



1



2



3



4

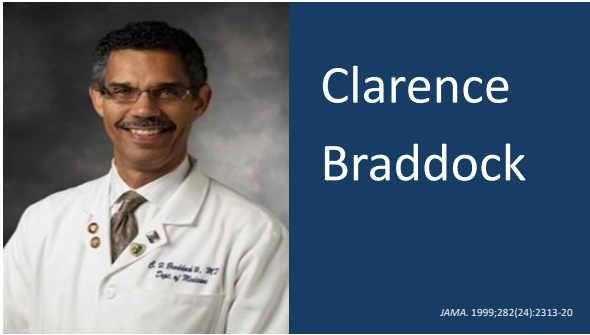


Although existing legal and procedural mandates ensure that generally patients are provided at least some information prior to signing a consent form, research suggests the current standard for informed consent is well below demonstrated patient preferences.

5



6



7



1000 MD-Pt encounters
3000 clinical decisions

8

how **frequent** was
discussion of risks
& benefits?

9

9%

10

outcome
measure

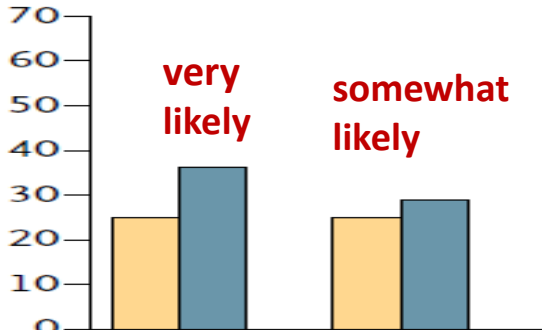
11

The NEW ENGLAND JOURNAL of MEDICINE

Patients' Expectations about Effects
of Chemotherapy for Advanced Cancer

chemotherapy for **incurable**
cancers – palliative only

12



13

no chance
chemotherapy
will cure them

14

2 problems

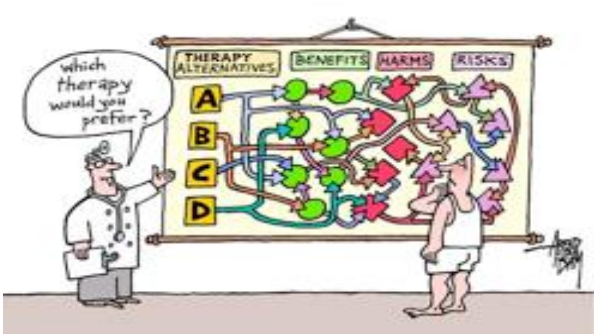
15

RBA **not**
disclosed

16



17



18

SO...

