

*The Future of Patient Decision Aids Post-Affordable Care Act Implementation: Whose Decision  
Is It Anyway?*

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THE FUTURE OF PATIENT DECISION AIDS POST-AFFORDABLE CARE ACT IMPLEMENTATION:  
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Introduction.....	1
I. The Rise of Decision Aids in Patient Treatment.....	3
A. Informed Consent Standard.....	4
B. Shared Decision-Making.....	6
II. Recent Changes in Decision Aid Standards.....	8
III. Changes in Federal Law.....	11
A. Conditions of Participation or Payment.....	12
B. ACA Programs.....	13
IV. Changes in State Law.....	16
A. Mandatory Decision Aid Use for Informed Consent.....	16
1. Physician Professional Disclosure Standard.....	18
2. Reasonable Patient Standard.....	19
B. Mandatory Decision Aid Use as a Condition of Payment.....	20
V. Recommendations for Federal and State Lawmakers.....	21
A. Physician Workload.....	22
B. Physician Discretion.....	23
C. Consistency and Effectiveness.....	25
D. Lower Costs.....	27
VI. Proposed Strategies for the Private Sector.....	28
A. Physicians Can Incorporate Decision Aids into Their Practices.....	28
B. Health Plans Can Require Decision Aid Use.....	30
Conclusion.....	31

## INTRODUCTION

Spencer is in excruciating pain. Spencer is a forty-five year old airport handler who has suffered with a chronic knee condition for the past ten years. A few days ago, Spencer's employer gave him the task of lifting heavy equipment. As Spencer was lifting a particularly heavy machine, he slipped and injured his right knee. Spencer promptly made an appointment with his primary care physician, who recommended that Spencer see an orthopedic surgeon.

When Spencer arrived for his appointment, he was examined by Dr. Smith, the orthopedic surgeon. After examining Spencer and taking x-rays, Dr. Smith determined that Spencer had a torn meniscus disk in his right knee. However, instead of providing Spencer with his recommended treatment options, Dr. Smith allowed Nurse Jones to come into the room and give Spencer several pamphlets regarding the potential treatment options for a torn knee.<sup>1</sup> The pamphlets discussed the risks of undergoing arthroscopic surgery to treat the injured knee and provided information on alternative treatments.<sup>2</sup> The pamphlets recommend against surgery. Spencer noticed that each pamphlet stated that it was certified by the federal government. Dr. Smith then entered the room. Dr. Smith had a different take on the risks and benefits of surgery from his own experience. He informed Spencer that he was required to provide Spencer with the pamphlets, but that he would recommend surgery because his previous patients have experienced a faster recovery with surgery. Dr. Smith did not provide further information because he had to attend to the next patient.

Spencer left the appointment confused. The pamphlet recommended alternatives to

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<sup>1</sup> For example, the Informed Medical Decisions Foundation has created a shared decision-making program on treatment options for a torn meniscus disk. See *What to Do with a Torn Meniscus?*, INFORMED MEDICAL DECISIONS FOUND., [http://www.informedmedicaldecisions.org/imdf\\_decision\\_aid/what-to-do-with-a-torn-meniscus/](http://www.informedmedicaldecisions.org/imdf_decision_aid/what-to-do-with-a-torn-meniscus/) (last visited Feb. 18, 2014); see also *Treatment & Drugs*, MAYO CLINIC, <http://www.mayoclinic.org/diseases-conditions/torn-meniscus/basics/treatment/con-20029237> (last visited Apr. 21, 2014).

<sup>2</sup> See *id.* The shared decision-making program created by the Informed Medical Decisions Foundation on this topic discusses alternatives to surgery, such as exercise and pain medications, and discusses the risks associated with surgery to repair the meniscus. *Id.*

surgery, but his physician believed that surgery was the best option. Which course of treatment should Spencer choose?

The above scenario illustrates a potential issue with federal and state regulation of information regarding the risks, benefits, and alternatives of treatment options. The pamphlet is an example of a decision aid, which is a tool utilized by physicians to inform patients of the risks, benefits, and alternatives to particular treatment options.<sup>3</sup> A decision aid is a form of physician “best practice,” meaning that decision aids are generally not required by law but are considered a beneficial treatment practice.<sup>4</sup> Section 3506 of the Patient Protection and Affordable Care Act (ACA) creates a program to review and certify patient decision aids.<sup>5</sup> However, the ACA does not specify whether physicians must incorporate federally-certified decision aids into their treatment practices. In addition, federal and statute authorities do not currently require physicians to use decision aids. Thus, it is unclear whether the federal government will mandate decision aid use in the future or whether decision aids will become the standard of care for state informed consent law. It is also unclear whether physicians and health plans should begin to incorporate decision aids into patient treatment practices in order to prepare for changes in federal or state law.

The decision aid certification program outlined in § 3506 of the Patient Protection and Affordable Care Act provides only a best practice standard for health care entities. This note will

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<sup>3</sup> Thaddeus Mason Pope & Melinda Hexum, *Legal Briefing: Shared Decision Making and Patient Decision Aids*, 24 J. CLINICAL ETHICS 70, 71 (2013) (discussing changes in state shared decision-making laws); Barry R. Furrow, *Regulating Patient Safety: The Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1727, 1766 (2011), available at [https://www.law.upenn.edu/journals/lawreview/articles/volume159/issue6/Furrow159U.Pa.L.Rev.1727\(2011\).pdf](https://www.law.upenn.edu/journals/lawreview/articles/volume159/issue6/Furrow159U.Pa.L.Rev.1727(2011).pdf); Samuel F. Hansen, *The Role of Decision Aids in the Affordable Care Act*, STAN. J. PUB. HEALTH (2013).

<sup>4</sup> See Nadia N. Sawicki, *Informed Consent Beyond the Physician-Patient Encounter: Tort Law Implications of Extra-Clinical Decision Support Tools*, 21 ANNALS HEALTH L. 1 (2012) (describing decision aids as part of the shared decision-making movement); Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 463-65 (2006) (describing decision aids as part of a shared decision-making best practice).

<sup>5</sup> Patient Protection and Affordable Care Act § 3506, 42 U.S.C. § 299b-36 (2012).

describe potential federal, state, and private responses to § 3506. Although both the federal government and state governments have the power to mandate federally-certified decision aid use, neither power should do so because a decision aid requirement is infeasible and interferes with physician autonomy. Private actors, on the other hand, should expand their use of decision aids because of increasing federal and state regulation.

Part I of this note will discuss the growth of shared decision-making and the rise of decision aids for patient treatment in the United States.<sup>6</sup> Part II will discuss the recent changes regarding decision aids and shared decision-making stemming from the Affordable Care Act.<sup>7</sup> Part III will discuss and develop federal options for expanding the decision aid program in the Affordable Care Act.<sup>8</sup> Part IV will discuss and develop the possibility that states will directly mandate decision aid use through conditions of payment for state healthcare programs or will indirectly mandate decision aid use through expansion of state informed consent law.<sup>9</sup> Part V will recommend that the federal government and individual states refrain from mandating decision aids for patient treatment.<sup>10</sup> Part VI will suggest that physicians and health plans expand their use of decision aids to prepare for possible federal and state decision aid use requirements.<sup>11</sup>

## I. THE RISE OF DECISION AIDS IN PATIENT TREATMENT

Decision aids developed as a mechanism for informing patients of the risks, benefits, and alternatives to proposed treatment options.<sup>12</sup> State informed consent law requires physicians to inform patients of the risks, benefits, and alternatives of treatment before conducting a course of

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<sup>6</sup> See *infra* Part I.

<sup>7</sup> See *infra* Part II.

<sup>8</sup> See *infra* Part III.

<sup>9</sup> See *infra* Part IV.

<sup>10</sup> See *infra* Part V.

<sup>11</sup> See *infra* Part VI.

