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Law

Legal Briefing: The New Patient Self-Determination Act

Thaddeus Mason Pope

ABSTRACT

This issue's "Legal Briefing" column covers recent legal developments involving the Patient Self-Determination Act (PSDA). Enacted in the wake of the U.S. Supreme Court's *Cruzan* decision in 1990, the PSDA remains a seminal event in the development of U.S. bioethics public policy, but the PSDA has long been criticized as inadequate and ineffective. Finally, recent legislative and regulatory changes promise to revitalize and rejuvenate it. The PSDA has been the subject of recent articles in *The Journal of Clinical Ethics*.[1]

I categorize new legal developments concerning the PSDA into the following eight sections:

1. Background and History
2. Rules and Requirements
3. Criticism and Challenges
4. Failed Efforts to Amend the PSDA
5. Personalize Your Care Act of 2013
6. New Regulations
7. New Regulatory Guidance
8. Expanded Enforcement

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1. BACKGROUND AND HISTORY

By the late 1980s, it was clear that individuals had an indisputable right to refuse treatment. But it was also clear that patients often lost that right when they lost capacity to make healthcare decisions. Even the U.S. Congress recognized that healthcare providers often subjected people to "unwanted and sometimes unnecessary treatment, treatment that unnaturally prolongs the dying process." The healthcare system had "become obsessed with extending life, at times neglecting the caring component of medicine and trampling on the rights of patients." Advance directives were seen as a key part of the solution. Without an advance directive, "doctors and families often just don't know a patient's wishes and fear the awesome responsibility of guessing what the patient would have thought was best."[2]

To encourage people to complete advance directives, Senator John Danforth (R-Missouri) introduced the "Patient Self-Determination Act of 1989" in the U.S. Senate in October 1989.[3] The bill had a simple goal: require Medicare and Medicaid providers to inform patients of the rights that they already have under state law to complete an advance directive. The Subcom-

mittee on Medicare and Long-Term Care of the Senate Committee on Finance held hearings.[4] But Danforth's bill died in committee. In April 1990, Representative Sander Levin (D-Michigan) introduced the Patient Self-Determination Act of 1990.[5] This bill also failed to advance.[6] But it is important to note that these early versions of the PSDA were more ambitious than the version later enacted. For example, they would have required facilities to "periodically review" advance directives and to establish "institutional ethics committees."[7] Compliance would have been burdensome and expensive.

Then, on 25 June 1990, the U.S. Supreme Court issued its opinion in *Cruzan v. Director, Missouri Department of Health*.[8] As readers of this journal are well aware, Nancy Cruzan was in a persistent vegetative state. Her family wanted to withdraw her clinically assisted nutrition and hydration.[9] But the Missouri Supreme Court denied the family's petition because they failed to present clear and convincing evidence that this treatment plan was consistent with Cruzan's wishes.[10] The Supreme Court affirmed, holding that the Constitution does not prohibit a state from requiring a family to present "clear and convincing evidence" of a patient's wishes before having authority to withdraw life-sustaining medical treatment.

The *Cruzan* case shined a bright spotlight on the importance of advance care planning.[11] This salience was apparently sufficient to reinvigorate the PSDA. Representative Levin introduced a new PSDA bill the same week.[12] While Levin's bill did not advance on its own, all of its provisions were included in the 400-page Omnibus Budget Reconciliation Act of 1990 (OBRA). Introduced on 15 October 1990, OBRA was signed into law just 20 days later, on 5 November 1990, by President George H.W. Bush.[13] OBRA did not refer to the PSDA provisions as the "Patient Self-Determination Act."[14] But the name stuck.[15] The PSDA went into effect on 1 December 1991.

2. RULES AND REQUIREMENTS

The PSDA applies to a range of healthcare facilities that participate in Medicare and Medicaid, including hospitals, nursing facilities, home health agencies, and hospice.[16] The PSDA spans fewer than 500 words in a more than 8,000-word list of requirements for participation in Medicare and Medicaid. But while it is short, the PSDA imposes five distinct duties on participating careproviders.[17]

First and most famously, the PSDA requires providers to:

1. "maintain written policies and procedures" to provide written information to each adult individual receiving medical care concerning both
   a. the individual's rights under state law to make decisions concerning medical care, including the right to formulate advance directives, and
   b. the provider's written policies respecting the implementation of such rights.[18]

The PSDA further requires providers to:

2. document in the individual's medical record whether the individual has executed an advance directive,
3. not condition the provision of care or otherwise discriminate against an individual based on whether the individual has executed an advance directive,
4. ensure compliance with requirements of state law respecting advance directives, and
5. provide education for both staff and the community on issues concerning advance directives.[19]

As it does with most other federal Medicare and Medicaid legislation, the U.S. Department of Health and Human Services (DHHS) quickly implemented the PSDA through regulations.[20] The requirements were included as Medicare "Conditions of Participation" relating to "Patient Rights."[21] While the regulations largely parrot the statutory text, they interpret and expand the statute in several places. For example, if a provider cannot implement an advance directive on the basis of conscience, the regulations specify the elements of a valid "statement of limitation."[22] At a minimum, it must:

1. clarify any differences between institution-wide conscience objections and those that

may be raised by individual physicians,
2. identify the state legal authority permitting such objection, and
3. describe the range of medical conditions or procedures affected by the conscience objection.

