

Development of Life-Sustaining Treatment Guidelines

Joint Commission on Health Care
September 7, 2016 Meeting

Andrew Mitchell

Senior Health Policy Analyst

Study Mandate

- In 2016, Delegate Stolle requested that the JCHC study the current legal and regulatory environment on life-prolonging care, focusing on:
 - Legal/regulatory requirements regarding disagreements over medical appropriateness of life-prolonging care
 - How other States address this issue, including how patients can pursue desired treatments and how providers are protected from providing medically inappropriate treatment
 - Recommendations for legislative changes clarifying actions after the current legal time period for patient transfer (14 days) has passed and patient is unable to be transferred
- The study was agreed to by JCHC members at the May 26, 2016 work plan meeting

Study Context

- § 54.1-2990 outlines procedures and provides a 14-day timeframe for resolution if a physician refuses to provide health care s/he determines to be inappropriate and if that determination is in conflict with a treatment preference expressed by a patient, or proxy (e.g., Advance Directive, instructions by patient's designated decision-maker)
 - However, Code is silent on legally permissible treatment decisions after 14 days has passed (e.g., in cases where consensus is not reached)
- During the 2015 General Assembly, Delegate Stolle introduced HB 2153 that included clarifying language in cases of no consensus after 14 days: “the physician may cease to provide care that he has determined to be medically or ethically inappropriate”
- HB 2153 was tabled in the House Health, Welfare and Institutions Committee by voice vote

BACKGROUND

Terms and Definitions

- *Life-sustaining care*: “Health care that utilizes mechanical or other artificial means to sustain, restore or supplant a spontaneous vital function, including hydration, nutrition, maintenance medication, and cardiopulmonary resuscitation.” (§ 54.1-2990). Other examples of life-sustaining treatment:
 - Blood transfusions/products
 - Dialysis
 - Intubation/mechanical ventilation
 - Surgery
- *Life-prolonging procedure*: life-sustaining “medical procedure, treatment or intervention that...when applied to a patient in a terminal condition, would serve only to prolong the dying process (§ 54.1-2982)
- *Comfort care*: basic palliative care interventions that provide immediate relief of symptoms in a patient who is very close to death but does not seek to cure or aggressively treat illness or disease

Terms and Definitions

- There are no widely accepted definitions for either “futile” or “medically inappropriate” treatments, and there are differing opinions on boundaries between futile and medically inappropriate treatment
- *Futile treatment.* Interventions that:
 - Cannot accomplish intended physiological goals; and/or
 - Will not prevent imminent death; and/or
 - Have an extremely small probability of success; and/or
 - Will not confer acceptable quality of life
- *Medically inappropriate treatment*
 - Interventions that may accomplish goals but clinicians determine are justifiably refused to be offered (e.g., burden far exceeds benefits; will never allow patient to leave Intensive Care Unit; is outside standard of care)

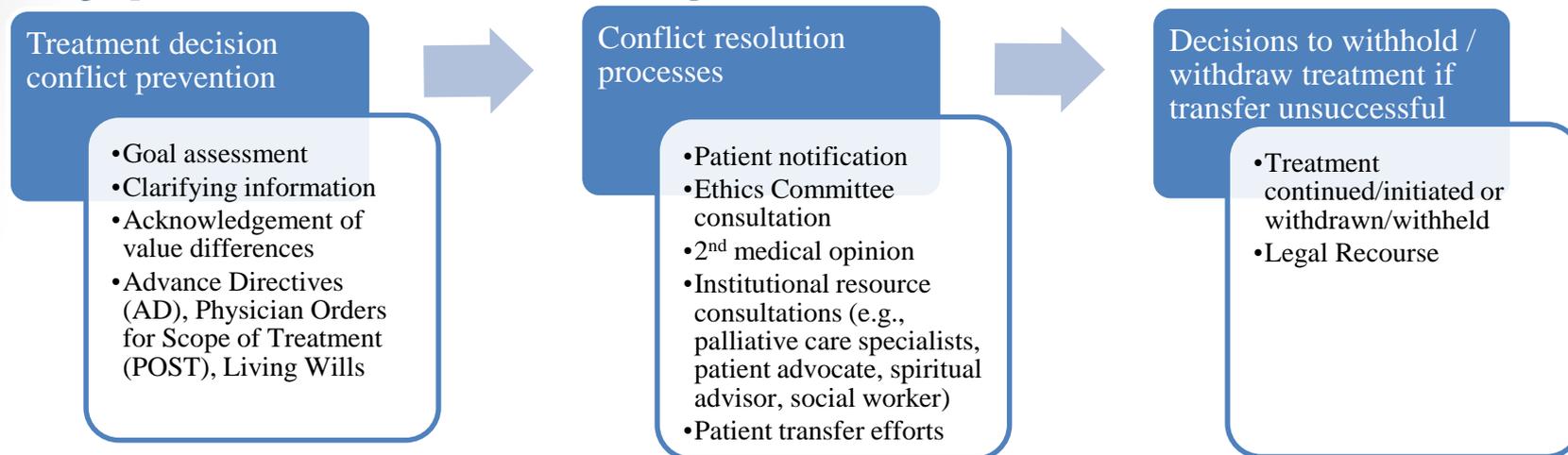
Patient Rights and Medical Treatment

- Patient right to refuse any treatment is well-established in:
 - Common law doctrine of informed consent; medical ethics (respect for patient autonomy to make informed and voluntary decisions regarding offered treatments)
 - Constitutional law (*In Re Quinlan* [1975], *Cruzan v. Director, Missouri Department of Health* [1990]: right to refuse treatment protected under right to privacy, 14th Amendment/due process clause, respectively)
 - Statutory documents (Advance Directives/Physician Orders for Scope of Treatment that provide patients opportunity to express desires to refuse or accept offered life-sustaining treatments)
- Patient right to demand any treatment has not been established:
 - Requested treatment can be contrary to medical ethics principles of beneficence – taking actions that serve the best interests of patients – and non-maleficence – not intentionally create a harm or injury to the patient, either through acts of commission or omission (“do no harm”).
 - The American Medical Association (AMA) states that: “Physicians are not ethically obligated to deliver care that, in their best professional judgment, will not have a reasonable chance of benefiting their patients. Patients should not be given treatments simply because they demand them.” (AMA Opinion E-2.035)
 - Inconsistent case law:
 - Court rulings in favor of family demands for treatment: *In Re the Conservatorship of Helga M. Wanglie*, *In the Matter of Baby K*
 - Court ruling in favor of physicians limiting treatment: *Gilgunn v Massachusetts General Hospital*
 - No ruling: *Betancourt v Trinitas Hospital*