19

new laws
to improve consent

20



21

roadmap

22



23

4 parts

24

part **1**

25

medical
malpractice

26

part **2**

27

federal
mandates

28

part **3**

29

state
mandates

30

part 4

31

advance directives

32

medical malpractice

33



34



35

2023 - 2024

36



37



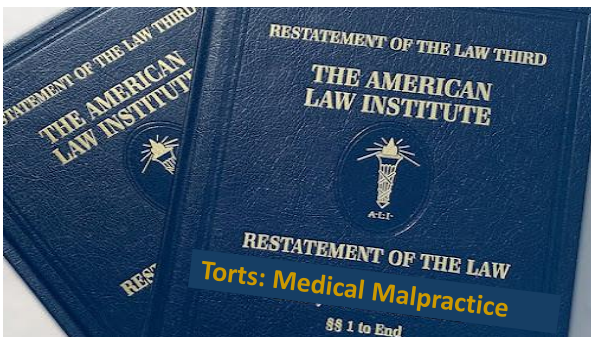
38



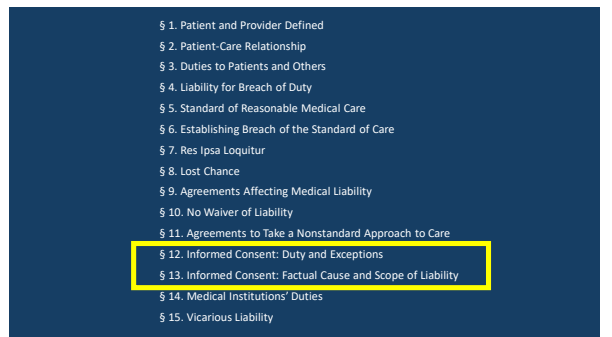
39



40



41



42

2 key changes

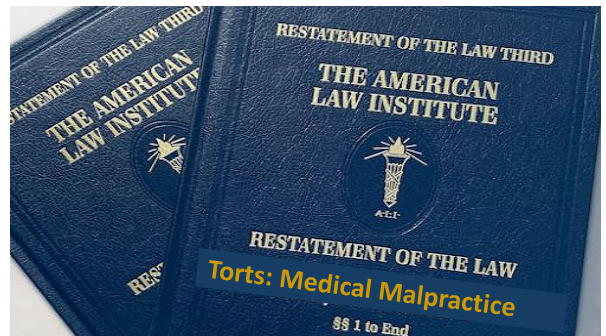
43

1

44

in 25 states, duty set
by **SOC**

45



46

“**not** endorse an **unqualified** version of the professional standard”

