, and it will remain.

Requiring hospitals to have disclosure policies and to do disclosure is the first step toward ensuring that hospitals are consistently having disclosure conversations with patients. And those experiences

of implementing disclosure policies and the reality of those disclosure conversations are steps toward genuinely recognizing issues of patient harm. And that recognition must take place before healthcare organizations can truly improve patient safety.

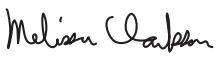
You are likely to hear many voices and opinions on our bill. You will hear from professionals representing physicians and professionals representing hospitals. But you will not hear from professionals representing patients—but no one is a professional patient. *Do not let the voice of the patient be lost.*

I ask that you move this bill forward and establish the right of patients in Kansas to know when they have been harmed while receiving medical care.

Continuing the conversation

You can find my blog, in which I record the experiences of my family and discuss disclosure of medical errors and patient safety, at **disclosemedicalerrors.wordpress.com**.

Please contact me with any questions, concerns, or suggestions you may have. My email address is **clarkson_melissa@yahoo.com**.



Melissa Clarkson, PhD

Daughter of Glenn Clarkson, who died after suffering preventable harm in a Kansas hospital in March of 2012

Literature Cited

1 Mazor KM, Simon SR, Yood RA, et al. "Health plan members' views about disclosure of medical errors." *Annals of Internal Medicine*, 2004; 140:40–18.

2 Witman AB, Park DM, Hardin SB. "How do patient want physicians to handle mistakes: A survey of internal medicine patients in an academic setting." *Archives of Internal Medicine*, 1996; 156(22):2565–2569.

3 American Medical Association, Code of Medical Ethics, Section 8.12.

4 American Nurses Association, Code of Ethics for Nurses, Sections 1.4 and 3.4.

5 American Society for Healthcare Risk Management, Code of Professional Conduct, Section "The responsibility to those we serve."

6 Iezzoni LI, Rao SR, DesRoches, CM, Vogeli, C. Campbell, EG." Survey shows that at least some physicians are not always open or honest with patients." *Health Affairs*, 2012; 31(2): 383–391.

7 Mastroianni AC, Mello MM, Sommer S, Hardy M, and Gallagher TH. "The flaws in state 'apology' and 'disclosure' laws dilute their intended impact on malpractice suits." *Health Affairs*, 2010; 29(9): 166–1619.

8 Teninbaum GH. "How medical apology programs harm patients." Suffolk Law School, Legal Studies Research Paper Series, Research Paper 11-30, November 2011.

9 Levinson DR, Inspector General. November 2010. "Adverse events in hospitals: National incidence among Medicare beneficiaries." Department of Health and Human Services. United States of America.

section 2

Definitions

a. Harm
b. Health care provider
c. Health care administrator
d. Medical care facility
e. Medical error
f. Unanticipated outcome
    1. Adverse event
    2. Sentinel event
g. Serious unanticipated outcome or medical error
h. Less serious unanticipated outcome or medical error
i. Minor unanticipated outcome or medical error
j. Patient's family member
k. Patient's representative

section 3

Disclosure policies

a. ***Medical care facilities*** must design and implement disclosure policies

b. ***Health care providers*** must also do disclosure, but do not need to develop formal policies

c. Things policies are to address:
    1. A statement that an unanticipated outcome or medical error occurred
    2. An explanation of the cause, facts, or context of the event
    3. An acknowledgement of harm, and an apology where appropriate
    4. An explanation of the impact on the patient's treatment plans and health status
    5. An explanation of the investigation that has occurred or will take place
    6. An offer of support services, as needed

d. Things medical care facilities are to do after development of the policies:
    1. Provide copies of the policy and provide training to their administrators and healthcare providers
    2. Establish a plan for providing disclosure coaching and support

e. Medical care facilities are to develop policies, do training, and implement the policies by July 2017

f. Policies are to be filed with the licensing agency

g. Any reports of reportable incidents are to include an account of disclosure

h. In the event of an unanticipated outcome or medical error, it is to be disclosed to the patient / patient's family member / representative

i. The initial disclosure conversation is to take place within 7 days of discovery of an error or unanticipated outcome. Once an investigation is completed, the result is to be disclosed. Disclosure conversations are to include:
    1. A statement that an unanticipated outcome or medical error occurred
    2. An explanation of the cause, facts, or context of the event
    3. An acknowledgement of harm, and an apology where appropriate
    4. An explanation of the impact on the patient's treatment plans and health status
    5. An explanation of the investigation that has occurred or will take place
    6. An offer of support services, as needed

j. "Serious" unanticipated outcomes and medical errors are to be disclosed both in oral and written form. "Less serious" ones may be only oral, and "minor" ones do not need to be disclosed at all.