Congress has never amended the PSDA itself.[23] But, in 1997, Congress clarified the scope of the PSDA when it enacted the Assisted Suicide Funding Restriction Act of 1997. This statute mandated that the PSDA must not be construed to require any provider "to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide, euthanasia, or mercy killing." The Assisted Suicide Funding Restriction Act further mandated that the PSDA not be construed to "apply to or to affect any requirement with respect to a portion of an advance directive that directs the purposeful causing of, or the purposeful assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing."[24]

3. CRITICISM AND CHALLENGES

For decades, a significant volume of medical and legal literature has criticized the PSDA. Commentators began expressing concerns during the first few years of the PSDA.[25] And the criticism has continued for the next 20 years.[26] Much of it has focused on the PSDA's failure to more ambitiously and expansively address problems in end-of-life healthcare decision making. For example, some had hoped that the PSDA would have fixed or pre-empted inadequate patient rights protections under state law.[27] Others have criticized the PSDA on a number of other grounds, such as failing to meet the needs of patients with limited English proficiency.[28] In 1999, I joined this growing chorus.[29] I argued that the PSDA "has promoted the execution of uninformed and under-informed advance directives, and has undermined, not protected, self-determination." I concluded that the PSDA "looks like an utter failure."

I may have been too strong. To be fair, facilities have generally complied with the law.[30] But the outcome has been simply increased documentation of advance directives. The PSDA has not increased the completion of either advance directives or advance care planning.[31] Some commentators have argued that this was an inevitable organizational failure.[32] After all, the PSDA mandates advance care planning information at the wrong place, at the wrong time, by the wrong person, and through the wrong mechanism. In short, most agree that the PSDA has been, at most, a "modest success."[33]

In just the past year, major legal and medical professional associations have urged Congress to expand and update the PSDA. For example, in August 2012, the American Bar Association House of Delegates passed a resolution calling on Congress to amend the PSDA to require that:

1. Every patient or patient's authorized representative be given an opportunity to discuss issues relating to advance care planning with an appropriately trained professional representative of the provider organization within a reasonable time after the patient's admission to a facility covered by the PSDA,
2. Health insurance exchanges developed pursuant to the Patient Protection and Affordable Care Act of 2010 be required under the PSDA to provide advance care planning information and resource options for follow-up assistance,
3. In the absence of a validly executed advance directive, any clear, undisputed expression of a person's healthcare wishes with respect to healthcare should be honored, as long as consistent with applicable law.[34]

Similarly, in 2013, the American Academy of Nursing (AAN) called for the PSDA to be "updated and expanded" beyond its mere "clerical function" of providing advance directive forms to patients on hospital admission.[35] The AAN urged that the PSDA's requirements be expanded to include conversations about advance care planning in outpatient settings, primary care clinics, long-term care facilities, and com-

munity based home care and acute care settings. The AAN also called for information on the planning process to be provided to both patients and significant others.

4. FAILED EFFORTS TO AMEND THE PSDA

So far, these calls for changes to the PSDA have not met with success. Bills to amend the PSDA were first introduced within two years of its enactment. For example, the National Organ Donor Awareness Campaign Act of 1992 would have required that the provision of information under the PSDA "be coordinated with the provision of organ donation information."[36] A 1994 bill introduced by the PSDA's original proponent, Senator Danforth, would have provided for the "portability" of advance directives by specifying that "an advance directive validly executed outside the state in which such directive is presented must be given effect to the same extent as an advance directive validly executed under the law of the State in which presented." The same bill also would have extended the PSDA to dialysis centers.[37]

Since the early 1990s, dozens more bills have been introduced to expand and strengthen the PSDA. For example, in the 112th Congress, the Senior Navigation and Planning Act of 2012 would have mandated advance care planning education campaigns, an information phone line, and a clearinghouse. It also would have required the inclusion of advance care planning materials in the *Medicare and You* handbook.[38] In the 111th Congress, nearly 10 separate bills, like the Advance Directive Promotion Act of 2009,[39] called for similar measures.[40] One bill would have even required student loan lenders to discuss advance directives.[41] But none of this legislation was enacted.

In the United States, much of the public debate over end-of-life issues has occurred in the courts rather than in the legislature.[42] The legislature is better positioned to deliberate about how to balance the competing interests at stake. For example, legislatures can conduct more extensive, resource-intensive hearings. But the lack of legislative movement suggests that end-of-life medicine is "too hot" for the political branch of government, especially in the wake of the highly charged public rhetoric regarding "death panels." A Pennsylvania court hearing a right to die case summarized this sentiment as follows: "Legislatures are often slow to act, and where the legislature has failed to act, the courts must respond to protect individual rights."[43]

5. PERSONALIZE YOUR CARE ACT OF 2013

The PSDA requires that patients be apprised, at the time of admission, of their right to complete an advance directive. It also requires providers to do some community education. But it neither requires providers to engage patients, nor compensates them for engaging patients, in early advance care planning, particularly in community and clinical practices. The PSDA takes only a last chance, safety net approach to advance directive completion.