47

minimum
professional
standard

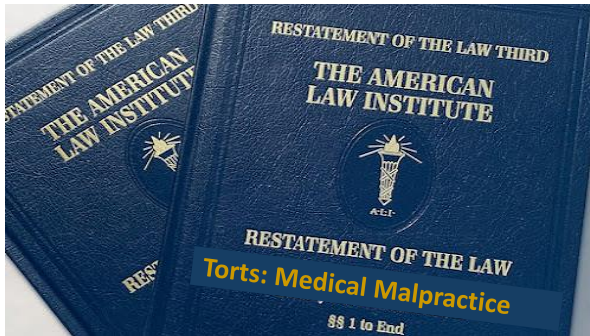
48

2

49

IC focuses on
what to disclose

50



51

what → **how**

52

disclosure must be
made in a manner
that is **reasonably
calculated to convey**

53

...that's tort

54

**federal
mandates**

55

4 worth
discussing

56

1557 FDA
NCDs OHRP

57

§ 1557

58

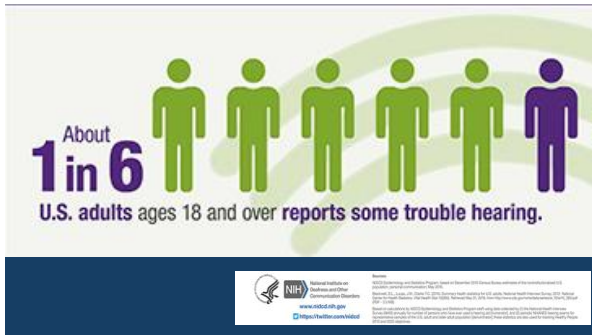
**hearing
impairment**

59

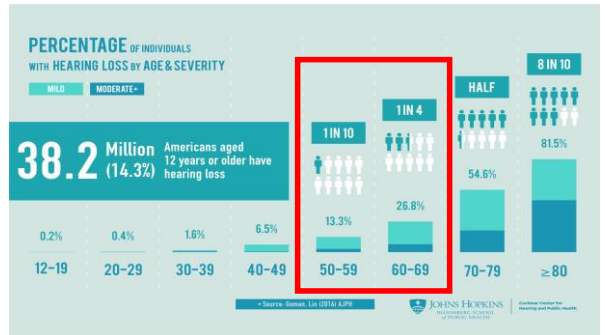


37.5 million
U.S. adults

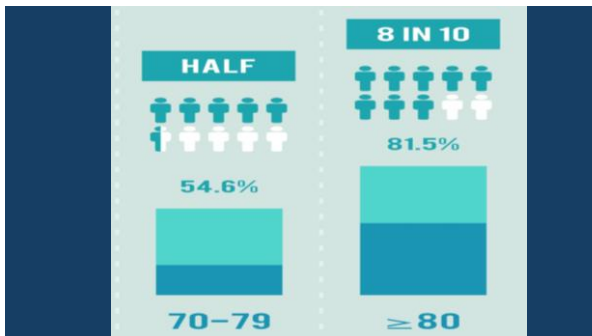
60



61



62



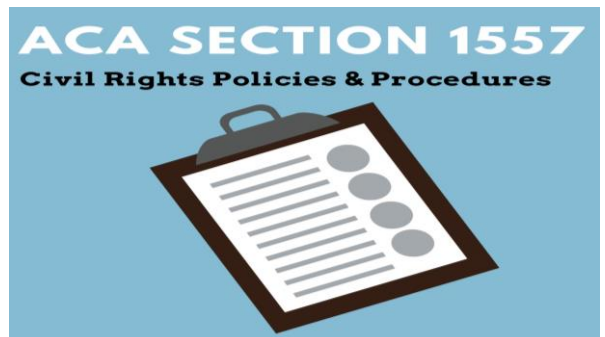
63



64



65



66

qualified interpreter



67



68

remote



69

limited English proficiency

70



71

25,000,000

72

1 in 13

73



Shots

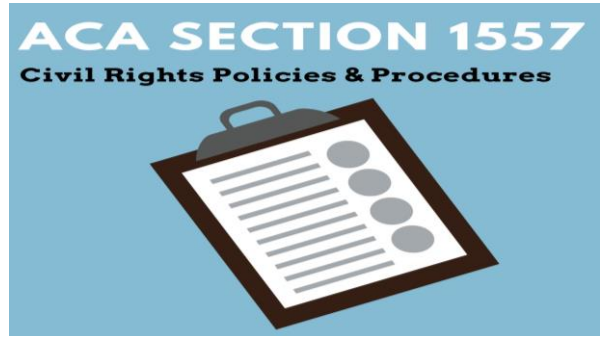
SHOTS - HEALTH NEWS

With Scarce Access To Interpreters, Immigrants Struggle To Understand Doctors' Orders

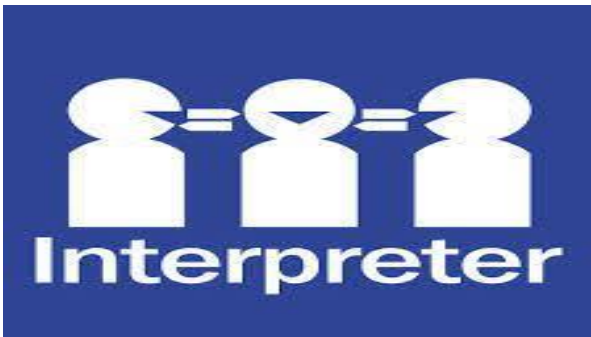
74



75



76



77



78

in person



79

2 communication duties:
LEP + deaf

80



81

in 2016 regulations

82

what's new

83

more enforcement

84



85

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

June 4, 2024

HHS Office for Civil Rights Takes Action to Ensure Access to Care for Patients Who Are Deaf or Hard of Hearing

This is the latest action that OCR has taken to strengthen access to health and human services for people with disabilities.

86



87



FOR IMMEDIATE RELEASE Friday, August 28, 2020

Providence Holy Cross Medical Center Agrees to Improve Access for Deaf and Hard of Hearing Patients and to Compensate Family

LOS ANGELES – Providence Health System – Southern California, which operates Providence Holy Cross Medical Center in Mission Hills, has entered into a settlement with the United States, agreeing to comply with the Americans with Disabilities Act (ADA) by ensuring effective communication for patients who are deaf or hard of hearing.

88



PRESS RELEASE

ADA Agreement Ensures Effective Communication with Deaf and Hard of Hearing Patients at Kent Hospital

89



90

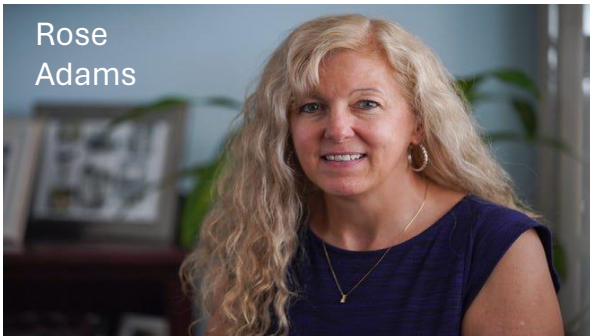
Prominent Cleveland Heights advocate for deaf issues sues Cleveland Clinic, accuses hospital of failing to provide sign language interpreters

Updated: Jan. 23, 2023, 5:42 p.m. | Published: Jan. 23, 2023, 5:16 p.m.

