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Best Practices for Establishing Georgia's Alzheimer's Disease Registry

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Best Practices for Establishing Georgia’s Alzheimer’s Disease Registry

Elizabeth Weeks Leonard,* Rui Bu** & Amanda Alexandra Brown***

ABSTRACT

In May 2014, the Georgia General Assembly enacted legislation establishing the Alzheimer’s Disease Registry (Registry) in order to generate new data for research and policy planning.1 The Georgia Alzheimer’s and Related Dementias State Plan Task Force (Task Force) bill followed similar federal legislation.2 This state action has not only drawn tremendous attention to the continued prevalence of Alzheimer’s disease

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among the population of Georgia but also raised a series of questions regarding the practicability, legality, and effectiveness of the Registry.\footnote{See, e.g., Memorandum from Toni Miles, MD, Institute of Gerontology, University of Georgia and Organizer of the North Georgia/UGA Sponsored Stakeholder’s Meeting to Brenda Fitzgerald, MD, State Health Commissioner, Georgia Department of Public Health (June 18, 2014) (on file with author) [hereinafter Sponsored Stakeholder’s Meeting Memorandum] (discussing the scope of the Registry in terms of data collection methods, data access, and data usage). An extensive review of the Stakeholder’s Meeting is discussed infra Part I.C.} The lessons learned in Georgia, as the Registry implementation moves forward, will provide guidance for other states interested in collecting similar data. In Section I of this article, we describe the legislative history and operation of the Registry. In Section II, we compare the two other population-based Alzheimer’s disease registries in the United States. In Section III, we identify legal and ethical problems that may arise as the Registry becomes fully operational. In Section IV, we identify specific concerns regarding the data collection and other procedural rules of the Registry. Finally, in Section V, we articulate best practices for the Georgia Registry, considering both the unique circumstances of the state as well as generalizable concerns for other states.

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INTRODUCTION

This article will recommend best practices for establishing a comprehensive population-based Alzheimer’s disease registry (the Registry) in Georgia. We anticipate that Georgia is leading a nationwide trend in addressing the rapidly rising incidence of Alzheimer’s disease and related dementia within the aging population. Accordingly, our recommendations will

4. There are two main types of Alzheimer’s disease registries: hospital-based and population-based. See generally N.Y. Dep’t of Health, Chronic Disease Teaching Tools – Disease Registries, HEALTH.NY.GOV (Apr. 1999), https://www.health.ny.gov/diseases/chronic/diseaser.htm (explaining hospital-based and disease-based disease registries). Population-based Alzheimer’s disease registries seek to collect data on all new cases of Alzheimer’s disease occurring in a well-defined population. See generally id. Usually, the population is the residents in a particular geographical region. Id. As a result, the main objective of this type of Alzheimer’s disease registry is to produce statistics on the occurrence of Alzheimer’s disease in a defined population and to provide a framework for assessing and controlling the impact of Alzheimer’s disease in the community. Thus, the emphasis is on epidemiology and public health. See also SEER Training Modules, Population-Based Registries, NAT'L CANCER INST., http://training.seer.cancer.gov/registration/types/population.html (last visited Sept. 13, 2015) (“In comparison to the hospital-based cancer registry, the data collected by the population-based registry serves a wider range of purposes.”).

be valuable not only for Georgia but also for other states that may establish similar databases in the future.\textsuperscript{6}