Treatment Decision Conflicts: Paradigmatic Scenarios

- Geriatric case:
 - 91-year old intensive care unit (ICU) patient with post-CPR anoxic encephalopathy, multi-system failure, multiple ulcers
 - Patient on ventilator, receiving artificial nutrition and hydration through surgically implanted tube
 - Patient likely can be kept alive for many months in the ICU but would not survive outside it
- Pediatric case:
 - 11 month-old child born with Down Syndrome, respiratory distress
 - Dependent on oxygen supplementation/noninvasive respiratory support
 - Diagnosed with cerebral visual impairment, hearing loss, subclinical seizure activity
 - Able to focus only briefly and occasionally grasp a finger, but no longer shows signs of recognition
 - Exhibits constant movement, facial grimacing, choking, coughing, and vomiting
- Unexpected medical event case:
 - 46-year old admitted to ICU and put on mechanical ventilation after suffering cardiac arrest and severe loss of oxygen to the brain
 - After 2 months in ICU, brain functioning had not returned/shown improvement (patient had not awakened or been conscious)
 - Patient's care had been complicated by infections, kidney failure and need for dialysis, worsening heart function
 - Patient too sick to be placed in an outpatient center

Treatment Decision Conflicts: Typical Pathway



• Medical society position statements:

Dimensions of conflict resolution	AMA	ATS	CDMA	CMA	SCCM
▪ Process-based	✓	✓	✓	✓	✓
▪ Transparent / documented		✓			✓
▪ Joint decisionmaking	✓	✓	✓	✓	✓
▪ Ethics committee review	✓	✓			
▪ Appellate mechanism	✓	✓			✓
▪ Ability to cease disputed treatment	✓	✓	✓	✓	

- AMA: American Medical Association (1997)
- ATS: American Thoracic Society (2015)
- CDMA: Christian Medical & Dental Association (1994)
- CMA: Catholic Medical Association (2007)
- SCCM: Society of Critical Care Medicine (1997)

Frequency of Treatment Decision Conflicts Nationally

- Treatment decision conflicts between clinicians and families are thought to arise frequently in ICU setting (e.g., 22% to 48% of admissions)
- Studies on the provision of potentially medically inappropriate treatment have found:
 - Almost 90% of ICU physicians believe inappropriate treatment has been provided during previous year
 - Almost 30% of ICU physicians believe they have provided inappropriate treatment
 - 20% of ICU patients receive treatment perceived by critical care clinicians to be likely inappropriate
 - Common reasons for providing potentially medically inappropriate treatment are: fear of litigation and/or lack of legal understanding
- Treatment decision conflicts:
 - Disputes are regularly identified as the single biggest ethical dilemma facing North American hospitals (e.g., over 50% of ethics consultations focus on withholding or withdrawing treatment). However, before disputes become intractable, consensus is reached in vast majority (over 95%) of cases.
 - Texas data on decision conflicts:
 - 1999-2004: 256 cases
 - 2005: 65 cases (974 related ethics consultations)
 - 2007-2011: 30 cases (3,718,916 hospital admissions)

Frequency of Treatment Decision Conflicts in Virginia

- Primary data were collected from Virginia hospitals and physicians (July to August, 2016) on frequency of treatment decision conflict and qualitative characteristics about those situations
- Hospitals:
 - 44 hospitals (out of 95) responded
 - Average bed size: 298 (VA average: 233)
- Physicians:
 - 109 physicians responded
 - Specialties:
 - Internal Medicine: 35%
 - Emergency Medicine: 29%
 - Hospitalist: 13%
 - Critical Care: 12%
 - Cardiologist: 9%
 - Other specialties: 10%
 - Average years of practice: 20 (range: 1 – 30+) (n=107)
 - Median yearly patient caseload as attending physician: 250 (range: 0 – 8000) (n=103)

Frequency of Treatment Decision Conflicts in Virginia (cont'd)

- Key hospital survey quantitative findings:
 - 274 reported cases of physicians declining to provide inappropriate treatment over past year
 - 187 instances of hospital ethics committee involvement in cases of physician declining to provide inappropriate treatment over past year
 - 85% of those cases involved treatment requested by patient's agent
 - 90% of cases involving hospital ethics committees were resolved because:
 - Consensus reached with family: 45%
 - Patient died: 36%
 - Consensus reached with agent replacement: 10%
 - Patient was transferred: 2%
 - In 66% of hospital ethics committee cases involving treatment decision conflict with an incapacitated patient, the patient had expressed health care decision preferences through an Advance Directive (AD) and/or Physician Orders for Scope of Treatment (POST)
- Key hospital survey comments:
 - Provide greater clarity on physician options to cease treatment after 14 days (6)
 - Expand use of and education about ADs/POSTs (4)

Frequency of Treatment Decision Conflicts in Virginia (cont'd)

- Key physician survey quantitative findings:
 - 71% (70) reported providing medically/ethically inappropriate treatment to patients because of patient/patient's agent demands to do so
 - Among that 71%, patients inappropriately provided treatment represented an estimated 2% (1,699) of physicians' patients seen in an in-patient setting last year
 - 45% (39) reported declining to provide treatment requested by patient/patient's agent because the treatment was medically/ethically inappropriate
 - Among that 45%, patients not provided treatment represented an estimated 1.5% (603) of physicians' patients seen in an in-patient setting over last year
 - Among those who reported providing or declining to provide medically inappropriate treatment requested by patients, almost all (84% to 94%, respectively) discussed at length with the patient/patient's agent reasons that the physician felt the requested treatment was inappropriate and the majority (59% to 63%, respectively) consulted with colleagues; however, only 10% - 20%, respectively, brought the decision conflict issue to the attention of their hospital's ethics committee
- Key physician survey comments:
 - Improve education for patients and/or providers on end-of-life decisionmaking (13)
 - Obtain 2nd medical opinion and/or 3rd-party review in cases of treatment decision conflict (12)
 - Legally protect physicians ability to cease treatment (11)
 - Have earlier initiation of end-of-life care discussions (8)