91

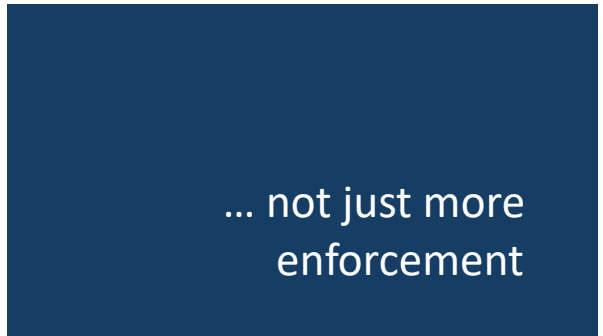


92



Rose Adams

93



94



95

37522 Federal Register / Vol. 89, No. 88 / Monday, May 6, 2024 /

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 438, 440, 457, and 460
Office of the Secretary
45 CFR Parts 80, 84, 92, 147, 155, and 156
RIN 0945-AA17
Nondiscrimination in Health Programs and Activities
AGENCY: Office for Civil Rights, Office of the Secretary, Department of Health and Human Services; Centers for Medicare & Medicaid Services, Department of Health and Human Services.
ACTION: Final rule and interpretation.

Office for Civil Rights
 Daniel Shieh, Associate Deputy Director, HHS Office for Civil Rights
 (301) 443-3000 (voice), (301) 443-7687 (TDD), via email at 3014433000@hhs.gov, for matters related to section 504 of the Rehabilitation Act of 1973.
Centers for Medicare & Medicaid Services
 John Giles, (410) 786-5545, for matters related to Medicaid.
 Becca Buccheri, (301) 492-4341 or Leigha Basini, (301) 492-4380, for matters related to 45 CFR 155.120, 155.220, 156.125, 156.200, and 156.1230.
 Lisa Cuzzo, (410) 786-1746, for matters related to 45 CFR 147.104.
 Hannah Katch, (202) 578-9381, for matters related to 45 CFR 147.104.

May 6, 2024

96

duties **broader**
more entities

97

July 2024						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

98

...that's 1557

99

FDA

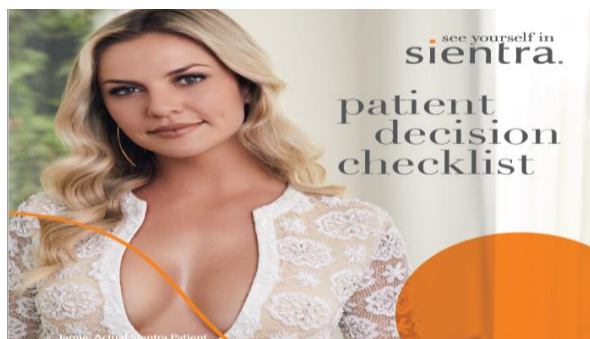
100

FDA Strengthens Safety Requirements and Updates Study Results for Breast Implants

Agency adds restrictions and approves new labeling for all approved breast implants



101



102

Patient Initials: _____

RECOMMENDED FOLLOW-UP

Even if I have no symptoms, I should have my first ultrasound or MRI at 3-4 years after my initial implant surgery and then every 2-3 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture at any time, an MRI is recommended.

I understand that I will need routine and regular follow-up with my physician as long as I have a breast implant for examination of my breast implant as well as to discuss any updates regarding breast implant issues.

National Breast Implant Registry (NBIR): I understand and have discussed with my physician that there is a National Breast Implant Registry where information regarding my health and breast implant information can be entered. The NBIR may help understand the long-term safety and performance of breast implants.

Patient Registry and Outcomes for breast implants and analogous large cell lymphoma (ALCL) etiology and Epidemiology (PROFILES): I understand and have discussed with my physician that there is a registry (PROFILES) where information is collected to better understand BIA-ALCL in patients with breast implants.

Patient Initials: _____

QUESTIONS FOR MY PHYSICIAN

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

OPTIONS FOLLOWING MASTECTOMY

I understand that breast reconstruction is an elective procedure which I can choose to do or not.

I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use

103

implant is the best option for me.

