

# Using Legislation and Policy to Promote Shared Decision Making and Utilization of Decision Aids

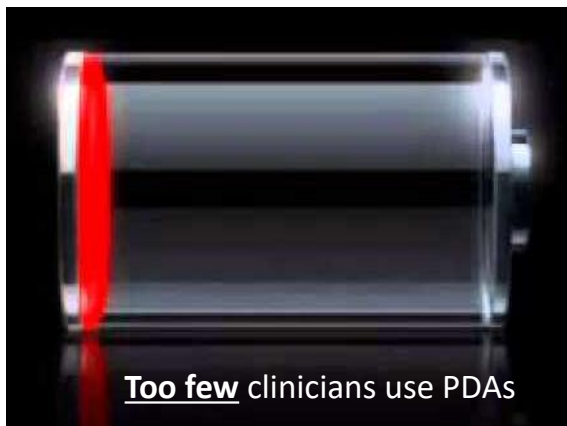
Harvard Law School • April 18, 2018

Thaddeus Mason Pope, JD, PhD

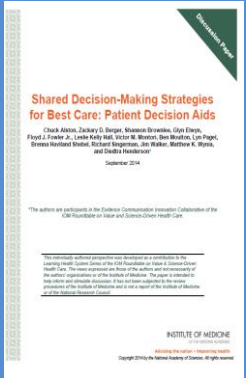


## The Development and Certification of Decision Aids: Promoting Shared Decision-Making for Patients with Serious Illness

“healthcare purchasers . . . **should be committed** to SDM”



“Promise remains elusive”



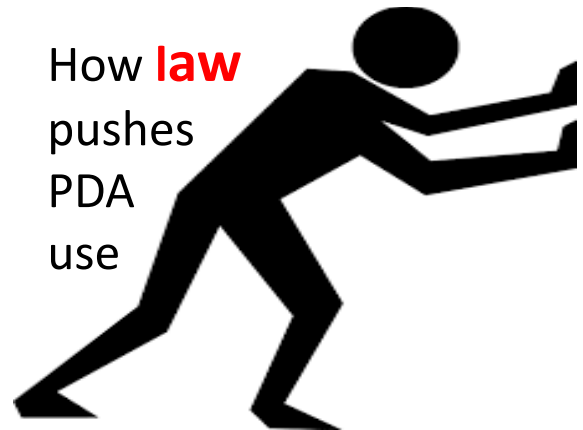
**Shared Decision-Making Strategies for Best Care: Patient Decision Aids**  
 Chuck Arora, Zackary J. Berger, Shamma Braveman, Clay Evvin, Floyd L. Fowler, Jr., James Hays, Bill Hutto, M. Elizabeth, Sam Marshall, Ian Png, Steven Reinher, Richard Saperstein, Jim Walker, Matthew K. Wynia, and David Henderson  
 September 2014

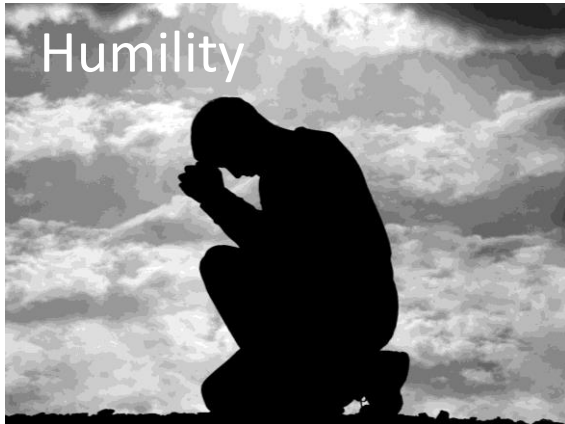
The authors are participants in the Evidence Communication Specialist Collaboration of the IOM Roundtable on Value and Science-Driven Health Care.

The information contained herein represents the opinions of a contributor to the Learning Health Care System project of the Institute of Medicine at the National Academy of Medicine. The views expressed are those of the author and not necessarily of the Institute of Medicine or the National Academy of Medicine. The report is intended to be used for informational purposes only and does not constitute the official position of the Institute of Medicine or the National Academy of Medicine.