TREATMENT DECISION CONFLICTS: STATE STATUTE COMPARISONS

Regulation of Health Care Decisions Nationally

1970s (7)	1980s (11)	1990s (20)	2000s (12)	2010+ (2)
Advance Directives / Living Wills (2)	Advance Directives / Living Wills (3)	Advance Directives / Living Wills (7)	Advance Directives / Living Wills (5)	Health Care Decisions (2)
Health Care Agents / Proxies / Power of Attorney (1)	Health Care Decisions (1)	Health Care Agents / Proxies / Power of Attorney (3)	Health Care Agents / Proxies / Power of Attorney (2)	
Life-Sustaining Procedures (1)	Death With Dignity (1)	Health Care Decisions (8)	Health Care Decisions (4)	
Medical Good-Faith Provisions (1)	Life-Sustaining Procedures (2)	Rights of Terminally Ill (1)	Natural Death (1)	
Natural Death (2)	Natural Death (2)			
	Removal of Life Support Systems (1)			
	Rights of Terminally Ill (1)			

- All States regulate Advance Directives:
 - Patient Self-Determination Act (PSDA; 1990) requires Medicare-participating health care facilities to document existence of patient's Advance Directive (AD), have written and patient-accessible AD policies/procedures, and provide written information on decision-making rights
- 10 States have enacted Statutes based on Uniform Health-Care Decisions Act (1993), approved by the National Conference of Commissioners on Uniform State Laws to address an "often fragmented, incomplete, and sometimes inconsistent set of rules"
- Most State Statutes cover one or more of the following in regulating health care decisions:
 - Procedures related to Advance Directives, Living Wills, Powers of Attorney, and/or Physician Orders for Scope of Treatment, including their construction, recommended form, scope, revocation, applicability, and reciprocity with other States
 - Procedures/obligations related to patient agents, including their selection, scope of decision-making authority, duties and standards for decision-making, and immunities
 - Procedures/obligations related to health care providers, including adherence to patient/surrogate decisions, refusal to comply with health care decisions and subsequent patient transfers, and immunities

Regulation of Health Care Decisions in Virginia

- VA code §54.1-2981-2993 (“Health Care Decisions Act”, 1983) encompasses:
 - Advance Directives (AD): construction procedures, form, exclusions/limitations, revocation, procedures in the absence of an AD and/or for patients incapable of making decisions, reciprocity
 - Patient capacity determination procedures
 - Judicial review
 - Duties/authorities of patient’s agent (including cases of patient protest)
 - Duties of physician
 - **Procedures if physician refuses to implement Advance Directive/health care decision**
 - Durable Do Not Resuscitate Orders
 - Immunities (patient’s agent, providers) and penalties
- §54.1-2990 “Medically unnecessary health care not required; procedure when physician refuses to comply with an advance directive or a designated person's health care decision; mercy killing or euthanasia prohibited” added in 1988, revised in: 1992, 1999, 2000, 2009.
 - 1988: delinks non-provision of treatment from mercy killing, suicide, euthanasia
 - 1992: introduced terms “medically or ethically inappropriate”; requires physician refusing to comply with health care decision to make reasonable effort to transfer patient
 - 1999: adds Durable Do Not Resuscitate Order as additional document for communicating patient treatment preferences
 - 2000: specifies a 14-day timeline to effect transfer, requirement to continue life-sustaining care to patient pending transfer, definition of life-sustaining care
 - 2009: revises scope of medically inappropriate care covered by section to include “health care”, not just “medical treatment”

Statute Comparisons: Decision-Making Conflicts

- Almost all States acknowledge existence of situations of patient/provider decision-making conflict and allow physicians/facilities to decline to follow health care directives:
 - For treatments that would be medically ineffective, inappropriate and/or contrary to generally accepted health care standards (15)
 - For religious, ethical, moral, or professional grounds (11)
 - For reasons of conscious or personal beliefs (17)
 - Reasons not specified (21)
- However, States vary widely in the degree to which decision conflict is addressed
 - MN: Word count: 67 (“A health care provider who is unwilling to provide directed health care under paragraph (a) that the provider has the legal and actual capability of providing may transfer the principal or declarant to another health care provider willing to provide the directed health care but the provider shall take all reasonable steps to ensure provision of the directed health care until the principal or declarant is transferred” [§145C.15])
 - TX: Word count: 967 (see Slide 27)

VA: Physician may decline to prescribe/render medically or ethically inappropriate health care

Statute Comparisons: Decision-Making Conflict Resolution Process

- Most States require basic process measures:
 - Provide notice to patient of provider refusal to follow requested treatment (32 States)
 - Require physicians to lead, assist in, and/or not inhibit efforts to transfer patient to another provider/institution (46 States)
- Almost one-half of States (25) require continued treatment/care while transfer sought (examples: continuing/ongoing care, life-sustaining treatment, artificial food and nutrition, comfort care, CPR, reasonably necessary consultation and care, care that complies with agent's decision)
- Three States stipulate more specific process steps:
 - NJ: Seek to resolve disagreements using health care institution's procedures/practices, including an institutional ethics committee, or seek judicial resolution; health care institutions should adopt policies/practices to inform health care professionals of their rights and responsibilities and provide a forum for discussion and consultation
 - TX: Physician's refusal is reviewed by 3rd party ethics/medical committee
 - Patient/agent provided a form outlining rights/process, including advance notice of committee meeting and entitlement to attend meeting, receive written explanation of committee decision, receive copy of relevant portion of medical record (see Slide 27)
 - VT: Document in the principal's medical record the conflict, the steps taken to resolve the conflict, and the resolution of the conflict.

VA: Physician must make a reasonable effort: to inform patient of reasons for refusing to provide treatment; transfer patient to another physician and provide requested life-sustaining treatment



Statute Comparisons: Treatment Options if Transfer Unsuccessful

- Most States do not directly address provider options/legal consequences for withdrawing/withholding requested treatment
 - E.g., AZ: “A health care provider is not subject to criminal or civil liability or professional discipline for...failing to comply with a decision or a direction that violates the provider's conscience if the provider promptly makes known the provider's unwillingness and promptly transfers the responsibility for the patient's care to another provider who is willing to act in accordance with the agent's direction” (§36.3205)
- Some States address legal consequence for refusal to provide treatment only in narrowly defined circumstances
 - E.g., PA: “A health care provider or another person may not be subject to criminal or civil liability...[for] refusing to comply with a [health care] decision [if the] decision would be unethical or...result in medical care having no medical basis in addressing any medical need...” (§5431)