Alzheimer’s disease destroys brain cells and affects memory, thinking, and behavior.\textsuperscript{7} The Centers for Disease Control and Prevention (CDC) estimates that “Alzheimer’s disease is perhaps the most common form of dementia”\textsuperscript{8} and the Alzheimer’s Association estimates it constitutes between sixty and eighty percent of dementia cases.\textsuperscript{9} The disease is “the sixth-leading cause of death in the United States”\textsuperscript{10} and costs more than $200 billion in annual health care costs.\textsuperscript{11} As of 2014, there are nearly 130,000 Georgians suffering from Alzheimer’s disease, and that number is expected to rise to 190,000 by the year 2025.\textsuperscript{12} As the Baby Boomer generation ages and medical advances extend life expectancy, the prevalence of Alzheimer’s disease will continue to grow.\textsuperscript{13} According to the report released in 2011 by Alzheimer’s Disease International, a global patient advocacy organization, thirty-six million people worldwide have Alzheimer’s disease or other dementias, and as many as twenty-eight million may have not been diagnosed.\textsuperscript{14} In fact, CDC research indicates that over

\begin{itemize}
  \item 6. Although the Registry is called an Alzheimer’s Disease Registry, it tracks both patients with Alzheimer’s disease and related dementias. See GA. CODE ANN. \textsection{} 31-2A-17 (2015) (“The registry shall provide a central data base of individuals with Alzheimer’s disease or related disorders.”) (emphasis added).
  \item 7. \textit{See What is Alzheimer’s?}, ALZHEIMER’S ASS’N, http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp (last visited Feb. 25, 2015) (“As damage spreads, cells lose their ability to do their jobs and, eventually die, causing irreversible damage in the brain.”).
  \item 9. 2014 \textit{ALZHEIMER’S DISEASE: FACTS AND FIGURES}, supra note 5, at 6 tbl.1 (stating that Alzheimer’s is the “[m]ost common type of dementia; account[ing] for an estimated 60 percent to 80 percent of cases”).
  \item 11. \textit{Id.} at 43 (“Total payments in 2014 (in 2014 dollars) for all individuals with Alzheimer’s disease and other dementias are estimated at $214 billion.”).
  \item 12. \textit{Id.} at 22 tbl.2.
  \item 13. \textit{Id.} at 23.
\end{itemize}
fourteen percent of Georgians ages sixty or older report that they have been increasingly experiencing confusion or memory loss.\textsuperscript{15}

In response to such widely shared concerns about Alzheimer’s disease, on March 20, 2014, the Georgia General Assembly passed House Bill 966,\textsuperscript{16} creating a statewide comprehensive population-based Alzheimer’s disease registry that will be housed within the Georgia Department of Public Health.\textsuperscript{17} The Georgia bill was signed by Governor Nathan Deal on April 29, 2014 and enacted into law on July 1, 2014.\textsuperscript{18} The bill follows a national trend, exemplified in President Obama’s Administration’s comprehensive plan to fight Alzheimer’s disease. The national Alzheimer’s plan aims to enhance research to more effectively treat and cure Alzheimer’s disease, increase efficiency and quality of care, support patients and their families, augment public awareness of Alzheimer’s disease, and improve data collection.\textsuperscript{19}

Senator Renee Unterman, Chair of the Senate Health and Human Services Committee, who sponsored Georgia’s legislation, has been enthusiastic about the new Registry.\textsuperscript{20}


\textsuperscript{17} See id. at § 1, art. 9 (“There is established within the Department of Public Health the Alzheimer’s Disease Registry.”).


Despite strong support, there is concern that the Registry invades patients’ personal privacy and could compromise physicians’ ethical duties to their patients.\textsuperscript{21} Also, because a disproportionate number of people diagnosed with Alzheimer’s disease, both nationally and in Georgia, are ethnic minorities,\textsuperscript{22} the Registry should be especially attuned to the special needs of those particular groups. By closer consideration of those and other concerns, this article will recommend best practices for Georgia and other states considering similar registries.

