Decline and Fall of Medical Self-Regulation

Yale Law ● March 28, 2014

Thaddeus Mason Pope, J.D., Ph.D.
Hamline University Health Law Institute

Roadmap

What is medical **self-regulation**?

Decline of medical-self regulation

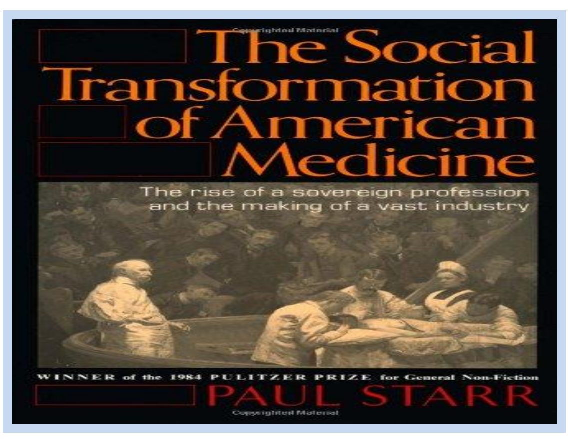
Futility safe harbors

Mandated disclosures

12:10 – 12:40

12:40 – 1:00

Self-Regulation

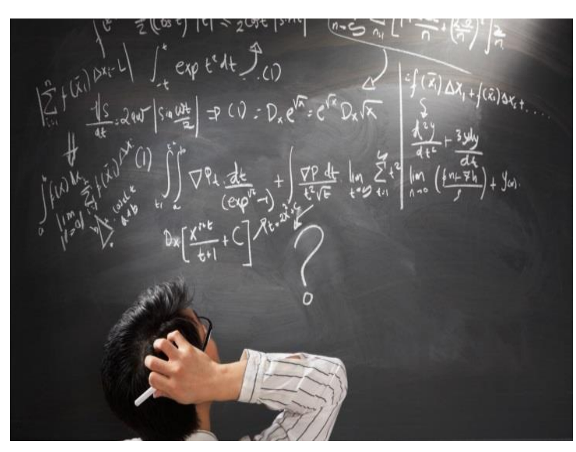


Entry

Medical Board

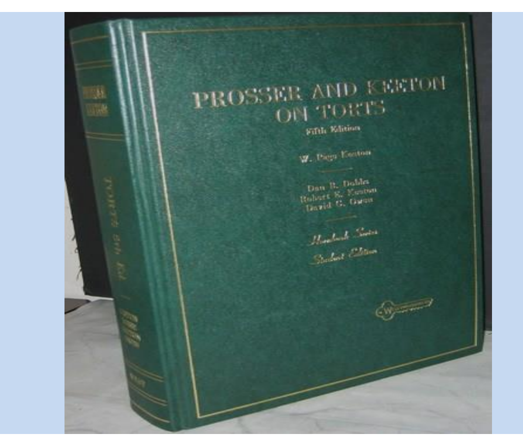
Regulation

Privileging & credentialing



Torts

Malpractice



Tort law "gives the medical profession . . . the privilege, which is usually emphatically denied to other groups, of **setting their own legal standards of conduct**, merely by adopting their own practices."

Deference

Delegation

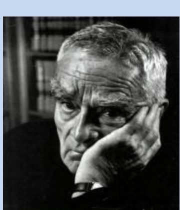
- Custom is what experts say
- Jury makes no normative, value judgments
- Jury does not say "X is what docs normally do, but they OUGHT to do x+1."

Normally -

Custom is just **evidence** on standard of care

T. J. Hooper 60 F.2d 737 (2d Cir. 1932)

"In most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged . . . . It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission."



Med Mal -

Custom **defines** standard of care

Helling v. Carey, 519 P.2d 981 (Wash. 1974)

Decline of self-regulation

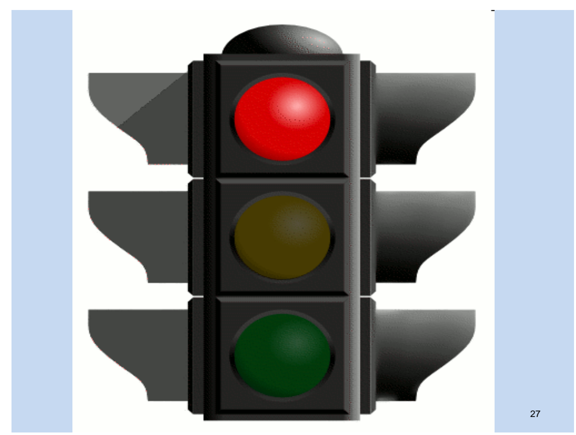
Futility red lights

Mandated disclosures

Futility red lights

Clinician | **Surrogate**

CMO | LSMT



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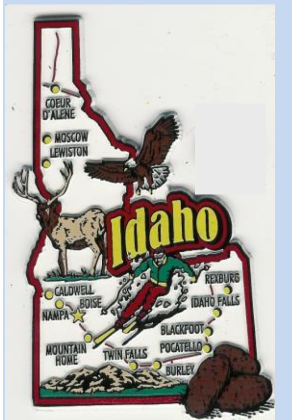
"If surrogate directs [LST] . . . provider that does not wish to provide . . . **shall nonetheless comply** . . . ."