HOWEVER

“Health care necessary to preserve life shall be provided to an individual who has *neither an end-stage medical condition nor is permanently unconscious*...An attending physician or health care provider shall comply with a health care decision made by a health care agent or health care representative.” (§ 5462; emphasis added)

VA: Legal consequences of withdrawing/withholding requested treatment not addressed

Treatment decision conflict prevention



Conflict resolution processes



Decisions to withhold / withdraw treatment if transfer unsuccessful

Statute Comparisons: Treatment Options if Transfer Unsuccessful (cont'd)

- In some States, provider options/legal consequences for withdrawing/withholding requested treatment are unclear
 - CA: “A health care provider...that declines to comply with a...health care decision shall...provide continuing care to the patient until a transfer can be accomplished *or until it appears* that a transfer cannot be accomplished ...A health care provider...is not subject to civil or criminal liability or to discipline for...declining to comply with an individual health care instruction or health care decision in accordance [with above]” (§4736; emphasis added)
 - CT: “any physician licensed...who...withholds, removes or causes the removal of a life support system of an incapacitated patient shall not be liable for damages...provided...the decision is in accordance with the usual and customary standards of medical practice[,] the attending physician deems the patient to be in a terminal condition or...permanently unconscious; and the attending physician *has considered* the patient’s wishes...” (§19a.571; emphasis added)
 - IL: “If the provider is unwilling to comply with the agent's decision, the provider shall promptly inform the agent who shall then be responsible to make the necessary arrangements for the transfer of the patient to another provider. It is understood that a provider who is unwilling to comply with the agent's decision will continue to afford reasonably necessary consultation and care in connection with the transfer. If the actions of a health care provider who fails to comply with any direction or decision by the agent are substantially in accord with reasonable medical standards at the time of reference and the provider cooperates in the transfer of the patient pursuant to subsection (b) of Section 4-7 of this Act, the provider shall not be subject to any type of civil or criminal liability or discipline for unprofessional conduct for failure to comply with the agent.” (§755.45/4-7)
 - KY: No [provider]...shall be...held liable for refusal to comply with the...health care decision...as long as the [provider] complies with the requirements...regarding patient notification and patient transfer ([Provider] shall not impede with the transfer of the patient to another physician...who will comply with the...health care decision) (§311.633)

Treatment decision conflict prevention



Conflict resolution processes



Decisions to withhold / withdraw treatment if transfer unsuccessful

Statute Comparisons: Treatment Options if Transfer Unsuccessful (cont'd)

- One State (FL) mandates continued provision of requested treatment if transfer unsuccessful
 - “If [within 7 days] the patient has not been transferred, [the health care provider or facility must] carry out the wishes of the patient or the patient’s surrogate or proxy” (§765.1105)
- Two States (AR, TN) unconditionally permit physician to refuse to provide treatment if transfer unsuccessful
 - “If a transfer cannot be effected, the healthcare provider or institution shall not be compelled to comply” (§20-6-109(e)(3)(B); §68-11-1808(f)(4))
- One State (TX) provides qualified permission:
 - “The attending physician...and the health care facility are not obligated to provide life-sustaining treatment after the 10th day after both the written decision and the patient's medical record...are provided to the patient, except that artificially administered nutrition and hydration must be provided unless, based on reasonable medical judgment, providing artificially administered nutrition and hydration would:
 - (1) hasten the patient's death; (2) be medically contraindicated such that the provision of the treatment seriously exacerbates life-threatening medical problems not outweighed by the benefit of the provision of the treatment; (3) result in substantial irremediable physical pain not outweighed by the benefit of the provision of the treatment; (4) be medically ineffective in prolonging life; or (5) be contrary to the patient's or surrogate's clearly documented desire not to receive artificially administered nutrition or hydration.” (§ 166.046(e))

Treatment decision conflict prevention



Conflict resolution processes



Decisions to withhold / withdraw treatment if transfer unsuccessful

Statute Comparisons: Artificial Nutrition and Hydration

- Context:
 - Consensus within medical community – also supported by case law – that artificial nutrition and hydration is a medical treatment that patients/agents may accept or refuse on the basis of the same considerations that guide all treatment decisions (e.g., potential medical benefits/risks; pain associated with treatment; patient’s personal/religious/cultural beliefs). There is little available evidence that artificial nutrition/hydration extends and/or improves quality of life for most terminally ill patients
 - However, nutrition/hydration often viewed by the general public as different from other medical treatments, requiring different or specific standards regulating its use
 - Within the Catholic tradition, Papal doctrine states that administration of nutrition/hydration in the context of a patient in a vegetative state is ordinary care in principle and that artificial nutrition/hydration is not a medical technology but a “natural means of preserving life”. While a U.S. Catholic directive affirms obligation to provide nutrition/hydration to chronically ill patients, although “medically assisted nutrition and hydration become “morally optional” when they cannot reasonably be expected to prolong life or when they would be “excessively burdensome for the patient or [would] cause significant physical discomfort...”
- Three States mandate continued provision of artificial nutrition/hydration throughout process:
 - ID: “Assisted feeding or artificial nutrition and hydration..., health care necessary to sustain life or to provide appropriate comfort for a patient other than assisted feeding or artificial nutrition and hydration may not be withdrawn or denied if its provision is directed, unless such care would be futile care...Futile care is a course of treatment: a) For a patient with a terminal condition for whom...death is imminent within hours or at most a few days; or b) The denial of which...will not result in or hasten the patient's death” (§39-4514)
 - NH: “Medically administered nutrition and hydration and life sustaining treatment shall not be withdrawn or withheld under this chapter unless...[s]uch treatment would have the unintended consequence of hastening death or causing irreparable harm” (§137-J:7)
 - OK: “It shall be presumed that every incompetent patient has directed his health care providers to provide him with hydration and nutrition to a degree that is sufficient to sustain life (§63-3080.3). Hydration or nutrition may not be withheld or withdrawn...if this would result in death from dehydration or starvation rather than from the underlying terminal illness or injury” (§63-3080.4)

VA: Does not specifically reference provision of artificial nutrition/hydration

Treatment decision conflict prevention



Conflict resolution processes



Decisions to withhold / withdraw treatment if transfer unsuccessful

Statute Comparisons: Artificial Nutrition/Hydration and Life-Sustaining Treatment