Other legislation has tried to complement the PSDA in this respect. For example, Medicare has long covered an "initial preventive physical examination" (IPPE), also known as the "Welcome to Medicare Preventive Visit."[44] The IPPE includes physicians' services consisting of a physical examination with the goal of health promotion and disease detection. In 2008, the Medicare Improvements for Patients and Providers Act of 2008 expanded the definition of the IPPE to include education, counseling, and referral with respect to screening and other preventive services as well as end-of-life planning.[45] The required "end-of-life planning" means verbal or written information regarding "(A) an individual's ability to prepare an advance directive in the case that an injury or illness causes the individual to be unable to make health care decisions; and (B) whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive."[46]

While useful, including end-of-life planning only at the IPPE is limited in the same way that the PSDA is limited. Just as the PSDA is limited to disclosure on facility admission, the IPPE is limited to disclosure on Medicare "admission." In response, the bill that would become

the Affordable Care Act (ACA) was, at one time, intended to more directly offer incentives for the use of tools for early end-of-life decision making.[47] Earlier drafts of the bill contained a provision that would have reimbursed physicians under Medicare for periodically consulting with patients about advance care planning and discussing POLST (physician orders for life-sustaining treatment, an important complement to advance directives for persons with advanced illness), when available and applicable.[48] In contrast to an advance directive, which must be interpreted to be implemented, a POLST form translates the patient's wishes into immediately actionable medical orders. Moreover, POLST is transportable from one care setting to another, and is authoritative in hospitals, nursing homes, and ambulances. A growing body of evidence demonstrates that POLST is an important complement to advance directives for persons with advanced illness. But political backlash (involving talk of "death panels") ultimately forced the removal of this provision.[49]

Still, the March 2010 enacted version of the ACA did authorize "annual wellness visits" under Medicare.[50] So, through regulations in late 2010, the DHHS authorized Medicare coverage of advance care planning conversations as an element of this "annual wellness visit."[51] But this also proved controversial,[52] and the regulation was rescinded just six weeks later.[53] In 2011, Representative Earl Blumenauer (D-Oregon), the proponent of the (ultimately eliminated) "voluntary advance care planning" language in the original ACA, introduced new legislation that would have provided Medicare and Medicaid coverage for advance care planning conversations and would have provided grants to develop POLST programs.[54] But his bill died.

In March 2013, Representative Blumenauer introduced a new version of his bill, titled the Personalize Your Care Act of 2013.[55] The bill supports advance care planning in five ways. First, it provides Medicare and Medicaid coverage for a "voluntary advance care planning consultation" every five years or in the event of a major change in health status.[56] This periodic revisiting of advance care documents and goals of care recognizes that an individual's preferences can change over time. It also recognizes that the advance care plan should be updated if an individual develops a serious or chronic illness, if additional curative and palliative treatment options become available, and to consistently reflect the individual's current circumstances and preferences. On the other hand, particularly with sudden conditions like quadriplegia, the updated plan might reflect only transient and not settled long-term preferences.

Second, the Personalize Your Care Act of 2013 expands the definition of "advance directive" to also include any "other statement that is recorded and completed in a manner recognized under State law by an individual with capacity to make health care decisions and that indicates the individual's wishes regarding medical treatment in the event of future incapacity of the individual to make health care decisions." Most notably, this would expand the PSDA, requiring facilities to provide information and education about POLST in addition to traditional advance directives.[57]

Third, the Personalize Your Care Act of 2013 helps make advance care planning documents accessible wherever care is provided. The legislation ensures that an individual's electronic health record is able to display his or her current advance directive and/or POLST, so that his or her wishes are easily accessible and respected.

Fourth, under the Personalize Your Care Act of 2013, advance directives would be portable, that is, that advance directives completed in one state are honored in another state. The states have taken at least four different approaches to portability. First, some states will honor the originating state's advance directive so long as it complies with the law of the receiving state. Second, some states will honor the originating state's advance directive so long as it just reasonably or substantially complies with the law of the receiving state. Third, some states honor the originating state's advance directive so long as it complies with the law of the originating state. Fourth, some states will honor the originating state's advance directive so long as it complies with either the law of the receiving state or the law of the originating state.

In light of this variation, portability is clearly an area in which federal law is needed and could be very effective. The Personalize Your Care Act of 2013 provides: "an advance directive validly executed outside the State in which such directive is presented must be given effect by a provider of services or organization to the same extent as an advance directive validly executed under the law of the State in which it is presented." The bill has an express pre-emption clause that would pre-empt any state law with inconsistent portability provisions.

Finally, the Personalize Your Care Act of 2013 provides grants to states to establish or expand POLST programs. For instance, the National POLST Paradigm Program Task Force provides consultation, guidance, and mentorship to developing states for program and form development, recognizing the uniqueness of each state.[58] These programs have a track record of promoting patient autonomy through:

a. documenting and coordinating a person's treatment preferences,
b. clarifying treatment intentions and minimizing confusion,
c. reducing repetitive activities in complying with the PSDA, and
d. facilitating appropriate treatment by emergency personnel.