Patient Initials: _____

BREAST AUGMENTATION OPTIONS

I understand that breast augmentation is an elective procedure to increase the size of I

I understand that breast augmentation may result in permanent changes to my breast's my implants are are removed. I may be left with unsatisfactory appearance, changes to shape of my breasts, including but not limited to drooping, skin-ell-venosity, ptosis, different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will its expense.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information booklet/s the specific implant that will be used during my surgery and that I have had time to do information in it and on the document with my physician. I have had the opportunity to and understand the benefits and risks of breast implants for me, given my specific health have considered alternatives to breast implants, including reconstruction without/breast reconstruction/augmentation, and their benefits and risks.

Patient Initials: _____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants elsewhere in the patient information booklet/brochure and in this checklist. I have also the benefits and risks of the alternatives. I have encouraged the patient to ask questions addressed of questions.

doc & Pt must review & sign

104

Patient Initials: _____

RECOMMENDED FOLLOW-UP

Even if I have no symptoms, I should have my first ultrasound or MRI at 3-4 years after my initial implant surgery and then every 2-3 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture at any time, an MRI is recommended.

I understand that I will need routine and regular follow-up with my physician as long as I have a breast implant for examination of my breast implant as well as to discuss any updates regarding breast implant issues.

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I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use

105

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Patient Initials: _____

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If I am an augmentation patient, any additional surgeries or medical procedures will its expense.

Patient Initials: _____

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Patient Initials: _____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants elsewhere in the patient information booklet/brochure and in this checklist. I have also the benefits and risks of the alternatives. I have encouraged the patient to ask questions addressed of questions.

...that's FDA

106



107

Vol. 89, No. 42/Friday, March 1, 2024/Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50
[Docket No. FDA-2022-D-2997]

Key Information and Facilitating Understanding in Informed Consent; Draft Guidance for Sponsors, Investigators, and Institutional Review Boards; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notification of availability.

this draft guidan begin work on th guidance.
ADDRESSES: You on any guidance
Electronic Subm
 Submit electr following way:
 • *Federal eRu*
<https://www.reg.>
 instructions for :
 Comments subm
 including attach
www.regulations
 the docket unch:
 comment will be
 solely responsib
 comment does n
 confidential infc
 third party may :

108

not only **what**
but also **where**
how

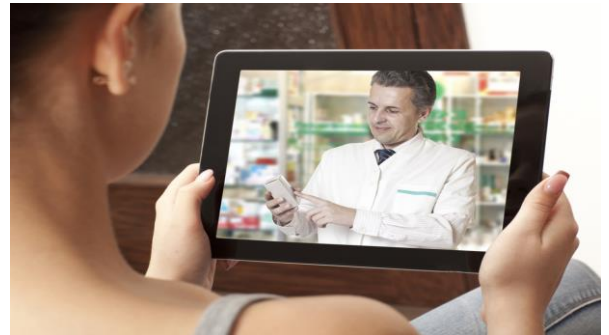
109

“key information”
in concise way
at front

110



111



112

...that's OHRP

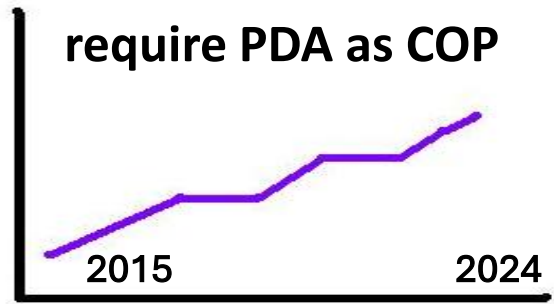
113

Medicare
NCDs

114



115



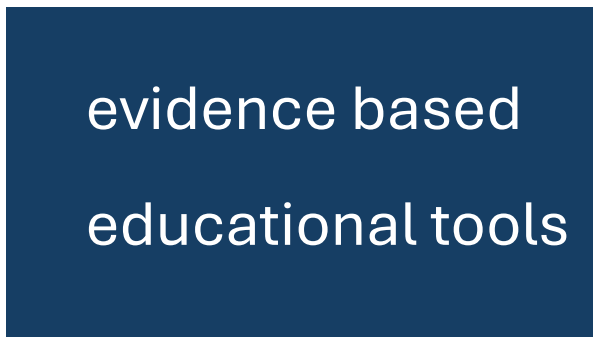
116



117



118



119



120

6 big
benefits

121

improved
knowledge

122

more accurate
expectations

123

more value
congruent
choice

124

higher
patient
satisfaction

125

less
decisional
conflict

126

less
patient
anxiety

127

SO...

