State Advisory Council

on Quality Care

at the End of Life

STUDY ON A STATEWIDE ADVANCE DIRECTIVE REGISTRY

December 2005

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Introduction

A written advance health care directive is a legal document expressing a competent individual's preferences about health care decision making should the individual become unable to make decisions directly. If an individual becomes incapacitated, health care providers ought to have quick access to the individual's advance directives, so as to be able to act in accordance with the individual's wishes. One approach to assuring that advance directives are immediately available is through the creation of an advance directive registry.

During the 2005 legislative session of the Maryland General Assembly, House Bill 1004 proposed the creation of a statewide registry for one type of advance directive, documents granting power of attorney for health care decisions. The House Health and Government Operations committee heard testimony on the bill, including a recommendation by the Advisory Council on Quality Care at the End of Life for a summer study on the creation of an advance directive registry. While the bill died in committee, interest in an advance directive registry continues, as indicated by the Governor's recent statement, in his veto message on Senate Bill 796, supporting the creation of a registry.[1]

Pursuant to the Advisory Council's recommendation to the Health and Government Operations committee, this report considers existing advance directive registries and discusses characteristics of a possible statewide registry. Lessons can be learned from the handful of registries that already exist in the public and private sectors.

Eight private entities store advance directives in either stand-alone registries or within larger repositories of health information. There are five stand-alone registries: America Living Will Registry (ALWR); Choices Bank, which currently services the city of Missoula, Montana; DocuBank; MyHealthDirective.com; and U.S. Living Will Registry (USLWR). Three private entities store advance directives within larger repositories of health information: FullCircle Registry, GIFTS Advance Directive Registry (GIFTS), and MedicAlert Foundation. Six states have statewide advance directive registries, five of which have statutorily mandated the creation of registries: Arizona,[2] California,[3] North Carolina,[4] Montana,[5] and Vermont.[6] (Wyoming's registry does not appear to be mandated by statute.[7]) California, North Carolina, and Wyoming created their registries from scratch. Arizona partnered with Health Directive Partners, Inc., the creator of MyHealthDirective.com, for registry services. Montana is in the process of selecting a private sector partner to operate its registry; the state favors the Life's End Institute, the creator and operator of Choices Bank.[8] Vermont has also considered partnering with Life's End Institute for registry services.[9]

Legislative activity in other states points to ongoing interest in advance directive registries. In the 2004 legislative session of the Florida Legislature, senators and representatives introduced bills proposing the creation of a statewide advance directive registry.[10] These bills, however, were not enacted. In the 2005 legislative

session of the California Legislature, senators introduced a bill proposing modernization of the state's existing advance directive registry.[11] This bill is in committee.

The report that follows has several objectives: to provide information about the existing registries, so that legislative consideration of a Maryland registry can be informed by others' experience; to identify the key public policy issues that the General Assembly will need to be resolve; and to offer the Advisory Council's recommendations, which include both a caution about proceeding immediately toward creation of a Maryland registry and, in case the General Assembly decides to move forward anyway, our views on certain desirable characteristics of a registry.

The Advisory Council is grateful to Assistant Attorney General Jack Schwartz and to Elizabeth November, a law and public health student at Saint Louis University and a 2005 summer intern in the Health Policy Division of the Attorney General's Office, for their work in preparing this report.

Recommendations

- The General Assembly should defer any action to create an advance directive registry until it:
  - receives and evaluates the report of the Task Force to Study Electronic Health Records and
  - gets the results of an effort, through community meetings or focus groups, to determine health care providers' and residents' support of a registry.

- If, notwithstanding the recommendation above, the General Assembly decides to move forward immediately to create an

advance directive registry, the General Assembly should seek to ensure, through legislative benchmarks and criteria for the entity given responsibility for the registry, that:

- the registration process is efficient;
- there is an adequate education and outreach program to encourage use of the registry by all Marylanders;
- documents are correctly filed;
- registrants and health care providers can quickly and easily access registered documents;
- the registry contains useable documents that represent registrants' current wishes for health care treatment;
- registered documents are secure; and
- health care providers can quickly identify a patient as a registrant and retrieve the patient's registered advance directive.

1. Governor Ehrlich's Veto Message for Senate Bill 796 (May 20, 2005), *available at* www.gov.state.md.us/billvetoes/2005/message_SB796.html (last visited July 18, 2005) (stating: "... a central registry of advance directives and related legal documents, maintained by the Department of Health and Mental Hygiene and accessible to health care providers with proper identity protections for individuals and couples, I believe, would better address the problems Senate Bill 796 seeks to resolve.").

2. ARIZ. REV. STAT. §36-3291 (2004).

3. CAL. PROBATE CODE §4800(a) (2004).

4. N.C. GEN. STAT. §130A-465 (2001).

5. H.R. 742, 59th Leg., Reg. Sess. (Mont. 2005), *available at* http://data.opi.state.mt.us/bills/2005/billhtml/HB0742.htm (last visited July 22, 2005).

6. H.R.115, 2005-2006 Reg. Sess. §9719(b)(1) (Vt. 2005), *available at* www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/acts/ACT055.HTM (last visited July 18, 2005).

7. The registry is maintained by the Mental Health Division of the Wyoming Department of Mental Health. Wyoming Department of Health, Mental Health Division webpage, *at* www.wymhd.us/pad/register/index.html (last visited July 18, 2005). A careful search of Wyoming laws and regulations found no legislation or rules establishing this registry.

8. *See* Press Release, Attorney General Mike McGrath, State of Montana, Governor Signs Bill to put Living Wills on Justice Web Site (Apr. 28, 2005), *available at* www.doj.state.mt.us/news/releases2005/04282005.asp (last visited July 18, 2005) (stating: "The Internet registry will likely be modeled after the Missoula Choices Bank ....").

9. In 2004, the Vermont Commissioner of Health was statutorily mandated to report to the Vermont legislature on developing a statewide registry. H.R. 752, 2003-2004 Reg. Sess., Sec. 2 (Vt. 2004), *available at* www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2004/acts/ACT162.HTM (last visited July 18, 2005). The Commissioner's report recommended that the state partner with Choices Bank for registry services. COMMISSIONER OF HEALTH, ADVANCE DIRECTIVE

ACCESSIBILITY STUDY 6 (Jan. 15, 2005), *available at* www.healthyvermonters.info/admin/pubs/AdvanceDirectiveRpt.pdf (last visited July 18, 2005).

10. S. 2902, 2004 Reg. Sess. (Fla.), *available at* www.flsenate.gov/data/session/2004/Senate/bills/billtext/pdf/s2902c1.pdf (last visited July 18, 2005); H.R. 1655, 2004 Reg. Sess. (Fla.), *available at* www.myfloridahouse.gov/loadDoc.aspx?FileName=_h1655c1.doc&DocumentType=Bill&BillNumber=1655&Session=2004 (last visited July 18, 2005).

11. S. 415, 2005-2006 Legis. Sess. (Cal.) *available at* http://info.sen.ca.gov/pub/bill/sen/sb_0401-0450/sb_415_bill_20050523_amended_sen.pdf (last visited July 18, 2005) (stating: "This bill would require the Secretary of State to establish an Internet Web site that would allow an individual to register with the registry, and specified entities to request information from the registry on a 24-hours-a-day, 7-days-a-week basis.").

Chapter 1

Determining the Need for an Advance Directive Registry

An essential first step in deciding whether to create a statewide registry is assessing whether a registry is needed. There is certainly a strong logical argument for the need, one that has led to the creation of existing registries: An advance directive that is unknown at the time of crucial treatment decisions is useless, and a well-functioning registry reduces the risk of this outcome. Yet, an important question is whether the need for timely access to advance directives can be met by other means. Furthermore, a logical argument is no substitute for evidence that those who would be the registry's customers and who would pay for it (through fees or taxes) actually see the need and support it.

This chapter explores some of the key considerations in the cost/benefit analysis that the General Assembly ought to undertake before moving forward with a registry.

A. Cost Considerations.

The fiscal note accompanying House Bill 1004 estimated that the limited registry described in the bill would cost over $90,000 to create and increasing amounts, starting at more than $80,000 per

year, to maintain. It is beyond the scope of this report, and of the Advisory Council's expertise, to evaluate this estimate or to determine the precise cost of establishing and maintaining a registry that would meets the State's needs. Several factors will affect the cost of the registry, including the type of registry (electronic or paper-based) and the site of operations (within a State agency or contracted out to a private company). Without having the specifications for a registry, it is impossible to obtain accurate cost estimates.

Even without knowing exactly how much the project will cost, however, we can identify a fundamental policy question, which has been answered in different ways by existing registries: Who should pay, the registry users or the taxpayers?

Most states do not charge registrants, whereas most private registries do. Three states (Arizona, California, Montana)[1] and two private registries (Choices Bank and USLWR)[2] do not charge registrants for filing advance directives. States are concerned that charging a registration fee will discourage many people from registering their advance directives.

North Carolina and four private registries (ALWR, DocuBank, FullCircle Registry, and MyHealthDirective.com) charge registrants. North Carolina charges registrants $10 per document registered. This fee covers the cost of creating material that is returned to the registrant. Among the private registries, the start-up fee (covering only the first year of registration) ranges from $5 (MyHealthDirective.com) to $99 (FullCircle Registry). Annual fees range from $2 (MyHealthDirective.com) to $99 (FullCircle Registry).