I. GEORGIA ALZHEIMER’S DISEASE REGISTRY

A. STATE INITIATIVE AGAINST ALZHEIMER’S DISEASE

Georgia has experienced an exponential increase of people who are diagnosed with Alzheimer’s disease. In the next ten years, incidence of Alzheimer’s disease in Georgia is projected to increase by 46.2%.\textsuperscript{23} One factor explaining the rise may be Georgia’s increasing popularity as a retirement destination.\textsuperscript{24} Alzheimer’s disease is a disease that almost exclusively affects the older population.\textsuperscript{25} This growing trend will continue to financially burden the state and its taxpayers.\textsuperscript{26} “The national

\begin{itemize}
\item trained nurse and a trained social worker, and she has been twice named “Public Health Hero” by the Georgia Public Health Association. \textit{Id.} She has also been a regular contributor to Aging Services of Georgia. \textit{Id.}
\end{itemize}


25. \textit{See} 2014 ALZHEIMER’S DISEASE: FACTS AND FIGURES, \textit{supra} note 5, at 16 (“\textit{A}n estimated 5 million people age 65 and older and approximately 200,000 individuals under age 65 who have younger-onset Alzheimer’s.” (internal footnote omitted)).

26. S. 14, 152d Gen. Assemb., Reg. Sess. §1, art. 9 (Ga. 2013) (“The General Assembly further finds that access to quality health care for
per patient lifetime cost for Alzheimer’s Disease care is currently estimated at $175,000.”27 With approximately 130,000 Georgians currently estimated to be diagnosed with Alzheimer’s disease, the state’s cost over the lifetime of all individuals suffering from the disease is estimated to exceed twenty billion dollars.28 Since Georgia is projected to have 190,000 Alzheimer’s patients in 2025,29 the economic impact of the disease could exceed thirty billion dollars.30 That staggering figure does not even account for the economic impact on unpaid caregivers, who, on a national scale, provide billions of hours of services, not reflected in these cost estimates.31 Those caregivers frequently suffer from their own medical issues as a result of the stress and frequently must take time off of work or retire early, which causes further economic impact.32

More information is needed to effectively address the increase of Alzheimer’s disease across the population.33 It is extremely difficult to count accurately even the number of current cases—let alone as-yet undiagnosed cases—to project

Alzheimer’s and related dementias and the rising cost of such care are vitally important to the citizens of Georgia.”).


28. See 2014 ALZHEIMER’S DISEASE: FACTS AND FIGURES, supra note 5, at 22 (projecting the number of Georgia citizens who are afflicted with Alzheimer’s).

29. Id. at 22.


31. 2014 ALZHEIMER’S DISEASE: FACTS AND FIGURES, supra note 5, at 33 (“Unpaid caregivers in each of the four most populous states . . . provided care valued at more than $14 billion.”).

32. Id. at 34 (“T]he care required of family members can result in . . . health impairments, [and] lost wages due to disruptions in employment and depleted income and finances.”).

33. E.g. Preventing Alzheimer’s Disease: What Do We Know?, NAT’L INST. ON AGING, https://www.nia.nih.gov/alzheimers/publication/preventing-alzheimers-disease/search-alzheimers-prevention-strategies (last updated Feb. 13, 2015) (“Observational studies have associated factors such as physical activity, blood pressure, and diabetes control with changes in risk. More research is needed to determine whether these factors can in fact directly help prevent Alzheimer’s or cognitive decline.”).
future growth.34 The influx of retirees to Georgia will make projections especially difficult.35 The Registry will provide clearer data regarding the impact of Alzheimer’s disease and related dementias on the state of Georgia, information that may be used for research, policy planning, and treatment purposes.36

Against this background, in 2013, the Georgia General Assembly passed Senate Bill 14, creating the Georgia Alzheimer’s and Related Dementias State Plan Task Force (Task Force).37 This bill resulted from “a joint effort of the [Georgia] Department of Human Services, the Division of Aging Services and the [Georgia] Department of Health.”38 The Task Force was greatly influenced by a federal statute, the National Alzheimer’s Project Act of 2011, “which required the U.S. Department of Health and Human Services to create a plan, coordinate research, and improve the care and treatment of Alzheimer’s disease.”39 Nationwide, more than forty states, including Georgia, are developing state plans consistent with

34. See Raines, supra note 2 (quoting Dr. Toni P. Miles: “[c]ounting the number of people with Alzheimer’s and projecting how it will grow isn’t as easy as it sounds.”).