<sup>12</sup> See *infra* Section I.B. (describing decision aids and their role in the shared decision-making process).

treatment.<sup>13</sup> The reason states require informed consent for patient treatment is based on the premise that patients make more informed decisions when they collaborate with physicians.<sup>14</sup>

#### A. Informed Consent Standard

A physician is negligent if he or she does not inform a patient of material risks, benefits, and alternatives of certain treatment options.<sup>15</sup> Under state informed consent law, the patient has the burden of proof to show that the physician violated the standard of care to inform the patient of the risks inherent in treatment and that the physician's negligence caused the plaintiff's injury.<sup>16</sup> The standard of care varies with jurisdiction.<sup>17</sup> In some states, a court will use a "professional disclosure" standard, which looks at whether a reasonable physician would have informed the patient of the risks and benefits of the proposed treatment options.<sup>18</sup> Other states follow a "reasonable patient" standard, which examines whether a reasonable patient in the patient's position would have found the risks to be material to their treatment decision and would have wished to have been informed of the different treatment options.<sup>19</sup> In the seminal case *Canterbury v. Spence*, the United States Court of Appeals for the D.C. Circuit adopted a "reasonable patient" standard. The Court reasoned that a physician "on the basis of his medical training and experience . . . can sense how the average, reasonable patient expectedly would react."<sup>20</sup> A physician in a jurisdiction adopting the "reasonable patient" standard must therefore

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<sup>13</sup> King & Moulton, *supra* note 4, at 439-40, 449-50.

<sup>14</sup> See 1 CCH, CCH'S LAW, EXPLANATION AND ANALYSIS OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT INCLUDING RECONCILIATION ACT IMPACT 421 (2010) [hereinafter CCH'S LAW, EXPLANATION AND ANALYSIS].

<sup>15</sup> *Id.*; William G. Cobb, *Defending the Informed Consent Case*, 72 DEFENSE COUNS. J. 330, 336 (2005); see VICTOR E SCHWARTZ, KATHRYN KELLY & DAVID F. PARTLETT, PROSSER, WADE AND SCHWARTZ'S TORTS 196 (12th ed. 2010).

<sup>16</sup> See generally *Malpractice: Physician's Duty to Inform Patient of the Nature and Hazards of Disease and Treatment*, 79 A.L.R.2d 1028 (1961).

<sup>17</sup> Cobb, *supra* note 15, at 332-36.

<sup>18</sup> *Id.* at 333-39.

<sup>19</sup> *Id.*; see also King & Moulton, *supra* note 4, at 458. Some states follow an objective causation standard, while others follow a subjective causation standard. Cobb, *supra* note 15, at 339; see also *Sard v. Hardy*, 379 A.2d 1014 (Ma. 1977) (objective); *Wilkinson v. Vessey*, 295 A.2d 676 (R.I. 1972) (subjective).

<sup>20</sup> *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972).

determine which risks and benefits the patient would deem significant.<sup>21</sup>

In addition, the patient must prove causation between the physician's negligence and the patient's injury.<sup>22</sup> The majority of states use an objective causation standard, which examines whether a reasonably prudent person would have consented to the treatment after all material risks were disclosed.<sup>23</sup> However, some states will use a subjective standard, which examines whether the plaintiff would have consented to the procedure after being informed of the risks.<sup>24</sup> In either situation, the patient must prove that there was a causal relationship between the physician's failure to provide adequate information for informed consent and the patient's injury.<sup>25</sup>

"Informed consent" is a vague standard. It is not clear what a physician must disclose to a patient in order to avoid liability under state law. One scholar recommends that physicians inform patients of the nature of the risks inherent in a treatment option, the material risks of the treatment options, the probability that the risk will come to fruition, the existence of alternative treatments, and the risks of not seeking treatment in order to meet the informed consent standard.<sup>26</sup> Thus, the physician must inform a patient of several different factors involved in a healthcare treatment option in order to avoid liability under state informed consent law.<sup>27</sup>

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<sup>21</sup> See *id.* (citing Waltz & Scheuneman, *Informed Consent to Therapy*, 64 N.W.U. L. REV. 628, 639-40 (1970) ("[a] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.")).

<sup>22</sup> Cobb, *supra* note 15, at 339.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*; see also Scott v. Bradford, 606 P.2d 554 (Okla. 1979) (stating that one element of the informed consent standard is whether the patient would have consented to the treatment had he or she been informed of the risks of treatment).

<sup>25</sup> See *supra* notes 23-24 and accompanying text.

<sup>26</sup> *Id.* at 340.

<sup>27</sup> See *id.*

## B. Shared Decision-Making

The idea of shared decision-making stems from the law of informed consent. The doctrine of shared decision-making strives to involve the patient in the treatment process.<sup>28</sup> Informed consent law is therefore vital to the shared decision-making process because informed consent requires physicians to consider alternative treatments and involve patients in the decision-making process.<sup>29</sup>

Decision aids have developed as a method of shared decision-making.<sup>30</sup> The Affordable Care Act defines a decision aid as an “educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, beliefs and preferences.”<sup>31</sup> Decision aids include books, pamphlets, DVDs, CDs, and other materials that help patients to make informed decisions concerning their medical care.<sup>32</sup> Decision aids are created and certified through a time-consuming process that involves research into the different treatment options for a medical problem.<sup>33</sup> First, decision aids are created by private entities that conduct research and recommend options.<sup>34</sup> Third party credentialing services then credential the decision aids.<sup>35</sup> Ultimately, the result is a book, pamphlet, or CD that the patient can review and come to a

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<sup>28</sup> See King & Moulton, *supra* note 4, at 463-64 (describing the structure and the goals of shared decision-making).

<sup>29</sup> See *id.* (describing shared decision-making as a “species to arise in the evolution of informed consent”).

<sup>30</sup> See CCH’S LAW, EXPLANATION AND ANALYSIS, *supra* note 14, at 422 (defining a patient decision aid as “an educational tool that helps patients and caregivers to understand and communicate their beliefs and preferences as related to their medical care”).

<sup>31</sup> Patient Protection and Affordable Care Act § 3506, 42 U.S.C. § 299b-36 (2012).

<sup>32</sup> Pope & Hexum, *supra* note 3, at 71; Furrow, *supra* note 3, at 1766; Hansen, *supra* note 3.

<sup>33</sup> King & Moulton, *supra* note 4, at 449-50, 464-66.

<sup>34</sup> See King & Moulton, *supra* note 4, at 465-66 (describing the process for manufacturing and certifying decision aids).

<sup>35</sup> See, e.g., *Decision Aids*, INFORMED MED. DECISIONS FOUND., <http://www.informedmedicaldecisions.org/shared-decision-making-in-practice/decision-aids/> (last visited Feb. 2, 2014). Some examples of third party credentialing services include the International Patient Decision Aid Standards Collaboration (IPDAS) and the Ottawa Hospital Research Institute (OHRI). Pope & Hexum, *supra* note 3, at 74-75.



treatment decision.

Originally, decision aids were a form of physician best practice, and physicians did not have to incorporate decision aids into their practices.<sup>36</sup> Instead, decision aids were mainly used by physicians for patient treatment options that had a wide difference in potential outcomes, a wide difference between short-term and long-term outcomes, and were even occasionally used when there was a very minimal difference between outcomes.<sup>37</sup>

In some states, however, the use of decision aids alters the standard of review for informed consent cases in favor of physicians. For example, the state of Washington has enacted legal protections for physicians utilizing decision aids.<sup>38</sup> A signed informed consent form provides prima facie evidence of consent.<sup>39</sup> The patient then has burden to rebut the signed consent form by a preponderance of the evidence.<sup>40</sup> If the patient signs a shared decision-making form instead of a traditional informed consent form, the patient must rebut the form by clear and convincing evidence.<sup>41</sup> Thus, if a physician uses a decision aid and has the patient signed a shared decision-making form, the patient has to rebut the presumption of informed consent with a higher burden of proof. The Washington law is now turning into a program to certify patient decision aids.<sup>42</sup> Washington recently enacted two statutes, one in 2011 and the other in 2012.<sup>43</sup> The first directs a state agency to consider strategies, such as the use of decision aids, for services with variations or high utilization.<sup>44</sup> It is unclear whether the agency will mandate decision aid use for services with high utilization or high variation. The second statute outlines a

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<sup>36</sup> Pope & Hexum, *supra* note 3, at 74.