29

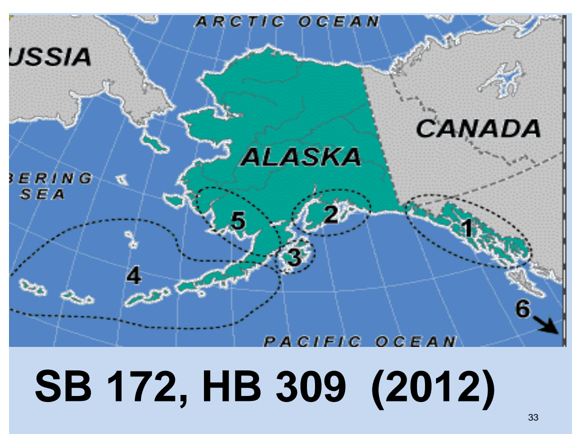


Discrimination in Denial of Life Preserving Treatment Act

30

"Health care . . . **may not be . . . denied** if . . . directed by . . . surrogate"

31



SB 172, HB 309 (2012)

33

Mandated Disclosures

Mandated Disclosures:

Introduction to informed consent

Legal duty of informed consent usually **framed** in terms of tort and negligence

Informed consent is **one type** of medical malpractice

What to disclose?

Not everything

You can't send patient to med school

2 main ways to **measure** MD duty

Material risk

20+ states

Reasonable MD

20+ states

Reasonable physician

- Duty measured by custom
- Like malpractice
- What a prudent **physician** would disclose under circumstances

Material risk

- Duty measured by patient needs
- What a reasonable **patient** would deem significant

Mandated Disclosures:

Problems with informed consent

Not happening

e.g. EOL treatment

At least in material risk jurisdictions, duty to disclose EOL options has existed for **decades**

Health Care Costs in the Last Week of Life

Associations With End-of-Life Conversations

Baohui Zhang, MS; Alexi A. Wright, MD; Haiden A. Huskamp, PhD; Matthew E. Nilsson, BS; Matthew L. Maciejewski, PhD; Craig C. Earle, MD; Susan D. Block, MD; Paul K. Maciejewski, PhD; Holly G. Prigerson, PhD

Only 31% with advanced cancer had EOL discussions

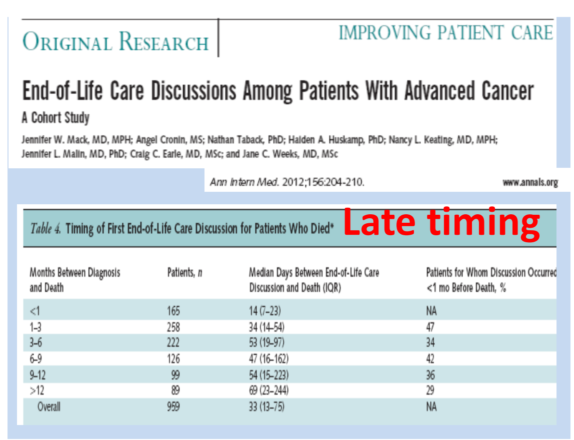
Background: Life-sustaining medical care of patients with advanced cancer at the end of life (EOL) is costly. Patient-physician discussions about EOL wishes are associated with lower rates of intensive interventions.

Methods: Funded by the National Institute of Mental Health and the National Cancer Institute, Coping With Cancer is a longitudinal multi-institutional study of 627 patients with advanced cancer. Patients were interviewed at baseline and were followed up through death. Costs for intensive care unit and hospital stays, hospice care, and life-sustaining procedures (eg, mechanical ventilator use and resuscitation) received in the last week of life were aggregated. Generalized linear models were applied to test for cost differences in EOL care. Propensity score matching was used to reduce selection biases.

Results: Of 603 participants, 188 (31.2%) reported EOL discussions at baseline. After propensity score matching, the remaining 415 patients did not differ in sociodemographic [illegible] illness acknowledgment, or treatment preferences. Further analyses, adjusted by quintiles of propensity scores and significant confounders, revealed that [illegible] mean (SE) aggregate costs [illegible] were $1876 ($177) for patients who reported EOL discussions compared with $2917 ($285) for patients who did not, a cost difference of [illegible] 7% lower among patients who reported EOL [illegible] (P=.002). Patients with higher costs had worse quality of death in their final week (Pearson production moment correlation partial r=−0.17, P=.006).