Representative Blumenauer's Personalize Your Care Act of 2013 has been referred both to the House Committee on Energy and Commerce, and to the House Committee on Ways and Means. Each committee will consider those provisions of the bill that fall within its jurisdiction. Unfortunately, the measure is not expected to pass.

6. NEW REGULATIONS

Furthering the objectives of the PSDA are new re-imbursement carrots in the electronic health records (EHR) incentive program.[59] To spread the use of EHRs to improve healthcare quality, the Centers for Medicare and Medicaid Services (CMS) issued "meaningful use" standards.[60] These relate to having complete and accurate information, to ensuring access to the information, and to assuring the empowerment of patients. By satisfying specific criteria, providers can earn incentive payments. One of these measures is "whether more than 50% of unique patients 65 years old or older admitted to a hospital's inpatient place of service have an indication of an advance directive status recorded as structured data."[61] CMS has already paid more than $8 billion in incentive payments, and advance directive documentation has presumably increased. But these significant financial incentives could increase the already documented risk that clinicians will badger or coerce patients into completing advance directives or POLSTs. A significant population of individuals are reluctant to complete advance directives. Some may distrust how clinicians will use them. Some find it too painful to imagine future states of critical illness. Others are simply not ready, because they have not yet reflected and discussed their preferences.

7. NEW REGULATORY GUIDANCE

On 15 April 2010, President Obama issued a Memorandum on Hospital Visitation to the Secretary of DHHS.[62] While largely focused on visitors for lesbian, gay, bisexual, and transgender patients, in this memorandum, the President asked that DHHS "ensure that all hospitals participating in Medicare or Medicaid are in full compliance with regulations . . . promulgated to guarantee that all patients' advance directives . . . are respected." The President further requested that DHHS "issue new guidelines . . . and provide technical assistance on how hospitals . . . can best comply with the regulations and take any additional appropriate measures to fully enforce the regulations."

By May 2010, CMS, the relevant DHHS agency, promulgated a proposed rule.[63] After receiving and reviewing comments, CMS promulgated a final rule in November 2010.[64] But perhaps more significantly, CMS revised two section of its State Operations Manual (SOM).[65] This manual contains interpretive guidelines that elaborate on the regulations. And it contains instructions for surveyors on how to monitor compliance.[66]

In September 2011, CMS first revised SOM Appendices A and W.[67] Appendix A relates to hospitals. Appendix W relates to critical access hospitals. CMS published a further update in December 2011.[68] The revisions provide additional guidance to surveyors on how to assess compliance with advance directive requirements. For example, they provide tips on conducting patient and family interviews and directions for performing document review.

In September 2012, CMS revised Appendix PP, the section focusing on long-term care facilities. CMS published a further update in March 2013.[69] Federal regulations have long provided that a nursing home resident "has the right to refuse treatment. . . ." But in its SOM update, CMS strengthened the implementation of this standard by better clarifying that "the resident may not be treated against his/her wishes."[70] Specifically, CMS issued detailed guidance for surveyors, helping them to identify noncompliant practices, policies, and procedures.

Surveyors conduct observations, interviews, and record reviews to assess compliance at two different levels. First, they determine whether "orders are consistent with the resident's documented choices and goals." Second, they determine whether "any treatment or interventions have been ordered . . . that are inconsistent with the resident's documented acceptance or refusal of treatment or with an existing advance directive." In short, the new CMS guidance directs surveyors to ensure (1) orders match wishes and (2) treatment matches orders.

Furthermore, the new guidance not only strengthens the rigor of the inspection process relative to life-sustaining treatment, but it also increases the penalties for noncompliance. The new guidance provides that "failure to obtain and implement medical orders related to life-sustaining treatments" is the highest level deficiency: "Level 4: Immediate Jeopardy to Resident Health or Safety."

7. EXPANDED ENFORCEMENT

In the past 20 years, a number of individuals have brought lawsuits against healthcare providers, alleging violations of the PSDA. But these claims have been uniformly dismissed. The courts have consistently held that the PSDA affords individuals no private cause of action.[71] Indeed, Congress specifically avoided changing this when, in March 2005, it enacted the infamous "Act for the Relief of the Parents of Theresa Marie Schiavo." This law gave jurisdiction to the United States District Court for the Middle District of Florida "to hear, determine, and render judgment on a suit or claim by or on behalf of Theresa Marie Schiavo for the alleged violation of any right . . . relating to the withholding or withdrawal of food, fluids, or medical treatment necessary to sustain her life." Some legislators may have been concerned that this law might imply that other patients were entitled to litigate PSDA violations. Accordingly, the Schiavo Act specifically provides that "nothing in this Act shall affect the rights of any person under the Patient Self-Determination Act of 1990."[72]

Since patients and families cannot themselves enforce the PSDA, enforcement authority rests with CMS.[73] CMS, in turn, contracts with the states to monitor healthcare facilities that want to be eligible to provide care to Medicare and Medicaid beneficiaries.[74] So the state, usually through its health department or department of human services, has the responsibility to certify a facility's compliance or noncompliance with quality and performance standards in Medicare and Medicaid regulations.