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# This talk





“**comprehensive** strategy required to promote wider uptake of SDM”

Coulter - World Psychiatry 16:2 - June 2017



NATIONAL QUALITY PARTNERS™ ACTION BRIEF  
Shared Decision Making:  
A Standard of Care for All Patients



NATIONAL QUALITY FORUM

“framing SDM as a part of . .  
. **patient rights** . . . bolster . .  
. culture change”

Roadmap

4 parts

Part **1**

Payment  
tools

Part **2**

Liability  
tools

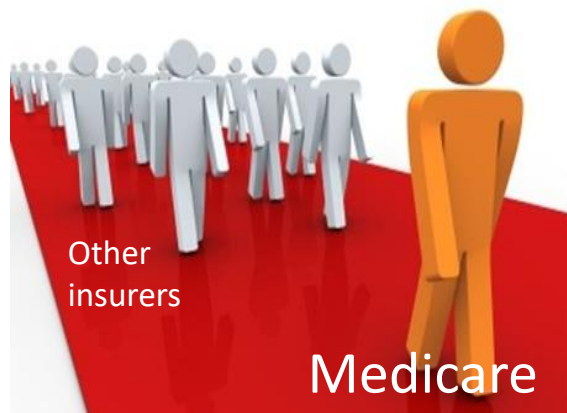
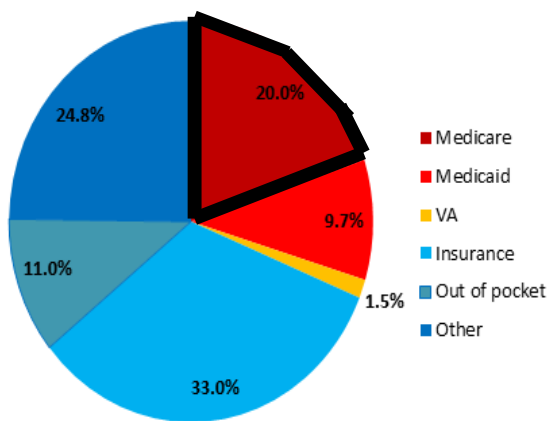
Part **3**

Mandate  
tools

# Part 4

Need for certification

# Payment Tools



PDA use =  
“condition  
for payment”

No  
PDA



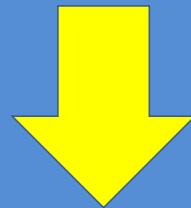
Logic

Medicare only pays

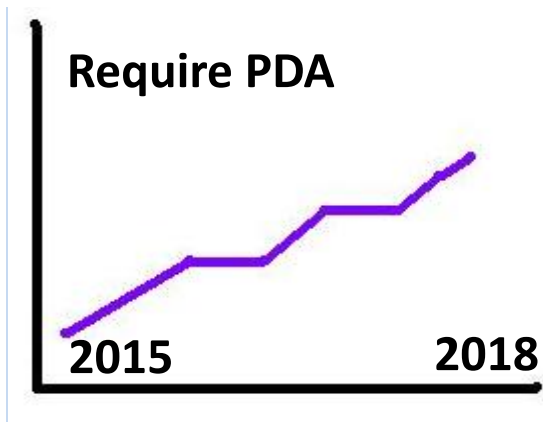
“**medical  
necessary**”

