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Law

Legal Briefing: Shared Decision Making and Patient Decision Aids

Thaddeus Mason Pope and Melinda Hexum

ABSTRACT

This "Legal Briefing" column covers recent legal developments involving patient decision aids. This topic has been the subject of recent articles in *JCE*.¹ It is included in the 2010 Patient Protection and Affordable Care Act.² And it has received significant attention in the biomedical literature, including a new book, a thematic issue of *Health Affairs*, and a recent article in the *New England Journal of Medicine*.³ Moreover, physicians and health systems across the United States are increasingly integrating decision aids into their clinical practice.⁴ Both federal and state laws play a significant role in promoting this expanded use. On the other hand, concerns about liability could stymie development and implementation. We categorize legal developments concerning patient decision aids into the following five sections:

1. Development of decision aids
2. Effectiveness of decision aids
3. Federal regulation of decision aids

4. State regulation of decision aids
5. Legal concerns regarding decision aids

1. DEVELOPMENT OF PATIENT DECISION AIDS

Over the past two decades it has become increasingly clear that the traditional informed consent process is deficient. It often fails to ensure that patients have the information and understanding necessary to make truly informed decisions regarding their medical treatment.⁵ This is particularly the case in the context of "preference sensitive treatment," situations in which no single treatment option is "correct" or clearly indicated over all others by the available medical evidence. Take, for example, the birth of a child with a disorder of sex development. Is it a boy or a girl? Should there be surgery? What kind? When?⁶ In such instances, there is more than one good option, more than one reasonable path forward. The best course of treatment for a particular patient depends on that patient's preferences, values, and cultural background.

In its 2001 *Crossing the Quality Chasm* report, the Institute of Medicine recommended greater use of decision aids to ensure that pa-

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tients' treatment decisions are consistent with their preferences and values.⁷ Today, there is a discernible shift away from traditional informed consent processes, toward shared decision making processes incorporating the use of decision aids. Indeed, the use of patient decision aids is perhaps the most rapidly growing means of addressing the failure of traditional informed consent.

Decision aids are educational "tools" that help patients understand the various treatment options available to them, including the risks and benefits of each choice.⁸ The tools include evidence-based educational literature with graphics, photographs, and diagrams. They also take the form of videos, website-based interactive programs such as sequential questions with feedback, and "structured personal coaching."⁹ But despite their self-directed and self-paced nature, decision aids do not supplant physician-patient conversation about treatment options. Instead, they supplement it, by better preparing patients to engage in that conversation.

Aids are already available for a large number of conditions, including breast cancer, prostate cancer, osteoarthritis, and childbirth.¹⁰ Many more decision aids are being developed by nonprofit and for profit companies and government entities. Nonprofit developers include: Advance Care Planning Decisions,¹¹ the Cardiff University Decision Laboratory,¹² Healthwise,¹³ the Informed Medical Decisions Foundation,¹⁴ and the Mayo Clinic.¹⁵ For-profit developers include: Dialog Medical,¹⁶ Emmi Solutions,¹⁷ Health Dialog,¹⁸ Krames StayWell,¹⁹ the Patient Education Institute,²⁰ and Welvie.²¹ Government developers include the U.S. Agency for Healthcare Research and Quality and the United Kingdom National Health Service RightCare.²²

2. EFFECTIVENESS OF PATIENT DECISION AIDS

Increasing focus on the aids is motivated by significant and growing evidence that they offer substantial benefits. Notably, a 2011 Cochrane Review of 86 studies found that patients who used decision aids were more knowledgeable about treatment options, less conflicted

about their decision, and more likely to play an active role in decision making than patients who did not.²³ Consequently, the patients who used decision aids may be better able to align their care with their preferences and values.

Furthermore, decision aids do more than improve patients' knowledge and satisfaction. They reduce the cost of care. Patients using decision aids are more likely to choose conservative treatment options, are less likely to choose surgical interventions,²⁴ are less likely to be admitted to the hospital.²⁵ And they are less likely to choose cardiopulmonary resuscitation.²⁶ One study estimates that implementing decision aids for 11 procedures would yield \$9 billion in savings in 10 years.²⁷ On the other hand, there remain some significant hurdles to implementation. For example, clinicians must be incentivized and trained to use them.²⁸

3. FEDERAL REGULATION OF PATIENT DECISION AIDS

Given that decision aids are a relatively recent development in clinical practice, it is not terribly surprising that there is relatively little government oversight of the development and use of such tools.²⁹ The most notable source of federal law that directly deals with patient decision aids is Section 3506 of the 2010 Patient Protection and Affordable Care Act (ACA).