- 18 States do not reference artificial nutrition and hydration in definition of life-sustaining treatment
- 18 States include artificial nutrition and hydration in definition of life-sustaining treatment:
 - Categorically (15)
 - If patient's Advance Directive orders it (3)
- 4 States exclude artificial nutrition and hydration:
 - Under certain circumstances (1)
 - Categorically (3)
- 11 States do not define life sustaining treatment

VA: Includes artificial nutrition and hydration in definition of “life-sustaining care”

Treatment decision conflict prevention



Conflict resolution processes



Decisions to withhold / withdraw treatment if transfer unsuccessful

Statute Comparisons: Judicial Review

- Almost one-half (23) of States do not explicitly reference process for judicial relief
- 15 States identify option for judicial review for health care decisions not specific to the context of treatment decision conflict/patient transfers
- 7 States identify process for judicial review but limit applicability such that treatment decision conflict is not covered or it is unclear
- 6 States identify process for judicial review specific to the context of treatment decision conflict/patient transfers

VA: “Nothing in this article shall limit the ability of any person to petition and obtain a court order for health care...” (§ 54.1-2985.1)

Treatment decision conflict prevention



Conflict resolution processes



Decisions to withhold / withdraw treatment if transfer unsuccessful

Statute Comparisons: Non-discrimination

- Context:
 - Some stakeholders have concerns that clinician determination of appropriateness of life-sustaining treatment will discriminate against vulnerable populations (e.g., disabled, elderly) by placing a lower valuation on expected benefits for those patients and/or a higher valuation on expected repercussions/ineffectiveness compared to other patients
 - While there is well-documented evidence of disparities in health outcomes for those with disabilities compared to the general population and studies indicating that disabled persons receive lower rates of health services than persons without disabilities, little data exist to support/refute concerns of discrimination in the context of life-sustaining treatment decisions
- Four (4) States reference non-discrimination:
 - AK: When determining the best interest of a patient under this chapter, health care treatment may not be denied to a patient because the patient has a disability or is expected to have a disability.
 - MO: Nothing...shall be construed to authorize, approve or condone discrimination against the handicapped or the disabled in the exercise of the authority of a durable power of attorney for health care
 - OK: A health care provider shall not deny to a patient a life-preserving health care service the provider provides to other patients, and the provision of which is directed by the patient or a person legally authorized to make health care decisions for the patient:
 - On the basis of a view that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill; or
 - On the basis of disagreement with how the patient or person legally authorized to make health care decisions for the patient values the trade-off between extending the length of the patient's life and the risk of disability.
 - PA: In all circumstances this subsection shall be construed so as to be consistent with the Americans with Disabilities Act of 1990
- Remaining States do not explicitly reference non-discrimination

VA: Does not explicitly reference non-discrimination/disabilities

Statute Comparisons: Medically Inappropriate/Ineffective Treatment

- 15 States permit physician to decline to provide “medically inappropriate” or “ineffective” treatment
- 5 States define “medically inappropriate” treatment
 - AK: “health care that according to reasonable medical judgment cannot cure the patient's illness, cannot diminish its progressive course, and cannot effectively alleviate severe discomfort and distress” (§ 13.52.060)
 - DE/MD: “medical procedure [that] will not [to a reasonable degree of medical certainty]: (1) Prevent or reduce the deterioration of the health of an individual; or (2) Prevent the impending death of an individual” (§ 2501)
 - ID: see Slide 22, “futile care”
 - NM: “treatment that would not offer the patient any significant benefit, as determined by a health-care practitioner” (§ 24-7A-7)
- Remaining States do not reference “medically inappropriate” treatment

VA: References – but does not define – medically inappropriate treatment

State Comparisons: Texas Advance Directives Act

- Texas Advance Directives Act (TADA, 1999) is the most comprehensive State Statute to address treatment decision conflicts between patients and physicians (§ 166.046). Its primary features are standardized facility-level conflict resolution processes, including:
 - Review of physician decision by 3rd party ethics or medical committee
 - Provision of information on the decision review process (written description, advance notice of meeting time, copy of registry list of providers willing to accept transfer/assist in locating provider)
 - Patient/patient agent's entitlements (attend review meeting, receive written explanation of decision/relevant portion of medical record)
 - Facility role in attempting patient transfer ("reasonable effort") and required health care pending transfer (life sustaining treatment, comfort care); patient responsibility for costs of transfer
 - Ability of physician/health facility to cease life-sustaining treatment after 10 days, with exception of artificially administered nutrition/hydration considered ordinary care (exceptions specified for cases of artificially administered nutrition/hydration considered extraordinary care; see Slide 21)
 - Judicial review of physician decision is limited to extending the 10-day time period if there is a "reasonable expectation" that another physician/facility will accept the patient and honor the treatment request
 - Exclusion of home and community support services facilities from conflict resolution process/requirements



RECOMMENDATIONS AND POLICY OPTIONS

Statute Revisions: Process and Considerations

- Working Group with representation from over 25 organizations convened 3 times from June – August to inform options for revising current Statute language. Subgroup met 5 times, making recommendations to Working Group for Statute revisions based on Statute models from other States, technical expertise, and Working Group input. Versions of all recommendations have been formulated with, discussed with, and received feedback from Working Group.

Association / Interest Group: 17	Health System: 8	State-funded agency: 3
<ul style="list-style-type: none"> – Patient-focused: 6 – Provider-focused: 6 – Other: 5 		

- Working Group considered many aspects of regulations governing medical decision conflicts and inappropriate care, including:
 - Clarifying terms (e.g., inappropriate health care; life-sustaining care; treatment vs care)
 - Specificity of decision review procedures
 - Scope of applicability (institutional; patient-level)
 - Transfer period timeframe
 - Allowable actions after transfer period passed
 - Judicial review
 - Non-discrimination/disabilities
- Recommendations:
 - Reflect a “minimalist” approach that considered adding processes and safeguards not currently articulated in Statute, but maintaining flexibility in facility-level implementation
 - Informed by output of stakeholder discussion, reflecting both areas of broad consensus and areas of differing perspectives
- Recommendations for Statute revisions focus on treatment decision conflict resolution process and allowable medical decisions if patient transfer unsuccessful
- Additional recommendation focused on treatment decision conflict prevention