<sup>37</sup> Annette O'Connor, *Using Patient Decision Aids to Promote Evidence-Based Decision Making*, 6 EVID. BASED MEDICINE 100 (2001).

<sup>38</sup> Pope & Hexum, *supra* note 3, at 73.

<sup>39</sup> *C.f.* Sawicki, *supra* note 4, at 4-5.

<sup>40</sup> *Id.*

<sup>41</sup> Pope & Hexum, *supra* note 3, at 73; Sawicki, *supra* note 4, at 1, 4-5.

<sup>42</sup> Pope & Hexum, *supra* note 3, at 73.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

process for certifying decision aids.<sup>45</sup> The Washington Health Care Authority (HCA) has passed regulations outlining the decision aid certification process.<sup>46</sup> Thus, decision aids are becoming a vital component of the informed consent standard in Washington, despite the absence of a direct mandate for their use.

Other states have also begun to incorporate decision aids into informed consent standards. For example, Vermont and Maine recently passed legislation establishing shared decision-making demonstration projects.<sup>47</sup> Other states, such as Connecticut and Oklahoma, are considering decision aid legislation.<sup>48</sup> Although none of these states have altered their informed consent standard to include decision aids, this trend toward shared decision-making indicates that other states may follow Washington's lead and incorporate decision aids into their informed consent laws.

## II. RECENT CHANGES IN DECISION AID STANDARDS

The federal government became involved with decision aid production with the passage of the Patient Protection and Affordable Care Act (ACA) in 2010. The ACA is a comprehensive health care reform measure that overhauls many areas of the law related to the health care industry.<sup>49</sup> In particular, § 3506 of the ACA creates a certification and grant program for patient decision aids.<sup>50</sup>

The ACA directs the Secretary of Health and Human Services (HHS) to create a program for developing and certifying patient decision aids.<sup>51</sup> Section 3506 of the Affordable Care Act

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<sup>45</sup> *Id.*

<sup>46</sup> *See id.* (citing WASH. ADMIN. CODE §§ 182-60-005 *et seq.* (2013)).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *See generally* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (codified in scattered sections of 21, 25-26, 29, and 42 U.S.C.).

<sup>50</sup> Patient Protection and Affordable Care Act § 3506, 42 U.S.C. § 299b-36 (2012).

<sup>51</sup> *Id.*

requires HHS to contract with a decision aid certifier to endorse decision aids focused on “preference-sensitive care,” which is defined 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, the use of such care should depend on the informed patient choice among clinically appropriate treatment options.<sup>52</sup>

The duties of the entity with which HHS will contract include developing standards for decision aids and endorsing decision aids.<sup>53</sup> The third-party entity will gather evidence, review decision aids, and develop a certification process.<sup>54</sup>

The ACA also provides several guidelines for the decision aids. The law states that decision aids:

(A) shall be designed to engage patients, caregivers, and authorized representatives in informed decision-making with health care providers;

(B) shall present up-to-date clinical evidence about the risks and benefits of treatment options in a form and manner that is age-appropriate and can be adapted for patients, caregivers, and authorized representatives from a variety of cultural and educational backgrounds to reflect the varying needs of consumers and diverse levels of health literacy;

(C) shall, where appropriate, explain why there is a lack of evidence to support one treatment option over another; and

(D) shall address health care decisions across the age span, including those affecting vulnerable populations including children.<sup>55</sup>

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<sup>52</sup> *Id.*; see also CCH’S LAW, EXPLANATION AND ANALYSIS, *supra* note 14, at 422 (defining preference-sensitive care as “medical care for which the evidence the clinical evidence does not clearly support one treatment option, so that the treatment depends upon the values and preferences of the patient”).

<sup>53</sup> § 3506. With regard to developing and identifying standards for decision aids, § 3506 states, “The entity shall synthesize evidence and convene a broad range of experts and key stakeholders to develop and identify consensus-based standards to evaluate patient decision aids for preference sensitive care.” *Id.* In addition, “[t]he entity shall review patient decision aids and develop a certification process whether patient decision aids meet the standards developed and identified under subparagraph (A). The entity shall give priority to the review and certification of patient decision aids for preference sensitive care.” *Id.*

<sup>54</sup> CCH’S LAW, EXPLANATION AND ANALYSIS, *supra* note 14, at 422.

<sup>55</sup> *Id.*

Decision aids must inform patients of the risks and benefits of treatment options, explain treatment options or the lack thereof, and provide information to a target audience.<sup>56</sup> The law does not elaborate on the certification process. Instead, HHS will determine the specifics of the program through regulations.<sup>57</sup>

The Secretary of Health and Human Services will establish a grant program for funding the endeavor.<sup>58</sup> The purpose of the grants will be to develop decision aids, test decision aids, and educate providers on decision aid use.<sup>59</sup> Grants will go to providers at HHS's discretion.<sup>60</sup> The law further provides that HHS must create a program to "provide for the phased-in development, implementation, and evaluation of shared decisionmaking using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options."<sup>61</sup> The law does not elaborate on how HHS should "phase-in" decision aids or which programs HHS must use to incorporate decision aids.

The ACA further provides that the contract with a third-party entity will last for eighteen months and will be renewed after a bidding process.<sup>62</sup> The ultimate result of § 3506 will be the development of Shared Decision-Making Resource Centers, which will present current information to physicians.<sup>63</sup> The exact structure and function of the resource centers remains unclear. The certification program and the Shared Decision-Making Resource Centers program

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<sup>56</sup> *Id.*

<sup>57</sup> *See* § 3506.

<sup>58</sup> *Id.*

<sup>59</sup> CCH'S LAW, EXPLANATION AND ANALYSIS, *supra* note 14, at 422-23.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> § 3506; *see also* CCH'S LAW, EXPLANATION AND ANALYSIS, *supra* note 14, at 423. The law states that the Shared Decisionmaking Resource Centers will "provide technical assistance to providers and . . . develop and disseminate best practices and other information to support and accelerate adoption, implementation, and effective use of patient decision aids and shared decisionmaking by providers." § 3506.

were set to begin as soon as practicable after the ACA was enacted.<sup>64</sup> As of this writing, the programs do not exist.

The decision aid certification process outlined in § 3506 raises many questions. For example, will the decision aids certified by the federal government become mandatory conditions of participation or payment in federal or state health care programs? Will physicians be required to use federally-certified decision aids under state informed consent law? Should physicians begin to incorporate decision aids into their practice if they have not already done so? Currently, the Department of Health and Human Services (HHS) has not issued regulations regarding certification of patient decision aids; therefore, many of these questions remain unanswered. This note will attempt to answer some of these questions and provide guidance to physicians and health plans.

### III. CHANGES IN FEDERAL LAW

The ACA does not include a provision mandating the use of decision aids for patient treatment. Instead, the law merely requires HHS to create a program to fund and certify decision aids.<sup>65</sup> Section 3506 of the ACA, therefore, is aspirational in nature. It is unclear, however, whether the drafters of the ACA intended § 3506 to culminate in a mandatory program. There are two main avenues that the federal government could take to require that physicians use HHS-certified decision aids for patient treatment. The first would be to mandate decision aid use as a condition of participation or payment in the Medicare or Medicaid programs. The federal government could also decide to incorporate decision aids into federal shared decision-making programs.

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<sup>64</sup> CCH'S LAW, EXPLANATION AND ANALYSIS, *supra* note 14, at 422.

<sup>65</sup> *See supra* Part II (explaining that the law does not require physicians to utilize decision aids, but rather creates a certification program).