35. Id. (quoting Dr. Toni P. Miles: “Georgia has special issue in that it is a retirement destination, so we aren’t sure how rapidly the elderly population is going to grow.”).

36. See Population-Based Registries, supra note 4 (“Data from population-based registries can be used for monitoring the distribution of late-diagnosed cases of cancer of the types for which early diagnosis is the strategy for control.”).


38. See Raines, supra note 2 (citing Dr. Toni P. Miles).

39. See id. (quoting Dr. Toni P. Miles); see also OBAMA ADMINISTRATION PRESENTS NATIONAL PLAN TO FIGHT ALZHEIMER’S DISEASE, supra note 19 (discussing the federal government’s “national plan to fight Alzheimer’s disease”).
the goals of the National Alzheimer’s Project.\textsuperscript{40} Georgia is one of the first states to establish a Registry.\textsuperscript{41}

Georgia’s Senate Bill 14 included formal recognition by the General Assembly of the gravity of Alzheimer’s disease throughout the nation.\textsuperscript{42} It also recognized the importance of assessing the strengths and weaknesses of Georgia’s ability to provide essential services and programs to patients with Alzheimer’s disease and other dementias.\textsuperscript{43} Finally, it noted the importance of leveraging resources from the private, public, and non-profit sectors (including faith-based) to improve the state’s ability to combat all forms of dementia.\textsuperscript{44}

On June 23, 2014, the Advisory Council “released a state plan that is expected to improve services, safety, treatment, housing, and public education for people with Alzheimer’s disease and other forms of dementia.”\textsuperscript{45} “The plan is the product of a six month consultation process that brought elected officials from both political parties together with patients, families, advocates, and 50 experts representing education, health care, public safety, financing, housing and transportation.”\textsuperscript{46} It features recommendations in five areas:

\begin{enumerate}
\item Coll. of Pub. Health: Inst. of Gerontology, \textit{Community, UGA Collaborate on Alzheimer’s Registry}, UNIV. OF GA. (June 16, 2014), http://www.publichealth.uga.edu/geron/news/community-uga-collaborate-alzheimer%E2%80%99s-registry (“Georgia is only the third state to create such a tool useful for research, first responders, policy makers, caregivers, and families.”).
\item \textit{See S. 14, 152d Gen. Assemb., Reg. Sess.} § 1 art. 9 (Ga. 2013) ("The General Assembly finds and declares that Alzheimer’s disease is a looming national public health crisis and impacts every state.").
\item \textit{Id.}
\item \textit{Id.}
healthcare, research, and data collection; workforce development; service delivery; public safety; and outreach and partnerships. Each area features a set of goals and corresponding strategies.

B. SCOPE AND OBJECTIVE OF THE GEORGIA REGISTRY

The reported incidence of Alzheimer’s disease in the aging population is increasing at an alarming rate both nationwide and in Georgia, and this may represent just the tip of the iceberg. Many people do not enter the medical system until the later stages of the disease, after they have developed other chronic illnesses such as diabetes or heart disease, which are often easier to diagnose. To improve data collection on actual Alzheimer’s disease incidence, this year, Georgia introduced its own population-based registry. The Alzheimer’s disease registry was created in order to provide accurate data for research and policy planning, including identification of Alzheimer’s/dementia risk factors and identification of

RELATED DEMENTIAS STATE PLAN, supra note 45, at 39 (listing the various collaborators to the Plan).

47. GEORGIA ALZHEIMER’S AND RELATED DEMENTIAS STATE PLAN, supra note 45, at 39–40.

48. Id. at 40–58.

49. Id. at 8–9 ("In the past six years alone, the number of Georgians reporting symptoms of dementia increased by 22 percent to 120,000 – this is a 427% increase from the 1985 estimates.").