Recommendations

- 1.*† Require hospitals to maintain written policies on life-sustaining treatment decision conflict resolution procedures
- 2.*† Require hospitals to take standard minimum steps in cases of life-sustaining treatment decision conflict
- 3.* Provide qualified permission to physician to cease inappropriate treatment after 14 days
- 4.* Provide physician immunity for following requirements
- 5.* Stipulate that all actions under this section must conform to federal non-discrimination standards
- 6.* Revise “life-sustaining care” term and definition
- 7.* Eliminate Durable Do Not Resuscitate Orders from applicable documents within § 54.1-2990
8. Form Working Group to study health care decisions more broadly, focused on preventing/improving resolution of treatment decision conflicts

* Via legislation introduced to amend section § 54.1-2990

† Via legislation introduced to amend section § 32.1-127 (if necessary)

Recommendation # 1

- Add requirement to § 54.1-2990 for hospitals to maintain written policies on life-sustaining treatment decision conflict resolution
 - Limited to hospitals (i.e., facilities equipped to provide life-sustaining treatment)
 - Would likely require amendment to §32.1-127 to provide Department of Health oversight authority on compliance
- Rationale:
 - Transparency in facility-level policies to address situations of conflict in the context of life-sustaining treatment decisions will heighten ability of clinicians, patients/patients' agents and facilities to more effectively resolve conflicts
 - The vast majority of situations of life-sustaining treatment decision conflict take place in the hospital setting. While it is possible that life-sustaining treatment decision conflict situations occur in other health care institutions (e.g., nursing homes), those institutions currently vary widely in their ability to execute written policies on life-sustaining treatment decision conflict resolution and other recommendations (e.g., convene/maintain medical review committees).
- Degree of Working Group support:
 - Written policies: broad support/no objections raised
 - Limitation to hospital setting: broad support/no objections raised

Recommendation # 2

- Specify four minimum steps to be taken in cases of life-sustaining treatment decision conflict in § 54.1-2990 (would likely require amendment to §32.1-127 to provide Department of Health oversight authority on compliance):
 - Rendering of 2nd medical opinion
 - Interdisciplinary medical review committee review of physician determination and issuance of its determination on appropriateness of requested treatment
 - Opportunity provided to patient/agent/decision-maker to participate in review meeting
 - Written explanation of review meeting decision included in the patient's medical record
- Rationale:
 - Stipulating key process-focused safeguards that all hospitals should develop/follow will promote standardization in hospital policies and due process procedures, while providing needed flexibility in implementation of policies and procedures across diverse hospital settings and patient cases
- Degree of Working Group support
 - Broad support for/no objections raised to premise of minimum process steps, although stakeholders expressed different preferences for desired level of detail

Recommendation # 3

- Provide qualified permission to physician in § 54.1-2990 to cease inappropriate treatment after 14 days:
 - Provide at least 14 days after documentation of physician's decision of inappropriate treatment in patient's medical record to effect transfer
 - Mandate physician to make a reasonable effort to effect a transfer as well as cooperate with others' efforts to effect a transfer
 - If transfer not effected, physician may cease to provide medically or ethically inappropriate treatment if hospital policies/steps under Recommendations #1 and 2 have been followed, except:
 - *Artificially administered nutrition and hydration*: must be provided unless it would be: medically harmful, non-beneficial and/or result in substantial irremediable physical pain not outweighed by the benefit of the provision of the treatment; or be contrary to the patient's/agent's desire not to receive artificially administered nutrition or hydration.
 - *Comfort care*: care directed toward the patient's pain and comfort must be provided
- Rationale:
 - Clarity in legally permissible actions by physicians after 14 days in cases of unresolved treatment decision conflict emphasized by many Working Group participants and hospital/physician survey respondents as a key aspect to Statute revision to accompany due process-oriented Recommendations #1 and #2
 - Many Working Group participants also stressed importance of additional safeguards related to provision of artificial nutrition and hydration in the context of ceasing inappropriate treatment.
- Degree of Working Group support:
 - Permission to physician to cease treatment: concerns expressed by some stakeholders
 - Stipulations re: artificial nutrition/hydration: Mixed degree of support, although few objections raised to premise of stipulations

Recommendation # 4

- Add statement to § 54.1-2990 of physician immunity for following requirements:
 - Health care provider/institution acting in good faith/in accordance with generally accepted health care standards is not subject to civil or criminal liability or to discipline for unprofessional conduct for any action in compliance with Recommendations #1 – #4
- Rationale:
 - Ensures that physicians/hospitals are legally indemnified for ceasing treatment if mandated processes have been followed in accordance with medical standard of care
- Degree of Working Group support:
 - Broad support/no objections raised

Recommendation # 5

- Add statement to § 54.1-2990 that all actions under this section must conform to federal non-discrimination standards:
 - Determination of medically or ethically appropriate life-sustaining treatment must conform to existing federal non-discrimination regulations that may apply to any other patient receiving care within the institution in which the patient is receiving care
- Rationale:
 - Provides additional protection to vulnerable populations and alignment with national-level norms
- Degree of Working Group support:
 - Mixed degree of support, although few objections raised

Recommendation # 6

- Revise “life-sustaining care” term and definition as used in § 54.1-2990
 - Current term/definition:
 - “B. For purposes of this section, "life-sustaining care" means any ongoing health care that utilizes mechanical or other artificial means to sustain, restore or supplant a spontaneous vital function, including hydration, nutrition, maintenance medication, and cardiopulmonary resuscitation.”
 - Proposed term/definition:
 - “B. For purposes of this section, "life-sustaining treatment" means any ongoing health care that utilizes mechanical or other artificial means to sustain, restore or supplant a spontaneous vital function.”
- Rationale:
 - “Care” reflects actions and interventions that are much broader than treatments. Revising the term to “life-sustaining treatment” eliminates any potential misinterpretation and/or misapplication of Recommendations
 - Under certain circumstances, examples specified in current Statute (e.g., hydration, nutrition) may be appropriately or inappropriately considered to be life-sustaining. Eliminating these examples recognizes that specificities of a particular case need to guide application of § 54.1-2990 in practice.
- Degree of Working Group support:
 - Broad support/no objections raised

Recommendation # 7

- Eliminate Durable Do Not Resuscitate Orders from applicable documents to § 54.1-2990
 - Example: if the physician's determination is contrary to the request of the patient, the terms of a patient's advance directive, the decision of an agent or person authorized to make decisions pursuant to § 54.1-2986, ~~or a Durable Do Not Resuscitate Order...~~
- Rationale:
 - Addition of Durable DNR (1999) is inconsistent with § 54.1-2990 that addresses situations of physician refusal to provide medically/ethically inappropriate treatment. Durable DNRs address situations in which treatment is not desired.
- Degree of Working Group support:
 - Broad support/no objections raised

Recommendation # 8

- Form Working Group to study health care decisions more broadly, focused on recommendations for preventing / improving outcomes of treatment decision conflict

“[Treatment decision conflict] is not something fixed through legislation. What is needed is a national conversation about the realities of modern medicine in the face of increasing longevity, the limitations, and perhaps a value-based conversation that can be held within family and friends about the difference between quality and quantity of life.”