No states charge health providers for accessing registered advance directives. California's legislature went so far as to prohibit the Secretary of State's Office from charging health care providers, public guardians, and authorized persons for requesting registered information.[3] Of the private registries, USLWR collects fees from some health care providers. USLWR differentiates between member and non-member "health care providers." By paying an annual fee, member health care providers have unlimited access to the registry's automated fax system and are credited with a limited number of registrations, which can be given to patients. Annual fees start at $795. Non-member health care providers do not have access to the registry's automated fax system; they can obtain registered documents over the Internet, using a patient's wallet card information, or by manual fax transmission. It may take non-members much longer to receive documents through manual fax transmission than it does for members to receive documents through the automated fax system.

If neither registrants nor health care providers are charged, and assuming federal or other grant sources are unavailable, the State will have to fund the registry through General Fund revenues.

B. Electronic Medical Records May Eliminate the Need for a Registry.

President Bush has called on all health care providers to transition to the use of electronic medical records within the next ten years.[4] A national electronic medical records system may consist of an Internet-based network "which would allow the confidential transmission of medical records across the country."[5] Electronic

records could be accessible to patients and to health care providers nationwide.

Electronic medical records could contain advance directives and related documents. We are aware of this method of storing patients' advance directives at the Oregon Health and Science University,[6] the Henry Ford Health System of Michigan,[7] and the Veterans Health Administration.[8] Like a registry, electronic medical records allow physicians and patients to access advance directives easily. Advance directives contained in electronic medical records would be readily available to physicians at the time of need and to patients for the purpose of periodically reviewing the documents.

In addition, the storage of advance directives in electronic medical records could avoid difficulties in assuring access to current information. Amendments to and revocations of advance directives, created while a patient is under a doctor's care, must be incorporated into the patient's medical record.[9] If there is a free-standing advance directive registry, and the patient's health system uses hard-copy medical records, some mechanism will be needed to ensure that the registry is notified of new documents that are only contained in a patient's medical record. It may be necessary to require health care providers to submit amendments and revocations to the registry to ensure that the registry's files are up-to-date. Even if such a requirement were in place, however, it is unlikely that the registry would receive all amendments and revocations, due to non-compliance and human error. By contrast, in a health system that uses electronic medical records, amendments and revocations would be added directly to the patient's electronic record, where the advance directive is being stored; the original advance directives and subsequent documents would be contained in one location.

Electronic medical records may be a more effective and efficient way to store and update advance directives.

C. Determining the Community's Perceived Need for and Support of a Registry.

The creation of a registry should be questioned if its future users (health care professionals and Maryland residents with advance directives) do not perceive a need for or support its creation, especially if they balk at the possibility of paying fees. One approach to gauging the community's receptiveness to a registry is through organized meetings, such as town hall meetings or focus groups.[10] These meetings could also be used to obtain feedback on registry characteristics.[11]

Conclusions

Adequacy of electronic medical records for this purpose. Before deciding whether it is worthwhile to create an advance directive registry, especially given the substantial start-up and ongoing costs, the Maryland General Assembly should consider the likelihood that there will be national or statewide use of electronic medical records in the near future. If there is a good chance that electronic medical records will increasingly become part of routine practice, we are skeptical that the creation of a separate advance directive registry is worthwhile. We recommend that the General Assembly defer any action to create an advance directive registry until it receives and evaluates the report of the Task Force to Study Electronic Health Records, created in 2005 and scheduled to submit its report by the end of 2007.[12]

Community support. We recommend that the General Assembly, prior to creating an advance directive registry, direct the Department of Health and Mental Hygiene to conduct an appropriate series of meetings or focus groups in an effort to determine health care providers' and residents' support of a registry.

1. Arizona registry webpage, *at* www.azsos.gov/adv_dir/ADRFAQs.htm#cost (last visited July 21, 2005) ("What does it cost? There is no fee for storing your advance directive in the Registry."). Although California statute authorizes the registry to charge registrants, no fee is collected from registrants. CAL. PROBATE CODE § 4800(f) (2004); California Secretary of State webpage, *at* www.ss.ca.gov/business/sf/sf_formsfees.htm (last visited July 21, 2005) ("Registration of Written Advance Health Care Directive: No Fee".).

2. Choices Bank webpage, *at* www.choicesbank.org/deposit/how_to_deposit.asp (last visited July 21, 2005) ("There is no charge for this service or for viewing, printing or depositing future revisions of your advance directive."); U.S. Living Will Registry webpage, *at* www.uslivingwillregistry.com/register.shtm (last visited July 21, 2005) ("Our goal is to make this service available to everyone, and that is why we offer registration free of charge through our Member Health Care Providers and Community Partners.").

3. CAL. PROBATE CODE § 4801 (1999).

4. President George W. Bush, Discussion at the Cleveland Clinic (Jan. 27, 2005), *available at* www.whitehouse.gov/news/releases/2005/01/20050127-7.html (last visited July 19, 2005); Michael Fletcher, *President Promotes Switching To Electronic Medical Records*, WASH. POST, Jan. 28, 2005, at A07, *available at* www.washingtonpost.com/wp-dyn/articles/A41595-2005Jan27.html (last visited July 19, 2005) ("In his 2004 State of the Union address and during the presidential campaign, Bush called for the nation to eliminate paper medical records within a decade.").

5. Fletcher, note 2 above.

6. Press Release, Oregon Health & Science University, OHSU Develops Instant, Computerized Notification System To Ensure Patients' End-Of-Life Wishes Are Followed (Apr. 8, 2005), *available at* www.ohsu.edu/ohsuedu/newspub/releases/040805POLSTcfm.cfm (last visited July 19, 2005) ("Physicians at Oregon Health & Science University have developed a new system to alert clinicians of an OHSU patient's end-of-life wishes upon arrival at OHSU Hospital. The system is part of OHSU's secure electronic medical records database and provides clinicians with near-immediate information when a patient's doctor has filled out a Physician's Orders for Life-Sustaining Treatment (POLST) form or the patient has an advance directive.").

7. Leslie J. Bricker, Angela Lambing, & Carolyn Markey, *Enhancing Communication for End-of-Life Care: An Electronic Advance Directive*

Process, 6 J. PALLIATIVE MED. 511 (2003) (describing the Henry Ford Health System's use of electronic medical records to store advance directives).

8. Notes on advance directives can be added to the VHA's electronic medical records. VETERANS HEALTH ADMINISTRATION, HANDBOOK 1004.2 at 5 (July 31, 2003) ("The AD portion of the ... progress note package triggers an alert when the patient's electronic medical record is accessed."); VETERANS HEALTH ADMINISTRATION, HANDBOOK 1907.1 at 49 (Apr. 15, 2004) ("If a patient revokes ... an Advance Directive, the attending physician, or clinical designee, must so note this in the patient's medical record as a progress note and on the Advance Directive itself, and flag it, whether paper or electronic. This requires a note title change in [the Computerized Patient Record System] and must be coordinated by [the Health Information Management Service].").

9. MD. CODE, HEALTH-GEN. §5-602(f)(2)(i)-(ii) (2004).

10. At a "Town Hall" meeting, Arizonans recommended the creation of a "centralized state repository" of advance directives. EIGHTY-SECOND ARIZONA TOWN HALL, HEALTH CARE OPTIONS: HEALTHY AGING – LATE LIFE DECISIONS vii (May 2003), *available at* www.aztownhall.org/82ND%20Report.pdf (last visited July 19, 2005). For general information on Arizona Town Hall meetings, see www.aztownhall.org/what.html (last visited July 19, 2005).

11. Arizona used focus groups to determine community response to certain characteristics of the registry, i.e., the location of the registry within the government and the accessibility of the documents through the online system.

12. This 26-member task force was created by Chapter 291 (Senate Bill 251) of 2005.

Chapter 2

Structure, Scope, and Site

Three basic decisions about a registry are (1) its structure, whether it is to be electronic or paper-based; (2) its scope, the kinds of advance directives that it will register; and (3) its site, the assignment of responsibility for its operation to a State agency or a private contractor. If the Maryland General Assembly decides to proceed with creation of a Maryland advance directive registry, it should resolve these fundamental questions.

Several factors should be considered: expense, the adequacy of security measures to safeguard registered information, the needs of the registry's users (health care providers and registrants), and the expertise required to operate a registry efficiently. This chapter discusses electronic and paper-based registries in terms of the needs of health care providers and registrants (in Sections A and B). It also discusses the scope of a registry (in Section C). Finally, it addresses some issues about a state-run registry (in Section D) and briefly describes the private companies that offer registry services to states (in Section E).

However, a detailed analysis of comparative costs and security considerations is beyond the scope of the Advisory Council's expertise and of this report. Consequently, we cannot determine which option

is most suitable for Maryland, should the General Assembly decide to proceed with a registry.

A. The Medium of the Registry Should Match Health Care Providers' Technological Capabilities.

Because health care providers play a pivotal role in implementing advance directives, the registry should be designed to match their technological capabilities. Health care providers vary in these capabilities. For instance, in some health care facilities, fax machines may be more accessible than Internet-equipped computers. If a registry operates without taking account of these everyday realities, retrieval of documents at the time of need will be difficult, and the registry will likely fail to achieve its purpose. Moreover, when Maryland health care providers move to the use of electronic medical records, they will need to be able to incorporate advance directives into the records. Hence, the registry should store advance directives in a form that can be used in electronic medical records.

If Maryland opts for a paper-based registry, the registry will store hard copies of documents that can be converted into electronic form and added to the patient's electronic medical record.[1] One strategy for converting advance directives into electronic form is scanning hard-copy documents to create an electronic file.

If Maryland opts for an electronic registry, the registry will contain electronic files of the advance directives. However, to make these files ready for use in electronic medical records, the registry should allow health care providers to download the files to a computer so that the files can be uploaded into electronic records.

