Revitalizing Informed Consent Law

SIIPC ● June 26, 2014

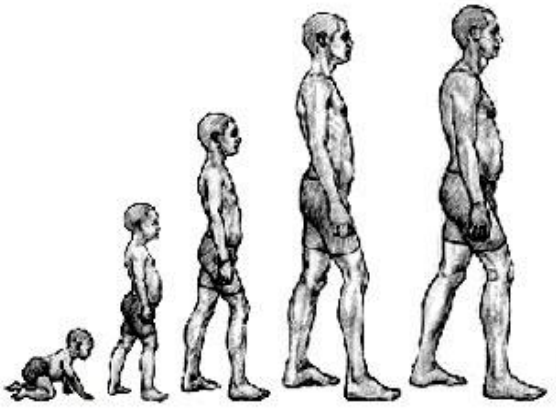
Thaddeus Mason Pope, J.D., Ph.D.
Hamline University Health Law Institute

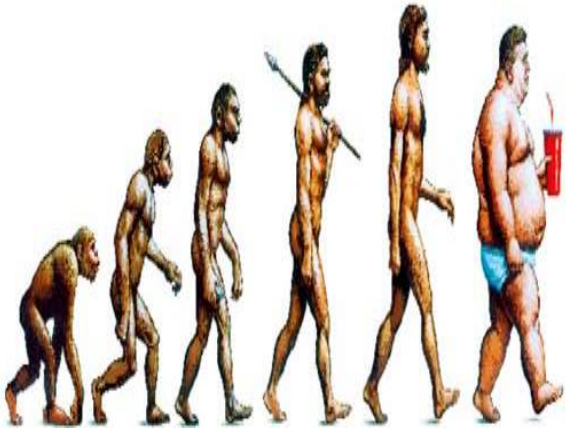
Roadmap

Yesterday

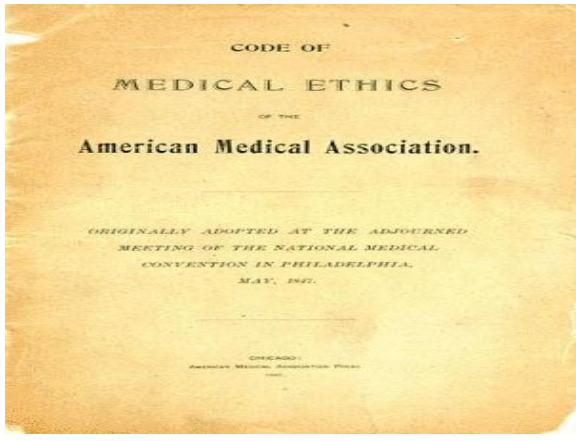
Today

Tomorrow





1847


CODE OF

MEDICAL ETHICS

OF THE

American Medical Association.

ORIGINALLY ADOPTED AT THE ADJOURNED MEETING OF THE NATIONAL MEDICAL CONVENTION IN PHILADELPHIA, MAY, 1847.

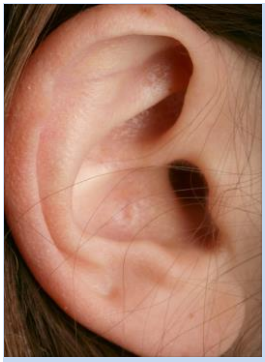
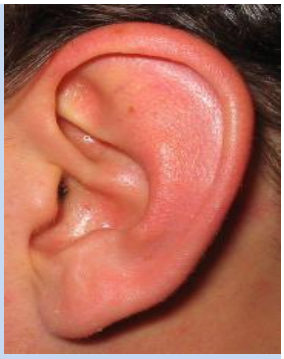
CHICAGO:

Do **NOT** consider patient's "own crude opinions"

1905

Battery

No consent
at all

Mohr v. Williams (Minn. 1905)

1914

Mary Schloendorff

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . . "

Consent

But not "informed"

Birth

1957

Salgo v. Leland Stanford (Cal.)

1960

Natanson v. Kline (Kan.)

1972

2014

Tort

Negligence

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

Obstacles

Duty

Breach

Causation

Damages

Duty

What to disclose?