## A. Conditions of Participation or Payment

HHS may choose to require physicians to use federally-certified decision aids as part of the Medicare or Medicaid conditions of participation or payment. The HHS Centers for Medicare and Medicaid Services (CMS) mandates certain conditions for participation and conditions for payment within the Medicare and Medicaid programs.<sup>66</sup> CMS may choose to mandate decision aid use as part of the Medicare or Medicaid conditions of participation.<sup>67</sup> This would mean that a physician must agree to provide patients with federally-certified decision aids in order to participate in Medicare or Medicaid.<sup>68</sup> Alternatively, CMS may decide to require decision aid use under the Medicare conditions of payment.<sup>69</sup> This would mean that physicians must provide proof of decision aid use in order to be reimbursed under Medicare or Medicaid.<sup>70</sup> The practical result of requiring that physicians use federally-certified decision aids as conditions of participation or payment will likely be that all physicians, even those who do not participate in federal payment programs, will have to incorporate decision aids into their practices due to the pervasive scope of the Medicare and Medicaid programs.<sup>71</sup> If a physician desired to participate in

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<sup>66</sup> *Conditions for Coverage (CfCs) & Conditions of Participations (CoPs)*, CMS.GOV (Nov. 6, 2013, 9:36 AM), <http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/CFCsAndCoPs/> (conditions of participation); *PFFS Plan Terms and Conditions of Payment*, CMS.GOV (Mar. 6, 2014, 12:05 AM), <http://www.cms.gov/Medicare/Health-Plans/PrivateFeeForServicePlans/TermsandConditions.html> (conditions of payment).

<sup>67</sup> Emily Oshima Lee & Ezekiel J. Emanuel, *Shared Decision Making to Improve Care and Reduce Costs*, 368 *NEW ENG. J. MED.* 6 (2013) (indicating that “CMS could rapidly certify [decision aids] and require their use in the Medicare and Medicaid programs”).

<sup>68</sup> *See id.*

<sup>69</sup> *See Lee & Emanuel, supra* note 67 (proposing that “full Medicare reimbursement could be made contingent on having documentation in the patient’s file of the proper use of a decision aid”).

<sup>70</sup> *See id.* (“Providers who did not document the shared-decision-making process could face a 10% reduction in Medicare payment for claims related to the procedure . . .”).

<sup>71</sup> For example, Medicaid covers 31 million children, 11 million non-disabled adults and 4.6 million dual-eligible senior citizens. *See By Population*, MEDICAID.GOV, <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Population/By-Population.html> (last visited Mar. 28, 2014). Medicare, by comparison, covered about 50 million beneficiaries in 2012. *See Total Number of Medicare Beneficiaries*, THE KAISER FAMILY FOUND., <http://kff.org/medicare/state-indicator/total-medicare-beneficiaries/> (last visited Mar. 28 2014). Recent data revealed by CMS states that over 880,000 providers received Medicare payment in 2012. *See Chad Terhune, Noam N. Levey & Doug Smith, Release of Medicare Doctor Payments Shows Some Huge Payouts*, L.A. TIMES (Apr. 8, 2014, 9:00 P.M.), <http://www.latimes.com/business/la-fi-medicare-doctor-pay-20140409,0,6562889.story#axzz2yNxUBTDz>.

the Medicare and Medicaid programs, he or she would have to use federally-certified decision aids. Even a physician who does not participate in a federal payment program may have to follow Medicare and Medicaid conditions of participation and payment as a condition of working with a health plan, insurer, or hospital.<sup>72</sup> Therefore, incorporating decision aids into Medicare or Medicaid conditions of payment or participation could have a vast impact on physician treatment practices and could effectively mandate federally-certified decision aid use.

## B. ACA Programs

Another course the federal government could take to mandate decision aid use would be to incorporate decision aids into federal programs implemented under the ACA, such as the Accountable Care Organization (ACO) program, and require decision aid use in these programs. Thus, all participants in federal programs developed under the ACA would have to utilize federally-certified decision aids. As these programs grow in size, decision aid use would become more widespread.

Section 3506 of the ACA does not require HHS to incorporate decision aids into any particular federal program. The law does, however, state that HHS will “establish a program to provide for the phased-in development, implementation, and evaluation of shared decisionmaking using patient decision aids . . . .”<sup>73</sup> Thus, HHS has the discretion to incorporate decision aids into federal programs that use shared decision-making because the ACA specifies that decision aids should be used in “phasing-in” shared decision-making.<sup>74</sup> Since the ACA does not specify which programs HHS should develop, HHS has discretion to develop a variety of

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<sup>72</sup> For example, a health plan could require a physician to utilize federally-certified decision aids if the health plan decides to follow Medicare and Medicaid requirements. A hospital may also require physicians to use federally-certified decision aids as a condition of staff privileges. If the hospital accepts Medicare and Medicaid payment, the hospital may seek uniformity and may require all physicians to follow Medicare and Medicaid requirements.

<sup>73</sup> Patient Protection and Affordable Care Act § 3506, 42 U.S.C. § 299b-36 (2012).

<sup>74</sup> *See id.*

shared decision-making programs and incorporate decision aids into the programs.

The ACA established the Medicare Shared Savings Program, which HHS determined will be carried out through the use of Accountable Care Organizations (ACOs).<sup>75</sup> ACOs are voluntary shared savings programs that require participating providers to meet certain quality performance standards.<sup>76</sup> Providers who participate in ACOs may receive a share of the savings generated from the program.<sup>77</sup> Those providers eligible for participation in an ACO program include physician group practices, networks of individual physicians, partnerships or joint ventures between hospitals and physicians, hospitals, and certain critical access hospitals.<sup>78</sup> Importantly, participation in an ACO program requires ACOs to have a process to achieve “patient engagement.”<sup>79</sup> CMS defines patient engagement as “the active participation of patients and their families in the process of making medical decisions.”<sup>80</sup> Currently, ACO providers may use decision aids for patient engagement, but decision aids are not required.<sup>81</sup>

Although providers do not currently need to utilize decision aids in order to participate in the ACO program, CMS has the ability to mandate their use.<sup>82</sup> For example, CMS has discretion to define “patient engagement.”<sup>83</sup> Thus, CMS could alter the current definition of “patient engagement” to include the use of federally-certified decision aids. As ACOs grow in size and scope, more and more providers will be required to incorporate patient engagement practices into

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<sup>75</sup> BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY STOLTZFUS JOST & ROBERT L. SCHWARTZ, *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 803 (West Publishing Co. 2013); MCDERMOTT, WILL & EMERY, *THE CONTROVERSIAL DRAFT MEDICARE ACO REGULATIONS: ANALYSIS, COMMENTS AND RECOMMENDED ACTION* 16 (Gary Scott Davis ed., 2011).

<sup>76</sup> MCDERMOTT, WILL & EMERY, *supra* note 75, at 1.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 2.

<sup>79</sup> *Id.* at 7-8 (citing Patient Protection and Affordable Care Act § 3022(b)(2)(G)).

<sup>80</sup> *Id.* at 8.

<sup>81</sup> *See id.* (Measures for promoting patient engagement may include the use of decision support tools . . .”).

<sup>82</sup> *See* Pope & Hexum, *supra* note 3, at 72-73.

<sup>83</sup> MCDERMOTT, WILL & EMERY, *supra* note 75, at 8.



patient treatments.<sup>84</sup> If CMS interprets the term “patient engagement” to include the use of federally-certified decision aids, then physicians who participate in the ACOs will be required to comply with the CMS requirements and incorporate decision aids into their practices.

The federal government may also utilize other federal programs governing shared decision-making and quality of care to mandate decision aid use. One example is the Center for Medicare and Medicaid Innovation (CMMI), which was established in the ACA as a federal program in charge of testing programs for cost savings and quality.<sup>85</sup> Other examples include the Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI).<sup>86</sup> Currently, HHS has not integrated decision aids into any of its quality programs. However, it is possible that HHS will use one of these entities as the conduit through which it will establish the decision aid certification program.<sup>87</sup> The entities may then use their regulatory powers to require physicians to integrate decision aids into their treatment practices.<sup>88</sup>

Although § 3506 does not require physicians to incorporate decision aids into their practices, it is possible that the federal government could mandate federally-certified decision aid use in the future through conditions of payment or participation in federal healthcare payment programs or by incorporating decision aids into ACA shared savings programs. Until HHS issues regulations on this issue, however, physician participation remains voluntary.

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<sup>84</sup> *Cf. id.*

<sup>85</sup> *See Pope & Hexum, supra note 3, at 72.*

<sup>86</sup> *See id.*

<sup>87</sup> *See id.*

<sup>88</sup> *See id.* (describing the relative powers of each entity and their potential role in the certification process).

