The American Association of Nurse Attorneys

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TAANA Position Paper on Samuel's Law
Executive Summary

The American Association of Nurse Attorneys supports efforts to prevent fatal medication errors. However, the approach of S. 371 is counterproductive and contrary to current approaches to preventing patient injury due to errors, undermines current state authority to regulate nursing, and is unconstitutional under federal law.

The American Association of Nurse Attorneys urges the South Carolina Legislature to oppose S.371 (Samuel's Law) for the following reasons:

The legislation's approach will likely result in increased risk of injury and death due to medication errors.
TAANA supports the approach of A Just Culture in health care delivery to reduce patient and health care personnel harm due to medical errors. This approach is also supported by the American Nurses Association, the South Carolina Hospital Association, and others to decrease patient harm due to medical error. [1]Modern health care is a very complex, high-risk, and error-prone activity. Medication error is the most frequently occurring type of medical error. A Just Culture approach discourages blaming individual health care professionals. Instead, open dialogue is encouraged to proactively identify system approaches that may lead to error.

The punitive approach of Samuel's Law will have the opposite effect by discouraging the voluntary reporting of medication errors by nurses.

Samuel's Law undermines the authority of State Boards of Nursing delegated by the state legislature to discipline nurses who cause patient harm.
Each individual state has an established Board of Nursing to regulate licensed nurses. Boards of Nursing establish regulations to uphold professional standards of practice and to protect patients against substandard nursing care. Because the provision of medical care can be complex, the function of a board of nursing is to diligently examine allegations of patient harm against a nurse carefully and render appropriate sanctions, including revocation of a license when warranted. Samuel's law usurps the role of professional licensing boards.

Samuel's Law is unconstitutional and violates due process protections
A nursing license is property protected under the United States Constitution. State Boards of Nursing is to provide constitutionally mandated processes to ensure that revocation of a nurse's license is justified under the law and the facts of a particular case. Enforcing due process through professional licensing boards protects nurses, physicians, and other health professions from arbitrary government action. Samuel's Law is discriminatory against nurses as it allows for arbitrary revocation of a nursing license.

[1] https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=106

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TAANA's POSITION PAPER ON SAMUEL'S LAW[2]

The American Association of Nurse Attorneys (TAANA), established in 1982, is a voluntary non-profit organization whose Fellow members have combined the legal and nursing professions, holding degrees in both nursing and law. TAANA's mission is to provide resources, education, and leadership to its members as well as the medical and legal communities on issues related to health law and policy.

Problem Presented:

Is South Carolina's proposed law, Samuel's Law, constitutional and is this proposed law consistent with the current health policy that favors a *Just Culture Model*?

TAANA's Position:

For the reasons stated below, Samuel's Law is unconstitutional. It violates due process, it usurps the authority of the regulatory agency, and it destroys the foundation for safe and reliable healthcare found in the Just Culture Model.

DUE PROCESS

Due Process of the law is a fundamental, constitutional guarantee that before the government can deprive a person of their life, liberty or property, that individual must be afforded notice of the government action and an opportunity to be heard before such government action takes place. The constitution also guarantees that the law shall not be unreasonable, arbitrary or capricious.[3]

Substantive Due Process (substantive law) creates, defines and regulates rights, such as the right to life. When government actions are arbitrary, the U.S. Supreme Court is likely to find due process violations. In 42 U.S.C. Section 1983 cases, for example, in which an individual is deprived of life, the substantive due process standard is extremely high; namely, the conduct of the government must be so arbitrary that it shocks the conscious. The intent to harm standard applies to all Section 1983 substantive due process claims.[4]

Procedural Due Process, on the other hand, works to enforce individual rights by providing a mechanism for redress when rights are violated. Procedural due process imposes constraints on government decisions that deprive individuals of liberty or property interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment.[5]

The Fourteenth Amendment guarantees that "[n]o State shall…deprive any person of life, liberty, or property without due process of law." The procedural component of the Due Process Clause protects property interests created not by the Constitution but by rules or understandings that stem from an independent source such as State law."[6] Identification of the specific dictates of due process generally requires consideration of three distinct factors: first, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguard; and finally, the Government's interest, including the function

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[3] U.S. CONST. amends. V, XIV, §§ 1, 5, in re the Due Process Clause which limits the powers of the States.