128

2015

129

Medicare requires
SDM w/ PDA

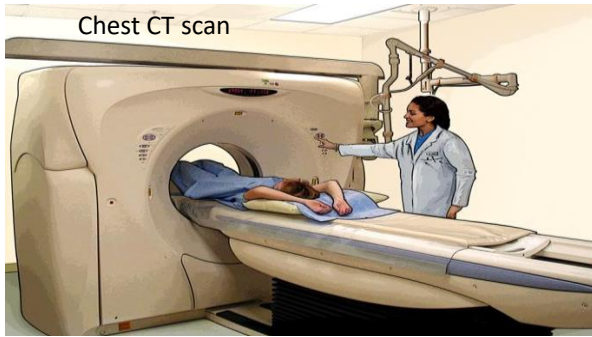
130

Screening for Lung
Cancer with Low
Dose Computed
Tomography

131



132



133

before
CT scan

134

“must receive
... SDM visit”

135

“include ...
one or more
decision aids”

136

why
require PDA?

137

doubt

138

accurate
unbiased
balanced

from the
clinician

139



140

your discussion
with patient is
not good enough

141

patient must
also get informed
with PDA

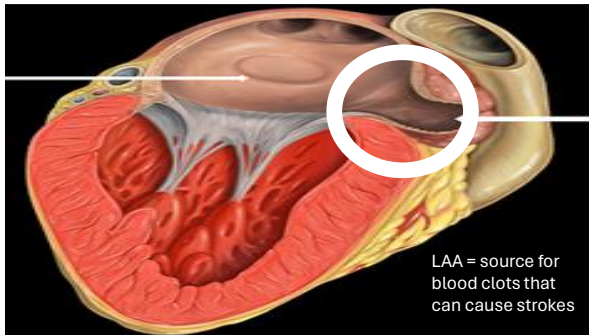
142

2016

143

Percutaneous Left
Atrial Appendage
Closure Therapy

144



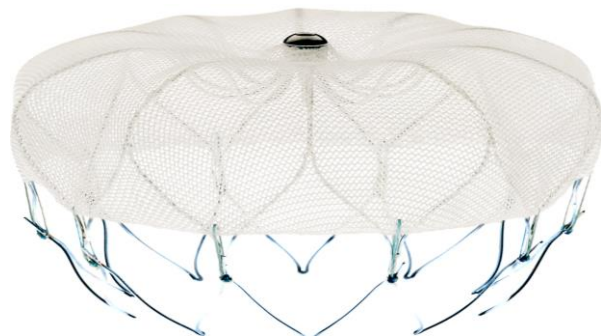
145



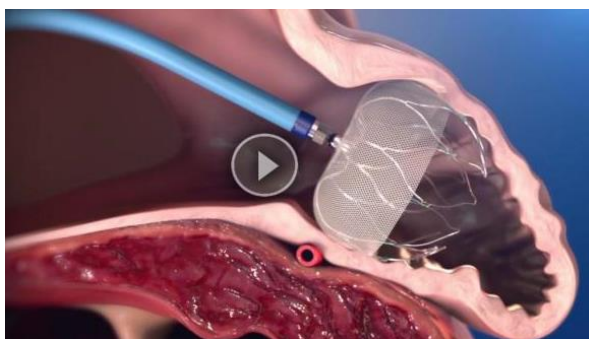
146



147



148



149



150

“formal **SDM**
interaction”

151

evidence-based
decision tool”

152

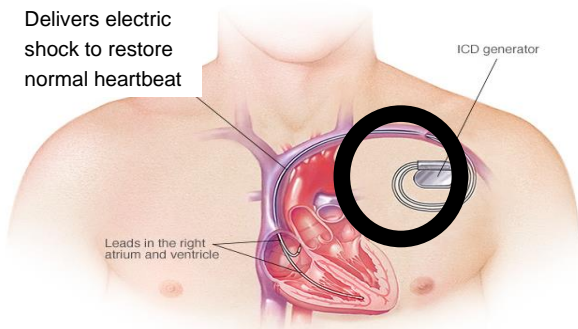
2018

153

implantable
cardioverter
defibrillator

154

Delivers electric
shock to restore
normal heartbeat



155

before
implantation

156

“formal SDM
encounter
must occur”