Conclusions: Patients with advanced cancer who reported having EOL conversations with physicians had significantly lower health care costs in their final week of life. Higher costs were associated with worse quality of death.

Arch Intern Med. 2009;169(5):480-488



ORIGINAL RESEARCH | IMPROVING PATIENT CARE

End-of-Life Care Discussions Among Patients With Advanced Cancer
A Cohort Study

Jennifer W. Mack, MD, MPH; Angel Cronin, MS; Nathan Taback, PhD; Haiden A. Huskamp, PhD; Nancy L. Keating, MD, MPH; Jennifer L. Malin, MD, PhD; Craig C. Earle, MD, MSc; and Jane C. Weeks, MD, MSc

Ann Intern Med. 2012;156:204-210. www.annals.org

Table 4. Timing of First End-of-Life Care Discussion for Patients Who Died* **Late timing**

Months Between Diagnosis and Death	Patients, *n*	Median Days Between End-of-Life Care Discussion and Death (IQR)	Patients for Whom Discussion Occurred <1 mo Before Death, %
<1	165	14 (7–23)	NA
1–3	258	34 (14–54)	47
3–6	222	53 (19–97)	34
6–9	126	47 (16–162)	42
9–12	99	54 (15–223)	36
>12	89	69 (23–244)	29
Overall	959	33 (13–75)	NA

Associations Between End-of-Life Discussions, Patient Mental Health, Medical Care Near Death, and Caregiver Bereavement Adjustment

Alexi A. Wright; Baohui Zhang; Alaka Ray; et al.

JAMA. 2008;300(14):1665-1673 (doi:10.1001/jama.300.14.1665)

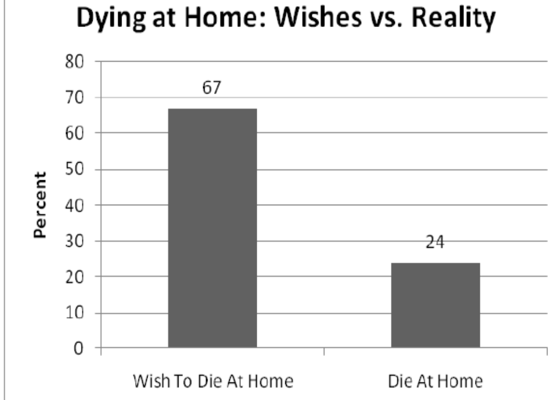
EOL discussion

Earlier hospice referral

Better patient QOL

Better family bereavement

51



Legislative Finding:

"patients with reduced life expectancy due to advanced illnesses . . . are often **unaware** of their legal rights, particularly with regard to controlling end-of-life decisions."

Mandated Disclosures:

Statutory mandates

1991

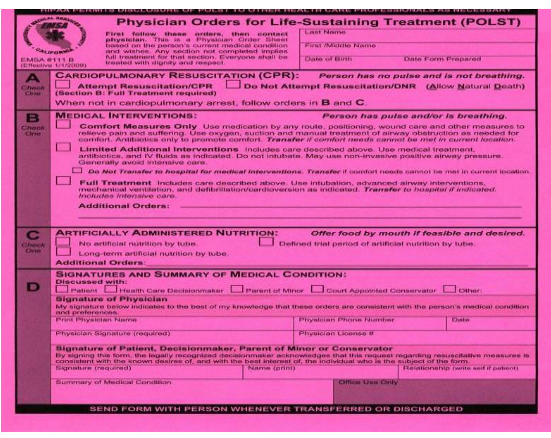
Patient Self Determination Act

Duty on facilities

Upon admission

Apprise of AD rights under state law

Last 5 years at state level



HIPAA PERMITS DISCLOSURE OF POLST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY

Physician Orders for Life-Sustaining Treatment (POLST)

EMSA #111 B (Effective 1/1/2009)

First follow these orders, then contact physician. This is a Physician Order Sheet based on the person's current medical condition and wishes. Any section not completed implies full treatment for that section. Everyone shall be treated with dignity and respect.

Last Name

First /Middle Name

Date of Birth | Date Form Prepared

A Check One — **CARDIOPULMONARY RESUSCITATION (CPR):** ***Person has no pulse and is not breathing.***

☐ **Attempt Resuscitation/CPR** (Section B: Full Treatment required) ☐ **Do Not Attempt Resuscitation/DNR** (Allow Natural Death)

When not in cardiopulmonary arrest, follow orders in **B** and **C**.