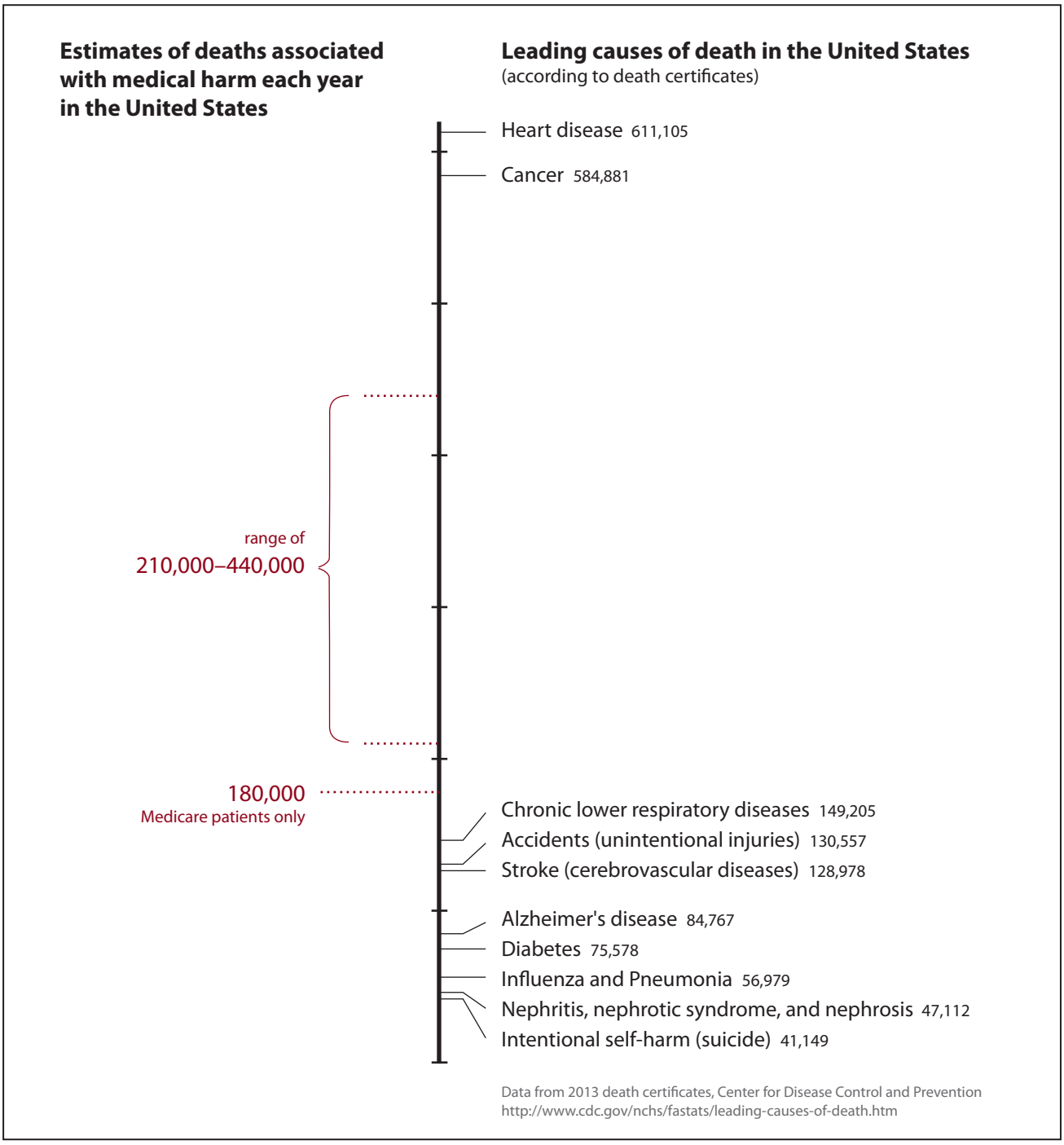
k. A note of the disclosure is to be recorded in the patient's medical record.

l. Failure to disclose will result in a fine of $10,000.

m. The patient shall be advised of their right to consult an attorney *(clarification: only if there is an offer of a settlement)*. If a patient wishes to proceed with a settlement without consulting an attorney, there is a six-month waiting period before the settlement can be accepted.

n. Patients cannot be asked to waive their right to litigation, except as a condition of settlement.

o. A settlement cannot be subject to confidential sequestering of any information relating to the case.



The 180,000 estimate is from a 2010 report by the Department of Health and Human Services.

This study was a chart review using a nationally representative sample of Medicare beneficiaries. The main findings are:

- An estimated 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays, with 1.5% experiencing an event that contributed to their death (projected to the entire population of Medicare patients, this is 15,000 per month or 180,000 per year).
- An additional 13.5 percent of Medicare beneficiaries experienced events during their hospital stays that resulted in temporary harm.
- Physician reviewers determined that 44 percent of adverse and temporary harm events were clearly or likely preventable.

The report can be downloaded at https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

The 210,000–400,000 estimate is from an analysis combining the Medicare study with three additional studies.

All four studies are two-tier chart reviews, with physicians determining whether an adverse event occurred. The 210,000 estimate comes from evidence found in the charts. The 440,000 estimate accounts for the limitations of medical charts to provide evidence of adverse events.

Reference: JT James. 2013. "A new, evidence-based estimate of patient harm associated with hospital care." *Journal of Patient Safety* 9(3): 122-128.