“Medically  
necessity” not  
a purely clinical  
determination

Unwanted



**Not** med. necc.



4 examples

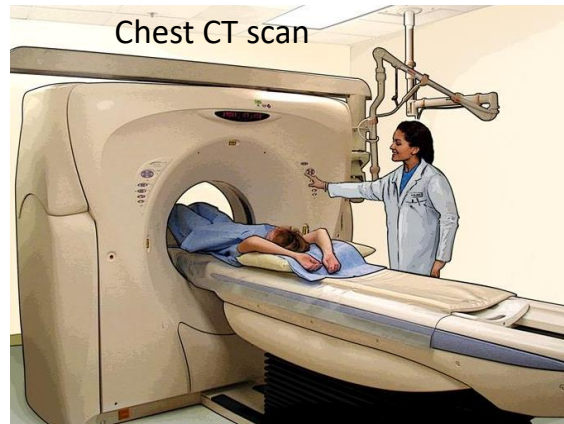
1

Screening for Lung  
Cancer with Low  
Dose Computed  
Tomography

National Coverage  
Determination  
Feb. 5, 2015

CAG-00439N

1<sup>st</sup> requirement  
of SDM for  
Medicare  
coverage



**Before**  
CT scan

**“must receive**  
... SDM visit”

**“include ...**  
one or more  
decision aids”





# Coding & Billing

**G0296**  
SDM

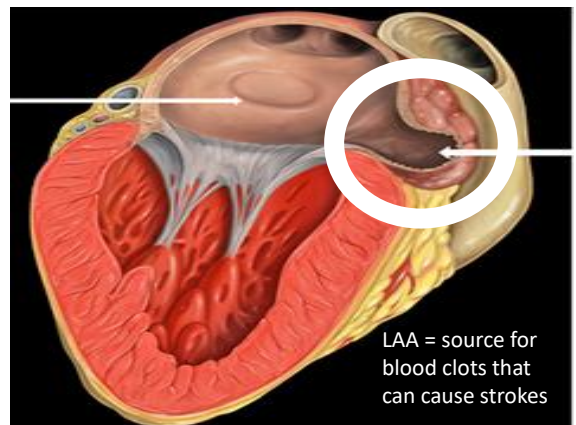
**G0297**  
CT scan

# 2

## Percutaneous Left Atrial Appendage Closure Therapy

National Coverage  
Determination  
Feb. 8, 2016

CAG-00445N



**Warfarin NA (Coumadin)**

**Thin blood with anticoagulant medication**

Mfg. By: Bristol-Myers Squibb Company  
Garden City, NY  
Repackaged by Aphena Pharma  
Cookeville, TN 38506

Warfarin NA (Coumadin) 2mg 90 Tablets

Batch:  
Exp:  
Lot:

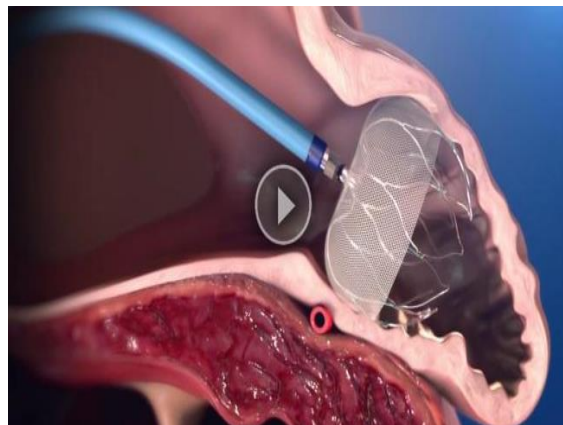
RX Only

Boston Scientific  
Advancing science for life®

PROFESSIONALS PATIENTS PRODUCTS ABOUT

**THERE'S AN ALTERNATIVE TO WARFARIN**

FOR PEOPLE WHO NEED ONE. IT'S CALLED WATCHMAN™.



**Before  
implantation**

“formal SDM  
interaction . . .  
evidence-based  
**decision tool**”

“with an  
**independent**  
non-interventional  
physician”

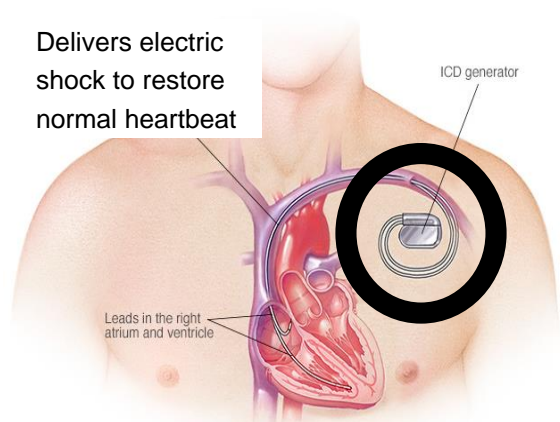


3

## Implantable Cardioverter Defibrillators

National Coverage  
Determination  
Feb. 15, 2018

CAG-00157R4



**Before**  
implantation

“formal SDM  
encounter  
**must occur**”

“evidence-based  
**decision tool**”

**Original**

SDM with an  
**“independent”**  
clinician

457 hospitals  
settle for  
\$250 million



THE UNITED STATES  
DEPARTMENT *of* JUSTICE

# BUT



December 20, 2017

“**delay** potentially lifesaving ICD”