#### IV. CHANGES IN STATE LAW

The enactment of § 3506 of the ACA also raises the question of whether states can mandate decision aid use. As discussed above, § 3506 of the ACA does not require states to mandate decision aid use.<sup>89</sup> Thus, states are free to consider the federally-mandated decision aids as evidence of the standard of care in an informed consent case, rather than as setting the standard of care.<sup>90</sup> State may directly mandate the use of decision aids certified by HHS as a requirement for informed consent, or decision aids use may indirectly become a standard best practice as a result of § 3506, causing decision aid use to become the standard of care under either the reasonable patient standard or the professional disclosure standard. A state may also require decision aid use as a condition of payment under a state healthcare payment program.

##### A. Mandatory Decision Aid Use for Informed Consent

One approach states may take to mandate decision aid use is to require physicians to use federally-certified decision aids as the standard of care for informed consent. Although no state currently requires a physician to use a decision aid as a condition of informed consent, states have begun to incorporate decision aids into their informed consent law.<sup>91</sup> For example, as discussed above, Washington law provides that a signed shared decision-making form is prima facie evidence of informed consent that the patient must rebut with clear and convincing evidence that he or she did not provide informed consent.<sup>92</sup> In addition, Washington has developed a process for certifying patient decision aids.<sup>93</sup> The current state regulations do not require physicians to use certified decision aids.<sup>94</sup> However, the trend in Washington is toward

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<sup>89</sup> See *supra* Section IV.A.

<sup>90</sup> See *supra* notes 36-37 (discussing that decision aids have traditionally been used as a physician best practice rather than as a standard of care).

<sup>91</sup> See discussion *supra* Section I.B.

<sup>92</sup> Sawicki, *supra* note 4, at 4-5.

<sup>93</sup> Pope & Hexum, *supra* note 3, at 73.

<sup>94</sup> See WASH. ADMIN. CODE §§ 182-60-005 *et seq.* (2013).

state regulation of decision aid use.

States may follow Washington's example and begin to certify decision aids. In fact, several states are currently engaged in shared decision-making demonstration projects, which may blossom into decision aid certification measures.<sup>95</sup> The next stage will likely be for states to follow Washington's example and incorporate decision aids into informed consent standards.<sup>96</sup> According to Professor Barry Furrow, the federally-certified decision aids "must replace the normal process of informed consent disclosure, at first in Medicare health plans, but realistically in most settings as providers strive for consistency in their informed consent approaches."<sup>97</sup> Under this formulation, the decision aids certified by HHS will become the standard for disclosure of risks and benefits of treatment.<sup>98</sup> At first, this will occur with regard to physicians who bill under Medicare health plans, but will later become the standard for all decisions that implicate state informed consent laws.<sup>99</sup> Absent a direct legislative mandate requiring that physicians use federally-certified decision aids, however, the effect of incorporating decision aids into state informed consent standards will vary depending on whether the state follows an ordinary physician standard or a reasonable physician standard.

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<sup>95</sup> See *supra* notes 47-48 (discussing state efforts to expand decision aid use).

<sup>96</sup> See *supra* notes 38-45 (outlining the effect that decision aids have on Washington's informed consent standards); see also Furrow, *supra* note 3, at 1767 (stating that the next stage after certified decision aids are introduced will be that

<sup>97</sup> Furrow, *supra* note 3, at 1767.

<sup>98</sup> *Id.* Professor Furrow argues that the decision aids will be the community standard for determining whether the disclosure met the standard for care for informed consent. *Id.* Thus, a patient will have a legal claim against a physician who does not utilize a decision aid and the patient is injured. *Id.* Professor Furrow argues that a failure to use a decision aid may even constitute negligence per se. *Id.* n.240. Professor Furrow appears to base his theory on the Washington statute incorporating decision aids into the state informed consent standard. See *id.* n.239.

<sup>99</sup> *Id.*

### 1. *Physician Professional Disclosure Standard*

As outlined above, the majority of states follow a professional disclosure standard, which looks at whether a reasonable physician would have informed the patient of the risks of treatment.<sup>100</sup> Unlike a reasonable patient standard, the professional disclosure standard examines whether the physician should have informed the patient of the risks of treatment, rather than whether the patient would have consented to the treatment.<sup>101</sup> Under Professor Furrow's formulation, the assumption is that a physician would utilize a federally-certified decision aid in all cases.<sup>102</sup> However, without legislation directly mandating decision aid use, decision aids can become the standard of care in professional disclosure jurisdictions only when a jury finds that an ordinary physician would utilize the decision aid.<sup>103</sup> This raises the question of whether federally-certified decision aids will become the standard for informed consent under an ordinary physician standard simply because a large number of physicians utilize decision aids in that jurisdiction. The answer to this question will depend on whether the jurisdiction uses a national or community standard of care, as well as how rigid the court will be in determining the standard of care.<sup>104</sup>

For example, in *Washington v. Washington Hospital Center*, the D.C. Court of Appeals held that a hospital's failure to use a carbon dioxide monitor to measure the carbon dioxide levels in the patient's blood during an elective surgery was contrary to a national standard of care, despite the fact that the evidence showed the monitors were only used in several other teaching

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<sup>100</sup> See Cobb, *supra* note 15, at 333.

<sup>101</sup> *Id.* at 333-39.

<sup>102</sup> See Furrow, *supra* note 3, at 1767.

<sup>103</sup> See Cobb, *supra* note 15, at 333-39 (explaining the standard of review).

<sup>104</sup> SEE SCHWARTZ, KELLY & PARTLETT, *supra* note 15, at 190-91 (stating that the majority rule for professional liability for physicians is a "similar community in similar circumstances" test, while the minority of states have adopted a national standard of care).

hospitals.<sup>105</sup> The Court mainly relied on the American Association of Anesthesiology (AAA) Standards, which recommended carbon dioxide monitor use, and expert testimony, which indicated that the carbon dioxide monitors were generally available.<sup>106</sup> Thus, the national standard of care was to provide carbon dioxide monitors in spite of the fact that there was no evidence that hospitals nationally required the monitors.

In Dr. Smith's case, this could mean that federally-certified decision aids will become the standard of care as long as a sufficient number of physicians incorporate them into their practice.<sup>107</sup> This could also mean that Dr. Smith must incorporate decision aids into his treatment practices if the guidelines or standards for orthopedic surgeons recommend decision aids.<sup>108</sup> Either way, Dr. Smith would have to incorporate decision aids into his practice in order to avoid liability under state informed consent law. Thus, Dr. Smith's liability under a professional disclosure standard will depend on the method his jurisdiction uses to determine whether a physician's actions violated the professional disclosure standard of informed consent.

## 2. *Reasonable Patient Standard*

A minority of states follow a reasonable patient standard, which examines whether the physician disclosed material risks to the patient and whether a reasonable patient in the patient's position would have consented to the treatment after being informed of the material risks.<sup>109</sup> Washington state uses a reasonable patient standard as the standard of care for informed consent.<sup>110</sup> Washington incorporated decision aids into its informed consent standard—a signed

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<sup>105</sup> *Washington v. Washington Hospital Ctr.*, 579 A.2d 177, 180-83 (1990).

<sup>106</sup> *Id.* at 182-83.

<sup>107</sup> In *Washington Hospital*, the fact that four other teaching hospitals used the monitors was persuasive. *Id.* at 183. Furthermore, the court also found persuasive the fact that an expert witness stated that the carbon dioxide monitors would be required in operating rooms. *Id.* at 182.

<sup>108</sup> *Id.* (stating that the anesthesiology standards “encouraged” the use of the carbon dioxide monitors).

<sup>109</sup> *See Cobb*, *supra* note 15, at 332.