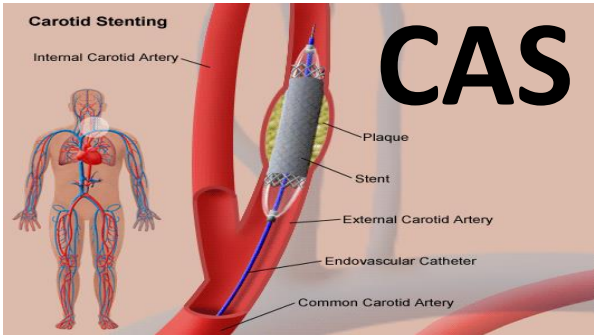
157

“evidence-based
decision tool”

158

2023

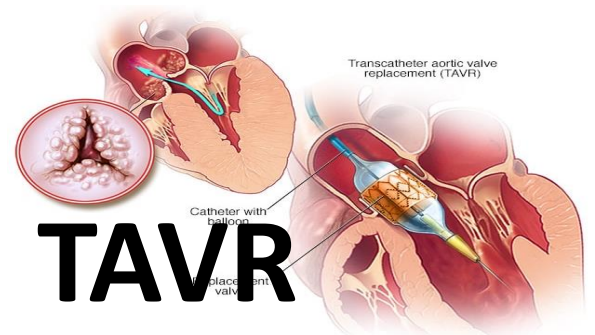
159



160

2024

161



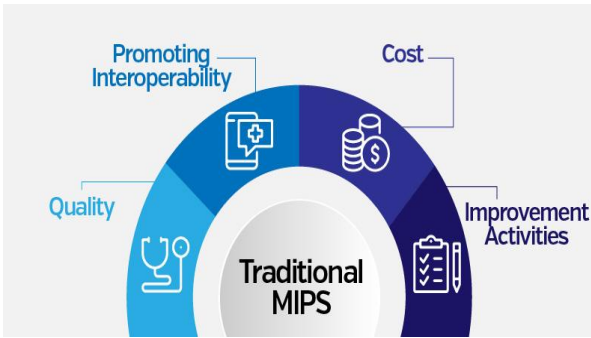
162

...that's NCDs

163



164



165

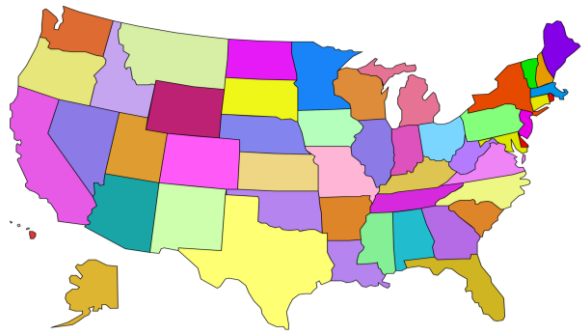
Medicare Shared Savings Program

- Better Care for Individuals.
- Better Health for Populations.
- Lowering Growth in Expenditures.

166

state mandates

167



168



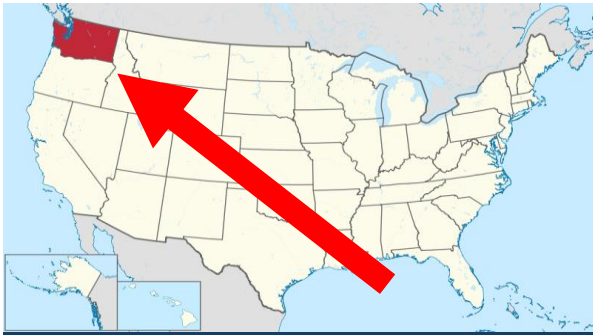
169

rules for ACOs

170

“must use decision support tools
... that enable Enrollees to assess
the merits of various treatment
options ... in the context of their
own values and convictions”

171



172

certifies
PDAs

173

accurate
up to date
no bias + No COI
understandable

174



175



176

... that's state mandates & incentives

177

advance directives

178

we are providing lots of
overtreatment

179

unwanted
treatment

180

value
discordant
treatment

181

this is for
patients
with capacity

182



183



184

RESPECTING PATIENTS' PREFERENCES

By Kuldeep N. Yadav, Nicole B. Gabler, Elizabeth Cooney, Saida Kent, Jennifer Kim, Nicole Herbst, Adjoa Mante, Scott D. Halpern, and Katherine R. Courtright

Approximately One In Three US Adults Completes Any Type Of Advance Directive For End-Of-Life Care

DOI: 10.1377/hlthaff.2017.0175
HEALTH AFFAIRS 36, NO. 7 (2017): 1244-1251
©2017 Project HOPE—The People-to-People Health Foundation, Inc.