B. Accessing Documents.

Health care providers and registrants need to have quick and easy access to registered documents. Health care providers need to implement the patient's wishes in timely fashion. Registrants need to be able to review their registered documents and retrieve copies of the documents. The discussion below touches on these access issues.

1. Paper-based Registries.

California and Wyoming operate paper-based registries. Because neither registry has been widely used, it is unclear how effective paper-based systems are in comparison to electronic systems. However, a recent bill in the California Legislature, to require the registry to become Internet-based,[2] indicates at least a strong perception that the paper-based system is inadequate.

In paper-based systems, the key issue is the speed with which registry staff can provide health care providers or registrants (for short, authorized requesters) with registered documents. For an authorized requester to obtain registered documents, registry staff would manually retrieve the documents from paper files and forward them to the authorized requester. The California registry receives requests for documents through a phone line maintained by the Secretary of State's Office. The line is staffed during weekday business hours. If requests are received when the office is closed, requests will be processed by the close of business on the next business day.[3] As a result of the registry's limited hours of operation,authorized requesters may have to wait hours or days before receiving the needed documents.[4]

Wyoming's registry is located in the Wyoming State Hospital (WSH).[5] Unlike California's registry, WSH staff operate the registry 24 hours a day, seven days a week.[6] Assuming adequate and efficient

staffing, around-the-clock operation of a paper-based registry assures authorized requesters quick access to registered documents.

2. Electronic Registries.

Electronic registries can be designed to allow people to access registered documents in two ways: (1) through the Internet and (2) through an automated fax service. Further, some electronic registries operate customer support phone lines that manually fax registered documents. The discussion below explores these means of access to registered documents.

i. Online Access.

Electronic registries that allow online access offer health care providers and registrants quick access to registered documents. Accessing the documents can be as simple as logging in to an online system. If the registry is accessible through the Internet, then authorized requesters can get registered documents around the clock from any Internet-linked computer.

Generally, online registries are designed to allow access in two ways: registrant-controlled access and provider-controlled access. In registrant-controlled access, the registrant is given a user name and password for accessing his or her documents. This account access information is printed on an item, such as a wallet card, that is carried by the registrant.[7] When health care providers encounter a registrant-patient, they use the registrant's access information to enter the registry and obtain the registered documents. Essentially, health care providers enter the system as the registrant. In provider-controlled access, the health care provider is given a user name and password for accessing the registry. When providers encounter a patient, they enter the registry and search for the patient's advance directives.

Existing registries allow for registrant-controlled access, provider-controlled access, or both. ALWR, FullCircle Registry, Arizona, and North Carolina allow only registrant-controlled access. Health care providers can access these registries only if they have the registrant's access codes. Arizona chose registrant-controlled access to avoid erroneous document retrieval by health care providers. One private registry, GIFTS, allows only provider-controlled access. Several private registries (Choices Bank, MyHealthDirective.com, and USLWR) and Montana's future registry allow for both registrant- and provider-controlled access.

ii. Automated Fax Systems.

Several registries deliver advance directives to health care providers through automated fax systems. USLWR allows health care providers to access documents online and through an automated fax system. Docubank operates just an automated fax system. These registries issue wallet cards containing a toll-free phone number and information identifying the registrant. When health care providers call the number, they are prompted to identify the registrant and to enter their fax number. The registry automatically sends the registrant's directives to the health care provider's fax machine. These systems offer around-the-clock access to advance directives.

iii. Customer Support Phone Lines: Manual Fax Delivery.

Several registries operate customer support phone lines. To obtain a patient's advance directive, health care providers call the phone number listed on the patient's wallet card and request the document. The person receiving the call will access the registered documents and fax them to the health care provider.

Electronic registries rely, in varying degrees, on phone lines to give health care providers access to registered documents. The Internet-accessible registries operated by MyHealthDirective.com and USLWR allow for provider-controlled access. Certain means of accessing documents are available only to health care providers who are associated with the registry. The phone lines serve as the means by which unassociated health care providers access registered documents. The Internet-accessible registry operated by ALWR allows for registrant-controlled access. ALWR's phone line serves as an alternative means by which health care providers can access registered documents. FullCircle Registry and GIFTS registry seem to operate phone lines as a courtesy.

The point of comparison for these phone lines is the speed with which advance directives can be faxed to health care providers. USLWR indicated it could take up to twelve hours to respond to requests for advance directives. ALWR's phone line leads to a voicemail paging system, allowing for prompt response to requests for documents. FullCircle Registry, GIFTS registry, and MyHealthDirective.com monitor their phone lines around-the-clock and quickly respond to requests for documents.

C. Scope of a Registry.

Various types of advance directives can take effect when a person loses decision-making capacity: appointment of a health care agent, which is known in other states and commonly too in Maryland as a durable power of attorney for health care decisions (DPA); the giving of health care instructions, commonly called a living will; an advance directive that combines a DPA and a living will; and appointment of an agent and instructions for mental health treatment (MHAD).[8] In the event that a person dies, a fourth type of advance directive could become operative: instructions for organ donation,

formally known as a declaration of anatomical gift (DAG).[9] Existing registries accept different combinations of these documents; see Table 1 below, comparing the scope of several state registries.

Registry	Durable Power of Attorney for Health Care	Living Will	Declaration of Anatomical Gift	Mental Health Advance Directive
Arizona	X	X		X
Missoula, MT	X	X	X	
Montana	X	X		
North Carolina	X	X	X	X
Vermont	X	X	X	
Wyoming				X

Table 1. Scope of Selected State /Local Registries.

i. Broadly Inclusive Scope.

House Bill 1004 proposed a registry limited in scope to DPAs.[10] DPAs and living wills are both available, however, separately or in combination, for decisions related to life-sustaining medical treatments.[11] It would be unduly restrictive for a registry to include one type of document and not the other. Any Maryland advance directive registry should include both.

In Maryland, a person can document a decision to be an organ donor in two ways: by creating a DAG, including an advance directive that otherwise addresses treatment issues,[12] or by indicating donor status on a driver's license (or State-issued identification card).[13] DAGs are documents that health care providers should have on hand at the end of a patient's life. If the patient's DAG is not available, the patient's family may make donation decisions contrary to the patient's wishes.[14] If the registry contained DAGs, the documents would be available at the time of need. To help ensure that

Marylanders' donation wishes are carried out, the advance directive registry should accept DAGs.[15]

ii. Mental Health Advance Directives.

Maryland also allows for the creation of MHADs.[16] Further, Maryland law requires health care providers to facilitate patients' creation of MHADs.[17] However, MHADs are infrequently used, here or elsewhere.

Wyoming's and Arizona's registries have received few MHADs. In 2001, Wyoming's Department of Health, Mental Health Division, established a "psychiatric advance directive" registry. The registry was allowed to sunset on June 30, 2005. During the registry's operation, it received no deposits. Wyoming residents rarely create MHADs because the documents are infrequently implemented. Arizona's advance directive registry accepts MHADs. Few MHADs have been registered, primarily because these documents are rarely created.

Infrequent use of MHADs in Maryland and the experiences of Wyoming and Arizona indicate that few MHADs will be submitted to Maryland's advance directive registry. In considering whether to broaden the scope of the registry to include MHADs, the General Assembly should carefully consider whether including MHADs in a registry would be worth the additional confidentiality considerations that including mental health records would entail.

D. Siting a Registry in a State Agency.

House Bill 1004 of 2005 proposed locating its registry within the Department of Health and Mental Hygiene (DHMH). A state health department is a logical site for a registry, but some state legislatures have opted instead for their Secretary of State's office or Office of

the Attorney General. The discussion below explores several issues that were significant to the states' placement decisions.

i. Perceived Conflict of Interest.

Arizona and Vermont had misgivings about allowing their Departments of Health to manage an advance directive registry. In Arizona, a focus group expressed concern that the Department of Health (perceived as being involved in providing health care) could use registered advance directives to inappropriately limit the health care registrants receive. This concern was reiterated in the Vermont Commissioner's report on the creation of a statewide registry.[18]

Arizona, Montana, and Vermont have used different tactics to allay concerns about this conflict of interest. Arizona decided to place the registry within the Secretary of State's Office.[19] Montana's placement of its registry in the Office of the Attorney General not only avoids any perceived conflict of interest but also builds on the Attorney General's interest in promoting end-of-life planning. Vermont's Commissioner's report recommended that the Department of Health partner with a local not-for-profit organization, the Vermont Ethics Network (VEN), to operate the registry. The Department of Health would be the behind-the-scenes "fiscal agent," and VEN would be the "registry administrator."[20]

The issue of whether the public might mistrust an advance directive registry in DHMH, given its responsibilities under the Medicaid program, is an issue that should be explored through town meetings and focus groups.

ii. Experience with Document and Data Management.

Arizona's and Vermont's placement decisions were, in part, driven by the agency's experience with handling documents or health data. The Arizona Secretary of State's Office has historically been a repository of important documents; it has a track record for managing and keeping safe personal filings. The Vermont Commissioner's recommendation to keep the registry within the Department of Health was based in part on the agency's experience with handling health-related data. For instance, Vermont's Department of Health maintains a cancer registry. DHMH, of course, not only houses data compilations like a cancer registry but also maintains vital records of individuals.

Similarly, North Carolina placed its registry in the Secretary of State's Office because of the Office's data management and technological capabilities. The North Carolina advance directive registry was created from the Secretary of State's existing information management system. With some assistance from a private contractor, Office Automation Solutions, North Carolina's Secretary of State's Office developed software for a large, information management system known as "Secretary of State Knowledge Base" (SOSKB).[21] North Carolina's advance directive registry is a subset of the SOSKB system. Because the registry is based on existing SOSKB technology, the cost of creating the registry was the manpower to write new computer code. North Carolina shares the code for the SOSKB system (including the advance directive registry) with other states, free of charge. After signing a licensing agreement, a state can download the source code of SOSKB, and then adopt the system to its needs. Further, North Carolina is willing to provide nominal technical support to states using SOSKB. Most states that have acquired the SOSKB system have contracted with Office Automation Solutions for technological services.