<sup>110</sup> *Id.* at 337.

acknowledgement of shared decision-making will act as prima facie evidence of informed consent, which the patient must rebut by clear and convincing evidence.<sup>111</sup> Thus, the presumption is that a patient consents to the treatment by signing the consent form.<sup>112</sup> This standard is highly beneficial for a physician who utilizes decision aids because it forces a patient who signs an acknowledgement of shared decision-making to rebut the presumption of informed consent with clear and convincing evidence.<sup>113</sup>

States may follow Washington's lead and favor physician practices that incorporate federally-certified decision aids. In contrast, states could take an alternative approach and pass legislation stating that the presumption is against a physician who does not utilize federally-certified decision aids. According to Professor Furrow, states will err on the side of physician liability, and a physician will need to supply a federally-certified decision aid in order to avoid liability under informed consent law.<sup>114</sup> Under a reasonable patient standard, this will mean that a jury will always find that a reasonable patient will follow the recommendations of a federally-certified decision aid.<sup>115</sup> Although no state has taken either of these approaches, states have begun to incorporate decision aids into their informed consent case law, and it is possible that states will take steps toward mandating federally-certified decision aid use through state informed consent law.

#### B. Mandatory Decision Aid Use as a Condition of Payment

Another alternative is for states to require decision aid use before reimbursing physicians. For example, two Minnesota bills, one in 2009 and the other in 2011, proposed requiring shared decision-making before a health plan under contract with the state would reimburse a provider

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<sup>111</sup> Sawicki, *supra* note 4, at 4.

<sup>112</sup> *Id.*

<sup>113</sup> *See id.*

<sup>114</sup> *See* Furrow, *supra* note 3, at 1767.

<sup>115</sup> *See* Cobb, *supra* note 15, at 332 (explaining the reasonable patient standard of care for informed consent).

through the health plan.<sup>116</sup> Oklahoma and Connecticut have also considered legislation promoting decision aid use.<sup>117</sup> Thus, states could require physicians to utilize federally-certified decision aids if the physician receives state funds. The outcomes would be very similar to those discussed above with regard to federal conditions of payment or participation.<sup>118</sup> A physician who does not utilize federally-certified decision aids would not receive state aid. This is an extreme tactic, however, and the idea of requiring decision aids as a condition of payment under a state health program has not yet been adopted by any state.<sup>119</sup> It is more likely that states will incorporate the federally-certified decision aids into their informed consent standards, as Washington has done and as other states appear prepared to do.<sup>120</sup> As the situation currently stands, no state requires decision aid use as a condition of payment or as a condition of informed consent, but states appear poised to do so in the future.

#### V. RECOMMENDATIONS FOR FEDERAL AND STATE LAWMAKERS

Federal and state lawmakers should refrain from requiring physicians to incorporate federally-approved decision aids in their practices. The federal government should refrain from requiring that Medicare and Medicaid participants use decision aids in patient treatment as a condition of payment or a condition of participation. The federal government should also avoid requiring decision aid use as a requirement of participation in ACA programs. States should not require physicians to use federally-certified decision aids under state informed consent law or as a condition of payment under a state healthcare program.

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<sup>116</sup> Pope & Hexum, *supra* note 3, at 73 (citing MINN. S.F. 696, 86th Legis. Sess. (2009); MINN. H.F. 1140, 86th Legis. Sess. (2009); MINN. S.F. 542, 87th Legis. Sess. (2011)).

<sup>117</sup> *Id.*

<sup>118</sup> *See supra* subsection III.B.1.

<sup>119</sup> *Cf.* Pope & Hexum, *supra* note 3, at 73 (mentioning that Minnesota considered the idea, but ultimately rejected it).

<sup>120</sup> *See supra* Section IV.A.

## A. Physician Workload

Federal and state authorities must be wary of imposing additional burdens on physicians. Physicians report being overburdened.<sup>121</sup> Thus, the additional requirement of incorporating decision aids into treatment decisions may create more problems than it solves. For example, although decision aids are ultimately designed to save physicians time in the long run by informing patients of the risks and benefits of treatment options, physicians will lack the time necessary in the short run to incorporate multiple new decision aids into their practices.<sup>122</sup> Physicians may also lack the time to provide sufficient guidance to a patient on how to utilize the decision aid.<sup>123</sup> This may force the patient to make an uninformed decision because the patient misunderstood the decision aid. The physician may also be unable to guarantee that the decision aids are distributed consistently due to his or her busy schedule.<sup>124</sup> Inconsistent distribution may lead to inconsistent results between patients who receive the decision aids and patients who do not.<sup>125</sup> This could cause two patients with similar medical histories and risk factors to make opposite treatment decisions. Therefore, federal and state governments should refrain from requiring physicians to use federally-certified decision aids because this will exacerbate the physician workload problem and will ultimately result in inconsistent advice given to patients.

In addition, physicians may lack sufficient training to fully participate in shared decision-

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<sup>121</sup> See Mark W. Friedberg, Kristin Van Busum, Richard Wexler, Megan Bowen & Eric C. Schneider, *A Demonstration of Shared Decision Making in Primary Care Highlights Barriers to Adoption and Potential Remedies*, 32 HEALTH AFFAIRS 268, 271 (2013) (explaining that lack of training is a barrier to shared decision-making).

<sup>122</sup> See *id.*

<sup>123</sup> See *id.*

<sup>124</sup> See *id.* The study by Mark W. Friedberg, Kristin Van Busum, Richard Wexler, Megan Bowen and Eric C. Schneider found that only 10-30 percent of patients for one testing site received a decision aid on a treatment option. *Id.*; see also Joseph Burns, *Renewed Interest in Shared Decision Making, Twenty Years after SDM's Introduction, Health Plans Are Seizing on It to Help Patients Choose Their Treatments. The Lower Cost for These Patients Are a Welcome Extra*, MANAGED CARE (Apr. 2013), available at <http://www.managedcaremag.com/archives/1304/1304.shareddecision.html> (“Recent research suggests that physicians are too overwhelmed to introduce shared decision making for their patients.”).

<sup>125</sup> The study also found that reminding physicians to incorporate decision aids on a patient-by-patient basis was not sustainable. See *id.*



making.<sup>126</sup> One of the barriers to implementing shared decision-making is that physicians lack proper training.<sup>127</sup> Forcing physicians to incorporate federally-certified decision aids into their practices without proper training is ineffective because a physician cannot engage patients in a conversation on the subject of the decision aid if the physician does not know the risks and benefits of the treatment option or does not know what the decision aid recommends.<sup>128</sup> In the introductory example, Dr. Smith did not discuss the treatment options for a torn meniscus with Spencer. Instead, Dr. Smith was too busy to study the decision aid or discuss the risks and benefits of surgery. This left Spencer confused and unsure of what decision to make. Federal and state governments should not require physicians to utilize federally-certified decision aids because the physicians' potential lack of training may lead to ineffective or detrimental treatment decisions.

## B. Physician Discretion

A decision aid mandate will also interfere with physician discretion. For example, a requirement that physicians use federally-certified decision aids for certain treatment options may also mandate that physicians abide by the risks and benefits of treatment as described by the federally-certified decision aids.<sup>129</sup> A physician will not retain the autonomy to discuss the pros and cons of treatment because the physician will be forced to provide the patient with the decision aid mandated by the federal government or state governments.<sup>130</sup> Requiring a physician to utilize federally-certified decision aids will therefore cause the physician to adopt a position on a treatment option which may not be the position that the physician would otherwise adopt.

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<sup>126</sup> *Id.*

<sup>127</sup> *See id.* at 271.

<sup>128</sup> *See id.* (explaining that physicians and patients cannot engage in effective decision-making when the physician is uninformed on the subject-matter).

<sup>129</sup> *C.f.* Sawicki, *supra* note 4, at 4-5.

<sup>130</sup> *Cf. id.*

As described above, the ACA states that HHS will work with third parties to create and certify decision aids and will establish a grant program to fund the certification process.<sup>131</sup> Thus, HHS will have discretion over which third party entities are chosen and which decision aids are ultimately chosen.<sup>132</sup> Ultimately, this means that HHS will have discretion over the information provided within, and recommendations of, the decision aids that it certifies. These recommendations may conflict with the recommendation that an individual physician would make in a particular case based on the physician's expertise and experience.