Not everything

Can't send patient to med school

2 main ways to **measure** MD duty

Material risk

20+ states

Reasonable MD

20+ states

Material risk

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

Odd → No duty

Reasonable physician

- Duty measured by **custom**
- What a prudent **physician** would disclose

Custom to not disclose → No duty

Breach

Focus on **disclosure** NOT understanding

Causation

3

1. **PTF** would have chosen differently

2. **RPP** would have chosen differently

3. Different choice would avoid injury

Damages

Problems

Health Care Costs in the Last Week of Life

Associations With End-of-Life Conversations

Only 31% with advanced cancer had EOL discussions

Baohui Zhang, MS; Alexi A. Wright, MD; Nancy L. Keating, MD; Holly G. Prigerson, PhD; Matthew E. Nilsson, BS; Matthew D. Zinkin, PhD; Craig C. Earle, MD; Susan D. Block, MD; Ellen P. McCarthy, PhD; Holly G. Prigerson, PhD

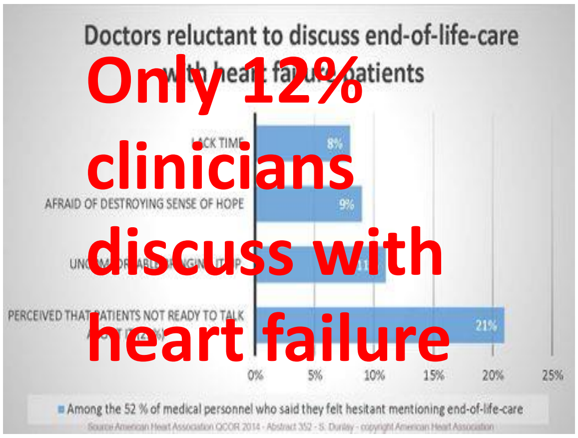
Background: Life-[illegible] with advanced cancer [illegible] Patient-physician [illegible] sociated with lower rates of intensive interventions.

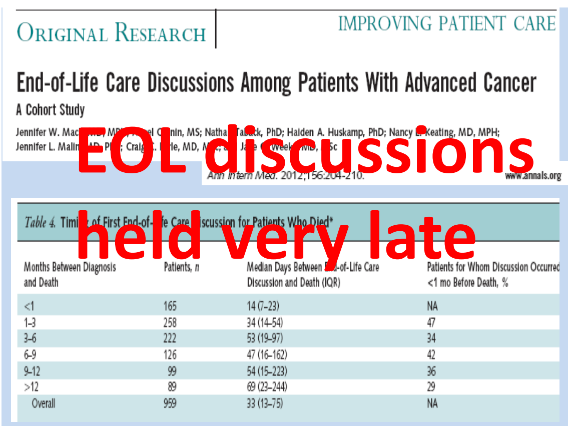
Methods: Funded by the National Institute of Mental Health and the National Cancer Institute, Coping With Cancer is a longitudinal [illegible] patients with advanced cancer [illegible] viewed at baseline and followed up through death. Costs for intensive care unit and hospital stays, hospice care, and life-sustaining procedures (eg, mechanical ventilator use and resuscitation) received in the last week of life were aggregated [illegible] applied to test for [illegible] sity score matchin[illegible]

Results: Of 603 participants, 188 (31.2%) reported EOL discussions at baseline. After propensity score matching, the remaining 415 patients did not differ in socio- [illegible] characteristics, recruitment sites, illness acceptance, or treatment preferences. Further [illegible] ated by quintiles of propensity scores and significant confounders, revealed that the mean (SE) aggregate costs of care (in 2008 US dollars) were $1876 ($177) for patients who reported EOL discussions compared with $2917 ($235) for [illegible] a cost difference [illegible] 5.79) [illegible] mon) [illegible] ents who reported [illegible] sions) ([illegible] .002). Patients with higher costs had [illegible] quality of death in the final week (Pearson production moment correlation partial $r=-0.17$, $P=.006$).