The express purpose of Section 3506 is to facilitate shared decision making.³⁰ It aims to do this in three ways. First, Section 3506 directs the U.S. Department of Health and Human Services (DHHS) to contract with an entity that will "synthesize evidence" and establish "consensus-based standards" for evaluating decision aids. This entity must then develop a "certification process" to endorse decision aids that meet those standards.³¹ Second, Section 3506 promotes the development and clinical use of patient decision aids by directing DHHS to make grants or contracts to develop, update, produce, and test patient decision aids and to "educate providers on the use of such materials."³² Third, Section 3506 directs DHHS to provide grants for the implementation and effective use of decision aids.³³

Unfortunately, the Center for Medicare Services (CMS) has not yet moved forward on the first aim by selecting an entity to certify patient decision aids. However, CMS *has* moved forward on supporting the initiation of decision aid demonstration projects. For example, MaineHealth and the Mayo Clinic have been selected as “Shared Decision Making Resource Centers” to “disseminate best practices and other information to support and accelerate adoption, implementation, and effective use” of decision aids.³⁴ Furthermore, there are a number of other federal programs that authorize the funding of research on decision aids.³⁵

For example, Section 3021 of the ACA establishes the Center for Medicare and Medicaid Innovation (CMMI).³⁶ The CMMI is charged with testing and evaluating “innovative payment and service delivery models” to identify approaches that will provide cost savings or improve the quality of care for populations served by Medicare, Medicaid, or the Children’s Health Program (CHIP).³⁷ CMMI tests and evaluates models to determine if they either decrease program costs without reducing the quality of care, or increase the quality of care without increasing spending. When CMMI identifies such models, it has the authority to promulgate rules implementing these models on a nationwide basis, through federal health programs.³⁸

One of several models specifically identified by Section 3021 as an opportunity for CMMI to address costs or the quality of care is in assisting individuals to make “informed health care choices by paying providers of services and suppliers for using patient decision-support tools” that “improve applicable individual and caregiver understanding of medical treatment options.”³⁹ Thus, it is likely CMMI will address payment and delivery models involving patient decision aids.

Indeed, part of CMMI’s work includes making grants to organizations that will implement “the most compelling ideas to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid, and Children’s Health Insurance Program.”⁴⁰ In 2012, CMMI awarded the first batch of the “Health Care Innovation Awards.” While none of the awarded

projects appear to specifically focus on patient decision aids, many address the larger issue of shared decision making and probably involve the use of decision aids.⁴¹

Like CMMI, the Agency for Healthcare Research and Quality (AHRQ) has promoted the development and implementation of patient decision aids. Its Effective Health Care Program funds “effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers,” including studies related to development, testing, or implementation of patient decision aids.⁴² Additionally, it has made publicly available two decision aids, “plain-language guides,” that it contracted to develop—one for postmenopausal osteoporosis, the other for “clinically localized” prostate cancer.⁴³

A potential source of federal funding for the development, testing, or implementation of patient decision aids is the Patient-Centered Outcomes Research Institute (PCORI).⁴⁴ The ACA mandated the establishment of PCORI as a nongovernmental, nonprofit corporation, and charged it with funding comparative clinical effectiveness research.⁴⁵ This will increase the availability and quality of evidence that patients and healthcare providers need to make “informed health decisions.” In May 2012, PCORI indicated that one of its national priorities for research funding will be “communication and dissemination research,” including support of “shared decision making between patients and providers.”⁴⁶ This strongly suggested that PCORI would support decision aid research. PCORI’s subsequent award of its first cycle of grants has confirmed this. Of 25 grants initially awarded, at least two directly deal with assessing the efficacy of decision aids for improving medical decisions by patients and their families.⁴⁷

Lastly, federal regulations promote the implementation of patient decision aids by accountable care organizations (ACOs) that partake in the ACA’s Medicare Shared Savings Program (MSSP).⁴⁸ Under the MSSP, groups of physicians, hospitals, and other healthcare providers contract with the Centers for Medicare and Medicaid Services to accept responsibility for the “quality, cost and overall care” of an assigned group of Medicare beneficiaries.⁴⁹ As an

incentive to provide quality, cost-efficient care, providers will continue to be paid under the Medicare fee-for-service model, but will be eligible for “shared savings” payments if the ACO meets certain cost and quality benchmarks.⁵⁰

One of the quality benchmarks required of ACOs is that these organizations “define processes to promote . . . patient engagement.”⁵¹ CMS regulations issued in 2011 clarified this requirement, explaining that measures that would promote patient engagement “may include, but are not limited to, the use of decision support tools and shared decision making methods with which the patient can assess the merits of various treatment options in the context of his or her values and convictions.”⁵²

4. STATE REGULATION OF PATIENT DECISION AIDS

Since patient decision aids have been reported to both improve care and reduce costs, federal policy makers have not been the only ones incentivizing their use. State policy makers have also been enacting legislation and administrative regulation that promotes the use of decision aids.⁵³ Most notable among these states is Washington.⁵⁴ In 2007, Washington enacted legislation that called for a demonstration project. It also incentivized the use of decision aids by creating a legal safe harbor.⁵⁵ A “regular” signed consent form constitutes *prima facie* evidence that the patient gave her or his informed consent to the treatment administered. The patient has the burden of rebutting this by a preponderance of the evidence (showing it 51 percent likely that her or his consent was not informed). A signed acknowledgment of shared decision making also constitutes *prima facie* evidence that the patient gave her or his informed consent to the treatment administered. But the patient has the heavier burden of rebutting this presumption by clear and convincing evidence (showing it 70 to 80 percent likely that his or her consent was not informed).