Even if the federal government or state governments do not explicitly require the physician to endorse the position taken by a decision aid, the physician may have to accept the positions and thoughts promoted by the decision aid because the physician may not have time to discuss treatment options with patients and incorporate decision aids into her practice.<sup>133</sup> Instead, the physician may be forced to hand the patient a decision aid rather than engage the patient in a discussion on the risks and benefits of treatment. For example, Dr. Smith may not have time to receive and distribute the decision aid on surgery for a torn meniscus disk as well as discuss the potential issues involved in treatment. Dr. Smith will most likely choose to distribute the decision aid he is required to give Spencer and will forgo any discussion of the treatment options. Thus, face to face discussion of the potential treatment options may suffer. This would contravene the main purpose of decision aids, which is to promote shared decision-making between physicians and patients.<sup>134</sup>

Those in favor of a decision aid mandate may point out that patients have a right to know

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<sup>131</sup> *See supra* notes 56-65 (describing the certification process).

<sup>132</sup> *See supra* notes 56-65 (describing the certification process).

<sup>133</sup> *See id.*

<sup>134</sup> *See id.* at 2.

the risks and benefits of treatment.<sup>135</sup> Therefore, physicians should distribute federally-certified decision aids to patients so that patients have as much information as possible before making a decision.<sup>136</sup> A decision aid mandate, however, is not necessary to achieve the goal of informed decision-making. Instead, state informed consent law requires that physicians provide the level of information that an ordinary physician would provide or that a reasonable patient would find material.<sup>137</sup> A federally-certified decision aid can act as evidence of the standard of care.<sup>138</sup> If a jury in an informed consent case were to find that the physician did not provide the patient with the information found in a federally-certified decision aid, and that the physician's failure to do so violated the standard of care in that jurisdiction, the physician would be found liable for negligence.<sup>139</sup> Thus, state informed consent law would cover a situation where a physician fails to provide the patient with the information necessary for the patient to make an informed decision. Federal and states governments, therefore, do not need to require physicians to make a recommendation based on federally-certified decision aids in order to inform patients of treatment options.

### C. Consistency and Effectiveness

One argument in favor of requiring physicians to incorporate federally-certified decision aids into their practices is that utilizing decision aids will create consistent treatment patterns and will enhance the effectiveness of treatment.<sup>140</sup> However, physicians can incorporate decision aids into their treatment practices without a federal or state mandate to use decision aids.

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<sup>135</sup> See *supra* notes 28-29 and accompanying text (describing the shared decision-making process and the goal to engage patients).

<sup>136</sup> See *supra* notes 28-29 and accompanying text (describing the shared decision-making process and the goal to engage patients).

<sup>137</sup> See *supra* Section I.A. (describing state informed consent law).

<sup>138</sup> See *supra* Section I.A. (describing state informed consent law).

<sup>139</sup> See *supra* Section I.A. (describing state informed consent law).

<sup>140</sup> See, e.g., Burns, *supra* note 124; Clarissa Hsu, David T. Liss, Emily O. Westbrook & David Arterburn, *Incorporating Patient Decision Aids into Standard Clinical Practice in an Integrated Delivery System*, 33 MED. DECISION MAKING 85, 96 (2013) (stating that decision aids will reduce "unwarranted variations in care").

Proponents of decision aid use argue that decision aids help to eliminate variation among patient decisions.<sup>141</sup> The idea is that decision aids prevent patients from obtaining the wrong treatment for their injuries or illnesses because the decision aids provide uniform advice and promote uniform decisions.<sup>142</sup> Thus, decision aids work similar to consumer reports for car or computer purchases.<sup>143</sup>

Although decision aids may promote uniform treatment outcomes, physicians can promote uniform treatment by privately incorporate decision aids into their practices.<sup>144</sup> For example, health plans can work with participating physicians to incorporate decision aids.<sup>145</sup> Physicians can also privately incorporate decision aids into their practices.<sup>146</sup> Therefore, although decision aids may promote consistency within a physician's practice, private entities can incorporate decision aids into patient treatment procedures without government intervention. The federal government and state governments do not need to mandate decision aid use in order to promote consistency or efficiency. Instead, the federal government and state governments can encourage physicians to incorporate decision aids into their practices through a process of recommending, rather than mandating, decision aids.<sup>147</sup>

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<sup>141</sup> Burns, *supra* note 124 (arguing that using decision aids will get patients involved in treatment decisions); Hsu et al., *supra* note 140 (arguing that decision aids reduce unexplained variations in healthcare decisions).

<sup>142</sup> *See id.* (“Shared decision making is one seemingly powerful tool to at least start to eliminate unwarranted variation.”).

<sup>143</sup> *See id.* (quoting a physician and researcher for the idea that a decision aid provides a serve similar to a consumer report).

<sup>144</sup> *See id.* (promoting a practice of incorporating decision aids into the informed consent process).

<sup>145</sup> *See id.* (describing a health plan's success in incorporating decision aids into physicians' treatment practices).

<sup>146</sup> For example, physicians can utilize Electronic Health Records (EHRs) or seek help from nurses or technicians to distribute decision aids. *Id.*

<sup>147</sup> In the case of the federal government, this would be the process outlined by the ACA. *See* Patient Protection and Affordable Care Act § 3506, 42 U.S.C. § 299b-36 (2012) (outlining a process for certifying decision aids and establishing a grant-making program to promote federally-certified decision aid use). States may also establish regulations for certifying decision aids. *See* WASH. ADMIN. CODE §§ 182-60-005 *et seq.* (2013) (outlining a process for certifying decision aids). Decision aids certified by the state of Washington must be created by a national certifying organization, credentialed by the third party credentialing service International Patient Decision Aid Standards (IPDAS), and must be “independently assessed and certified” by the medical director in charge of the state agency's program if the decision aid cannot be evaluated by another organization in the United States or Canada. *See id.* § 182-60-010.

#### D. Lower Costs

In addition, proponents of decision aid use argue that decision aids lower treatment costs.<sup>148</sup> For example, studies show that decision aids lead to a decrease in expensive surgical procedures.<sup>149</sup> This is because decision aids tend to promote noninvasive procedures over surgical procedures, thus saving the patient the cost of expensive surgical procedures.<sup>150</sup>

Although decision aids may promote long-term savings, the federal government and state governments do not need to mandate decision aid use in order to take advantage of cost savings. Decision aids currently reduce health care costs in states in which they are not mandated.<sup>151</sup> There is nothing to indicate that physicians cannot continue to reduce health care costs through private use of decision aids.

Furthermore, requiring decision aid use may lead to greater health care costs. As described above, physicians tend to be overworked and may lack training in the proper use of decision aids.<sup>152</sup> A federal or state law requiring physicians to use decision aids will exacerbate these issues.<sup>153</sup> Ultimately, this may lead to higher health care costs because physicians will need training in decision aid use and may have to increase their fees as a result of incorporating decision aids into their practices.<sup>154</sup> Therefore, federal and state governments should not require physicians to incorporate decision aids in their practices because the outcome may be increased costs instead of decreased costs.

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<sup>148</sup> See Hansen, *supra* note 3 (suggesting that decision aids reduce costs for certain health conditions and indicating that decision aids promote alternatives to surgical treatment); Lee & Emanuel, *supra* note 67, at 6 (stating that decision aids reduce “unwarranted variation in care and costs”). *But see* King & Moulton, *supra* note 4, at 466 (stating that decision aid production can cost around \$150,000 to \$200,000 in 2006 dollars).

<sup>149</sup> See Hansen, *supra* note 3.

<sup>150</sup> See *id.*

<sup>151</sup> See *id.*

<sup>152</sup> See *supra* Sections V.A-B.

<sup>153</sup> See *supra* Sections V.A-B.

<sup>154</sup> See *supra* Section V.A (explaining that physicians are overburdened and will require additional training in decision aid use).

## VI. PROPOSED STRATEGIES FOR THE PRIVATE SECTOR

Dr. Smith is not currently required to distribute federally-certified decision aids. However, the federal government may require Dr. Smith to distribute decision aids in the future. In addition, Dr. Smith may need to distribute federally-certified decision aids as part of the standard of care under state informed consent law or as part of the conditions of payment under a state program. Therefore, physicians like Dr. Smith should take the following measures to incorporate decision aids into their practices.