[4] *Terrell v. Larson,* 396 F.3d 975, 980-81 (8th Cir. 2005) citing *County of Sacramento v. Lewis,* 523 U.S. 833, 836, 118 S. Ct. 1708, 140 L. Ed. 2d 1043 (1998)

[5] *Mathew v. Eldridge,* 424 U.S. 319, 96 S. Ct. 893; 47 L. Ed. 2d 18 (1976)

[6] *Castle Rock v. Gonzales,* 545 U.S. 748, 125 S. Ct. 2796, 2803 (2005)

involved and the fiscal administrative burdens that the additional or substitute procedural requirement would entail.[7] In *Goldberg*, the Court held that the pre-termination (of benefits) hearing must include the following elements: (1) timely and adequate notice detailing the reasons for a proposed termination; (2) an effective opportunity for the recipient to defend by confronting any adverse witnesses and by presenting his own arguments and evidence orally; (3) retained counsel, if desired; (4) an impartial decision-maker; (5) a decision resting solely on the legal rules and evidence adduced at the hearing; (6) a statement of reasons for the decision and the evidence relied.[8]

The requirements of procedural due process apply only to the deprivation of interests encompassed by the Fourteenth Amendment's protection of liberty and property. When protected interests are implicated, the right to some kind of prior hearing is paramount.[9] In essence, procedural due process is designed to limit the power of the state and federal government by requiring that certain procedures are followed.

A nursing license confers a property interest that is constitutionally protected and sufficient to invoke the protection of the Due Process Clause.[10] Nurses who are granted the property interest of a license, nonetheless, must practice under the licensing agency's regulations.

At issue here is proposed legislation entitled "Samuel's Law," which violates the Due Process Clause of the U.S. Constitution. The proposed legislation violates substantive due process because the actions of the government are arbitrary, at best. Substantive due process is designed to protect individual from arbitrary actions of government. When government has absolute discretion, there is a violation of due process rights.[11]

The proposed Bill also fails to afford the nurse with procedural due process protections. Specifically, under the requirements of the proposed bill, the agency "shall" revoke a nurse's license to practice if there is a finding that the licensed nurse misread a physician's order and either over or under-medicated a patient. Under a Due Process analysis, the proposed Bill is unconstitutional. A revocation of a nurse's license to practice based on a finding that the nurse misread a physician's order to medicate a patient without a mandated prehearing or a sufficiently timely post hearing violates the nurse's due process.[12]

Further, the language of the proposed Bill is vague, and as such, is void and unconstitutional. A statute "fails to meet the requirements of the Due Process Clause if it is so vague and standardless that it leaves the public uncertain as to the conduct it prohibits…"[13] The language of the proposed legislation is void of any procedural due process to the nurse.[14] In addition, the language of the proposed Bill lacks an evidentiary standard; rather, it applies a strict liability standard without regard for any mitigating or aggravating factors.

The proposed Bill is discriminatory because it treats nurses differently from other licensed health care providers that may have a role in prescribing and/or dispensing medications, including physicians or pharmacists. For example, if a pharmacist misreads a prescription and dispenses the wrong medication, that pharmacist would not be subject to an automatic revocation of his or her license. Likewise, if a physician