B Check One — **MEDICAL INTERVENTIONS:** ***Person has pulse and/or is breathing.***

☐ **Comfort Measures Only** Use medication by any route, positioning, wound care and other measures to relieve pain and suffering. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. Antibiotics only to promote comfort. ***Transfer** if comfort needs cannot be met in current location.*

☐ **Limited Additional Interventions** Includes care described above. Use medical treatment, antibiotics, and IV fluids as indicated. Do not intubate. May use non-invasive positive airway pressure. Generally avoid intensive care.

☐ ***Do Not Transfer to hospital for medical interventions. Transfer*** if comfort needs cannot be met in current location.

☐ **Full Treatment** Includes care described above. Use intubation, advanced airway interventions, mechanical ventilation, and defibrillation/cardioversion as indicated. ***Transfer** to hospital if indicated. Includes intensive care.*

Additional Orders:

C Check One — **ARTIFICIALLY ADMINISTERED NUTRITION:** ***Offer food by mouth if feasible and desired.***

☐ No artificial nutrition by tube. ☐ Defined trial period of artificial nutrition by tube.

☐ Long-term artificial nutrition by tube.

Additional Orders:

D — **SIGNATURES AND SUMMARY OF MEDICAL CONDITION:**

Discussed with: ☐ Patient ☐ Health Care Decisionmaker ☐ Parent of Minor ☐ Court Appointed Conservator ☐ Other:

Signature of Physician

My signature below indicates to the best of my knowledge that these orders are consistent with the person's medical condition and preferences.

Print Physician Name | Physician Phone Number | Date

Physician Signature (required) | Physician License #

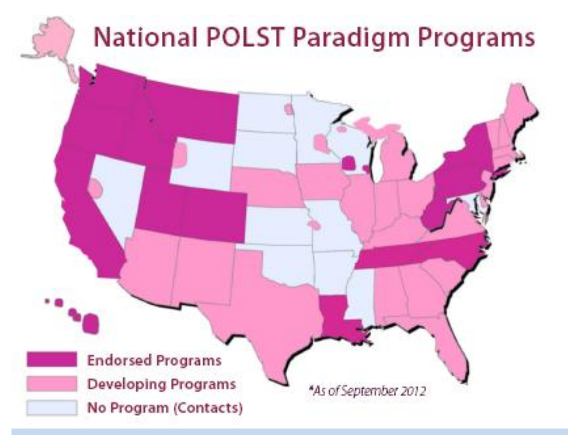
Signature of Patient, Decisionmaker, Parent of Minor or Conservator

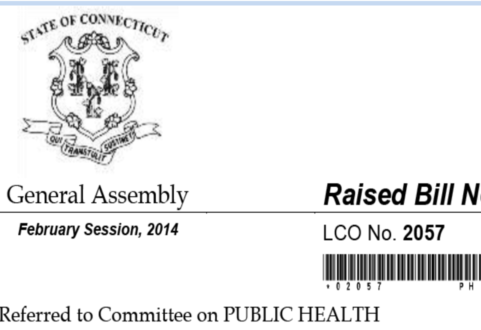
By signing this form, the legally recognized decisionmaker acknowledges that this request regarding resuscitative measures is consistent with the known desires of, and with the best interest of, the individual who is the subject of the form.

Signature (required) | Name (print) | Relationship (write self if patient)

Summary of Medical Condition | Office Use Only

SEND FORM WITH PERSON WHENEVER TRANSFERRED OR DISCHARGED




STATE OF CONNECTICUT

General Assembly — *Raised Bill No. 413*

February Session, 2014 — LCO No. **2057**

Referred to Committee on PUBLIC HEALTH

Introduced by:
(PH)

healthcare facilities must determine "which of those individuals who do not have a [POLST] should be offered the opportunity to complete [one]."

Utah Admin. R. 432-31 (2011)

1996

Michigan Dignified Death Act
Mich. Comp. Laws 333.5651

2008

Right to Know End-of-Life Options Act
Cal. H&S Code 442.5

When . . . provider diagnoses . . . terminal illness, . . . shall, **upon the patient's request**, provide . . . comprehensive information and counseling regarding legal end-of-life options.