50. See id. at 16 (stating that the exact number of Georgians with dementia is unknown).

51. For a discussion on how late diagnoses is a major problem among minority populations that are already at greater risk for developing Alzheimer’s and related diseases, see Brenda Patoine, Alzheimer’s and Dementia in Minority Populations: Unraveling Risks, Overcoming Barriers, THE DANA FOUND. (2015), http://www.dana.org/Briefing_Papers/Alzheimer_s_and_Dementia_in_Minority_Populations__Unraveling_Risks__Overcoming_Barriers/. For a more detailed discussion of the impact of Alzheimer’s and dementia on minorities, see Part V.

52. Cf. ALZHEIMER’S ASS’N, 2015 ALZHEIMER’S DISEASE FACTS AND FIGURES: DISCLOSING A DIAGNOSIS (MAR. 2015), https://www.alz.org/facts/downloads/ff_quickfacts_2015.pdf ("Less than half (45 percent) of seniors diagnosed with Alzheimer’s disease or their caregivers are aware of the diagnosis, compared with 90 percent or more of those diagnosed with cancer and cardiovascular disease." (emphasis added)).

53. See GEORGIA ALZHEIMER’S AND RELATED DEMENTIAS STATE PLAN, supra note 45, at 61 app. I (presenting the number of individuals at-risk for Alzheimer’s and related dementias in the Georgia population).

demographic groups in which the prevalence of Alzheimer’s/dementia is higher. 55

The Georgia Department of Public Health (DPH) is tasked with the responsibility of “promulgat[ing] rules and regulations for the establishment and operation of the registry.” 56 The DPH must collect and evaluate prevalence data, create data retention policies, create appropriate data sharing policies for researchers and public policy makers, and create a system to both gather additional data from patients and inform them about available resources. 57 Currently, the promulgation of the procedural rules is still ongoing within the DPH. As part of the rulemaking process, DPH sought public comment and input from a wide range of stakeholders. 58 In July 2014, the Institute of Gerontology at the University of Georgia 59 convened a day-long meeting to develop a set of comments for submission to DPH, as described in the next section. 60

C. STAKEHOLDERS’ EFFORTS TO ESTABLISH REGISTRY

On June 16, 2014, in order to involve the broader Alzheimer’s disease community and address the questions of various groups affected by the legislation, the University of Georgia Institute of Gerontology hosted the Alzheimer’s Disease Registry Stakeholder Conference. 61 According to Dr. Toni Miles, 62 the key convenor, the conference was held as a “follow-up” to a DPH meeting on May 22, 2014, in an effort to give additional people an opportunity to contribute to the conversation. 63 Dr. Miles and co-convenors invited the University of Georgia and Athens-Clarke County communities to come together to discuss potential elements of and uses for

55. GEORGIA ALZHEIMER’S AND RELATED DEMENTIAS STATE PLAN, supra note 45, at 11.
56. Id.
57. Id.
58. See infra Part I.C.
59. Authors Weeks, Leonard, and Bu served as reporters and conveners, under the Institute’s Director, Dr. Toni Miles.
60. See Community, UGA Collaborate on Alzheimer’s Registry, supra note 41.
61. Id.
62. Dr. Miles is the current Director of the Gerontology Institute at the University of Georgia and was the organizer of the Alzheimer’s Disease Registry Stakeholder Conference. Id.
63. Id.
the Registry.64 The University of Georgia community included representatives from the Law School, the College of Public Health, the Carl Vinson Institute of Government, and other outreach divisions of the University that collaborate directly with the surrounding communities.65 Athens-Clarke County community members included law enforcement officers, health workers, and representatives of local social service and other nonprofits that support health or aging issues.66 The keynote speaker was a neurologist from Emory University.67

Following an opening presentation related to current diagnosis and treatment of Alzheimer’s and related dementias, attendees were divided into groups of eight and ten people to engage in a facilitated discussion. The break-out groups were asked to consider the following questions:

1. Who are the end-users of this [R]egistry?
2. What type of information should be collected in the Registry?
3. How (or from whom) should the information be collected?
4. How should the information be shared or disclosed for policy planning [or for] research purposes?68

The entire assembly then reconvened to report and compile comments from the break-out groups.69

Regarding the end-users question, groups identified “[s]trategic planners, law enforcement, public safety[, c]ounty government [particularly] as it plans budget related policies[, . . . h]ospitals, [e]mergency [d]epartments, [e]state planners, and d]isaster and emergency evacuation planners.”70 Regarding the type of information to be collected, stakeholders listed: de-identified “[d]emographics[]; h]ealthcare utilization history and community resources used by the individual[]; l]iving arrangements[]; a]ssociated health conditions . . . [including the]
need for assistive technology; and licenses held by the person with dementia.”\footnote{Id.} Regarding how and from whom data should be collected, the groups were reticent to mandate reporting by health care providers.\footnote{Cf. id. (illustrating how health care providers are absent from the suggested list of sources which data should be collected from).} Instead, they suggested alternative data sources such as Georgia’s Online Analytical Statistical Information System (OASIS), “[a]pplications for handicap [parking] tags[, d]eath certificates, medical examiner[s], health insurance claims[, l]aw enforcement calls[, and] allowing patients and families to enter their own data.”\footnote{Id.} Finally, in response to the question regarding disclosure for research purposes, they suggested that aggregate, de-identified data should be made widely available.\footnote{Id.} They also suggested a “[r]estricted electronic version for researchers and budget planners with a well-developed application process.”\footnote{Id.}

Following the Stakeholder Conference, the conveners debriefed, then summarized and reported the findings back to DPH.\footnote{Id. The Sponsored Stakeholder’s Meeting Memorandum was sent to Brenda Fitzgerald, the State Health Commissioner at the Georgia Department of Public Health. Id.} The hope was that those comments would be included with other, similar sets of comments to assist in promulgating rules and regulations for the establishment and operation of the Registry. The Registry and its online portal for submitting data launched in March 2015. According to news reports, “[i]t will be populated by a mix of existing data sources from health plans and government repositories, including Medicare and Medicaid, and patient information reported by physicians.”\footnote{Nancy Nydam, Alzheimer’s Disease and Related Dementias Registry: Georgia’s Blueprint for the Future, GA. DEPT PUB. HEALTH BLOG (Mar. 30, 2015), https://dph.georgia.gov/blog/2015-03-30/alzheimer%E2%80%99s-disease-and-related-dementias-registry-georgia%E2%80%99s-blueprint-future.} For now, only physicians may access the portal to report new cases, and reporting is voluntary.\footnote{GA. DEPT PUB. HEALTH, GEORGIA ALZHEIMER’S AND RELATED DEMENTIAS REGISTRY (GARDR) USERS GUIDE (2015), http://dph.georgia.gov/sites/dph.georgia.gov} No detailed reporting procedures and requirements have been formalized.

\footnotesize

\begin{itemize}
\item \textsuperscript{71} Id.
\item \textsuperscript{72} Cf. id. (illustrating how health care providers are absent from the suggested list of sources which data should be collected from).
\item \textsuperscript{73} Id.
\item \textsuperscript{74} Id.
\item \textsuperscript{75} Id.
\item \textsuperscript{76} Id. The Sponsored Stakeholder’s Meeting Memorandum was sent to Brenda Fitzgerald, the State Health Commissioner at the Georgia Department of Public Health. Id.
\item \textsuperscript{78} GA. DEPT PUB. HEALTH, GEORGIA ALZHEIMER’S AND RELATED DEMENTIAS REGISTRY (GARDR) USERS GUIDE (2015), http://dph.georgia.gov/sites/dph.georgia.gov
\end{itemize}
II. OTHER COMPREHENSIVE POPULATION-BASED ALZHEIMER’S DISEASE REGISTRIES IN U.S.