Washington enacted further legislation in 2011 and 2012. The 2011 statute directs the Washington Health Care Authority (HCA) to convene a collaborative to “identify health care

services for which there are substantial variations in practice patterns or high utilization trends.” For such services, the statute directs the collaborative to “consider strategies that will promote improved care outcomes, such as patient decision aids.”⁵⁶ The 2012 statute, enacted in March, outlines a process for certifying decision aids.⁵⁷ By the end of 2012, the HCA had promulgated regulations defining the process by which it will certify patient decision aids.⁵⁸

Washington is not alone. In 2012, Massachusetts established a Center for Health Information and Analysis. Among other things, this center must “maintain a consumer health information website” containing “information comparing the quality, price and cost of health care services.” The statute mandates that, to the extent possible, this website must include decision aids “on but not limited to, long-term care and supports and palliative care.”⁵⁹

In 2009, Vermont enacted legislation calling for a shared decision-making demonstration project.⁶⁰ In 2010, the Vermont Blueprint for Health commenced a one-year shared decision-making pilot in the Barre Hospital Service Area.⁶¹ Similarly, in 2009, Maine enacted legislation calling for an “advisory group of stakeholders” to “develop a plan to implement a program for shared decision making.”⁶² In 2011, the group issued its final report, recommending a demonstration project.⁶³

At the regulatory level, in 2010, the Maine Board of Licensure in Medicine incorporated shared decision-making principles into its guidelines on informed consent.⁶⁴ That same year, the Minnesota Department of Health incorporated such principles into its certification requirements for healthcare homes.⁶⁵

Several other states have also explored promoting the use of decision aids. Legislation has been considered in Connecticut and Oklahoma.⁶⁶ In Minnesota, bills in 2009 and 2011 proposed requiring shared decision making for certain surgical procedures before reimbursement could be paid by a health plan company under contract with the state commissioner of human services or finance.⁶⁷ More legislation and regulation is sure to be considered and enacted by additional states over the next few years.

5. LEGAL CONCERNS ASSOCIATED WITH PATIENT DECISION AIDS

Regardless of whether the trend toward shared decision making and the emergence of patient decision aids effectively address all the problems associated with the traditional informed consent framework, it is clear that these changes have important legal implications. The relative newness of decision aids means that there is little systematic oversight of their development or use. But federal and state governments' intent to facilitate shared decision making, along with concerns regarding harm to patients from biased or inaccurate decision aids, make it likely that this will be an evolving area of law and regulation in the near future. Below, we summarize legal issues that are likely to emerge as the use of decision aids becomes more prevalent in clinical practice.

Lack of Oversight of the Quality of Patient Decision Aids

While patient decision aids have been promoted as a positive movement toward both more meaningful informed consent and more cost-effective care, there is also an emerging recognition that some kind of quality-control measures are needed to ensure that decision aids do not do more harm than good.⁶⁸ There are several features of patient decision aids that increase the likelihood of misinformation or bias, relative to other types of patient educational materials.⁶⁹

First, the aids are generally developed by third parties that are not involved in providing care to patients,⁷⁰ including professional associations, government agencies, hospitals and health centers, nonprofit organizations, and for-profit companies.⁷¹ There is concern that for-profit corporations and other decision-aid creators "have little incentive to maintain the integrity of their products other than market pressures to maintain good business practices. But in other contexts, such as environmental regulation, products liability, and pharmaceuticals, it has become clear that market pressures are often insufficient to protect consumers."⁷² Ad-

ditionally, the American Medical Association has expressed concern about the use of patient decision aids "by insurers and others" as a vehicle to steer or "nudge" patients toward less-expensive treatment options on the basis of biased or misleading information.⁷³

The creation and use of decision aids that are biased or misleading is exacerbated because they are generally used by patients outside interactions with their physicians, meaning that "physicians may have limited opportunities to mediate or interpret the information" provided by third parties in decision tools.⁷⁴ Further complicating the issue, patient aids are frequently used in medical decisions that "involve moral and political controversies that may impact the way information is provided to patients" (for example, reproductive issues).⁷⁵ The interaction of these elements raises concerns regarding quality and objectivity that are not yet addressed in a systematic way by private or government oversight.⁷⁶ Commentators have expressed the same concern about the development of clinical practice guidelines.⁷⁷

Fortunately, there is a growing recognition of the need for some kind of formal credentialing process.⁷⁸ A few nongovernmental organizations have already begun compiling and assessing the quality of available patient decision aids.⁷⁹ Notably, the International Patient Decision Aid Standards Collaboration (IPDAS) has developed a detailed set of evidence-based criteria to guide evaluation of the quality of decision aids.⁸⁰ These criteria include: (a) describing the health condition, (b) listing the options, (c) listing the option of doing nothing, (d) using visual diagrams, (e) using stories that represent a range of positive and negative experiences, (f) reporting the source of funding used to develop the materials, and (g) describing the quality of scientific evidence presented.