Prognosis with or without disease-targeted treatment

Right to accept **disease-targeted treatment**, with or without palliative care

Right to refuse or withdraw from **life-sustaining treatment**

Right to have comprehensive **pain** and symptom management

Meaning and availability of **hospice** care

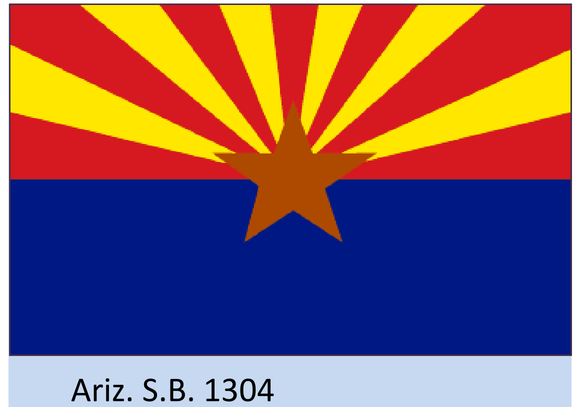
Right to give individual health care **instruction** (POLST; AD)

Attend to emotional cues, ability to absorb…

2009

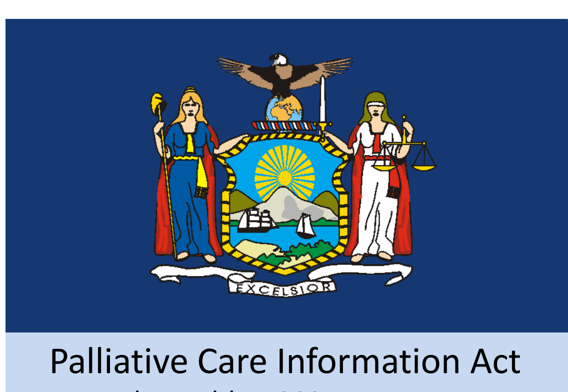
Patient's Bill of Rights for Palliative Care & Pain Management (Vt. Stat. tit. 18 § 1871)

Maryland S.B. 546, H.B. 30



Ariz. S.B. 1304

2010



Palliative Care Information Act
NY Pub. Health L. 2997c

Similar to CA

But better

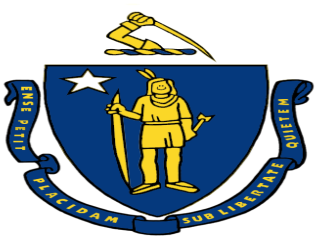
CA: “upon the patient’s request”

NY: “shall offer to provide”

2011

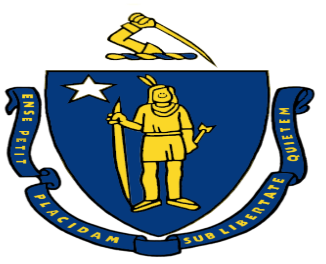
Palliative Care Access Act
NY Pub. Health L. 2997d

2012



Massachusetts Act Improving the Quality of Health Care & Reducing Costs through Increased Transparency, Efficiency & Innovation

2014



Hospital Licensure Regulations
105 CMR. 130.1900

Mandated Disclosures:

Enforcement

New York

$2000 civil penalty

$5000, if repeat violations

1 year prison, if willful

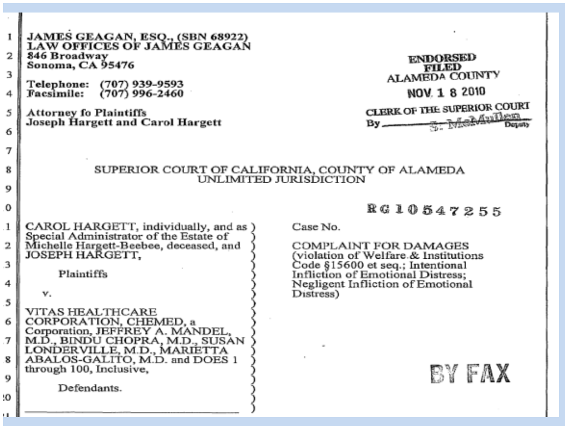
California

No separate penalties

But **defines** duties under common law

Michelle Hargett

terminal pancreatic cancer



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Attorney fo Plaintiffs
Joseph Hargett and Carol Hargett

ENDORSED
FILED
ALAMEDA COUNTY
NOV. 1 8 2010
CLERK OF THE SUPERIOR COURT
By ______ Deputy

SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
UNLIMITED JURISDICTION

RG10547255

CAROL HARGETT, individually, and as Special Administrator of the Estate of Michelle Hargett-Beebee, deceased, and JOSEPH HARGETT,

Plaintiffs

v.

VITAS HEALTHCARE CORPORATION, CHEMED, a Corporation, JEFFREY A. MANDEL, M.D., BINDU CHOPRA, M.D., SUSAN LONDERVILLE, M.D., MARIETTA ABALOS-GALITO, M.D. and DOES 1 through 100, Inclusive,

Defendants.

Case No.