E. Contracts with Private Companies for Registry Services.

Instead of creating its own registry, Maryland could contract with a private organization for registry services, including the creation and operation of a registry. Several private organizations provide registry services to the public sector. Arizona partnered with MyHealthDirective.com (Health Directive Partners) for the creation and maintenance of a registry and for processing registrations. Choices Bank, the registry for the city of Missoula, is operated by the Life's End Institute (a not-for-profit organization). Montana and Vermont are considering contracting with Life's End Institute for statewide registry services.

All seven private organizations that operate registries expressed interest in providing registry services to the state of Maryland. However, some of these organizations may be unable to accommodate the State's particular needs, once they are defined. If Maryland chooses to contract with a private company for registry services, it must select its partner carefully.

Conclusions

Structure. To design a registry that allows health care providers and registrants quick and easy access to registered documents, the technological capabilities of local health care providers and the features of paper-based and electronic registries should be assessed. Electronic registries can allow health care providers and registrants quick, around-the-clock access to registered documents. Paper-based registries would not likely allow this ease of access to registered documents. If the General Assembly were to favor an electronic registry, it should provide that registry users be able to quickly access registered documents through multiple means (the Internet, an automated fax system, and a customer service phone line). An Internet-accessible registry requires a decision whether to allow

registrant-controlled access, provider-controlled access, or both. Looking ahead, the General Assembly would want to ensure that the registry's design will allow for registered advance directives to be incorporated into electronic medical records.

Scope. The registry should be open to receiving health care agent advance directives (DPAs), instructional advance directives (living wills), combined documents, and anatomical gift documents. It is doubtful whether the registry should extend to mental health advance directives.

Site. Based on the considerations discussed in this chapter and others, especially cost, the General Assembly will need to make the fundamental decision whether operation of the registry will be a direct responsibility of a State agency or will be contracted out. There are a number of advantages to a state-created registry. Sometimes commercially available products do not adequately match a state's wishes or needs. By creating its own system, a state ensures that it gets a product attuned to its needs. Relying on a private organization to create or operate a state system can be risky; the private company could fail or be bought out.

Maryland could follow North Carolina's example and create its own registry. Maryland could design its own registry from scratch or use North Carolina's SOSKB as a base for creating a registry. Regardless, the agency responsible for creating the registry will need to have technological staff capable of carrying out this work. If the agency's staff is insufficient, the agency will need to obtain additional expertise.

1. *See* Leslie J. Bricker, Angela Lambing, & Carolyn Markey, *Enhancing Communication for End-of-Life Care: An Electronic Advance Directive Process*, 6 J. PALLIATIVE MED. 511, 512 (2003) (discussing three strategies for adding advance directives to electronic medical records: (1) the patient's advance directive is scanned into a graphic read-only format and added to the electronic medical record, (2) the health care provider dictates a note using a telephone transcription service, and (3) the health care provider types a note directly into the electronic medical record).

2. S. 415, 2005-2006 Legis. Sess. (Cal.) *available at* http://info.sen.ca.gov/pub/bill/sen/sb_0401-0450/sb_415_bill_20050523_amended_sen.pdf (last visited July 18, 2005) (stating: "This bill would require the Secretary of State to establish an Internet Web site that would allow an individual to register with the registry, and specified entities to request information from the registry on a 24-hours-a-day, 7-days-a-week basis.").

3. CAL. PROBATE CODE § 4800(b) (2004) ("The Secretary of State shall respond by the close of business on the next business day to a request for information made pursuant to Section 4717 by the emergency department of a general acute care hospital.").

4. For instance, if a request is made after the close of business on Friday evening, the person would not receive the document until Monday; if a request is made after the close of business on Monday evening, the person would not receive the document until Tuesday.

5. Wyoming Department of Health, Mental Health Division webpage, *at* http://mentalhealth.state.wy.us/pad/register/ (last visited July 20, 2005) ("The Wyoming State Hospital (WSH) in Evanston is designated as the Central Registry for your PAD.").

6. *Id.* ("The WSH has knowledgeable staff operating the Registry twenty four (24) hours a day, seven (7) days a week. The Registry provides copies by whatever means as necessary in an emergency or when you may not be competent to make requisite decisions on your own.").

7. Most existing registries issue wallet cards to registrants. Arizona registry webpage, *at* www.azsos.gov/adv_dir/Register.htm (last visited July 20, 2005); Choices Bank website, *at* www.choicesbank.org/deposit/how_to_deposit.asp (last visited July 20, 2005); H.R. 742, 59th Leg., Reg. Sess., sec. 3(2)(c)(i) (Mont. 2005), *available at* http://data.opi.state.mt.us/bills/2005/billhtml/HB0742.htm (last visited July 22, 2005) (Montana's statewide registry); NORTH CAROLINA DEPARTMENT OF THE SECRETARY OF STATE, REGISTRY BROCHURE: ADVANCE HEALTH CARE DIRECTIVE REGISTRY, *available at* www.secretary.state.nc.us/imaging/Dime/IVDOC_9003025.pdf (last visited

July 20, 2005); America Living Will Registry webpage, *at* www.alwr.com/section.cfm?id=14 (last visited July 20, 2005); DocuBank webpage, *at* www.docubank.com/General_Info/general_info.asp (last visited July 20, 2005); FullCircle Registry webpage, *at* www.fcrinfo.com/ (last visited July 20, 2005); U.S. Living Will Registry webpage, *at* www.uslivingwillregistry.com/faq.shtm (last visited July 20, 2005).

8. MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE, MENTAL HYGIENE ADMINISTRATION, ADVANCE DIRECTIVE FOR MENTAL HEALTH TREATMENT, *available at* www.dhmh.state.md.us/mha/misc%20pdf/4752%20advance.pdf (last visited July 21, 2005).

9. A form for organ donation instructions is available through the Maryland Attorney General's Office. STATE OF MARYLAND OFFICE OF THE ATTORNEY GENERAL, ADVANCE DIRECTIVES: A GUIDE TO MARYLAND LAW AND HEALTH CARE DECISIONS, "Organ Donation Addendum," *available at* www.oag.state.md.us/healthpol/adirective.pdf (last visited July 21, 2005).

10. H.D. 1004, 2005 Gen. Assem., 420th Reg. Sess. (Md.), *available at* http://mlis.state.md.us/2005rs/bills/hb/hb1004f.pdf (last visited July 18, 2005).

11. M. Rose Gasner, *The Unconstitutional Treatment of Nancy Cruzan*, 7 N.Y.L. SCH. J. HUM. RTS. 1, 17 (Spring 1990) ("Use of both living wills and durable powers of attorney for health care ... allows an individual to make known his or her own wishes ... regarding artificial life support and permits the individual to indicate who would be best suited to communicate those treatment preferences to the health care providers, interpreting and supplementing the instructions if necessary."); Ilene V. Goldberg, *S. Ct. Case Shows When Living Wills Can Be Used To Carry Out A Client's Wishes*, 17 ESTATE PLANNING 328, 331 (Nov. / Dec. 1990) ("If the living will does not specifically address the individual's circumstances and no one has been appointed to make health care decisions on the patient's behalf, it is possible that there will be conflict and confusion among the family members and health care providers, and the living will may be rendered ineffective. If a durable power of attorney is used, a proxy who understands the patient's wishes will be authorized to make appropriate decisions on the patient's behalf.").

12. MD. CODE, HEALTH-GEN. § 5-604.1 (1994) ("... an anatomical gift in an advance directive is valid and effective for all purposes under ..." the Maryland Anatomical Gift Act.).

13. MD. CODE, TRANSP. § 12-303(c) (1998) ("The donor designation noted on the driver's license or identification card: (1) is sufficient legal authority for the removal of a body organ or part on the death of the donor.").

14. MD. CODE, EST. & TRUSTS § 4-503(b) (1998) (If the patient's organ donation wishes are unknown, the patient's family, guardian or friend can make the donation decisions.).

15. An issue that will require careful consideration is how to reconcile any inconsistencies between a restricted anatomical gift in a DAG (for example, for transplantation but not research purposes) and the unqualified gift that arises from the designation of donor status on a driver's license. This issue, however, while it might become more prominent if DAGs were readily available from a registry, is present now.

16. MD. CODE, HEALTH-GEN. § 5-602.1(b) (2002) ("An individual who is competent may make an advance directive to outline the mental health services which may be provided to the individual if the individual becomes incompetent and has a need for mental health services either during, or as a result of, the incompetency.").

17. MD. CODE, HEALTH-GEN. § 10-809(b)(1)(iii)-(2) (2003).

18. VERMONT COMMISSIONER OF HEALTH, ADVANCE DIRECTIVE ACCESSIBILITY STUDY 15 (Jan. 15, 2005), *available at* www.healthyvermonters.info/admin/pubs/AdvanceDirectiveRpt.pdf (last visited July 18, 2005). In 2004, the Vermont Commissioner of Health was statutorily mandated to report to the Vermont legislature on developing a statewide registry. H.R. 752, 2003-2004 Reg. Sess., Sec. 2 (Vt. 2004).

19. ARIZ. REV. STAT. § 36-3291(A) (2004) ("Subject to the availability of monies, the secretary of state shall establish and maintain a health care directives registry.").