Similar to IPDAS, the Ottawa Hospital Research Institute (OHRI) has compiled a library of decision aids that meet a few basic criteria. To be included in OHRI's database, a decision aid must: (a) provide information about the "options and outcomes that are relevant to a patient's health status," (b) report the date it was most recently updated and be no more than five

years old, (c) “provide references to scientific evidence used,” (d) report conflicts of interest, and (e) be publicly available.⁸¹

The ACA’s mandate for the creation of an entity to establish criteria for certifying patient decision aids itself promises to provide at least some standardized indicia of quality to guide physicians’ use of such tools. However, this mandate has yet to yield a certifying entity, let alone standards or evaluation of specific decision aids. And the Washington HCA has not yet begun rating decision aids. This means that, at the moment, the issue of patient decision aids is largely devoid of oversight or standardization, absent the activities of nongovernmental organizations.

Does Use of Decision Aids Expand Liability for Healthcare Providers?

Under state common law or statute, physicians face liability for medical malpractice under a theory of informed consent if a patient is harmed as a result of a physician’s failure to disclose information necessary to make an informed medical decision.⁸² While the use of decision aids is intended to make the informed consent process more meaningful and effective, there are concerns the aids potentially create new opportunities for malpractice liability.

One concern is that physicians who use patient decision aids could be held liable for deviating from an existing standard of care, represented by the “traditional” informed consent process.⁸³ Washington, at least, addressed such concerns by creating statutory protections for physicians who engage in shared decision making with patients through the use of decision aids.⁸⁴ Under Washington law, a patient who signs “an acknowledgment of shared decision making” to consent to a particular treatment has to present a higher level of evidence to succeed in an informed consent suit than a patient who signed a regular consent form.⁸⁵ While such a law may make careproviders more willing to incorporate decision aids into their practice, Washington’s strategy of providing *greater* liability protections for physicians who use aids to facilitate shared decision making may not be

necessary. Use of such aids has the potential to improve physician-patient communication and overall satisfaction of patients with treatment decisions, which might reduce the incidence of medical malpractice claims in general.⁸⁶

Nadia Sawicki articulates another concern: that physicians will be found liable to patients harmed by decision aids that provided inaccurate or outdated information or presented information in a biased manner.⁸⁷ Under the “learned intermediary doctrine,” it is possible that physicians’ special knowledge regarding the practice of medicine may absolve “product manufacturers and information providers” from liability. With drugs and devices, for example, courts have generally refused to impose a duty to warn on manufacturers, because physicians are in the best position to evaluate risks and benefits and to communicate with patients. However, the learned intermediary doctrine is generally applied to pharmaceutical company package inserts. It is unclear whether it will readily extend to decision aids, particularly when the information provided by third parties is itself inaccurate or misrepresented.

Can Patients Recover from Creators of Inaccurate or Biased Decision Aids?

Another legal question raised by the increasing use of decision aids is whether patients harmed by inaccurate, biased, or otherwise defective aids will have any kind of meaningful redress against the creator or manufacturer of the aid. Sawicki argues that patients will be unlikely to succeed in a product liability suit against a manufacturer, because courts have generally determined that product liability does not apply “where injury arises as a result of the words or ideas within a book, pamphlet, brochure, or similar product.”⁸⁸ Other possible theories for lawsuits against creators of aids, such as negligence or negligent misrepresentation, also may be unlikely to succeed.

One of the problems with such suits in the decision aid context is the difficulty associated with proving causation under the current legal standards.⁸⁹ A patient suing for negligence based on a claim of inadequate informed consent gen-

erally has to prove that a “reasonable patient” would have not chosen the procedure had the defendant accurately conveyed its risks.⁹⁰ This “objective” standard for causation would likely be problematic in the context of patients suing the creators of decision aids, because decision aids are intended for use in “preference-sensitive” medical decisions,⁹¹ situations in which “clinical evidence does not clearly support one treatment option over another.”⁹² Thus, it is inherently unclear what treatment a “reasonable patient” would choose, since that decision depends on a patient’s values and preferences, not objective medical evidence.⁹³

Such quandaries have led commentators to call for courts and legislatures to abandon the “objective” causation standard in the context of informed consent suits in favor of a standard that recognizes the importance of the individual patient’s values and preferences.⁹⁴ Under a “subjective” causation standard, instead of determining whether a hypothetical reasonable patient would still have consented with disclosure, the jury determines whether *this particular patient* would still have consented.⁹⁵ In at least the short term, however, the take-home message is that patients who are harmed by biased or inaccurate decision aids will likely have difficulty finding legal recourse against the creators or manufacturer of these tools, unless current legal standards are altered to accommodate the changing face of informed consent.