# 4



~~Direct Decision Support Model~~

~~Canceled Feb. 2018  
Too burdensome~~

~~Shared Decision Making Model~~

~~Canceled Nov. 2017  
Not enough ACO interest~~

Quality  
measure  
for PFP (e.g. ACO)

Payment Tools  
State Level

5 examples

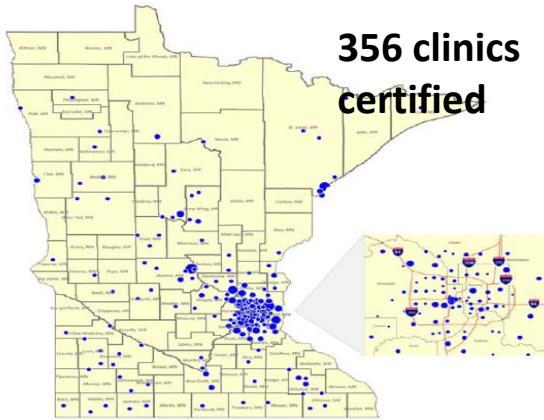
1



2010



Comprehensive  
**primary care** liked to  
wellness, prevention,  
self-management, and  
community services



Certification requires  
“participants are given  
the opportunity to fully  
engage in . . . **shared  
decision-making**”

Minn. Admin. 4764.0010 to 4764.0040

2

MASSACHUSETTS  
**PCMHI**  
Patient-Centered Medical Home Initiative

Mass. Law 6D § 14 (certify med homes)

**MASSACHUSETTS**  
HEALTH POLICY COMMISSION

Mass. Law 6D § 14 (certify ACOs)

3



# VERMONT2009

## *Shared Decision Making*

Report to the Legislature on Act 49, Section 4  
January 15, 2010

ACO cert.  
5.206(i)(2) 2018



Green Mountain Care Board



SENATE, No. 1891

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED FEBRUARY 15, 2018

Sponsored by:  
Senator TROY SINGLETON  
District 7 (Burlington)

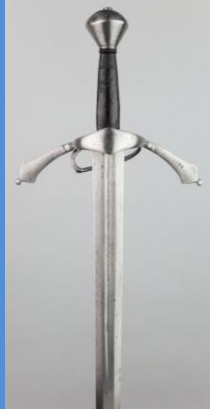
**Medicaid cover  
advance care  
planning**



“Advance care  
planning shall  
consist . . . **SDM** .  
. . . **decision aids**”

That’s federal  
and state  
**payment** tools

## Liability Tools



PDA  
as  
shield

**2** examples

1



**Safe harbor**  
for using PDA

2

*De facto*  
safe harbor

**Reactions of Potential Jurors to  
a Hypothetical Malpractice Suit  
Alleging Failure to Perform a  
Prostate-Specific Antigen Test**

*Michael J. Barry, Pamela H. Wescott, Ellen J. Reifler, Yuchao Chang,  
and Benjamin W. Moulton*

summer 2008


Malpractice  
premium  
discounts

That's PDA  
as **shield**



PDA  
as  
sword

Contrast  
WA

**TEXAS**  
Health and Human  
Services

Texas Department of State  
Health Services

Texas Medical  
Disclosure Panel

2/6/2017

Texas Medical Disclosure Panel

Figure: 25 TAC §601.8(1)

### DISCLOSURE AND CONSENT FOR HYSTERECTOMY

*TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.*

**NOTICE:** Refusal to consent to a hysterectomy will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving federal funds or otherwise affect your right to future care or treatment.

I (we) voluntarily request Dr. \_\_\_\_\_ as my physician, and such associates, technical assistants and other health care providers as they may deem necessary, to treat my condition which has been explained to me (us) as:

**No** form →

presumption that  
**violated** duty

Could use  
PDAs instead  
of “forms”

Summary of  
liability tools



Enhanced  
malpractice  
**protection**  
for using  
PDA



Expanded  
malpractice  
**exposure**  
for NOT  
using PDA

We looked at  
Payment tools  
Liability tools

Mandate  
Tools

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.