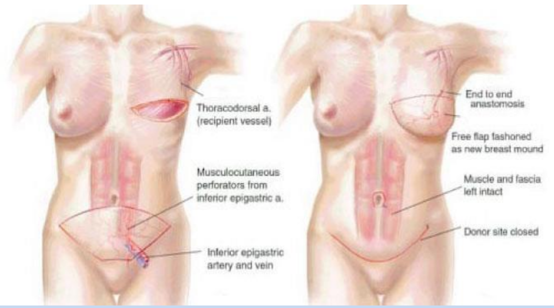
COMPLAINT FOR DAMAGES (violation of Welfare & Institutions Code §15600 et seq.; Intentional Infliction of Emotional Distress; Negligent Infliction of Emotional Distress)

BY FAX

Not Only EOL

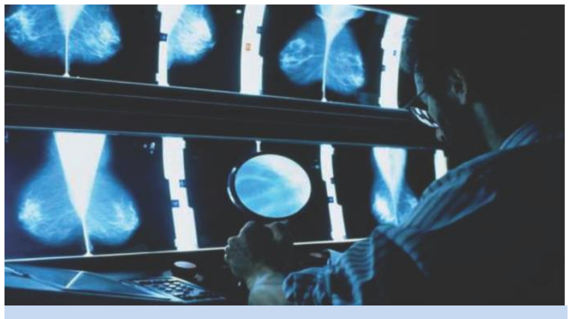
Other gaps

Other mandates



Breast reconstruction coverage

N.Y. A.B. 10094, S.B. 6993 (2010)



Breast density

Cal. S.B. 1538 (2013)

Mandated Disclosures:

Opposition

4 types of opposition to mandated disclosures

Mandated Disclosures:

Opposition 1

The New York Times Reprints

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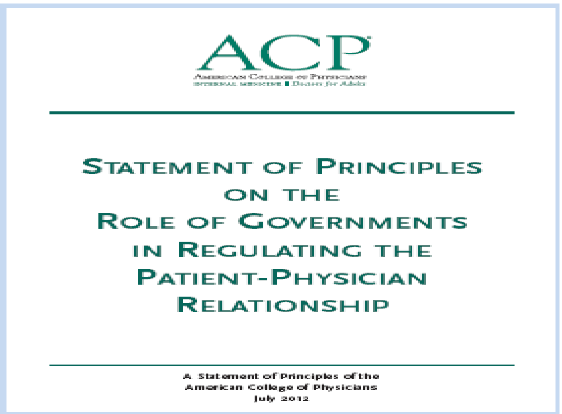
June 6, 2011

Law on End-of-Life Care Rankles Doctors

By JANE E. BRODY



ACP

American College of Physicians

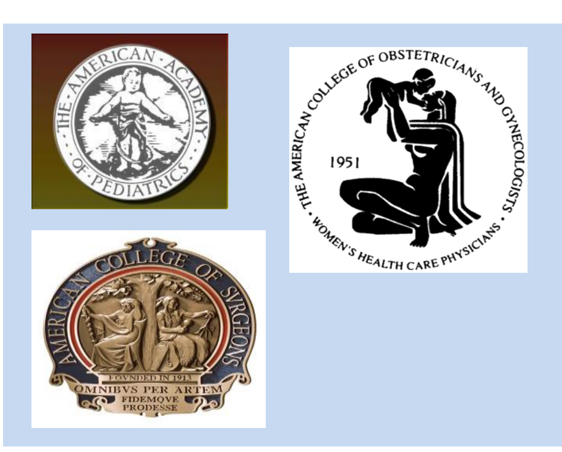
Internal Medicine | Doctors for Adults

STATEMENT OF PRINCIPLES ON THE ROLE OF GOVERNMENTS IN REGULATING THE PATIENT-PHYSICIAN RELATIONSHIP

A Statement of Principles of the American College of Physicians

July 2012

"Laws . . . **should not mandate** . . . provision . . . of information . . . that, in the physician's clinical judgment and based on clinical evidence and the norms of the profession, are not necessary or appropriate . . . ."



Response

Trust us to elicit & document Pt preferences

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Legislative Interference with the Patient–Physician Relationship

Steven E. Weinberger, M.D., Hal C. Lawrence III, M.D., Douglas E. Henley, M.D., Errol R. Alden, M.D., and David B. Hoyt, M.D.

In contrast, government must avoid regulating the content of the individual clinical encounter without a compelling and evidence-based benefit to the patient, a substantial public health justification, or both.

