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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*.<sup>1</sup> It is included in the 2010 Patient Protection and Affordable Care Act.<sup>2</sup> 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*.<sup>3</sup> Moreover, physicians and health systems across the United States are increasingly integrating decision aids into their clinical practice.<sup>4</sup> 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.<sup>5</sup> 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?<sup>6</sup> 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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