My own preliminary investigation suggests that surveyors are stepping up enforcement of the PSDA. For example, my examination of a new hospital inspection database created by the Association of Health Care Journalists indicates there were twice as many inspections relating to advance directives in 2012 compared to 2011.[75] My research in a DHHS database reveals the same thing. When providers dispute imposed sanctions, they can appeal to an administrative law judge and then to the DHHS Departmental Appeals Board.[76] A search for Departmental Appeals Board cases concerning advance directives found there were as many cases (11) concerning advance directives since 2010 as in the previous 10 years combined.[77]

Right to Refuse

One type of PSDA obligation that surveyors have been aggressively enforcing is the right to refuse treatment. For example, the Kentucky Cabinet for Health and Family Services Office of Inspector General (OIG) is Kentucky's regulatory agency for licensing all long-term care facilities.[78] To monitor and enforce the rights of residents in Kentucky long-term care facilities, the OIG conducts unannounced inspections.[79] For example, according to the South Carolina Nursing Home Blog, in March 2008, the OIG issued a citation to Green Meadows Health Care for trying to revive a resident who had signed a do-not-resuscitate (DNR) order.[80] And, according to the *Independent Online*, in March 2009 the OIG cited Louisville's Jefferson Manor after staff resuscitated 95-year-old Eva Karem, despite a DNR order.[81]

Other states have similarly sanctioned facilities for resuscitating residents contrary to their instructions. For example, in June 2012, a Florida facility was cited for initiating CPR on a resident "who had stated on admission that he did not want to be resuscitated."[82] Many additional cases concerning PSDA rights are included in ProPublica's Nursing Home Inspect database.[83]

Furthermore, the states have been sanctioning facilities not only for inappropriate resuscitation, but also for improperly or inadequately recording residents' preferences not to be resuscitated. For example, one facility "failed to place the signed DNRs in the patient's records," placing them "at risk for their [DNR] wishes not being followed."[84] Another facility lacked "necessary policies and procedures for assuring that residents' advance directives would be honored."[85]

Right to Futility Policies

Surveyors have also been enforcing other PSDA requirements. One of these requirements is to "provide written information" to all admitted patients concerning "the written policies of the provider or organization respecting the implementation of . . . an individual's rights . . . to make decisions concerning such medical care."[86] Several hospitals have recently been penalized for failing to disclose their medical futility policies. To be clear, the PSDA does not restrict a hospital's ability to adopt or implement a medical futility policy. It simply requires disclosure of the policy.

For example, according to reports by the Association of Health Care Journalists (AHCJ), based on information from CMS, in January 2012, clinicians at Milwaukee's Froedtert Hospital had an actively dying patient who had 21 hospitalizations in the past year and had received 20 units of blood in the past month. Clinicians concluded that this patient had no capacity to benefit either from nearly daily transfusions or from being a full code. But the family would not consent to the proposed treatment plan. So, pursuant to the institution's futility policy, clinicians wrote a DNR order over the objections of the patient's family. Surveyors found that Froedtert violated the patient's rights under the PSDA because the "hospital failed to notify patient of the hospital's Medical Futility Policy prior to implementing the policy."[87]

Surveyors reached a similar conclusion, in February 2012, at Botsford Hospital in Farmington Hills, Michigan, according to AHCJ. Surveyors found that there was no information in the "Patient Folder" informing patients of the hospital's "Medical Futility" and "Resuscitation Not Indicated" policies, even though those policies may limit a patient's rights to formulate advance directives and have them honored by the facility. Furthermore, surveyors found that patients and surrogate decision makers were not provided with written information on facility policies when a physician determines medical futility and writes an order for "no CPR" (cardiopulmonary resuscitation.)[88]

CONCLUSION

The legislative history of the PSDA indicates that its proponents had six clearly distinguishable goals for the act.[89] These were:

1. to empower people,
2. to produce more advance directives,
3. to ensure the honoring of advance directives,
4. to spur more state advance directive statutes,

5. to reduce overtreatment, and
6. to control medical costs.

But the PSDA has substantially failed to achieve most of these goals. Its main outcome has been just the routine distribution of information about advance directives and patients' rights to accept or refuse medical treatment.

This should not be surprising. The PSDA's mandates are too modest to produce broader change. Recognizing this, recent legislative and regulatory efforts have focused not only on enforcing the PSDA but also on expanding and supplementing the reach of the PSDA. Still, even this is not enough. CMS alone cannot achieve the PSDA's original goals, due to limitations imposed by the PSDA itself. The agency has repeatedly confirmed that the PSDA "defers to State law to govern advance directive issues."[90] Consequently, to achieve the original objectives of the PSDA, state legislatures and health agencies must strengthen state laws concerning informed consent, advance directives, POLST, and surrogate decision making.