CONCLUSION

Since its origins in the early 1970s, the doctrine of informed consent has been largely a creature of the common law. Depending on the jurisdiction, a physician must disclose either what a reasonable patient would deem material or what a prudent physician would disclose under the circumstances. The imminent federal certification of decision aids under Section 3506 may soon displace these state standards and impose much-needed consistency and uniformity to informed consent processes. We may finally close (or at least narrow) the persistent gap between the legal principles and the clinical reality of informed consent.

NOTES

1. T.M. Pope, “Legal Briefing: Informed Consent,” *The Journal of Clinical Ethics* 21, no. 1 (Spring 2010): 72-82.

2. Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, tit. III, sec. 3506, codified at 42 U.S.C. § 299b-36.

3. P.A. Ubel, *Critical Decisions: How You and Your Doctor Can Make the Right Medical Choices Together* (New York: HarperCollins 2012); “New Era of Patient Engagement,” *Health Affairs* 32, no. 2 (2013): 202-426; E.O. Lee and E.J. Emanuel, “Shared Decision Making to Improve Care and Reduce Costs,” *New England Journal of Medicine* 368, no. 1 (2013): 6-8.

4. C. Hsu et al., “Incorporating Patient Decision Aids into Standard Clinical Practice in an Integrated Delivery System,” *Medical Decision Making* 33, no. 1 (2013): 85-97; J.C. Brehaut, “Informed Consent Documents Do Not Encourage Good-Quality Decision Making,” *Journal of Clinical Epidemiology* 65, no. 7 (2012): 708-24; M. Hostetter and S. Klein, “Helping Patients Make Better Treatment Choices with Decision Aids,” *Quality Matters* (October-November 2012). Notably, Dialog Medical’s iMedConsent solution is being used in “more than 200 hospitals, and in thousands of physician practices.” <http://www.dialogmedical.com/products/>, accessed 15 February 2013. And 10 healthcare organizations, including Massachusetts General Hospital, are implementing and testing decision aids as “demonstration sites” for the Informed Medical Decisions Foundation. Decision aids are also being used in clinical trials. B.W. Palmer et al., “Effectiveness of Multimedia Aids to Enhance Comprehension of Research Consent Information: A Systematic Review,” *IRB: Ethics and Human Research* 34, no. 6 (2012): 1-15. Myrtus is evaluating how digital patient decision aids might simplify enrollment and enhance patients’ understanding during the informed consent process for human subject research. <http://www.myrtus.com/>, accessed 15 February 2013.

5. D. McCarthy et al., “What Did the Doctor Say? Health Literacy and the Recall of Medical Instructions,” *Medical Care* 50, no. 4 (2012): 277-82; F.J. Fowler Jr. et al., “Improving and Involving Patients to Improve the Quality of Medical Decisions,” *Health Affairs* 30, no. 4 (2011): 699-706; M. Brezis et al., “Quality of Informed Consent for Invasive Procedures,” *International Journal for Quality Health Care* 20, no. 5 (2008): 352-7; D.B. White et al., “Toward Shared Decision Making at the End of Life in Intensive Care Units Opportunities for Improvement,” *Ar-*