20. COMMISSIONER OF HEALTH, note 2 above, at 15.

21. Office Automation Solutions webpage, *at* www.oasolutions.com/soskb.asp (last visited July 20, 2005).

Chapter 3

Registry Operation

If Maryland went forward with a registry, its operation should serve the underlying goal of applying a patient's wishes accurately. Discussed below are mechanisms for ensuring that registered documents are usable (Section A), the means of submitting documents (Section B), updating registry records (Section C), and promoting public awareness of the opportunity to register their advance directives (Section D). Also discussed are two issues concerning health care providers' use of the registry: retrieval of advance directives from the registry (Section E), and immunizing health care providers from liability for failing to access registered documents or for using registered advance directives (Section F).

A. Ensuring the Registry Contains Usable Documents.

A key aspect of having an advance directive registry is that the registered documents can be implemented at the time of need. Barriers to the implementation of registered advance directives include concerns that a document is not authentic, does not comply with statutory requirements, is illegible, or is incomplete (e.g., it is missing a page). The discussion below explores steps that can be taken during the registration process to ensure that registered documents can be used.

1. Requiring Registrants to Submit Original Documents.

The issue is whether a registry should accept copies of advance directives, or if only original documents are acceptable. Registries take different stances on this issue. For instance, Arizona and Vermont allow registrants to submit copies of their advance directives,[1] whereas Choices Bank requires registrants to submit original advance directives.[2]

In Maryland, unaltered copies of advance directives are considered to be as valid as the originals.[3] Therefore, Maryland's registry would likely follow the example of the Arizona and Vermont registries and allow registrants to file copies of advance directives.

2. Requiring the Registry to Review Documents for Compliance with State Law, Legibility, and Completeness.

A registered advance directive may not be useable if it is non-compliant with the statutory requirements (e.g., dated, signed, and witnessed),[4] illegible, or incomplete (e.g., missing a page). Several registries address these issues by reviewing documents for compliance with state law, legibility, and completeness.

Such a requirement can be imposed by law. Montana's registry, for example, is required to review documents for compliance with state law.[5] If the document is not in compliance with state law, the registry will not register the document, and return it to the registrant.[6] On the other hand, a state legislature can excuse a registry from any compliance review, as is the case in Arizona and North Carolina.[7]

Several registries that do not review documents for compliance with state law check the legibility and completeness of documents.

The Arizona registry's document review is limited to checking the legibility of documents. The GIFTS registry's document review is limited to checking to see if all pages of a document were received.

If a registry does review documents, it should not review the substance of the registrant's health care instructions. It would be inappropriate for the registry to pass judgment on a declarant's wishes for health care. Furthermore, if document review constitutes the "practice of law," it must be performed by a lawyer.

3. Ensuring that Documents Are Correctly Filed: Record Verification.

It is important to ensure that documents are filed correctly in the registry. This can be achieved by having registrants verify that the registry's records are correct, or by designing the registry to have safeguards that protect against filing errors.

The Arizona registry and Choices Bank illustrate, respectively, rigid and relaxed approaches to registrant verification of registry records. Arizona requires registrant approval of records. The Arizona Legislature, concerned about incorrect filings of advance directives, statutorily mandated a verification process.[8] Each registrant receives, by mail, a printed record of the documents submitted to the registry.[9] The registrant must return a signed statement indicating "no corrections required," or submit corrections.[10] The registrant's account in the registry is activated after the registry receives confirmation that no corrections are required.[11] According to information from the Arizona Secretary of State's Office, there is a poor return rate on the verification forms: Of the 2100 documents registered, approximately 1000 have been activated. This low return rate indicates that the verification requirement is burdensome for registrants. Although Arizona's requirement is likely to ensure verification, its burden seems to outweigh its benefit. Choices Bank

recommends that registrants review their records. Each registrant receives, by mail, information on how to access their registered advance directives through the internet.[12] Registrants are encouraged to review their records online.[13] Because record review is optional, this approach to verification has no teeth. For different reasons, the methods of record verification used by Arizona and Choices Bank both seem unsatisfactory.

An alternative to registrant verification of registry records is to design the registry to have safeguards against filing errors. For instance, registry staff could be required to follow a protocol for filing the documents, thereby ensuring that documents are correctly deposited into the registry. More sophisticated safeguards may be possible with electronic registries (e.g., the registry could be designed to prompt the registry administrator when there are multiple registrants with the same name).

B. Means of Submitting Documents: In Person or by Mail

Existing registries use two primary methods to collect documents,in person or by mail.[14] The pros and cons of each method are discussed below.

Choices Bank requires registrants to submit documents to one of twenty deposit locations.[15] This gives registrants an opportunity to receive one-on-one assistance. Staff at the receiving locations can answer questions about advance directives and immediately review submitted advance directives to make sure the documents are originals, legible, and compliant with state law. If problems are identified, the documents can be handed back to the registrant immediately. However, in-person registration could be inconvenient for people, especially those who would not benefit from the one-on-one interaction. Further, establishing multiple deposit locations could

be costly; local organizations must provide space and staffing, and those operating the deposit locations must be trained.

Registration by mail appears to be convenient and cost-effective, but it lacks the element of personal interaction. If registrants are allowed to register documents by mail, they need not make a special trip to a deposit location to register. Costs are reduced because there need only be one location, where the mail is received. However, registrants would miss out on the benefits of one-on-one interaction with registry staff, including on-the-spot identification of problematic documents. A registry may be able to maximize convenience to all registrants by offering both in-person and mail-in registration, but at a higher overall cost than mail-in registration alone.

C. Updating Registered Advance Directives.

1. Annual Reminders.

USLWR and Choices Bank mail annual reminders to registrants, encouraging them to update the registry on any changes to their advance directives.[16] USLWR asks registrants to return a signed statement confirming their contact information and "certify[ing] that the advance directive previously submitted to the U.S. Living Will Registry has not been changed or revoked .... "[17] Choices Bank takes a different approach. It reminds the registrant that he or she "can update [the] advance directive by depositing a new one."[18] Unlike USLWR, Choices Bank does not ask their registrants to return written statements indicating the registered documents are current. Neither registry includes a hard copy of the currently registered document in the annual mailing.

Sending annual reminders to registrants may be an effective way of encouraging registrants to review their registered documents. If it decides to go forward with a registry, the Maryland General Assembly should consider whether to require such reminders. The reminders used by USLWR and Choices Bank provide a starting point for determining the content of a reminder letter, although additional material may be warranted. For instance, a thorough reminder could consist of the following: instructions to review directives and print-outs of currently registered advance directives (to facilitate review); an explanation of the reasons for, and benefits of, reviewing material regularly; a request for information as to whether the registrant amended or revoked the documents within the past year; and a return component, by which the registrant certifies that the registered documents express his or her current wishes.

2. Revocations and Amendments.

Registrants may amend or revoke their registered advance directives at any time "by a signed and dated writing, by physical cancellation or destruction, by an oral statement to a health care practitioner or by the execution of a subsequent directive."[19] Amending an existing advance directive would be the "execution of a subsequent directive," and therefore a revocation.[20] A registrant who revokes or amends a registered document should follow a clearly delineated process to inform the registry.

Revocation by written statement or a subsequent directive is ideal for an advance directive registry. In this situation, a registrant just needs to submit the document to the registry. The challenge lies in ensuring that people actually do so. As mentioned above, annual reminders could be used to encourage people to report amendments and revocations. Vermont law supports the registry's ability to learn of changes to registered documents by expressly allowing the registrant's health care providers and appointed agents to notify the

registry of changes to the registrant's advance directives. A health care provider "who becomes aware of an amendment, suspension, or revocation while treating a [patient] with capacity shall ... on request, assist the [patient] in notifying ... the registry."[21] Further, "[a]n agent or guardian who becomes aware of an amendment, suspension, or revocation shall make reasonable efforts to ... provide notice of the amendment, suspension, or revocation to ... the registry ...."[22]

Revocation by an oral statement made to a health care practitioner poses special challenges. For a person to revoke an advance directive by an oral statement to a health care practitioner, "the practitioner and a witness to the oral revocation shall document the substance of the oral revocation in the declarant's medical record."[23] However, statements recorded in a patient's medical record may never make their way to the registry. Registrants, health care providers, and appointed agents should be encouraged, or perhaps even required, to submit the revocation documentation to the registry.

Revocation by a registrant's physical destruction of an advance directive may not be a feasible option for documents housed in a registry. For example, if the registry is electronic, the registrant would have to destroy the electronic file of his or her advance directive. The General Assembly should consider disallowing this method of revocation for registered documents.

What if a registrant revokes or amends an advance directive but does not notify the registry? The laws of California, Montana, and North Carolina expressly preserve the validity of the new action. Although California law requires registrants to notify the registry of revocations and to reregister amended documents,[24] another provision states that failure to register an advance directive "does not affect the validity of any advance health care directive."[25]

Likewise, under the laws of Montana and North Carolina, failure to file a directive with the registry and failure to notify the registry of a revocation does not affect the validity of either the amendment or the revocation.[26] These laws effectively preserve registrants' discretion to amend or revoke advance directives. A negative consequence, however, is that the registries may not contain up-to-date documents.

D. Public Outreach

To make the creation and maintenance of a statewide registry worthwhile, it is important that residents be encouraged to create advance directives and to use the registry. The discussion below explores means by which the registry and end-of-life planning can be made more accessible to Marylanders.