Conclusions: Patients with advanced cancer who reported [illegible] conversations with physicians had [illegible] 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. Mac[illegible]; [illegible] C[illegible]nin, MS; Natha[illegible] Ta[illegible]ck, PhD; Halden A. Huskamp, PhD; Nancy [illegible] Keating, MD, MPH; Jennifer L. Malin[illegible]; Craig [illegible]; [illegible]

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

Table 4. Timi[illegible] of First End-of-[illegible]fe Care [illegible]iscussion for Patients Who Died*

Months Between Diagnosis and Death	Patients, n	Median Days Between [illegible]d-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

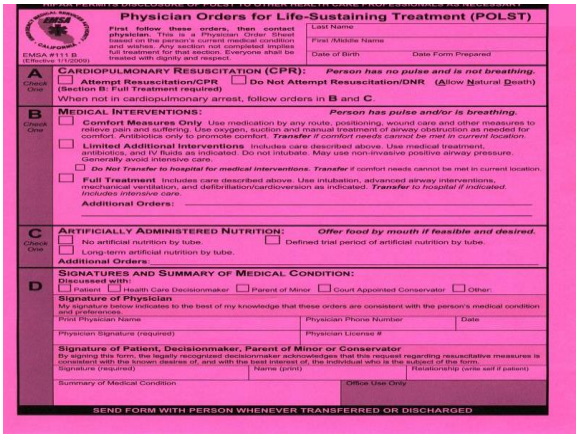
Mandated Disclosures

1991

Patient Self Determination Act

- Duty on facilities
- Upon admission
- Apprise of AD rights under state law

Last 6 years at state level



Physician Orders for Life-Sustaining Treatment (POLST)

First follow these orders, then contact physician. These orders are voluntary and 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.

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

Last Name | First /Middle Name | Date of Birth | Date Form Prepared

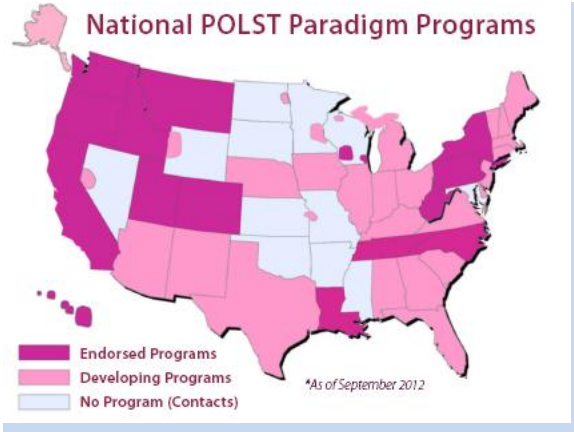
A Check One — CARDIOPULMONARY RESUSCITATION (CPR): *Person has no pulse and is not breathing.*
☐ Attempt Resuscitation/CPR ☐ Do Not Attempt Resuscitation/DNR (Allow Natural Death)
(Section B: Full Treatment required)
When not in cardiopulmonary arrest, follow orders in **B** and **C**.

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



"which of those individuals who do not have a [POLST] should . . . 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, . . . 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)

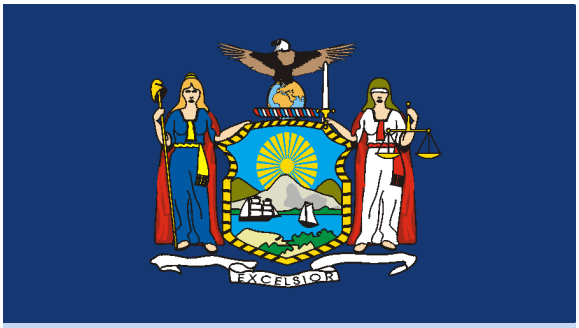
2009

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

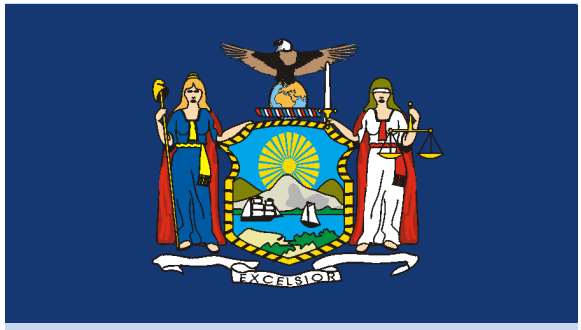
Similar to CA

But better

CA: "upon the patient's request"

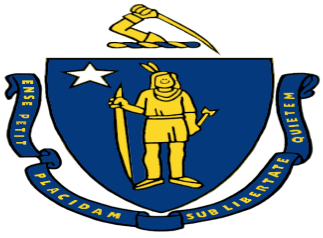
NY: "shall offer to provide"

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

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Attorney fo Plaintiffs
Joseph Hargett and Carol Hargett

ENDORSED
FILED
ALAMEDA COUNTY
NOV 18 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.