- chives of Internal Medicine* 167, no. 5 (2007): 461-7; J.S. King and B.W. Moulton, "Rethinking Informed Consent: The Case for Shared Medical Decision-Making," *American Journal of Law & Medicine* 32, no. 4 (2006): 429-501; M.M. Bottrell et al., "Hospital Informed Consent for Procedure Forms: Facilitating Quality Patient-Physician Interaction," *Archives of Surgery* 135, no. 1 (2000): 26-33; C.H. Braddock et al., "Informed Decision Making in Outpatient Practice: Time to Get Back to Basics," *Journal of the American Medical Association* 282, no. 24 (1999): 2313-20.
6. 42 U.S.C. § 299b-36(b)(2); Patient-Centered Outcomes Research Institute, "PCORI PFA Cycle I Awardees," (21 December 2012), <http://www.pcori.org/assets/PFA-Awards-Cycle-1-2012.pdf>, accessed 15 February 2013 (Decision Support for Parents Receiving Genetic Information about Child's Rare Disease, p. 21).
 7. IOM, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington, D.C.: National Academy Press, 2001).
 8. 42 U.S.C. § 299b-36(b)(1).
 9. B.L. McAneny, "Report of the Council on Medical Services," CMS Report 7-A-10: Shared Decision Making (2010), <http://www.ama-assn.org/resources/docs/cms/a10-cms-rpt-7.pdf>; accessed 15 February 2013. G. Elwyn et al., "Investing in Deliberation: A Definition and Classification of Decision Support Interventions for People Facing Difficult Health Decisions," *Medical Decision Making* 30, no. 6 (2010): 701-11.
 10. "Patient Decision Aids," Ottawa Research Hospital Institute, <http://decisionaid.ohri.ca/AZlist.html>, accessed 15 February 2013.
 11. <http://www.acpdecisions.org/>, accessed 15 February 2013.
 12. <http://www.decisionlaboratory.com/>, accessed 15 February 2013.
 13. <http://www.healthwise.org/>, accessed 15 February 2013.
 14. <http://www.informedmedicaldecisions.org/>, accessed 15 February 2013.
 15. <http://shareddecisions.mayoclinic.org/>, accessed 15 February 2013.
 16. <http://www.dialogmedical.com/> (developer of "iMedConsent"), accessed 15 February 2013.
 17. <http://www.emmisolutions.com/home>, accessed 15 February 2013.
 18. <http://www.healthdialog.com/Main/default>, accessed 15 February 2013.
 19. <http://kramestaywell.com/Home>, accessed 15 February 2013.
 20. <http://www.patient-education.com/> (developer of "X-Plain"), accessed 15 February 2013.
 21. <https://www.welvie.com/index.aspx>, accessed 15 February 2013.
 22. <http://www.effectivehealthcare.ahrq.gov/ehc/decisionaids/prostate-cancer/>, accessed 15 February 2013; <http://www.rightcare.nhs.uk>, accessed 17 February 2013.
 23. D. Stacey et al., "Decision Aids for People Facing Health Treatment or Screening Decisions," *Cochrane Database of Systematic Reviews* 10, no. CD001431 (2011): doi: 10.1002/14651858.CD001431.pub3.
 24. D. Arterburn et al., "Introducing Decision Aids at Group Health Was Linked to Sharply Lower Hip and Knee Surgery Rates and Costs," *Health Affairs* 31, no. 9 (2012): 2094-104; A.D.M. Kennedy et al., "Effects of Decision Aids for Menorrhagia on Treatment Choices," *Health Outcomes and Costs*, *Journal of the American Medical Association* 288, no. 21 (2002): 2701-8.
 25. D. Veroff et al., "Enhanced Support for Shared Decision Making Reduced Costs of Care for Patients with Preference-Sensitive Conditions," *Health Affairs* 32, no.2 (2013): 285-93.
 26. A.E. Volandes et al., "Randomized Controlled Trial of a Video Decision Support Tool for Cardiopulmonary Resuscitation Decision Making in Advanced Cancer," *Journal of Clinical Oncology* 31, no. 3 (2013): 380-6; A.E. Volandes et al., "A Randomized Controlled Trial of a Goals-of-Care Video for Elderly Patients Admitted to Skilled Nursing Facilities," *Journal of Palliative Medicine* 15, no. 7 (2012): 805-11; J. McCannon et al., "Augmenting Communication and Decision Making in the Intensive Care Unit with a Cardiopulmonary Resuscitation Video Decision Support Tool: A Temporal Intervention Study," *Journal of Palliative Medicine* 15, no. 12 (2012): 1382-7; A. El-Jawahri et al., "Use of Video to Facilitate End-of-Life Discussions with Patients with Cancer: A Randomized Controlled Trial," *Journal of Clinical Oncology* 28, no. 2 (2010): 305-10.
 27. Lewin Group, *Bending the Curve: Technical Documentation* (New York, N.Y.: Commonwealth Fund, 2008), <http://www.lewin.com/publications/Publication/325>, accessed 15 February 2013.
 28. G.A. Lin et al., "An Effort to Spread Decision Aids in Five California Primary Care Practices Yielded Low Distribution, Highlighting Hurdles," *Health Affairs* 32, no.2 (2013): 311-20; M.W. Friedberg, "A Demonstration of Shared Decision Making in Primary Care Highlights Barriers to Adoption and Potential Remedies," *Health Affairs* 32, no.2 (2013): 268-75; V.A. Shaffer, "Why Do Patients Derogate Physicians Who Use a Computer-Based Diag-

nostic Support System?” *Medical Decision Making* 33, no. 1 (2013): 108-18; D.L. Frosch et al., “Authoritarian Physicians and Patients’ Fear of Being Labeled ‘Difficult’ among Key Obstacles to Shared Decision Making,” *Health Affairs* 31, no. 5 (2012) 1030-8.

29. Even before the ACA, the Empowering Medicare Choices Act would have required the U.S. DHHS to promulgate regulations establishing standards and requirements for shared decision making under Medicare, based on the results of a pilot program. H.R. 2580, 111th Cong., 1st Sess. (2009) (Blumenauer, D-Ore.); S. 1133, 111th Cong., 1st Sess. (2009) (Wyden, D-Ore.). The companion bills ultimately died in committee.

30. The stated purpose of this section of the Affordable Care Act is to “facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages [sic] the patient, caregiver or authorized representative in decision making, provides patients, caregivers or authorized representatives with information about treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.” 42 U.S.C. § 299b-36(a).

31. 42 U.S.C. § 299b-36(c).

32. 42 U.S.C. § 299b-36(d).

33. 42 U.S.C. § 299b-36(e).

34. 42 U.S.C. § 299b-36(e).

35. In addition to those measures described below, Section 3013 of ACA authorizes DHHS to award grants to develop, improve, update, or expand “quality measures.” 42 U.S.C. § 299b-31. Section 3013 directs DHHS to prioritize those measures that allow the assessment of “use of shared decision making tools.” 42 U.S.C. § 299b-31(c)(2).