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[7] *Mathew, supra*, citing *Goldberg v. Kelly,* 397 U.S. 254 (1970)
[8] *Goldberg, supra* at 397 U.S. 266-271
[9] *Morrissey v. Brewer,* 408 U.S. 471, 481, 92 S. Ct. 2593; 33 L. Ed. 2d 484 (1972)
[10] *Neal v. Fields,* No. 04-3743 (8th Cir. 2005), citing *Barry v. Barchi,* 443 U.S. 55, 99 S. Ct. 2642, 61 L. Ed. 2d 365 (1979)
[11] *Terrell, supra*
[12] *Barchi, supra*
[13] *City of Chicago v. Morales,* 527 U.S. 41, 56 (1999)(citation omitted)
[14] *Mathew, supra*, 424 U.S. 319 (1976)

orders the wrong dose of medication or illegibly writes an order that the nurse administers pursuant to such order, then that physician would not be subject to an automatic revocation of his or her license. Therefore, it seems that the revocation of a nurse's license based on a medication error is unconstitutional if and when other health care providers are being held to a different standard.

Finally, the language of the proposed legislation, on its face, deprives the regulatory agency the ability to consider other facts and circumstances surrounding any violations of law. As such, the proposed law is arbitrary and unconstitutional because it usurps the regulatory agency's authority by mandating the revocation of a nursing license.

USURPING AUTHORITY OF THE REGUALTORY AGENCY

The Nurse Practice Act (NPA), laws guiding and governing nursing practice, is enacted in all states and territories. Each state's NPA is passed through the state's legislature, ultimately having the full effect and force of law. As the NPA standing alone is insufficient to provide the necessary guidance for the nursing profession, each state's NPA establishes an administrative agency, the Board of Nursing (BON), to execute the laws within the NPA. The BON is granted the authority to regulate nursing practice by developing administrative rules or regulations, overseeing and ensuring the safe practice of nursing, and taking action against nurses who have exhibited unsafe nursing practice.[15]

South Carolina's NPA is codified in Title 40, Chapter 33, Article 1 of South Carolina's Code of Laws Annotated. Section 40-33-110 establishes the grounds for discipline of licensees, expressly stating in part, "…upon finding misconduct *the board may* cancel, fine, suspend, revoke, issue a public reprimand or a private reprimand, or restrict, including probation or other reasonable action such as requiring additional education and training (emphasis added)…"[16] A former proposed legislation, "Samuel's Law", suggested the aforementioned section change to, "Upon a finding by the board that a licensed nurse misreads the physician's order and over-medicates or under-medicates a patient, the board shall revoke the person's license to practice nursing in this State (emphasis added)."[17] The proposed legislation usurps an administrative agency's authority to execute its delegated powers by mandating the specific action the BON must take in reprimanding and disciplining nurses and contravenes the fundamental mission and purpose of the BON in the protection of the public. South Carolina's BON is more than competent to discipline misconduct of nurses without an amendment to Section 110 of the NPA. After all, South Carolina's BON is composed of seven registered nurses, one of which is licensed as an advanced practice registered nurse[18], who utilizes evidence-based practice and research to establish educational nursing program standards, requirements for nursing licensure, and standards and scope of nursing practice. To propose legislation that will thwart the essential function of the BON by requiring the board to automatically revoke a nurse's license after involvement of a medication error[19] vehemently usurps the authority of the BON.

The distinction between the delegation of power to make the law and conferring authority as to its execution was explained in *Picton v. Cass County*.[20] Here, the court stated, "[t]he Legislature cannot delegate its power to make a law, but it can make a law to delegate a power to determine some fact or state of things upon which the