Research indicates that the rate of use of advance directives varies significantly among segments of the population. Generally, studies indicate that whites and Asians are more likely to create advance directives than Hispanics and blacks.[27] Further, research indicates that people with higher levels of formal education are more likely to create advance directives than people who are less educated.[28] In explaining these differences, studies have found that lack of knowledge about advance directives is a factor. For instance, when blacks and whites were asked why they did not execute advance directives, blacks were much more likely to cite lack of knowledge of the existence of advance directives in their answers.[29] Education and outreach programs could help bring the discussion of end-of-life planning to more people. As seen in Ohio, a statewide education program can result in a significant increase in residents' creation of advance directives.[30] Consequently, an education and outreach effort should be an ongoing responsibility of whoever operates a registry.

For persons who have poor English comprehension, language can be a barrier to their creation of advance directives and use of a registry.[31] Consideration must be given to facilitating non-English speaking Marylanders' access to end-of-life planning and the advance directive registry. The Vermont legislature has required the Department of Health (the operator of the registry) to provide sample forms of advance directives for persons with "limited English proficiency."[32] USLWR accommodates Spanish-speaking registrants.[33]

E. Health Care Providers' Retrieval of Advance Directives from the Registry.

For the registry to be effective, health care providers must be able to have quick and easy access to the registered documents. As discussed in Chapter 2, the medium of the registry and the means by which a health care provider can access the documents determine whether providers have easy access to documents. Here we discuss two other issues concerning health care providers' retrieval of documents from the registry: the means by which newly admitted patients can be identified as registrants, and safeguards for ensuring that health care providers access the correct records.

1. Identifying Patients as Registrants.

Health care providers should be able to quickly and easily determine if a patient has registered an advance directive. Existing registries provide registrants with material that will help identify them as having registered an advance directive. Indicators of registration include wallet cards, pendants, and stickers to be placed on identification cards like a driver's license or health insurance card. Further, Montana and Vermont will modify driver's licenses and identification cards to include an indicator that the card holder is a registrant.[34] In the event that the patient possesses no indicators of

being a registrant, there should be a means by which health care providers can determine if a patient is registered. The health care provider could contact the registry through a customer service line, and a staff person could determine if the patient is a registrant; or health care providers could be allowed to search the registry to determine if the patient has registered documents. The latter is discussed in greater detail in Section 2, below.

2. Ensuring Health Care Providers Retrieve the Correct Documents When Using Online Registries.

One byproduct of having health care providers gain access to registered documents online is the concern that providers will somehow access the wrong document. For instance, if a health care provider is allowed free reign to search the registry, he or she may encounter multiple records with the same name as the patient. The provider might access the wrong record and implement the wrong advance directive. Arizona's registry and MyHealthDirective.com illustrate how this problem can be protected against.

Arizona's registry prohibits health care providers from searching the online system to determine if their patient is registered. The Arizona legislature was extremely concerned that if health care providers were allowed to search for this purpose, they could end up accessing the wrong person's advance directive. Consequently, Arizona established an online system in which access is registrant-controlled. Under this approach, health care providers are required to have the registrant's unique file number and password to access the system. This prevents providers from independently searching the registry, and in the eyes of the Arizona legislature, reduces the chance for error.

MyHealthDirective.com allows health care providers to search the registry to see if their patient is registered, but requires them to search with identifying information that is unique to the patient. To search the registry, the health care provider must provide the registrant's first and last name and either the registrant's social security number or member number (printed on the registrant's wallet card). By requiring a unique number in addition to the patient's name, the registry effectively eliminates the risk of retrieving the wrong record.

F. Liability of Health Care Providers

Arizona's statute protects health care providers against liability arising from their failure to access registered advance directives and from certain acts related to implementing registered advance directives. First, the Arizona statute expressly negates any duty on the part of health care providers to "request from the registry information about whether a patient has executed a health care directive."[35] Second, regarding health care providers' use of registered advance directives, the statute states: "A health care provider who makes good faith health care decisions in reliance on the provisions of an apparently genuine health care directive received from the registry is immune from criminal and civil liability ...."[36]

Conclusions

Registration. Ideally, usable documents will be easily registered and correctly filed in the registry. Maryland's registry should be able to accept copies of advance directives, as opposed to requiring the submission of original documents. The General Assembly should consider requiring the registry to review documents for compliance with state law, legibility, and completeness. To make registration

easy for all residents, the General Assembly should consider allowing for in-person registration and registration by mail. If the General Assembly determines it is worthwhile to verify that the registered documents are correctly filed, it should select an approach to record verification that is effective but not overly burdensome on registrants.

Updates. The General Assembly can take a number of steps to ensure that registered documents accurately represent registrants' current wishes for health care treatment. The General Assembly should consider creating a registry that is easily accessible to registrants, to encourage them to regularly review their registered documents. The General Assembly should consider the registry's use of annual reminders to prompt registrants to review their registered documents, and to certify that these documents represent their current wishes for health care treatment. The General Assembly should consider establishing requirements for registrants, health care providers, and appointed agents to notify the registry of amendments to and revocations of registered advance directives.

*Outreach.*To ensure that the registry is used and accessible, the State should provide education and outreach on advance directives and the registry. These efforts may need to be intensified for those groups that tend to be less informed about the existence of advance directives. Further, the State should make end-of-life planning accessible to Marylanders who have poor English skills by providing translated material on advance directives and the advance directive registry.

Use by health care providers. The registry and ancillary documents like identification cards should be designed so that health care providers are able to quickly determine if a patient has registered documents, and retrieve the correct advance directives from the registry. The General Assembly should consider immunizing

health care providers against liability for their good-faith failure to access registered documents. Given the broad grant of immunity already found in the Health Care Decisions Act,[37] a further grant of immunity related to good-faith reliance on advance directives obtained from the registry is probably unnecessary.

1. Arizona registry webpage, *at* www.azsos.gov/adv_dir/Register.htm (last visited July 22, 2005) ("Attach a copy of your witnessed or notarized Advance Directive to the Registration Agreement."); H.R.115, 2005-2006 Reg. Sess. § 9717 (Vt. 2005), *available at* www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/acts/ACT055.HTM (last visited July 18, 2005) ("A photocopy or facsimile of a duly executed original advance directive shall be relied upon to the same extent as the original.").

2. Choices Bank webpage, *at* www.choicesbank.org/deposit/how_to_deposit.asp (last visited July 22, 2005).

3. Letter from Jack Schwartz, Director, Health Policy Development, Maryland Office of the Attorney General, to Sigrid C. Haines, Lerch, Early & Brewer, Chtd. (May 21, 2004), *available at* www.oag.state.md.us/Healthpol/haines.pdf (last visited July 22, 2005); *See* Maryland Office of the Attorney General webpage, *at* www.oag.state.md.us/healthpol/AdvanceDirectives.htm (last visited July 22, 2005) ("Copies are just as valid as the originals.").

4. Under Maryland's Health Care Decisions Act, written advance directives must be "dated, signed by or at the express direction of the declarant, and subscribed by two witnesses." MD. CODE, HEALTH-GEN. § 5-602(c)(1) (2004). Further, the statute spells out who can serve as the witnesses. § 5-602(c)(2). If these requirements are met, the patient's advance directive should be implemented when the patient is incapable of making informed decisions or at the time specified in the document. § 5-602(e)(1); *See* 79 *Opinions of the Attorney General* 218, sec. VII (1994), *available at* www.oag.state.md.us/Opinions/1994/79oag218.pdf (last visited July 22, 2005). Maryland caselaw indicates that an advance directive does not have legally binding effect if the directive was not made according to statutory requirements. *Wright v. Johns Hopkins Health Systems Corp.*, 728 A.2d 166, 177-78 (Md. 1999).

5. H.R. 742, 59th Leg., Reg. Sess., sec. 3(1) (Mont. 2005), *available at* http://data.opi.state.mt.us/bills/2005/billhtml/HB0742.htm (last visited July 22, 2005) ("Upon receipt of a declaration pertaining to life-sustaining treatment, the attorney general shall determine if the declaration is in compliance with the provisions of 50-9-103."); MONT. CODE § 50-9-103 (2003) (The declarant must be 18 years old, and "[t]he declaration must

be signed by the declarant or another at the declarant's direction and must be witnessed by two individuals.").

6. H.R. 742, sec. 3(1) ("If the declaration is not in compliance with the provisions of 50-9-103, the attorney general shall return the declaration together with a statement that the declaration was not filed due to its nonconformance with the requirements of 50-9-103.").

7. ARIZ. REV. STAT. § 36-3294(B) (2004) ("The secretary of state is not required to review a document to ensure that it complies with the particular statutory requirements applicable to the document."); N.C. GEN. STAT. § 130A-468(a) (2001) ("The Secretary is not required to review a document to ensure that it complies with the particular statutory requirements applicable to the document.").

8. ARIZ. REV. STAT. § 36-3294(C)–(F) (2004).

9. ARIZ. REV. STAT. § 36-3294(C).

10. § 36-3294(D)–(E).

11. § 36-3294(F).

12. Choices Bank webpage, *at* www.choicesbank.org/deposit/how_to_deposit.asp (last visited July 22, 2005) ("Within two weeks of your deposit, you will also receive a Choices Bank Depositor Kit in the mail. This kit includes your original advance directive, two wallet cards with your confidential access code, instructions for reviewing your advance directive online, and information about updating it in the future.").

13. *Id.* ("Once you receive your Choices Bank Depositor Kit, use the information on the enclosed wallet cards to review your advance directive in the Choices Bank at www.choicesbank.org. If you don't have direct access to the Internet, you may use public Internet access at the Missoula Public Library (301 E. Main St.) and Missoula Aging Services (337 Stephens Avenue). You can also ask your health care provider, attorney's office, or faith community to review your advance directive online with you.").