36. ACA § 3021, codified at 42 U.S.C. § 1315a(a).

37. ACA § 3021, codified at 42 U.S.C. § 1315a(a).

38. ACA § 3021, codified at 42 U.S.C. § 1315a(c).

39. ACA § 3021, codified at 42 U.S.C. § 1315a(b)(2)(B)(ix).

40. CMMS, CMMI, “Health Care Innovation Awards,” <http://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/>, accessed 15 February 2013.

41. CMMS, CMMI, “Healthcare Innovation Award Project Profiles,” <http://innovation.cms.gov/Files/x/HCIA-Project-Profiles.pdf>, last updated 30 July 2012. A search of the document for “decision” turned up a handful of projects with a focus on implementation of shared decision-making models, including: (1) MedExpert International, Inc.’s Quality Medical Management System, (2) the Trustees of Dartmouth College’s “Patient and Family Activators” project, and (3) Welvie, LLC’s “Shared decision-mak-

ing for preference-sensitive surgery” project.

42. 42 U.S.C. § 299b-7; <http://www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/>, accessed 15 February 2013; http://gold.ahrq.gov/projectsearch/grant_search.jsp, accessed 15 February 2013. Search in abstract title field for “decision aid” or “decision tool” for AHRQ-funded projects related to patient decision aids.

43. <http://effectivehealthcare.ahrq.gov/index.cfm/tools-and-resources/patient-decision-aids/>, accessed 15 February 2013.

44. R. Fleurence et al., “How the Patient-Centered Outcomes Research Institute Is Engaging Patients and Others in Shaping its Research Agenda,” *Health Affairs* 32, no. 2 (2013): 393-400.

45. ACA § 6301, codified at 42 U.S.C. § 1320e.

46. Patient-Centered Outcomes Research Institute, “National Priorities for Research and Research Agenda” (21 May 2012) <http://www.pcori.org/assets/PCORI-National-Priorities-and-Research-Agenda-2012-05-21-FINAL.pdf>, accessed 15 February 2013.

47. Patient-Centered Outcomes Research Institute, “PCORI PFA Cycle I Awardees” (21 December 2012) <http://www.pcori.org/assets/PFA-Awards-Cycle-1-2012.pdf>. At least two studies sought to assess whether decision aids improved the quality of decision-making or clinical outcomes (for pediatric type I diabetes, Shared Medical Decision Making in Pediatric Diabetes, p. 17; for chest pain patients in the emergency department, Shared Decision Making in the Emergency Department: The Chest Pain Trial, p. 4). One study sought to develop a decision tool to inform the medical decision making of parents of children with disorders of sex development (Decision Support for Parents Receiving Genetic Information about Child’s Rare Disease, p. 21).

48. ACA § 3022, codified at 42 U.S.C. § 1395jjj.

49. ACA § 3022, codified at 42 U.S.C. § 1395jjj(a-b).

50. ACA § 3022, codified at 42 U.S.C. § 1395jjj(b) & (d).

51. ACA § 3022, codified at 42 U.S.C. § 1395jjj(b)(2)(G).

52. DHHS, “Final Rule: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations,” 76 Fed. Reg. 67,802, 67,828 (2 Nov. 2011).

53. A. Shafir and J. Rosenthal, *Shared Decision Making: Advancing Patient-Centered Care through State and Federal Implementation* (Informed Medical Decisions Foundation, 2012); D.L. Frosch et al., “Shared Decision Making in the United States: Policy and Implementation Activity on Multiple Fronts,”

German Journal for Evidence and Quality in Health Care 105, no. 4 (2011) 305-12.

54. J. King and B. Moulton, "Group Health's Participation in a Shared Decision-Making Demonstration Yielded Lessons, Such As Role of Culture Change," *Health Affairs* 32, no. 2 (2013): 294-302.

55. Wash. S.B. 5930 (2007), enacted as 2007 Laws Ch. 259, codified at Wash. Rev. Code §§ 7.70.060 & 41.05.033.

56. Wash. H.B. 1311 (2011), enacted as 2011 Laws Ch. 313, codified at Wash. Rev. Code § 70.250.050.

57. Wash. H.B. 2318 (2012), enacted as 2012 Laws Ch. 101, codified at Wash. Rev. Code § 7.70.060.

58. Wash. Admin. Code §§ 182-60-005 to -030.

59. 2012 Mass. Acts. Ch. 224 § 19, codified at Mass. Gen. Laws Ann. 12C § 20.

60. Vt. S.B. 129 (2009) (Lunge); enacted as 2009 Act 49.

61. Vermont Department of Health, "VERMONT2009: Shared Decision Making: Report to the Legislature on Act 49, Section 4" (15 January 2010), <http://www.leg.state.vt.us/reports/2010ExternalReports/252637.pdf>, accessed 15 February 2013.