NOTES

1. T.M. Pope, "Legal Briefing: Advance Care Planning," *The Journal of Clinical Ethics* 20, no. 4 (Winter 2009): 289-96.

2. Sen. Danforth, "Patient Self-Determination Act," 35 *Cong. Rec.* S13,564 (17 October 1989).

3. S.1766, 101st Cong., 1st Sess. (1989) (Danforth).

4. Senate Hearing 101-1168 (20 July 1990).

5. H.R. 4449, 101st Cong., 2nd Sess. (1990) (Levin).

6. The bill was referred to the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce.

7. An exhaustive legislative history is provided in E.J. Larson and T.A. Eaton, "The Limits of Advance Directives: A History and Assessment of the PSDA," *Wake Forest Law Review* 32, no. 1 (1997): 249-93.

8. 497 *U.S.* 261 (1990).

9. W. Colby, *Long Goodbye: The Deaths of Nancy Cruzan* (Hay House, Carlsbad, Calif.: 2002).

10. *Cruzan v. Harmon,* 760 S.W.2d 408 (Mo. 1989).

11. Rep. Levin, "Introduction of the Patient Self-Determination Act," 136 *Cong. Rec.* H4222 (27 June 1990); Rep. Levin, "Patient Self-Determination," 136 *Cong. Rec.* E2190 (28 June 1990).

12. H.R. 5067, 101st Cong., 2nd Sess. (1990) (Levin).

13. H.R. 5835, 101st Cong., 2nd Sess. (1990) (Panetta), enacted as Pub. L. No. 101–508 §§ 4206 and 4751, 104 Stat. 1388-115 to -117 and -204 to -206 (5 November 1990), codified at 42 *U.S.C.* §§ 1395cc(f) and 1396a(w).

14. The provisions were included in Title IV of OBRA (Omnibus Budget Reconciliation Act), ("Medicare, Medicaid, and Other Health-Related Programs") in Section 4206 ("Medicare Provider Agreements Assuring the Implementation of a Patient's Right to Participate in and Direct Health Care Decisions Affecting the Patient").

15. A. Meisel and K.L. Cerminara, *The Right to Die: The Law of End-of-Life Decisionmaking,* 3rd ed. (New York: Aspen, 2013), § 7.04[c].

16. 42 *U.S.C.* § 1395cc(a)(1)(Q); 42 *U.S.C.* § 1396a(a)(57); 42 *U.S.C.* § 1396r(c)(2)(E); 42 *U.S.C.* § 1395i-3(c)(1)(E); 42 *U.S.C.* § 1395bbb(a)(6). The PSDA also applies to Medicare HMOs. 42 U.S.C. § 1395mm(c)(8); 42 U.S.C. § 1395w-22(i).

17. Many of these same duties are separately imposed by Joint Commission accreditation requirements or by state law. The Joint Commission, *2013 Comprehensive Accreditation Manual for Hospitals* (Oakbrook Terrace, Ill.: Joint Commission, 2013), § RI.01.05.01; N.J. Stat. § 26-2H-65(2).

18. 42 U.S.C. § 1395cc(f)(1)(A); 42 *U.S.C.* § 1396a(w)(1)(A). In the case of a hospital, this information must be provided upon admission. 42 *U.S.C.* § 1395cc(f)(2); 42 *U.S.C.* § 1396a(w)(2).

19. 42 *U.S.C.* § 1395cc(f)(1)(B)-(E); 42 *U.S.C.* § 1396a(w)(1)(B)-(E).

20. DHHS, "Medicare and Medicaid Programs; Advance Directives: Interim Final Rule," 57 *Fed. Reg.* 8,194 (6 March 1992). These regulations were later amended several times. DHHS, "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rate," 59 *Fed. Reg.* 45,403 (1 September 1994); DHHS, "Medicare and Medicaid Programs; Advance Directives: Final Rule," 60 *Fed. Reg.* 33,262 (27 June 1995); DHHS, "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1998 Rates: Final Rule," 62 *Fed. Reg.* 46,037 (29 August 1997); DHHS, "Medicare and Medicaid Programs; Religious Nonmedical Health Care Institutions and Advance Directives: Interim Final Rule," 64 *Feg. Reg.* 67,052 (30 November 1999); DHHS, "Medicare and Medicaid Programs; Religious Non-

medical Health Care Institutions and Advance Directives: Final Rule," 68 *Fed. Reg.* 66,710 (28 November 2003). "All CMS regulations related to advance directives are based in 1866(f)(3) of the [Social Security] Act." DHHS, "Final Rule: Medicare and Medicaid Programs: Changes to the Hospital and Critical Access Hospital Conditions of Participation to Ensure Visitation Rights for All Patients," 75 *Fed. Reg.* 70,831, 70,841 (19 November 2010).

21. 42 *C.F.R.* § 482.13(b)(3). This regulation provides that patients have "the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance . . . 489.102." The substantive PSDA requirements are included in 42 *C.F.R.* § 489.102.

22. 42 *C.F.R.* § 489.102(a)(1)(ii).