Mandated Disclosures:

Opposition 2

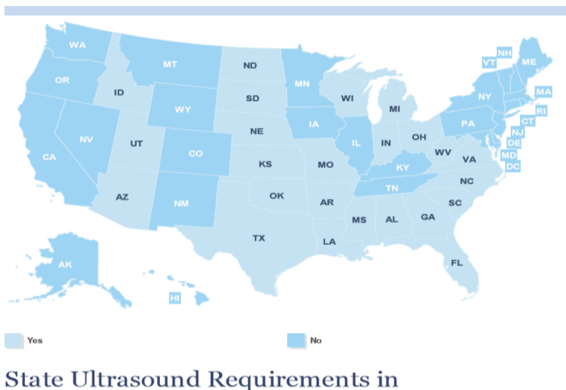
“**misrepresentation and misuse** of medical information in the pursuit of partisan aims”

Perspective

Physicians and the (Woman’s) Body Politic

R. Alta Charo, J.D.

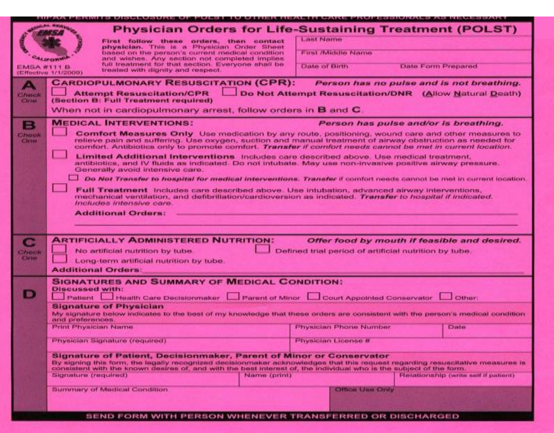
“[L]egislatures have been encroaching on the realm of medicine . . . declaring medical ‘facts,’ specifying or forbidding medical procedures, and dictating to doctors what they must say”



State Ultrasound Requirements in Abortion Procedure

Response

Let’s not throw the baby out with the bath water.



HIPAA PERMITS DISCLOSURE OF POLST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY

Physician Orders for Life-Sustaining Treatment (POLST)

EMSA · CALIFORNIA

EMSA #111 B (Effective 1/1/2009)

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First /Middle Name
Date of Birth | Date Form Prepared

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Additional Orders:

C (Check One) **ARTIFICIALLY ADMINISTERED NUTRITION:** ***Offer food by mouth if feasible and desired.***

☐ No artificial nutrition by tube. ☐ Defined trial period of artificial nutrition by tube.
☐ Long-term artificial nutrition by tube.

Additional Orders:

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Discussed with: ☐ Patient ☐ Health Care Decisionmaker ☐ Parent of Minor ☐ Court Appointed Conservator ☐ Other:

Signature of Physician

My signature below indicates to the best of my knowledge that these orders are consistent with the person's medical condition and preferences.

Print Physician Name | Physician Phone Number | Date
Physician Signature (required) | Physician License #

Signature of Patient, Decisionmaker, Parent of Minor or Conservator

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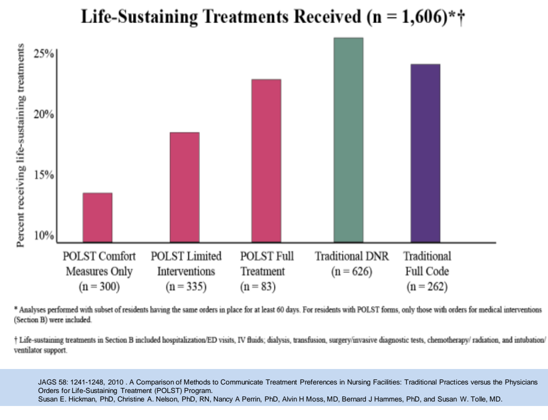
Signature (required) | Name (print) | Relationship (write self if patient)
Summary of Medical Condition | Office Use Only

SEND FORM WITH PERSON WHENEVER TRANSFERRED OR DISCHARGED



Nursing facility residents divided by None vs. Limited/Full Treatments

N = 898	Section A Resuscitation**		Section B Medical Interventions*		Section C Antibiotics**		Section D Feeding Tubes*	
	DNR	Full	None	Lim/Full	None	Lim/Full	None	Lim/Full
Oregon	85%	15%	50.9%	49.1%	9.8%	90.2%	56.9%	43.1%
Wisconsin	94.7%	5.3%	50.5%	49.5%	0%	100%	73.5%	26.5%
West Virginia	83.6%	16.4%	38.3%	61.7%	5.5%	94.5%	63.7%	36.3%

*p < .01; ** p < .001

Note: Analysis does not control for potential covariates including age, cognitive status, race, life status, or hospice use

Source: unpublished R01 data - see Hickman, Nelson, Perrin, Moss, Hammes, & Tolle (2010)