62. Me. LD 1358 (2009) (Mills), enacted as 2009 Maine Laws Ch. 104. The original bill would have required health insurance carriers and the MaineCare program to implement shared decision making.

63. Shared Decision Making Study Group for the Dirigo Health Agency's Maine Quality Forum, *The Practice and Impact of Shared Decision Making* (February 2011) http://muskie.usm.maine.edu/Publications/PHHP/Shared-Decision-Making_Final-Report.pdf, accessed 15 February 2013.

64. "INFORMED CONSENT: Guidelines from the Maine Board of Licensure in Medicine," <http://www.docboard.org/me/administrative/POLICIES/INFORMED%20CONSENT.doc>, accessed 15 February 2013.

65. Minn. Admin. Rules 4764.0040.

66. Conn. H.B. 5193 (2009) (Sayers); Okla. S.B. 1002 (2012) (Adelson).

67. Minn. S.F. 696, 86th Legis. Sess. (2009); Minn. H.F. 1140, 86th Legis. Sess. (2009); Minn. S.F. 542, 87th Legis. Sess. (2011) (Bergrlin).

68. The AMA Council on Medical Services notes that "the clinical quality and ethical design of patient decision aids will become increasingly important as the concept of shared decision making gains popularity." See McAneny, note 9 above. Legal commentators have also indicated the need for "credentialed, neutral bodies" to approve the information provided by patient decision aids to address the real potential for "biased" or "misleading" decision aids. See King and Moulton, note 5 above.

69. N. Sawicki, "Patient Protection and Decision-Aid Quality: Regulatory and Tort Law Approaches," *Arizona Law Review* 54, no. 3 (2012): 621-72.

70. *Ibid.*, 634-35.

71. *Ibid.*, 633.

72. *Ibid.*, 627.

73. See McAneny, note 9 above, p. 4.

74. See note 69 above, p. 634.

75. *Ibid.*, 634-35.

76. *Ibid.*, 626.

77. R. Avraham, "Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System," *American Journal of Law & Medicine* 37, no. 1 (2011): 7-40; M.J. Mehlman, "Medical Practice Guidelines as Malpractice Safe Harbors: Illusion or Deceit?" *Journal of Law, Medicine and Ethics* 40, no. 2 (2012): 286-300. Advance directives are also often developed by nonclinicians, yet meant for implementation by clinicians.

78. J.S. King and B. Moulton assert, "a rigorous accreditation process [for patient decision aids], such as the Cochrane System Review, is necessary to protect the interests of physicians and patients." They note, "While many creators of decision aids have spent significant time and resources developing their instruments and techniques, these efforts have largely been ad hoc and may differ substantially from one another. Additionally, these aids may be biased toward or against treatments." See King and Moulton, note 5 above, p. 490.

79. See Brehaut et al., note 4 above; J.E. Wennberg et al., "Extending the P4P Agenda, Part 1: How Medicare Can Improve Patient Decision Making and Reduce Unnecessary Care," *Health Affairs* 26, no. 1 (2007): 1564-74.

80. G. Elwyn et al., "Assessing the Quality of Decision Support Technologies Using the International Patient Decision Aid Standards Instrument (IPDASI)," *PLoS ONE* 4, no. 3: e4705, doi:10.1371/journal.pone.0004705.

81. Ottawa Hospital Research Institute, Decision Aid Library Inventory (DALI), <http://decisionaid.ohri.ca/cochinvent.php>, accessed 15 February 2013. For an exploration of the decision aids in the Ottawa Hospital Research Institute's Library, see <http://decisionaid.ohri.ca/AZinvent.php>, accessed 15 February 2013.

82. See note 1 above.

83. N.N. Sawicki, "Informed Consent Beyond the Physician-Patient Encounter: Tort Law Implications of Extra-Clinical Decision Support Tools," *Annals of Health Law* 21, no. 1 (2012): 1-10.

84. Wash. Rev. Code Ann. § 7.70.060.

85. Wash. Rev. Code Ann. § 7.70.060.

86. See King and Moulton, note 5 above; M.J. Barry, Jr., et al., "Reactions of Potential Jurors to a Hypothetical Malpractice Suit Alleging Failure to Perform a Prostate-Specific Antigen Test," *Journal of Law, Medicine and Ethics* 36, no. 2 (2008): 396-402.

87. See note 83 above, p. 9.

88. *Ibid.*, 7; see note 69 above, p. 644-45.

89. See note 83 above, p. 8; see note 69 above, p. 647.

90. Only four states—New Hampshire, Rhode Island, Oklahoma, and Oregon—have case law or statutes that reject the objective "reasonable patient" standard. E.M. Tenenbaum, "Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation," *Oklahoma Law Review* 64, no. 4 (2012): 697-758.

91. See note 69, p. 647; 42 U.S.C. § 299b-36 (intending to promote the use of patient decision aids for "preference sensitive care").

92. 42 U.S.C. § 299b-36(b)(2) (defining "preference sensitive care" as "medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option.").

93. See note 69 above, p. 647.

94. See Tenenbaum, note 90 above.

95. *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979).