23. Interestingly, one bill proposed the partial repeal of the PSDA. H.R. 566, 102nd Cong., 1st Sess. (1991) (Donnelly).

24. H.R. 1003, 105th Cong., 1st Sess. (1997) (Hall), enacted as Pub. L. No. 105-12, § 7, (30 April 1997), 111 Stat. 26, codified at 42 *U.S.C.* § 14406.

25. S.M. Wolf et al., "Sources of Concern about the Patient Self-Determination Act," *New England Journal of Medicine* 325, no. 23 (1991): 1666-71; E.J. Emanuel et al., "How Well Is the Patient Self-Determination Act Working? An Early Assessment," *American Journal of Medicine* 95, no. 6 (1993): 619-28; A.M. Capron, "The Patient Self-Determination Act: Not Now," *Hastings Center Report* 20, no. 5 (September/October 1990): 35-6; M.A. Refolo, "Patient Self-Determination Act of 1990: Health Care's Own Miranda," *Journal of Contemporary Health Law and Policy* 8 (1992): 455-71.

26. L.P. Ulrich, *The Patient Self-Determination Act: Meeting the Challenges in Patient Care* (Washington, D.C.: Georgetown University Press, 2001); G. Duke et al., "The PSDA 20 Years Revisited," *Journal of Nursing Law* 13, no. 4 (2009): 114-23; A.W. Foster, "Bacon, Eggs, and Advance Directives: The PSDA 20 Years Later," *University of Houston Health Law Perspectives* (May 2011); O. Ben-Shahar and C.E. Schneider, "The Failure of Mandated Disclosure," *University of Pennsylvania Law Review* 159, no. 3 (2011): 647-749; E.H. Bradley et al., "Institutional Efforts to Promote Advance Care Planning in Nursing Homes: Challenges and Opportunities," *Journal of Law, Medicine, and Ethics* 25, no. 2 and 3 (1997): 150-59.

27. R.E. Shugrue, "The Patient Self-Determination Act," *Creighton Law Review* 26, no 3 (1993): 751-83; L. Rutkow, "Dying to Live: The Effects of the PSDA on Hospice Care," *NYU Journal of Legislation and Public Policy* 7, no. 2 (2004): 393-435.

28. C.J. Jones, "Say What? How the PSDA Leaves the Elderly with Limited English Proficiency out in the Cold," *Elder Law Journal* 13, no 2 (2005): 489-518.

29. T.M. Pope, "The Maladaptation of Miranda to Advance Directives: A Critique of the Implementation of the Patient Self-Determination Act," *Health Matrix* 9, no. 1 (1999): 139-202.

30. *Patient Self-Determination Act—Providers Offer Information on Advance Directives but Effectiveness Uncertain,* GAO/HEHS Doc. No. 95-135 (1995).

31. See Meisel and Cerminara, note 15 above, § 7.04 fn.222.

32. D. Leahman, "Why the Patient Self-Determination Act Has Failed," *North Carolina Medical Journal* 65, no. 4 (2004): 249-51.

33. See Larson and Eaton, note 7 above, p. 284.

34. *Resolution 106A, Adopted by the American Bar Association House of Delegates* (6 August 2012), *http: //www.abanow.org/2012/06/2012am106a/,* accessed 3 June 2013. The resolution further encouraged requiring "the annual Medicare wellness examination, or other periodic doctor-patient interactions, to include both an opportunity to engage in and assistance with have resource options available relating to advance care planning for health decisions."

35. American Academy of Nursing, "Policy Brief: Advance Care Planning as an Urgent Public Health Concern" (15 April 2013), *http: //www.aannet.org/policy-brief—advance-care-planning-as-an-urgent-public-health-concern—2013-,* accessed 3 June 2013.

36. H.R. 5785, 102nd Cong., 2nd Sess. (1992) (Roybal).

37. S.2556, 103rd Cong., 2nd Sess. (1994) (Danforth).

38. S.3684, 112th Cong., 2nd Sess. (2012) (Warner).

39. H.R. 3253, 111th Cong., 1st Sess. (2009) (Levin).

40. Advance Directive Incentive Act, H.R. 2705, 111th Cong., 1st Sess. (2009); Personalize Your Care Act of 2010, H.R. 5795, 111th Cong., 2nd Sess. (2010) (Blumenauer); Advance Planning and Compassionate Care Act of 2009, S.1150, 111th Cong., 1st Sess. (2009); Advance Planning and Compassionate Care Act of 2009, H.R. 2911, 111th Cong., 1st Sess. (2009) (Blumenauer); Senior Navigation and Planning Act of 2009, S.1263, 111th Cong., 1st Sess. (2009) (Warner); Senior Navigation and Planning Act of 2009, S.1251, 111th Cong., 1st Sess. (2009) (Warner); Senior Navigation and Planning Act of 2009, H.R.

3172, 111th Cong., 1st Sess. (2009) (Baldwin).

41. Christopher's Law, H.R. 5458, 111th Cong., 2nd Sess. (2010) (Adler).

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43. *In re Jane Doe,* 45 Pa. D. and C.3d 371 (1987).