[15] Kathleen A. Russell, *Nurse Practice Acts Guide and Govern Nursing Practice*, 3 J. NSG. REG. 3 (October 2012)
[16] Title 40 - Professions and Occupations, CHAPTER 33, ARTICLE 1, Nurse Practice Act
[17] "Samuel's Law" S. 371
[18] SECTION 40-33-10. State Board of Nursing; membership; seal; promulgation of regulations; powers and duties
[19] "Samuel's Law" S. 371
[20] Picton v. Cass County, 13 N.D. 242, 100 N.W. 711 (1904)

law makes, or intends to make, its own action depend."[21] Additionally, the court opined, to deny administrative agencies the authority to execute its delegation of power "would be to stop the wheels of government."[22] In *Trinity Medical Ctr. v. North Dakota Bd. of Nursing*, the Supreme Court of North Dakota court addressed whether North Dakota's BON usurped legislative powers by establishing nursing standards. The court stated, "It would be difficult if not impossible for the Legislature to establish more definitive standards with the flexibility necessary to keep abreast of the developments in medical science."[23] The California court in *Lee v. Board of Registered Nursing* opined the board's power to take action against a licensee "cannot be the subject of dispute in the face of the Legislature's declaration that "[p]rotection of the public shall be the highest priority for the Board of Registered Nursing in exercising its … disciplinary functions.""[24]

As an administrative agency, South Carolina's BON is conferred with the authority to regulate nursing practice, empowering the board with the ability to establish administrative rules or regulations resulting in the discipline of nurses who exhibit unsafe nursing practice. By mandating the BON revoke a registered nurse's license to practice nursing, usurps the authority of the BON granted by the state to determine the proper disciplinary action taken against registered nurses. The detailed nature of medical sciences, the complexity of nursing care, and the difficulty of determining whether standard of care is delivered, promulgates the intervention of a regulatory body composed of, at least, nurses. Nurses are in the best position to assess whether another nurse's action, or inaction, falls below the standard of care, posing a risk of harm to the public, the essence of the BON. It is absolutely incongruent with public policy to allow a non-nursing agency or legislative body to determine the competency of a licensed nurse. The court in *Picton* stated it best, "There are many things upon which wise and useful legislation must depend which cannot be known to the lawmaking power, and must therefore be a subject of inquiry and determination outside of the halls of legislation."[25] The BON serves the interest of the public to ensure the safety and welfare of citizens of the state, usurping the authority of the board places the public in greater harm by discouraging the voluntary reporting of medication errors.

JUST CULTURE MODEL

"The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes." -Lucian Leape[26]

TAANA, like many experts in the healthcare industry, recognizes and supports the Just Culture philosophy as the requisite foundation for safety and reliability in healthcare. The Just Culture Model promotes non-punitive transparency in situations which arise as a result of an unintended medical injury. The appropriate response to a medication error is investigation to distinguish between recklessness (which requires discipline), unknowing risk-taking (which requires coaching and remediation), and blameless normal human error.

The principles of a fair and *Just Culture* are based upon organizational justice theory.[27] A fair and *Just Culture* is one that is focused on fixing the system rather than fixing blame.[28]

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[21] Picton, 13 N.D. 242
[22] Picton v. Cass County, 13 N.D. 242, 100 N.W. 711 (1904)
[23] Trinity Medical Ctr. v. North Dakota Bd. of Nursing, 399 N.W.2d 835 (1987)
[24] Lee v. Board of Registered Nursing, 209 Cal. App. 4th 793 (2012)
[25] Picton v. Cass County, 13 N.D. 242, 100 N.W. 711 (1904)
[26] Testimony, United States Congress, House Committee on Veterans' Affairs, Dr. Lucian L. Leape, MD, October 12, 1997.
[27] Bryan Jeffery Weinera, et al., *The Meaning of Justice in Safety Event Reporting,* 66 Social Sciences and Medicine, 2, Jan. 2008
[28] CAL. PATIENT SAFETY IMPROVEMENT CORP TEAM, PATIENT SAFETY PROGRAM MANUAL 19, http://www.cdph.ca.gov/programs/Documents/PatientSafetyProgramManual12-12-2005.pdf (last visited July 29, 2015).