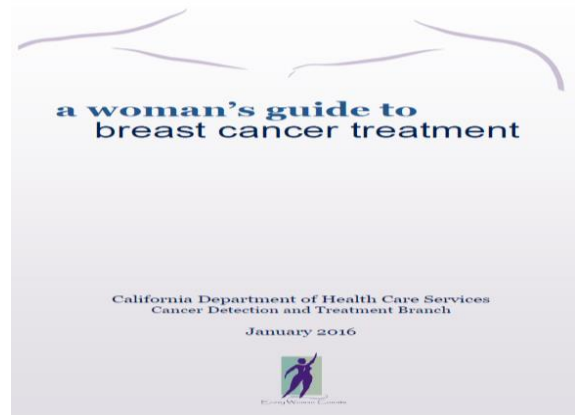
ACP  
AMERICAN COLLEGE OF PHYSICIANS  
ESTABLISHED 1915 • DEDICATED TO AIDING

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



“Mandated  
standardized  
written information  
for patients”



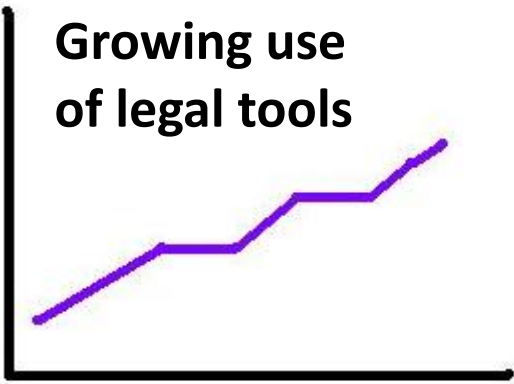
Still focused  
on **disclosure**



Could use  
PDAs instead  
of MSWI

**Need for  
Certification**

**Growing use  
of legal tools**



**2** problems

Problem **1**

Ineffective

“SDM”

**Plugged in**

to statutes &  
regulations

BUT



Not always  
defined



LDCT

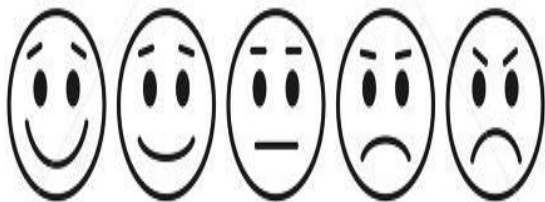
“not requiring . .  
. . a specific  
instrument . . .  
practitioners  
may select”

Doctor  
choice



# LAAC

“variable  
understanding . . .  
regarding the  
concept of SDM”



Problem **2**

# Rare



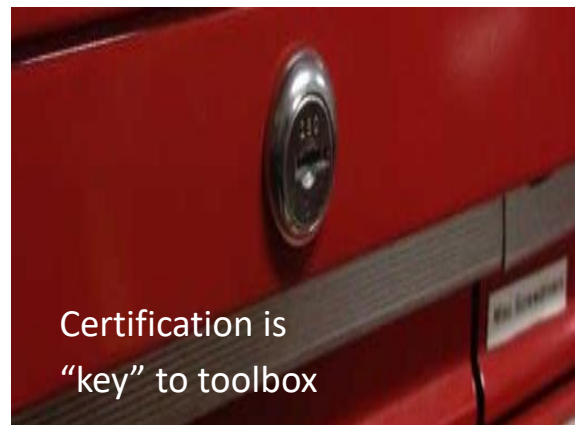
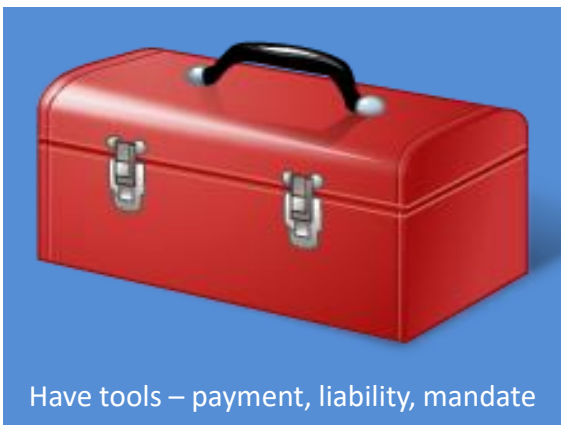
Obstacle

PDAAs widely  
**varying**  
quality

**Cannot**  
attach legal  
consequences

Assure PDA  
**quality**

**Conclusion**



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