### A. Physicians Can Incorporate Decision Aids into Their Practices

Physicians should take the following steps in anticipation of further regulation of decision aid use: (1) physicians should research and follow HHS and state guidelines and regulations regardless of whether the physicians receive federal funds; (2) physicians should begin to incorporate decision aids, including federally-certified decision aids, into their practices in anticipation of an increase in decision aid use.

Physicians should ensure that that they are knowledgeable on all applicable HHS and state regulations and should abide by federal and state regulations with regard to decision aid use. As discussed above, physicians tend to be overworked and may be unfamiliar with how to use decision aids.<sup>155</sup> Thus, it may be difficult for physicians to find time to research decision aids standards, and physicians may be unfamiliar with the new decision aids standards and how they work. However, physicians can work with attorneys to create a treatment practice that complies with the law. In addition, physicians can receive updates through the Department of Health and Human Services and through state health agency websites.<sup>156</sup>

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<sup>155</sup> See *supra* Section V.A.

<sup>156</sup> For example, CMS maintains a website for the CMMI program, which explains the program and provides recent news updates. See *Innovation Center*, CMS.GOV, <http://innovation.cms.gov/> (last visited Mar. 25, 2014). CMS also maintains a website that contains information on federal regulations and rules. See *Regulations & Guidance*,

Physicians can also begin to incorporate decision aids into their practice in anticipation of new federal or state regulations. Physicians can first familiarize themselves with decision aids currently in circulation. Once HHS certifies decision aids, physicians should familiarize

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CMS.GOV, <http://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html> (last visited Mar. 25, 2014). CMS also maintains a physician center, which compiles important links for physicians to follow to determine their responsibilities under the Medicare and Medicaid systems. *Physician Center*, CMS.GOV, <http://www.cms.gov/Center/Provider-Type/Physician-Center.html> (last visited Mar. 25, 2014). State agency websites also contain updates for providers. *See, e.g., Laws/Regulations*, ALB. DEP'T PUB. HEALTH, <http://www.adph.org/administration/Default.asp?id=498> (last visited Mar. 28, 2014); *Newsroom*, ALASKA DEP'T HEALTH AND SOC. SERVICES, <http://dhss.alaska.gov/News/Pages/Newsroom.aspx> (last visited Mar. 28, 2014); *Office of Public Health Updates, Public Health Updates (Prevention Bulletins)*, ARIZ. DEP'T HEALTH SERVICES, <http://www.azdhs.gov/diro/pio/preventionbulletin/> (last visited Mar. 28, 2014); *News Releases*, ARK. 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STATE DEP'T HEALTH, <http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders.aspx> (last visited Mar. 28, 2014); *Current News*, WYO. DEP'T HEALTH, <http://www.health.wyo.gov/news.aspx> (last visited Mar. 28, 2014).

themselves with these decision aids in particular. Physicians can then begin to incorporate these decisions into their practices when the physicians agree with the decision aid treatment recommendations and are able to incorporate the decision aid without overburdening their workload. This will make the transition easier if the federal government or state governments do decide to mandate decision aid use, or if third party entities, such as health plans or medical malpractice insurance carriers, decide to mandate federally-certified decision aid use for participating providers.<sup>157</sup>

#### B. Health Plans Can Require Decision Aid Use

Health plans should begin to endorse decision aids and provide decision aids to physicians. Since the passage of the ACA in 2010, health plans have focused on implementing the insurance exchanges and care coordination mandated by the statute.<sup>158</sup> However, now that health plans have implemented the insurance exchange programs and care coordination programs, health plans can draw their attention to implementing decision aids into participating physician practices.<sup>159</sup>

Health plans have two major options for incorporating decision aids into participating physicians' treatment practices. One option would be to provide physicians with certified decision aids and require their use. Another option is to provide decision aids to physicians but only encourage physicians to incorporate them into their treatment practices. Health plans should choose the latter option and begin to incorporate decision aids into participating physicians' treatment practices by providing certified decision aids for physician use. This way, physicians have access to decision aids, and health plans will begin to incorporate decision aids into their

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<sup>157</sup> See *supra* Parts III-IV (discussing the possibility of federal or state decision aid requirements); see *infra* Section VI.B. (discussing proposed strategies for health plans).

<sup>158</sup> See Burns, *supra* note 124.

<sup>159</sup> See *id.* (indicating that health plans will invest in decision aids in 2014).



operations in case federal or state authorities mandate federally-certified decision aids for physicians or health plans receiving federal or state funding. Health plans should refrain from requiring physicians to use federally-certified decision aids or decision aids certified by third parties for the reasons outlined above with regard to federal or state laws that would mandate decision aid use.<sup>160</sup> This will allow physicians to have access to decision aids when the physicians feel they are necessary, but will not overburden the physicians or interfere with their discretion.<sup>161</sup>

#### CONCLUSION

ACA § 3506 creates a scheme for certifying and granting patient decision aids.<sup>162</sup> The law does not mandate decision aid use.<sup>163</sup> However, the federal government has potential mechanisms for implementing decision aid use through Medicare and Medicaid conditions of participation and payment or through federal programs established by the ACA. State governments can use informed consent law or conditions of payment to mandate decision aids in patient treatment.<sup>164</sup> For Dr. Smith, this means that the federal government or the state government can require him to provide Spencer with a decision aid for a torn meniscus in a person over the age of 40.<sup>165</sup> Dr. Smith would have to provide Spencer with the decision aid. He would then face the choice of either giving his personal recommendation or letting the decision aid provide the information to Spencer. Either option interferes with Dr. Smith's autonomy over his practice and treatment recommendations.

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<sup>160</sup> See *supra* Sections V.A.-B (discussing the fact that physicians are overworked and wish to maintain discretion over their practices).

<sup>161</sup> See *supra* Sections V.A.-B (discussing the fact that physicians are overworked and wish to maintain discretion over their practices).

<sup>162</sup> See *supra* Part III.

<sup>163</sup> See *supra* Part III.

<sup>164</sup> See *supra* Part IV.

<sup>165</sup> See *supra* note 1 (discussing the Informed Medical Decisions Foundation's decision aid regarding surgery for a torn meniscus disk in persons over 40 years old).

Both the federal government and state governments should refrain from mandating federally-certified decision aid use because this will interfere with physician practices. Many physicians are overworked and many are unfamiliar with a variety of decision aid forms.<sup>166</sup> A decision aid mandate would force physicians to abruptly alter their treatment practices.<sup>167</sup> Furthermore, a decision aid requirement would interfere with physician autonomy.<sup>168</sup> Additionally, a decision aid requirement may create unnecessary variation between the decisions of patients who receive conflicting advice from the decision aid and from the physician.<sup>169</sup> The situation may change as physicians begin to incorporate decision aids into their practices and as decision aids become more uniform over time.<sup>170</sup> At least until mandatory decision aid use becomes possible and practical, the federal government and state governments should err the side of maintaining physician autonomy.

However, physicians and private health care organizations should begin to incorporate decision aids into their practices in anticipation of federal and state laws requiring their use.<sup>171</sup> Physicians can incorporate decision aids into their practices for potentially risky procedures or for procedures for which there is not a clear choice.<sup>172</sup> Health plans can provide physicians with access to decision aids but should refrain from mandating decision aid use.<sup>173</sup> For Dr. Smith, this may mean providing Spencer with a decision aid discussing the risks and benefits of orthopedic surgery for a torn meniscus. Dr. Smith can select a decision aid that he believes fairly represents the issues, or Dr. Smith can determine how to balance the decision aid's recommendations with

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<sup>166</sup> *See supra* Section V.A.

<sup>167</sup> *See supra* Sections V.A-B (discussing the idea that a decision aid mandate will interfere with physician workload and autonomy).

<sup>168</sup> *See supra* Section V.B.

<sup>169</sup> *See supra* Section V.C.

<sup>170</sup> *See supra* Part VI.

<sup>171</sup> *See supra* Part VI.

<sup>172</sup> *See supra* Section VI.A.

<sup>173</sup> *See supra* Section VI.B.

his own. Either way, Spencer will be informed regarding his treatment options, and Dr. Smith will maintain his autonomy as a physician.