- Hospital Survey respondent

“Patients with conditions such as advanced [Congestive Heart Failure], advanced [Chronic Obstructive Pulmonary Disease], advanced cancer, and [end-stage renal disease] on [dialysis] should all have discussions with providers/caregivers regarding life support when they have the capacity to make informed decisions. Too often this conversation is left until the patient has lost capacity, leaving loved ones a very difficult decision at an emotional time. Patients need to guide their caregivers and express their wishes so they get what they want and the caregivers don't feel guilty. PCP's, Cardiologists, Oncologists, Nephrologists and Pulmonologists need to have time to educate and counsel patients in the outpatient setting prior to the patient decompensating. This conversation takes a great deal of time...”

- Physician Survey respondent

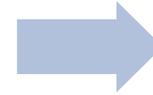
- Rationale:
 - Leverage Working Group formed for this study to focus on recommendations and policy options for preventing and improving outcomes of treatment decision conflict, such as through expansion of use and knowledge of Advance Directives/Physician Orders for Scope of Treatment, and earlier initiation of end-of-life care conversations between patients and providers

Recommendations: Summary

Treatment conflict prevention



Conflict resolution processes



Decisions to withhold / withdraw treatment if transfer unsuccessful

Existing Statute	Proposed revisions
<ul style="list-style-type: none"> Not addressed 	<ul style="list-style-type: none"> None; however, form Working Group to consider future options (Recommendation 8)

Existing Statute	Proposed revisions
<ul style="list-style-type: none"> Physician makes reasonable effort 	<ul style="list-style-type: none"> Add written hospital policies / minimum steps (Recommendations 1, 2) Add physician cooperation with other's efforts (Recommendation 2)

Existing Statute	Proposed revisions
<ul style="list-style-type: none"> Physician make reasonable effort Allowable actions / liabilities unclear 	<ul style="list-style-type: none"> Clarify allowable physician actions (Recommendation 3) and immunity (Recommendation 4)

- Cross-cutting:

Non-discrimination

Existing Statute	Proposed revisions
<ul style="list-style-type: none"> Not addressed 	<ul style="list-style-type: none"> Add non-discrimination protections (Recommendation 5)

Life-sustaining treatment

Existing Statute	Proposed revisions
<ul style="list-style-type: none"> Defined as "life-sustaining care" 	<ul style="list-style-type: none"> Revise term/definition (Recommendation 6)

Durable DNR

Existing Statute	Proposed revisions
<ul style="list-style-type: none"> Included in referenced documents for communicating health care decision 	<ul style="list-style-type: none"> Exclude from referenced documents for communicating health care decision (Recommendation 7)

Policy Options

1. Take no action
2. Introduce legislation to amend § 54.1-2990 of the Code of Virginia to:
 - 2a. Add requirement for written hospital policies on life-sustaining treatment decision conflict resolution and specify minimum steps to be taken by hospitals in cases of life-sustaining treatment decision conflict (also amend section § 32.1-127 as applicable)
 - 2b. Provide qualified permission to physician to cease inappropriate treatment after 14 days and add statement of physician immunity for following requirements
 - 2c. Add stipulation that all actions under this section must conform to federal non-discrimination standards
 - 2d. Revise “life-sustaining care” term and definition
 - 2e. Eliminate Durable Do Not Resuscitate Orders from applicable documents within § 54.1-2990
3. Include in the 2017 JCHC work plan that staff form a work group to study health care decisions more broadly, focused on preventing/improving outcomes of treatment decision conflict in Virginia, and report back to the JCHC in 2017

Public Comments

Written public comments on the proposed options may be submitted to JCHC by close of business on September 28, 2016.

Comments may be submitted via:

- ❖ E-mail: jchcpubliccomments@jchc.virginia.gov
- ❖ Fax: 804-786-5538
- ❖ Mail: Joint Commission on Health Care
P.O. Box 1322
Richmond, Virginia 23218

Comments will be provided to Commission members and summarized and presented during JCHC's October 5th meeting.

Appendix I: Recommended revisions to § 54.1-2990

§ 54.1-2990. Medically unnecessary treatment not required; procedure when physician refuses to comply with an advance directive or a designated person's treatment decision; mercy killing or euthanasia prohibited

Nothing in this article shall be construed to require a physician to prescribe or render health care to a patient that the physician determines to be medically or ethically inappropriate. However, in such a case, if the physician's determination is contrary to the request of the patient, the terms of a patient's advance directive, the decision of an agent or person authorized to make decisions pursuant to § 54.1-2986, ~~or a Durable Do Not Resuscitate Order~~, *the policies of the hospital in which the patient is receiving health care will be followed. Policies of the hospital that is equipped to provide life-sustaining treatment shall be documented and shall include, at a minimum the following steps:*

- *Rendering of a second medical opinion;*
- *Review of the physician's determination by an interdisciplinary medical review committee, followed by issuance of its own determination on the appropriateness of requested treatment. The patient, agent or person will be afforded reasonable opportunity to participate in the medical review committee meeting;*
- *Written explanation of the decision reached during the medical review committee review process that will be included in the patient's medical record*

If the patient, agent or person authorized to make medical decisions pursuant to § 54.1-2986 requests life-sustaining treatment that the attending physician determines to be medically or ethically inappropriate, the physician shall document his decision in the patient's medical record and make a reasonable effort to inform the patient or the patient's agent or person with decision-making authority pursuant to § 54.1-2986 of such determination and the reasons for the determination. ~~If the conflict remains unresolved,~~ The physician shall make a reasonable effort – *and cooperate with others' efforts* – to transfer the patient to another physician who is willing to comply with the request of the patient, the terms of the advance directive, the decision of an agent or person authorized to make decisions pursuant to § 54.1-2986, ~~or a Durable Do Not Resuscitate Order~~. The physician shall provide the patient or his agent or person with decision-making authority pursuant to § 54.1-2986 a reasonable time of not less than fourteen days *after documentation of the decision in the patient's medical record* to effect such transfer. During this period, the physician shall continue to provide any life-sustaining *treatment* to the patient which is reasonably available to such physician, as requested by the patient or his agent or person with decision-making authority pursuant to § 54.1-2986.