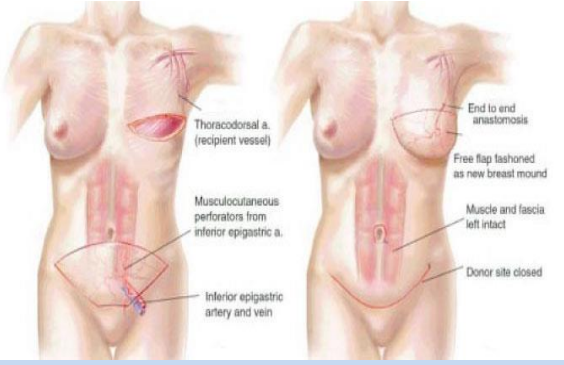
COMPLAINT FOR DAMAGES
(violation of Welfare & Institutions Code §15600 et seq.; Intentional Infliction of Emotional Distress; Negligent Infliction of Emotional Distress)

BY FAX

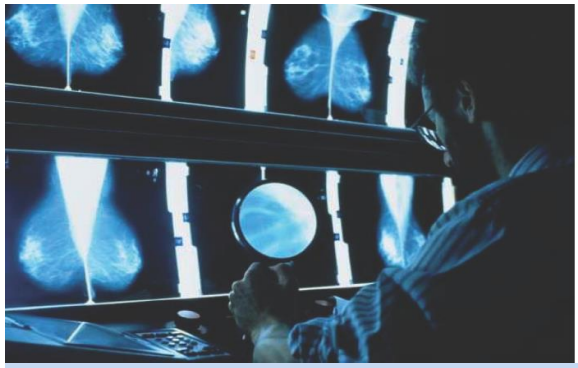
Not Only EOL

Other gaps

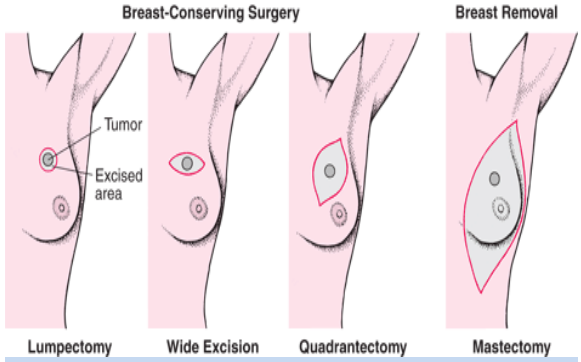
Other mandates



Breast reconstruction coverage



Breast density



Breast cancer (1979-1986)

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

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.

Mandated CME

Safe Harbors

"No lengthy polsyllabic discourse"

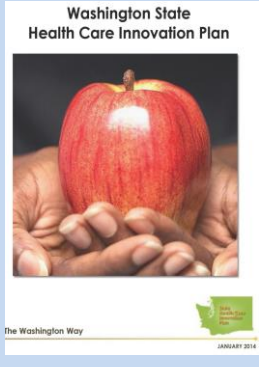
Cobbs v. Grant (Cal. 1972)

THE COCHRANE COLLABORATION®

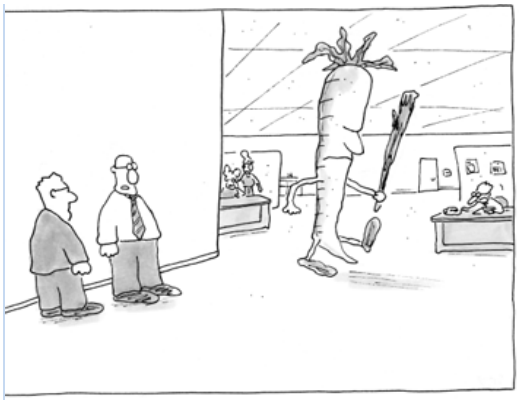
Safe harbor
for using
"certified" PtDA

Wash. Rev. Code 7.70.060(2)

"Providers of state-financed health care [must] use patient decision aids"



EBM CPG



"This is their new big carrot and stick method."