185

Uniform Law Commission

186

Uniform Health-Care Decisions Act (2023)

drafted by the

NATIONAL CONFERENCE OF COMMISSIONERS
ON UNIFORM STATE LAWS

187



188

fewer witnesses
fewer formalities

189

“electronic or other
medium ... retrievable
in perceivable form ...
captured on video”

190

... last point

191



192

enforcement

193

The Boston Globe

SPOTLIGHT TEAM FOLLOW-UP

Hospital staff revived a man's stopped heart — and he sued

A successful 'wrongful prolongation of life' lawsuit in Montana, among other things, reflects the extent to which many Americans will go to gain — and enforce — their rights to control their final days.

By Mark Arsenault Globe Staff, Updated December 26, 2020, 2:48 p.m.

194

The New York Times

The Patients Were Saved. That's Why the Families Are Suing.

Paula Span

THE NEW OLD AGE APRIL 10, 2017

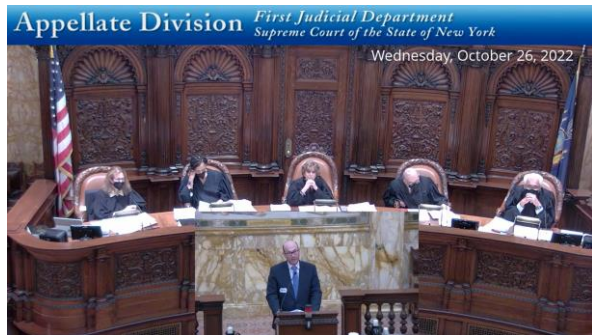
195

noncompliance is compensable injury

196



197



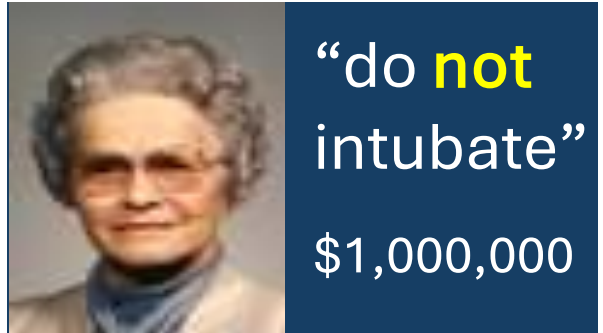
198



News & Features

Hospital Ordered to Pay \$400K in Do-Not-Resuscitate Lawsuit

199



200

County Settles Magney Case for \$1 Million Right-to-die lawsuit ends without the county admitting liability

BY KIMBERLY WEAR

[click to enlarge](#)

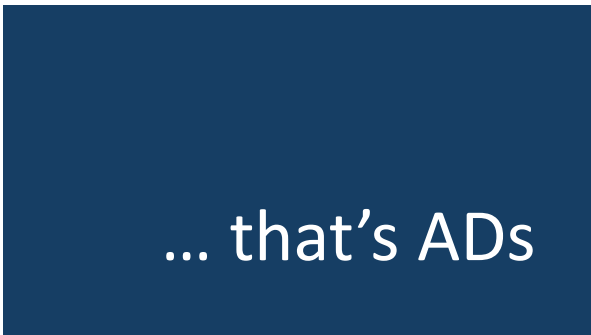


Judy and Dick Magney, circa 1992.

201



202



203



204

top 10 informed consent legal developments

205

Rest.3d	FDA
1557 LEP	OHRP
1557 deaf	state laws
NCDs	UHCDA
PFP	AD

206



207

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 C 310-270-3618
 E Thaddeus.Pope@mitchellhamline.edu
 W www.thaddeuspoppe.com
 B medicalfutility.blogspot.com

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