14. America Living Will Registry is the exception. ALWR allows people to submit the registration form (but not the advance directives) through the Internet. ALWR also allows people to submit advance directives by fax. America Living Will Registry webpage, *at* www.alwr.com (last visited July 22, 2005).

15. Choices Bank webpage, *at* www.choicesbank.org/deposit/how_to_deposit.asp (last visited July 22, 2005). For a list of deposit locations see www.choicesbank.org/deposit/where_to_deposit.asp (last visited July 22, 2005).

16. U.S. Living Will Registry webpage, *at* www.uslivingwillregistry.com/info-english.shtm (last visited July 22, 2005) ("The registrant is contacted annually by mail to confirm that the advance directive has not been changed or revoked, and to update personal and emergency contact information."); Choices Bank webpage, *at* www.choicesbank.org/privacy.asp (last visited July 22, 2005) ("Once a year the Choices Bank will send a reminder to your address of record advising you to review your advance directive and revise it if necessary.").

17. U.S. Living Will Registry sample annual reminder (May 26, 2005) (on file with author). Note: a return component has the added feature of documenting a registrant's continued approval of the advance directives.

18. Choices Bank sample annual reminder (Feb. 11, 2005).

19. MD. CODE, HEALTH-GEN. § 5-604(a) (2005).

20. *Id.*

21. H.R.115, 2005-2006 Reg. Sess. § 9704(c)(2) (Vt. 2005), *available at* www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/acts/ACT055.HTM (last visited July 18, 2005).

22. H.R.115, § 9704(c)(4).

23. *Id.* § 5-604(b).

24. CAL. PROBATE CODE § 4802(b)-(c) (1999) ("(b) Each registrant must notify the registry upon revocation of the advance directive. (c) "Each registrant must reregister upon execution of a subsequent advance directive.").

25. CAL. PROBATE CODE § 4803 (1999).

26. H.R. 742, 59th Leg., Reg. Sess., sec. 2(3)(a)-(b) (Mont. 2005), *available at* http://data.opi.state.mt.us/bills/2005/billhtml/HB0742.htm (last visited July 22, 2005); N.C. GEN. STAT. § 130A-467 (2001).

27. Dan K. Kiely et al., *Racial and State Differences is the Designation of Advance Directives in Nursing Home Residents*, 49 J. AM. GERIATRICS SOC'Y

1346, 1350 (2001); G. Paul Eleazer et al., *The Relationship Between Ethnicity and Advance Directives in a Frail Older Population*, 44 J. AM. GERIATRICS SOC'Y 938, 942-43 (1996); Etienne Phipps et al., *Approaching the End of Life: Attitudes, Preferences, and Behaviors of African-American and White Patients and Their Family Caregivers*, 21 J. CLINICAL ONCOLOGY 549, 551 (2003).

The research results are not uniform. A study by Morrison and Meier of New York City seniors found that "African American, Hispanic, and White community-dwelling, older adults had similarly high rates of advance directive completion." R. Sean Morrison and Diane E. Meier, *High Rates of Advance Care Planning in New York City's Elderly Population*, 164 ARCHIVES INTERNAL MED. 2421, 2421 (2004).

28. Mathy D. Mezey et al., *Why Hospital Patients Do and Do Not Execute an Advance Directive*, 48 NURSING OUTLOOK 165, 169 (2000).

29. Mezey et al., note 28, at 168 (One reason given by hospitalized patients for not executing an advance directive was: "never heard about ADs before." From a sample of 779, 17 whites, 30 blacks, and 43 Hispanics gave this answer.); Elizabeth D. McKinley et al., *Differences in End-of-Life Decision Making Among Black and White Ambulatory Cancer Patients*, 11 J. GEN. INTERNAL MED. 651, 655 (1996) ("Four major themes emerged from patients' answers about why they did not have a living will (n= 169). These included:... 'I don't know about them' (29% black, 7% white) ....").

30. In Ohio, a statewide campaign sought to educate people on advance directives. Kiely et al., note 27, at 1351. Researchers comparing use of advance directives in California, Massachusetts, New York, and Ohio found that Ohio residents were much more likely to have a living will than were residents in the other states.

31. Eleazer et al., note 27, at 942-93 (Researchers consider language to be a barrier to the creation of advance directives by Hispanics and Asians.).

32. H.R.115, 2005-2006 Reg. Sess. § § 9719(a) (Vt. 2005), *available at* www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2006/acts/ACT055.HTM (last visited July 18, 2005) ("The commissioner shall also provide, but without the obligation to adopt a rule, optional forms for advance directives for individuals with disabilities, limited English proficiency, and cognitive translation needs.").

33. U.S. Living Will Registry webpage, *at* www.uslivingwillregistry.com/hospfaq.shtm (last visited July 23, 2005) ("The Registry has prepared Spanish translations of the information packet and the Registration Agreement.").

34. Montana's driver's license is being completely overhauled. It will allow the licensee to indicate whether he or she has advance directives in the registry. Vermont's license similarly will be modified to "allow the license holder ... to indicate that he or she has an advance directive and whether it is in the registry." H.R.115, 2005-2006 Reg. Sess. § § 9719(c)(2) (Vt. 2005). A California bill proposes that the Department of Motor Vehicles "print the term 'AD' or another appropriate designation on the face of the driver's license or identification card issued after January 1, 2006, to a person who submitted an enrollment form pursuant to this subdivision." S. 415, 2005-2006 Legis. Sess. (Cal.) *available at* http://info.sen.ca.gov/pub/bill/sen/sb_0401-0450/sb_415_bill_20050523_amended_sen.pdf (last visited July 18, 2005).

35. ARIZ. REV. STAT. § 36-3296(B) (2004).

36. *Id.*

37. MD. CODE, HEALTH-GEN. § 5-609 (2005).

INFORMATION ON PRIVATE ENTITIES

America Living Will Registry

The homepage for the America Living Will Registry is www.alwr.com/ (last visited July 18, 2005). The registry is owned by America Living Will, L.L.C. *See* America Living Will Registry webpage, *at* www.alwr.com/page.cfm?id=1 (last visited July 18, 2005).

Choices Bank

The homepage for Choices Bank is www.choicesbank.org/ (last visited July 18, 2005). The registry was created by the Life's End Institute: Missoula Demonstration Project. Choices Bank webpage, *at* www.choicesbank.org/faq.asp#21 (last visited July 18, 2005). Life's End Institute is a Not-For-Profit organization. Telephone interview with Susan Hancock, Choices Bank Project Director (May 25, 2005) (notes on file with author). The Institute "... focuses on a small western city, Missoula, Montana, as a proving ground for a new way of thinking" about dying. Life's End Institute webpage, *at* www.lifes-end.org/our_story.phtml (last visited July 21, 2005).

DocuBank

The homepage for DocuBank is www.docubank.com/ (last visited July 18, 2005). The registry is owned by Advance Choice, Inc. DocuBank website, *at* www.docubank.com/advance_choice/advance_choice.asp (last visited July 18, 2005).

MyHealthDirective

The homepage for MyHealthDirective.com is www.myhealthdirective.com/index.jsp (last visited July 18, 2005). The registry is owned by Healthcare Directive Partners. MyHealthDirective.com webpage, *at* www.myhealthdirective.com/page_server/AboutUs/About%20Us.html (last visited July 18, 2005).

U.S. Living Will Registry

The homepage for U.S. Living Will Registry is www.uslivingwillregistry.com/default.htm (last visited July 18, 2005). The registry is owned by National Living Will Registry, Inc. U.S. Living Will Registry sample Membership Agreement 1 (May 27, 2005) (on file with author).

FullCircle Registry

The homepage for FullCircle Registry is www.fcrinfo.com/ (last visited July 18, 2005). The registry is owned by FullCircle Registry, Inc. *See* FullCircle Registry homepage, *at* www.fcrinfo.com/ (last visited July 18, 2005).

GIFTS Advance Directive Registry

GIFTS Advance Directive Registry is one facet of the GIFTS suite of products, created by Gateway Files Systems, Inc. GATEWAY FILE SYSTEMS, INC., INTRODUCTION TO THE GIFTS SUITE OF PRODUCTS, available at www.giftsdirectives.com/Articles_pps/Giftsbooklet.pdf (last visited July 18, 2005). MedicAlert Foundation operates a repository of health information. MedicAlert website, *at* www.medicalert.org/Main/AboutUs.aspx (last visited July 18, 2005). The repository can hold advance directives. MedicAlert website, *at* www.medicalert.org/Main/AdvanceDirectives.aspx (last visited July 18, 2005).