2015-2020 Reforms

PATIENTS' PREFERENCES MATTER

Stop the silent misdiagnosis

Al Mulley, Chris Trimble, Glyn Elwyn

The King's Fund

Dartmouth

1960s

2014

Consumer power
Transparency
Technology
Reimbursement
Fraud
Costs

1. Consumer Power

ZocDoc
Get well sooner.

Consumer Reports

RateMDs.com

healthgrades
How America finds a doctor.

vitals℠

2.

Transparency

Breaking Down the Payments

Medicare disclosed payments of $77 billion in 2012 to more than 880,000 doctors and other medical providers for services and equipment. The breakdown for the top 15 medical specialties ranked by average paid to individual billers:

Provider type	Number of providers	Total paid in millions	Average amount paid per provider
Hematology/oncology	7,374	$2,703.9	$366,677
Radiation oncology	4,135	1,499.6	362,666
Ophthalmology	17,067	5,585.0	327,239
Medical oncology	2,613	806.6	308,702
Portable X-ray	7	2.0	288,020
Rheumatology	4,053	1,044.5	257,701
Nephrology	7,503	1,685.6	224,657
Cardiology	22,241	4,965.3	223,248
Dermatology	10,507	2,235.3	212,745
Interventional pain management	1,856	366.1	197,229
Peripheral vascular disease	74	14.3	193,441
Hematology	687	127.6	185,757
Cardiac electrophysiology	1,117	204.0	182,641
Vascular surgery	2,696	485.3	180,019
Urology	8,791	1,385.4	157,589

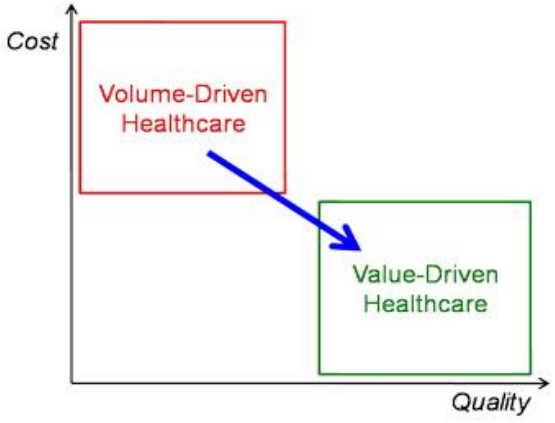
Source: Centers for Medicare and Medicaid Services

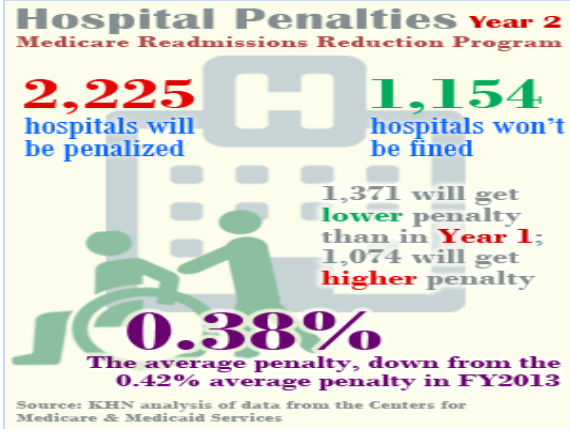
The Wall Street Journal

©Eleanor Mills / NewsArt.com, used with permission

3.