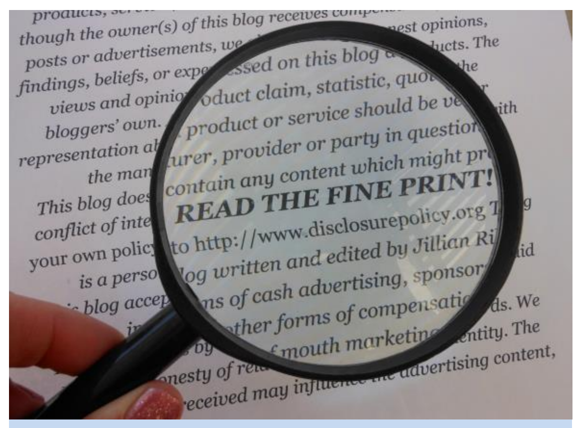
Mandated Disclosures:

Opposition 3

More Than You Wanted to Know: The Failure of Mandated Disclosure

Omri Ben-Shahar & Carl E. Schneider
(April 2014)

"most common and **least successful** regulatory technique in American law"



Response

VOLUME 31 · NUMBER 6 · FEBRUARY 20 2013

JOURNAL OF CLINICAL ONCOLOGY — ORIGINAL REPORT

Electronic Prompt to Improve Outpatient Code Status Documentation for Patients With Advanced Lung Cancer

Jennifer S. Temel, Joseph A. Greer, Emily R. Gallagher, Vicki A. Jackson, Inga T. Lennes, Alona Muzikansky, Elyse R. Park, and William F. Pirl

See accompanying editorial on page 663

Conclusion
e-mail prompts may improve the rate and timing of code status documentation in the EHR and warrant further investigation.

Ongoing process
NOT a one-time event

Arch Intern Med. 2009;169(5):480-488

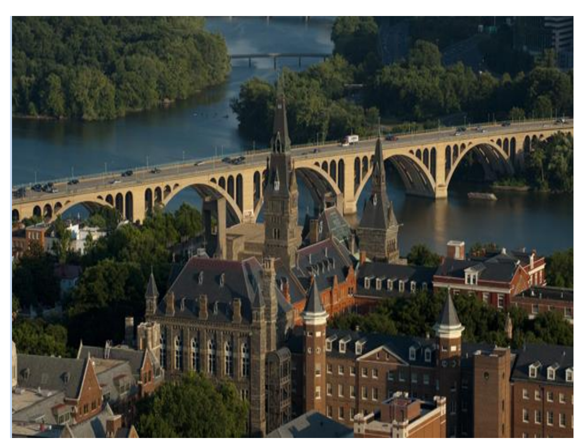
Variable	Discussed EOL Care Preferences With Physician	
	Yes (n=75)	No (n=70)
Medical care received during the last week of life, No. (%)		
Intensive care unit stay	2 (2.7)	10 (14.3)
Ventilator use	1 (1.3)	10 (14.3)
Resuscitation	1 (1.3)	6 (8.6)
Chemotherapy	4 (5.3)	7 (10.0)
Inpatient hospice used	8 (10.7)	5 (7.1)
Inpatient hospice stay ≥1 wk	4 (5.3)	2 (2.9)
Outpatient hospice used	58 (77.3)	40 (57.1)
Outpatient hospice stay ≥1 wk	52 (69.3)	34 (48.6)
Place of death, No. (%)[b]		
Intensive care unit	2 (2.9)	9 (13.2)
Hospital	15 (21.7)	18 (26.5)
Inpatient hospice	5 (7.2)	3 (4.4)
Home	47 (68.1)	38 (55.9)

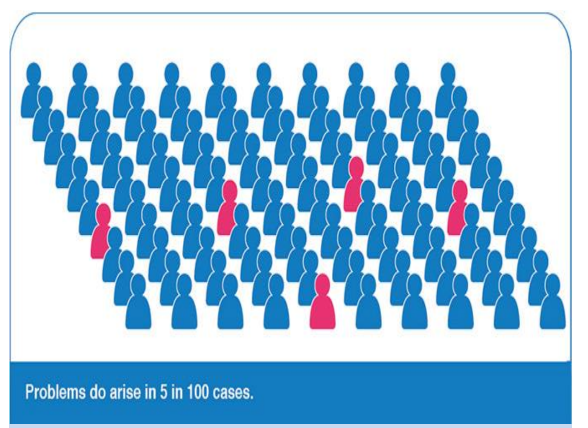
Mandated Disclosures:

Opposition 4

Wrong focus on **content** of information, than **manner** of delivery

Response





PCORI

CMMI

AHRQ

Next 5 years:

Safe harbor for using “certified” PtDA

Conclusion

113TH CONGRESS
2D SESSION

H. R. 4106

To provide for the development and dissemination of clinical practice guidelines and the establishment of a right of removal to Federal courts for defendants in medical malpractice actions involving a Federal payor, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 27, 2014

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