Appendix I: Recommended revisions to § 54.1-2990 (cont'd)

If, at the end of the 14-day period, the policies of the hospital in which the patient is receiving health care have been followed and the physician has been unable to transfer the patient to another physician who is willing to comply with the request of the patient, the terms of the advance directive, the decision of the agent or person authorized to make decisions pursuant to § 54.1-2986 despite reasonable efforts, the physician may cease to provide the treatment that the physician has determined to be medically or ethically inappropriate, except that artificially administered nutrition and hydration must be provided unless, based on the physician's medical judgment, providing artificially administered nutrition and hydration would be:

- (1) medically harmful, non-beneficial and/or result in substantial irremediable physical pain not outweighed by the benefit of the provision of the treatment; or*
- (2) be contrary to the patient's or surrogate's clearly documented desire not to receive artificially administered nutrition or hydration.*

In all cases, care directed toward the patient's pain and comfort shall be provided.

Pursuant to § 54.1-2988, a health care provider or hospital acting in good faith and in accordance with generally accepted health care standards is not subject to civil or criminal liability or to discipline for unprofessional conduct for any action in compliance with this article.

B. For purposes of this section, "life-sustaining ~~care~~treatment" means any ongoing health care that utilizes mechanical or other artificial means to sustain, restore or supplant a spontaneous vital function, ~~including hydration, nutrition, maintenance medication, and cardiopulmonary resuscitation.~~

C. Nothing in this section shall require the provision of health care that the physician is physically or legally unable to provide, or health care that the physician is physically or legally unable to provide without thereby denying the same health care to another patient.

D. Nothing in this article shall be construed to condone, authorize or approve mercy killing or euthanasia, or to permit any affirmative or deliberate act or omission to end life other than to permit the natural process of dying.

E. Determination of medically or ethically appropriate life-sustaining treatment must conform to existing federal non-discrimination regulations that may apply to any other patient receiving care within the institution in which the patient is receiving care.

Appendix II: Working Group Stakeholders

Stakeholder

- B2B Consulting
- Bon Secours Health System
- Carilion Clinic
- Department of Aging and Rehabilitative Services
- disAbility Law Center of Virginia
- Inova
- Kemper Consulting
- LeadingAge
- LifeNet Health
- Mary Washington Health Care
- Medical Society of Virginia
- Riverside Health System
- Sentara Healthcare
- The Arc of Northern Virginia
- The Family Foundation

Stakeholder

- University of Virginia Health System
- Vectre
- Virginia Association for Hospices & Palliative Care
- Virginia Association of Centers for Independent Living
- Virginia Association of Health Plans
- Virginia Board of Medicine
- Virginia Catholic Conference
- Virginia Commonwealth University Health System
- Virginia Department of Health
- Virginia Health Care Association
- Virginia Hospital and Healthcare Association
- Virginia Nurses Association
- Virginia Society for Human Life

Appendix III: References

Slide 5:

- Blinderman et al (2015). “Comfort Care for Patients Dying in the Hospital.” *New England Journal of Medicine*. 373:2549-2561.

Slide 6:

- Bosslet et al (2015). “An Official ATS/AACN/ACCP/ESICM/SCCM Policy Statement: Responding to Requests for Potentially Inappropriate Treatments in Intensive Care Units.” *American Journal of Critical Care Medicine*. 191(11):1318-30.
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Slide 7:

- American Medical Association. 1994. *AMA Opinion 2.035 – Futile Care*.

Slide 8:

- Anderson, J (undated) *Managing Patients or Families who demand Medically Futile Care*. University of Oklahoma Medical Sciences.
- Mains et al (2008). “Case studies in medical futility.” *Journal of Hospital Marketing & Public Relations*. 18(1):61-70.
- Prager, K (2013). “When Physicians and Surrogates Disagree about Futility.” *AMA Journal of Ethics*. 15(12):1022-1026.

Appendix III: References (cont'd)

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- American Medical Association. 1997. *AMA Opinion 2.037 – Medical Futility in End-of-Life Care*.
- Bosslet et al (2015). “An Official ATS/AACN/ACCP/ESICM/SCCM Policy Statement: Responding to Requests for Potentially Inappropriate Treatments in Intensive Care Units.” *American Journal of Critical Care Medicine*. 191(11):1318-30.
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Slide 11:

- Breen et al (2001). “Conflict associated with decisions to limit life-sustaining treatment in intensive care units.” *Journal of General Internal Medicine*. 16(5):283-9.
- Fine, Robert (2009). “Point: The Texas Advance Directives Act Effectively and Ethically Resolves Disputes About Medical Futility.” *Chest*. 136(4):963-967 (<http://journal.publications.chestnet.org/article.aspx?articleid>)
- Maryland Health Care Ethics Committee Network. 2010. Maryland HCDA – Survey of Hospital Attorneys and Risk Managers Summary of Findings. (https://www.law.umaryland.edu/programs/health/mhecn/documents/HCDA_JD_RM_survey_summary.pdf)
- Pope, Thaddeus (2010). “Surrogate Selection: An Increasingly Viable, But Limited, Solution to Intractable Futility Disputes.” *Saint Louis University Journal of Health Law & Policy*. 3:183-252.
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- Studdert et al (2003). “Conflict in the care of patients with prolonged stay in the ICU: types, sources, and predictors.” *Intensive Care Medicine*. 29(9):1489-97.
- Swetz et al (2007). “Report of 255 clinical ethics consultations and review of the literature.” *Mayo Clinic Proceedings*. 82(6):686-91.

Appendix III: References (cont'd)

Slide 15:

- National Conference of Commissioners on Uniform State Laws. 1994. *Uniform Health-Care Decisions Act*.
(http://www.uniformlaws.org/shared/docs/health%20care%20decisions/uhcda_final_93.pdf)

Slide 22:

- Casarett et al. (2005). "Appropriate Use of Artificial Nutrition and Hydration—Fundamental Principles and Recommendations." *New England Journal of Medicine*. 353(24): 2607-2612.
- Brody et al. (2011). "Artificial Nutrition and Hydration: The Evolution of Ethics, Evidence, and Policy." *Journal of General Internal Medicine*. 26(9):1053–1058.
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