44. 42 U.S.C. § 1395x(ww).

45. H.R. 6331, 110th Cong., 2nd Sess. (2008) (Rangel), enacted as Pub. L. No. 110-275 (2008).

46. 42 *U.S.C.* § 1395x(ww)(3).

47. America's Affordable Health Choices Act of 2009, H.R. 3200, § 1233, 111th Cong., 1st Sess. (2009) (Dingell).

48. C.P. Sabatino, "The Evolution of Health Care Advance Planning Law and Policy," *Milbank Quarterly* 88, no. 2 (2010): 211-39.

49. G. Kessler, "Sara Palin, Death Panels, and Obamacare," *Fact Checker* (27 June 2012), *http: //www.washingtonpost.com/blogs/fact-checker/post/sarah-palin-death-panels-and-obamacare/2012/06/27/gJQAysUP7V_blog.html,* accessed 3 June 2013.

50. Pub. L. No. 111-148, § 4103.

51. DHHS, "Medicare Program: Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2011," 75 *Fed. Reg.* 73,170 (29 November 2010).

52. R. Pear, "U.S. Alters Rule on Paying for End-of-Life Planning," *New York Times,* 4 January 2011; letter from Rep. Fred Upton to Secretary Kathleen Sebelius (14 March 2011).

53. DHHS, "Medicare Program: Amendment to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2011," 76 *Fed. Reg.* 1366 (10 January 2011).

54. H.R. 1589, 112th Cong., 1st Sess. (2011) (Blumenauer).

55. H.R. 1173, 113th Cong., 1st Sess. (2013) (Blumenauer); 159 *Cong. Rec.* E300 (14 March 2013).

56. The bill would amend 42 *U.S.C.* § 1395x(s) by expanding the definition of "medical and other health services."

57. I comprehensively covered recent legal developments concerning POLST in T.M. Pope and M. Hexum, "Legal Briefing: POLST (Physician Orders for Life Sustaining Treatment)," *The Journal of Clinical Ethics* 23, no. 4 (Winter 2012): 353-76.

58. *http: //www.polst.org,* accessed 3 June 2013.

59. Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), Pub. L. No. 111-8 §§ 4101, 4101-04 and 4201, 123 Stat. 115, 467-94, codified *inter alia* at 42 U.S.C. § 1395w–4(n)(-(o).

60. 42 *C.F.R.* §§ 495.2 to 495.370.

61. 42 *C.F.R.* §§ 495.6(g)(2) and 495.6(m); Centers for Medicare and Medicaid Services, "The Official Web Site for the Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs," *http://cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/*, accessed 3 June 2013.

62. *http: //www.whitehouse.gov/the-press-office/presidential-memorandum-hospital-visitation,* accessed 3 June 2013; 75 *Fed. Reg.* 20,511 (15 April 2010).

63. DHHS, "Proposed Rule: Medicare and Medicaid Programs: Proposed Changes Affecting Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoPs): Credentialing and Privileging of Telemedicine Physicians and Practitioners," 75 *Fed. Reg.* 29,479 (26 May 2010).

64. DHHS, "Final Rule: Medicare and Medicaid Programs: Changes to the Hospital and Critical Access Hospital Conditions of Participation To Ensure Visitation Rights for All Patients," 75 *Fed. Reg.* 70,831 (19 November 2010).

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66. DHHS, Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights, 64 *Fed. Reg.* 36,070 (2 July 1999).

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68. Centers for Medicare and Medicaid Services, "CMS Manual System: Pub 100-07 State Operations Provider Certification: Transmittal 75," 2 December 2011, *http: //www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R75SOMA.pdf,* accessed 3 June 2013.

69. Centers for Medicare and Medicaid Services,

"Survey and Certification Letter 13-16: F tag 155—Advance Directives-Revised Advance Copy," 8 March 2013, *http: //www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-16.pdf,* accessed 3 June 2013. Around this same time, CMS released updated interpretive guidelines to CMS state survey agencies and CMS regional offices clarifying the obligations of ambulatory surgery centers to honor advance directives.

70. See Survey and Certification Letter 12-47, note 65 above; see also J.K. Feldkamp, "Four Recent Releases by CMS for Nursing Facilities," American Health Lawyers Association, December 2012, p. 1, *http://m.babc.com/files/Publication/d17cf251-c6ae-49ba-88b4-391f51ad6246/Presentation/PublicationAttachment/27ac985a-877d-43c7-bf47-ad2950933457/LTC_Dec12.pdf,* accessed 3 June 2013.

71. *Scheible v. Joseph L. Morse Geriatric Center,* 988 So. 2d 1130, 1132 (Fla. App. 2008); *Turner v. Jackson Park Hosp.,* 264 Fed. Appx. 527 (7th Cir 2008); *Asselin v. Shawnee Mission Med. Ctr.,* 894 F. Supp. 1479 (D. Kan. 1995).

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85. *Evergreen Commons v. CMS,* No. CR2372 (20 May 2011), *http: //www.hhs.gov/dab/decisions/civildecisions/cr2372.pdf,* accessed 3 June 2013.

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