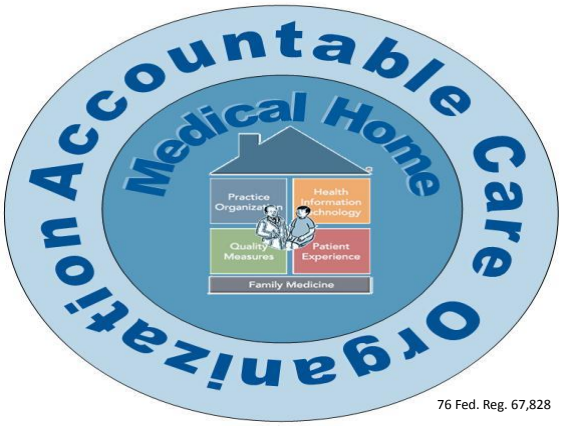
Reimbursement





Manage wellness

~~Treat the sick~~



76 Fed. Reg. 67,828

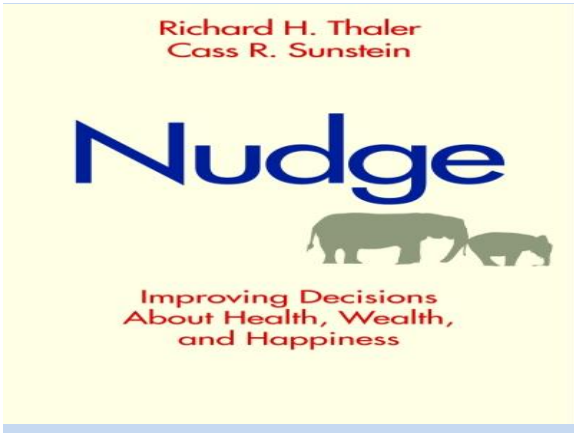
4. Technology

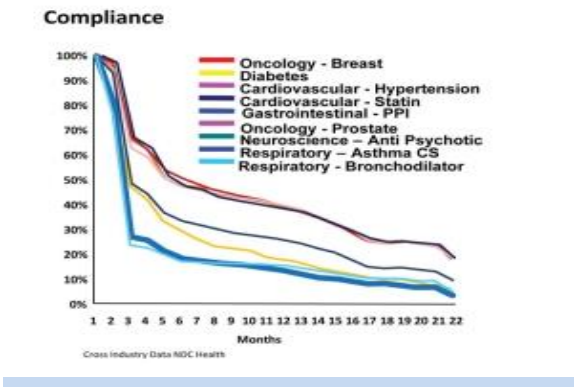
Usually for MEDICAL diagnosis, now PREFERENCE diagnosis too

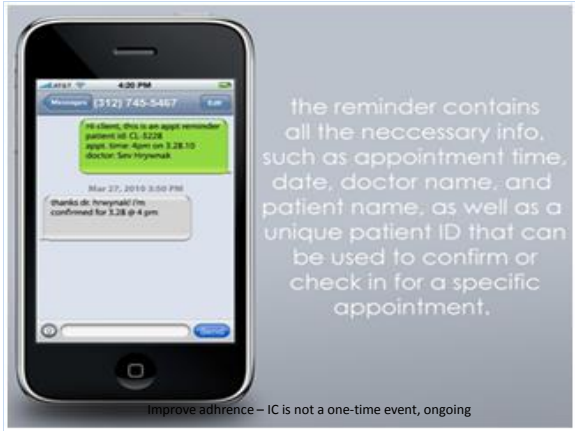
BlueButton
Download my data®

OpenNotes®

Ask questions, identify inaccuracies


Richard H. Thaler
Cass R. Sunstein
Nudge
Improving Decisions
About Health, Wealth,
and Happiness


Compliance
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
Months
Oncology - Breast
Diabetes
Cardiovascular - Hypertension
Cardiovascular - Statin
Gastrointestinal - PPI
Oncology - Prostate
Neuroscience – Anti Psychotic
Respiratory – Asthma CS
Respiratory - Bronchodilator
Cross Industry Data NDC Health


the reminder contains all the neccessary info, such as appointment time, date, doctor name, and patient name, as well as a unique patient ID that can be used to confirm or check in for a specific appointment.
Improve adhrence – IC is not a one-time event, ongoing

5.

Fraud

THE UNITED STATES DEPARTMENT of JUSTICE

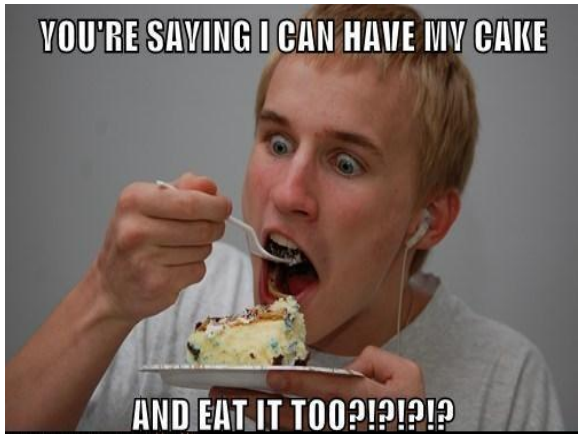
Unnecessary

Ineffective

Unwanted

6.

Costs



Conclusion

Consumer power
Transparency
Technology
Reimbursement
Fraud
Costs

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