Modern health care is a very complex, high-risk, and error-prone activity.[29] Individuals directly involved in patient care possess important safety information that is not readily available through other means. However, fear of punishment is widely reported in patient safety research as a reason why health care providers do not report near misses, errors, and/or adverse events. The prevailing view among safety experts is that health care facilities must implement policies of *Just Culture* in order to encourage the reporting of near misses, errors, and adverse events and, by extension, improve patient safety.[30]

In a Just Culture, adverse events require an examination of the complex system in which the event occurred. Severity bias occurs when outcomes are used to determine the appropriate action to be taken concerning the healthcare provider.[31] Technological, environmental, cultural, and workflow problems beyond the control of any individual nurse can all lead to medical injuries. In order for the Just Culture model to be effective healthcare leaders have the non-delegable responsibility to ensure that the system is designed safely. "The goal of a "Just Culture" environment is to design safe systems that will reduce the opportunity for human error and capture errors before they reach the patient."[32] The individual nurse has little to no control over the design of the system in which they deliver nursing care.

A Just Culture does not mean non-accountability nor does it mean an avoidance of critiques or assessment of competency. A *Just Culture* seeks to balance the need to learn from mistakes and the need, given certain facts and circumstances, to take corrective, remedial and or disciplinary action that is proportional to the transgression[33] and consistent with applicable policy procedure in order to protect patients from future harm.[34]

The Just Culture model recognizes three classes of human fallibility.[35] The first is inadvertent human error, which refers to unintentional error resulting from inadvertently doing other than what should have been done.[36] Examples of this human error may include mishearing or misreading an order, a calculation error, or placing a decimal point in the wrong place, each of which can be the result of a slip, a lapse, or a human mistake.

The second category is at-risk behavior or, more specifically, making a behavioral choice that increases risk where risk is not recognized or is mistakenly believed to be justified.[37] An example of at-risk behavior would be excessive overtime (known to increase medical errors). Just Culture response to at-risk behavior is

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[29] *Id*.
[30] Institute of Medicine (IOM), To Err is Human: Building a Safer Health System. Washington DC: National Academy Press, 1999.
[31] Severity bias means the severity or the outcome of an event plays a major role in choosing how to respond to the event. In a *Just Culture* responses to events are not based on the outcome or the severity but rather are based on behaviors of the individual and contributing factors of the system and not on the severity of the results.
[32] http://www.childrenscentralcal.org/PressRoom/Publications/NursingExcellence Vol.6 Just Culture
[33] Robert M. Wachter & Peter J. Pronovost, *Balancing "No Blame" with Accountability in Patient Safety*, 361 NEW. ENG. J. MED.1401, 1403 (2009).
[34] DAVID MARX, PATIENT SAFETY AND THE "JUST CULTURE": A PRIMER FOR HEALTH CARE EXECUTIVES 7-8 (2001), http://www.mers-tm.org/support/Marx_Primer.pdf.
[35] AGENCY FOR HEALTH CARE RESEARCH AND QUALITY, IN CONVERSATION WITH…DAVID MARX, J.D., http://www.webmm.ahrq.gov/perspective.aspx?perspectiveID=49 (last visited July 29, 2015).
[36] *Id*.
[37] DAVID MARX, PATIENT SAFETY AND THE "JUST CULTURE" 15 (2007), http://www.health.state.ny.us/professionals/patients/patient_safety/conference/2007/docs/patient_safety_and_the_just_culture.pdf.

coaching the individual to modify behavior, increase sensitivity to the risk and make safer behavioral choices in the future.

The final category of human fallibility is reckless behavior where an individual makes a behavioral choice to consciously disregard a substantial and unjustifiable risk.[38] This type of reckless behavior is worthy of discipline. An example of reckless behavior would be disregarding known protocols and proceeding to act, such as not identifying the patient prior to administering a blood product. Such sentinel events would require an immediate response to prevent future patients' harm.