PERSONAL CONTACT SOURCES OF INFORMATION

Apaco, William
Director, Division of Health Surveillance, Vermont Department of Health (May 26, 2005)

Barmakian, Joseph
President, U.S. Living Will Registry (May 25, 2005)

Dale, Matt
Director, Office of Consumer Protection and Victim Services, Office of Montana's Attorney General (May 31, 2005)

Hancock, Susan
Choices Bank Project Director (June 6, 2005)

Hayes, Chuck
Acting Administrator, Wyoming Department of Health, Mental Health Division (May 27, 2005)

Keaton, Karen
Chief Operating Officer, America Living Will Registry, L.L.C. (June 7, 2005)

McGlaughlin, Madeline
DocuBank (May 26, 2005)

McManus, Jim
Applications Development Manager, North Carolina Department of the Secretary of State (June 10, 2005)

Myers, Cheri
Acting Corporations Administrator, North Carolina Department of the Secretary of State (June 6, 2005)

Oakley, Trent
Executive Vice President and Chief Marketing Officer, FullCircle Registry, Inc. (May 28, 2005)

O'Neal, Dave
President, Health Directive Partners (May 26 and June 6, 2005)

Proctor, Liz
North Carolina Department of the Secretary of State (June 6, 2005)

Steinberg, Susan

Deputy Director, Community Programs and Managed Care, Mental Hygiene Administration, Maryland Department of Health and Mental Hygiene (June 2, 2005)

Towler, Frank

Gateway File Systems (May 31, 2005)

Volk-Craft, Barbara

Director of Program Development, Hospice of the Valley (May 26, 2005)

HEALTH INFORMATION PRIVACY

Regulations issued pursuant to the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) ensure the privacy of individually identifiable health information[1] and the security of electronic protected health information.[2] Under HIPAA, advance directives can be considered both individually identifiable health information and electronic protected health information.[3] While certain uses of confidential information are exempt from HIPAA requirements, it is unlikely that the use of advance directives (to direct the provision of health care) would qualify as an exception.[4]

HIPAA requires "covered entities" to protect the security and privacy of health information.[5] Covered entities are: (1) health plans; (2) health care clearinghouses; and (3) health care providers who transmit any health information in electronic form in connection with a transaction covered by HIPAA.[6] An advance directive registry itself would not fall into any of these categories.[7] However, those who access the registered document will often be health care providers subject to HIPAA requirements.

Maryland's laws on confidentiality of medical records limit disclosure of information contained in a patient's medical records. Under Maryland law, an advance directive would be considered a medical record.[8] Principally, the Maryland laws restrict health care providers' disclosure of information contained in medical records. The statutory definition of "health care provider" would cover the caregivers who access the registered advance directives, but would not include the registry itself.[9] Further, Maryland law prohibits anybody's redisclosure of protected information.[10]

The discussion below explores two issues pertaining to advance directives in the context of HIPAA and Maryland law: the transferability of advance directives and the security of registered advance directives.

A. Transferability of Advance Directives.

1. Transferring Documents from the Registry to Health Care Providers.

The registry itself would not be subject to either HIPAA requirements or Maryland's confidentiality laws. The registry's disclosure of advance directives to

health care providers does not present an issue under federal or state law. Therefore, the registry should be able to freely disclose the documents to the appropriate persons (i.e., health care providers and health care decision makers).

2. Transferring Documents from Health Care Providers to the Registry.

One approach to ensuring that registered documents are current is to require health care providers to provide the registry with amendments to and revocations of advance directives created while caring for registrant-patients. HIPAA would apply to a health care provider's disclosure of amended advance directives or statements of revocation to the registry. HIPAA addresses a number of circumstances in which a covered entity may disclose protected information. Depending on the circumstances, a health care provider may or may not be required to obtain a patient's consent, authorization, or agreement prior to disclosing the patient's advance directive (protected information) to the registry.[11] 45 C.F.R. § 164.506 could be interpreted as indicating that a health care provider would not be required to obtain a registrant-patient's consent prior to submitting documents to the registry.[12] If this interpretation is incorrect, another provision of HIPAA would apply. 45 C.F.R. § 164.510 would require health care providers to obtain the registrant-patient's oral agreement to the submission of documents to the registry.[13] However, if the patient is not available to agree to the disclosure, the health care provider could submit the documents to the registry without the patient's agreement.[14]

Maryland confidentiality law would apply to a health care provider's disclosure of amended advance directives or statements of revocation to the registry. Under Maryland law, a health care provider would need to obtain the registrant-patient's written consent to this disclosure.[15] However, the Legislature could relax this requirement in registry legislation through a provision that allows health care providers to disclose a registrant-patient's documents to the registry without obtaining the patient's consent.[16]

3. Redisclosure of Advance Directives Obtained from the Registry.

Under Maryland law, "[a] person to whom a medical record is disclosed may not redisclose the medical record to any other person unless the redisclosure is ... [a]uthorized by the person in interest ...."[17] An advance directive is a medical record under §4-301(g)(1) of the Maryland Code and is entered into the patient's

medical file under §5-602(f)(2)(i)-(ii) of the Code. Therefore, a health care provider who obtains an advance directive from the registry is not to share the document with other health care entities or individuals (i.e., the patient's family members) without the patient's consent. This restriction on sharing the advance directives with concerned parties could become problematic. Imagine a situation in which an incompetent patient did not inform his family that he created an advance directive (i.e., a Living Will, but not a DPAHC), and did not authorize redisclosure of the document. The doctors treating the patient identify him a registrant, and obtain his advance directive from the registry. Under Maryland law, the doctors would be required to implement the directive without sharing it with the patient's family. The family, unable to see the document, could become wary of the doctors' treatment of the patient. One approach to avoiding the prohibition on redisclosure is for the registrant to prospectively authorize individuals and groups (e.g., caregivers) to redisclose the documents. A clause to this effect could be added to the advance directive or a registration agreement.

B. Security of Registered Advance Directives.

HIPAA requires covered entities to comply with security standards for the protection of electronic protected health information.[18] As noted above, an advance directive registry would not be considered a covered entity. Therefore, the registry is not required to comply with HIPAA security standards as spelled out in 45 C.F.R. Part 164 Subpart C.

1. 45 C.F.R. part 164 subpart E.

2. 45 C.F.R. part 164 subpart C.

3. The terms "individually identifiable health information" and "electronic protected health information" are defined under 45 C.F.R. § 160.103 (2003).

   Advance directives fit the definition of "individually identifiable health information." An advance directive: (1) is received by a health care provider; (2) relates to the provision of health care to an individual; and (3) identifies the individual.

   "Electronic protected health information" is individually identifiable health information that is either maintained or transmitted in electronic media. If the registry stores electronic files of the advance directives, they would qualify as electronic protected health information.

4. Use of protected health information for public health purposes is exempt. The HIPAA statutes do not " invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b) (1996). The HIPAA regulations further explain: the general rule applies, except if "State law ... provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention." 45 C.F.R. § 160.203(c) (2002). It is not likely that the registry and its services would constitute public health investigation, intervention, or surveillance.

5. Several sections of the Code of Federal Regulations specify the applicability of HIPAA security and privacy provisions to covered entities. 45 C.F.R. § 164.104(a)(1)-(3) (2003); § 164.302 (2003); § 164.500(a) (2003).

6. 45 C.F.R. § 160.103 (2003) (defining the term "covered entity.").

7. 45 C.F.R. § 160.103 defines the three terms:

   (1) Health plan: " means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2))." 45 C.F.R. §160.103.

   (2) The definition of health care clearinghouse is convoluted. To summarize: A clearinghouse is an entity that handles the data for "transactions" which are covered by HIPAA. A clearinghouse converts the transaction data into standardized or non-standardized forms; the standardized form of data is the data coding format prescribed by HIPAA. 45 C.F.R. § 160.103 (definition of "health care clearinghouse"); 45 C.F.R. § 162.103 (2003) (definitions of "format," "data content," "data elements"). The issue is: would the registry be considered an entity which handles *transactions* data? Transmission of advance directives to and from the registry would not be considered a "transaction" under HIPAA.

   (3) Health care provider: "means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business." 45 C.F.R. § 160.103.

8. MD. CODE, HEALTH-GEN. § 4-301(g)(1) (defining "medical record." Advance directives fit the definition. First, a registered advance directive will be stored in written and / or electronic form. Second, a directive will be "entered in the record of a patient .... " according to § 5-602(f)(2)(i)-(ii). Third, the directive identifies a patient. Fourth, the directive "[r]elates to the health care of the patient ....").

9. *Id.* § 4-301(h).

10. MD. CODE, HEALTH-GEN. § 4-302(d).

11. 45 C.F.R. § 164.506 (2002) (subsection (b) states that a covered entity "may obtain consent."); *id.* § 164.508 (2002) (authorization required); *id.* § 164.510 (2002) (an individual must have the opportunity to agree to, prohibit, or restrict the disclosure); *id.* § 164.512 (2002) (circumstances when a covered entity does not need to obtain written authorization prior to disclosure of protected health information).

12. Reading 45 C.F.R. § 164.506(b)(1) and § 164.506(c)(2) together, a covered entity is not required to obtain a patient's consent prior to disclosing the patient's protected information for "treatment activities." Section 164.501 (2003) defines "treatment" as follows: "Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another." A health care provider's submission of an updated advance directive to the registry could be considered "coordination of health care" under the definition of "treatment." The submission of new advance directives to the registry ensures that the registered documents are up-to-date, and thereby ensures that a registrant-patient's future health care providers give the patient appropriate care.

13. Under 45 C.F.R. § 164.510: "A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section." Section 164.510(b)(1)(i) specifies that if the individual agreed to the disclosure, or if the individual could not agree to the disclosure and the covered entity deemed the disclosure to be in the individual's best interest, the ". . . covered entity may . . . disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's care or payment related to the individual's health care." The registry could be considered "any other person

identified by the individual." Since the registry has housed the patient's documents in the past, receiving updated documents is directly relevant to the registry's involvement in the patient's care.

14. Under 45 C.F.R. 164.510(b)(3): "If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care."

15. MD. CODE, HEALTH-GEN. § 4-303(a)-(b).

16. MD. CODE, HEALTH-GEN. § 4-302(a)(2)(ii).

17. *Id.* § 4-302(d)(1). Under § 4-302(d) there are four situations in which redisclosure is allowed: (1) redisclosure is authorized by the person in interest; (2) redisclosure is otherwise permitted by Title 4, Subtitle 3; (3) the reports/records concern child abuse or neglect, and disclosure is permitted under Article 88A, § 6(b) of the Code; or (4) directory information is being redisclosed. Only the first is relevant to the redisclosure of advance directives obtained from the registry.

18. 45 C.F.R. § 164.302 (2003).