Punishment does not reduce the incidence of error; rather, it drives errors underground due to a nurse's fear of reprisal. "Samuel's Law" as proposed fails to address the manner in which patient safety can be improved. Instead, "Samuel's Law" would impose a strict liability standard requiring revocation of a nursing license in a situation where a nurse "misreads" a medication order. This action contravenes the widely accepted and endorsed models of safety, which have documented success. Strict liability should not be the standard in situations that may involve error or negligence. Since the South Carolina Board of Nursing has the authority to investigate and take action resulting from a medication error, "Samuel's Law" is not necessary.

Furthermore, TAANA recognizes the legal principle of proportionality and fairness; namely, disciplinary action should not be arbitrary and that action should be consistent with remediating the misconduct. With this principle in mind, the mental state of the nurse at the time of the adverse incident is highly relevant. Intentional conduct should be punished more harshly than accidental conduct. "Samuel's Law" would disregard this foundational legal principle by imposing an automatic revocation of the nursing license for accidental conduct (misreading a prescription). For this reason, the bill must be abandoned altogether in order to recognize that, although the harm caused by a medication error can be catastrophic, the conduct specifically targeted by "Samuel's Law" should be addressed by the South Carolina Board of Nursing, and the Board must be permitted to assign the disciplinary action it deems appropriate under the circumstances.

In summary, a just and fair culture is a non-punitive environment in which health care providers feel comfortable reporting near misses, errors, and/or adverse events knowing they will receive fair treatment. A just culture is one in which there is no blame; but there is always accountability. If systems are a cause or contributing factor to an adverse event, then systems will be analyzed for process and systems improvements. If behavior is a cause or contributing factor to an adverse event, then accountability for behavior will be sought based on the guidelines and all applicable policies and procedures.

In further support of TAANA's opposition to the proposed Samuel's Law, TAANA recognizes a position statement originated by the Congress on Nursing Practice and Economics and adopted by the American Nurses Association Board of Directors on January 28, 2010. One tenant of **"Just Culture"** is to support; rather than punish, which is a philosophy supported by all patient safety advocates and endorsed by the American Nurses Association.[39] The ANA Position paper page 6 specifically states:

> "The *Just Culture* concept establishes an organization-wide mindset that positively impacts the work environment and work outcomes in several ways. **The concept promotes a process where mistakes or errors do not result in automatic punishment, but rather a process to uncover the source of the error. Errors that are not deliberate or malicious result in coaching, counseling,**

[38] Marx, *supra* note 17 at 7.
[39] ANA Position Statement, *Just Culture* (January 28, 2010).

> **and education around the error, ultimately decreasing likelihood of a repeated error**. Increased error reporting can lead to revisions in care delivery systems, creating safer environments for patients and individuals to receive services, and giving the nurses and other workers a sense of ownership in the process. The work environment improves as nurses and workers deliver services in safer, better functioning systems, **and the culture of the workplace is one that encourages quality and safety over immediate punishment and blame**." [Emphasis added]

The position statement of the ANA supports "the collaboration of state boards of nursing, professional nursing associations, hospital associations, patient safety centers and individual health care organizations in developing regional and state-wide *Just Culture* initiatives."[40] The proposed Samuel's Law would directly conflict with the ANA position statement and recommendations to support a *Just Culture*. TAANA believes that the appropriate response to unintended medical error is to develop and embrace a non-punitive atmosphere where healthcare workers are supported when unintentional errors occur, not punished.

Reckless conduct or intentional violations of safety rules warrant discipline; however, no legitimate purpose is served by punishing nurses for blameless human errors, particularly since many adverse events occurring in complex healthcare systems are the result of unreliable systems largely beyond the control of the individual nurse. The proposed Samuel's Law would perpetuate the unrealistic expectation of consistent perfect human performance by nurses, while ignoring the analysis of the interacting components of the system in which the nurse was situated.

The proposed Samuel's Law undermines patient safety as it creates a punitive environment which could encourage nurses to hide their errors and not report for fear of license revocation. In actuality, the Proposed Samuel's Law is the antithesis of the *Just Culture* Model of patient safety.

[40] Id at 1.