Georgia’s Registry operates within long-established strategies to address diseases affecting the public’s health, but is somewhat unique in targeting a widespread but non-contagious disease. Governments and public health officials have long struggled to protect their citizens from health crises. Over the past century, monitoring of and intervention against specific diseases have become central features of public health systems in most developed countries. “Registry systems designed to collect detailed data enabling governments to track and prevent dangerous diseases are one of the most widely used forms of government monitoring.” Although the vast majority of public health registries in the past century have focused on collection of infectious disease data, registries for non-infectious diseases, such as Alzheimer’s disease, diabetes, and cancer, have also been created. In 1988, South Carolina was one of the first states to begin collecting information on Alzheimer’s disease diagnoses with a population-based disease registry and was later followed by

/files/GARDR%20Provider%20User%20Guide.pdf (explaining how to add new cases to the registry and search for existing cases). The User’s Guide does not specify who may or must report or identify other sources of data. Id.


80. See id.

81. See id.


84. See Krent et al., supra note 82, at 1–2 (“New York’s diabetes registry is the first in the nation to require collection of personal testing date for the purpose of monitoring treatments for a noninfectious disease.” (emphasis added)).

85. See Caroline Macera et al., The South Carolina Alzheimer’s Disease Patient Registry: A Progress Report, 6 AM. J. OF ALZHEIMER’S CARE & RELATED DISORDERS & RES. 35–38 (Jan./Feb. 1991) (“In April 1988, the American
West Virginia in 2006. In 1984, the California legislature also established the Alzheimer Disease Program (ADP) in the California Department of Health Services (CDHS). In 1986, New York State established the Alzheimer’s Disease and Other Dementias Registry. The New York and California registries operate mostly from voluntary reporting and are underutilized. Because we anticipate more rigorous enforcement of Georgia’s Registry, for the purpose of this article, we will focus on the experiences of South Carolina and West Virginia.

A. SOUTH CAROLINA

The South Carolina Alzheimer’s Disease Registry (South Carolina Registry), previously the Statewide Alzheimer’s Disease and Related Disorders Registry, “is a comprehensive statewide [population-based] registry of SC residents diagnosed with Alzheimer’s disease.” In South Carolina, Alzheimer’s disease is notoriously prevalent. About 11.5% of people over age sixty-five and 42.7% over age eighty-five have Alzheimer’s disease, according to a data comparison from 2004 to 2008. As

Health Assistance Foundation . . . provided major funding to establish a registry of persons in South Carolina.”).


89. See California Alzheimer’s Disease Program, supra note 87; see also Lillquist, supra note 88, at 2 (“Reporting is mandated for physicians and facilities . . .”).


91. See generally UNIV. OF S.C. ARNOLD SCH. OF PUB. HEALTH, ANNUAL REPORT OF SOUTH CAROLINA ALZHEIMER’S DISEASE REGISTRY 2012, at 1–2 (2012), http://www.sph.sc.edu/osa/2012%20Annual%20Report_FINAL.pdf (“The number of new cases added to the Registry has increased from 2004-2008 at an average of 2.9% per year.”).

92. Id. at 1.
the most comprehensive Alzheimer’s disease registry in the United States, the South Carolina Registry has maintained a record of diagnosed cases in the state since January 1, 1988.\textsuperscript{93} The South Carolina Registry could not have been established without joint efforts from non-profit organizations and state government at that time.\textsuperscript{94}

The South Carolina Registry comprises multiple data sources, including inpatient hospitalizations, mental health records, state health plans, Medicaid, emergency departments, memory clinics, vital records, and long-term care evaluations.\textsuperscript{95} The South Carolina Registry is maintained by “the Arnold School of Public Health of the University of South Carolina . . . , in cooperation with the South Carolina Department of Health and Human Services . . . , the SC Department of Mental Health, the USC School of Medicine, and the SC Office of Budget and Control.”\textsuperscript{96}

Reporting to the South Carolina Registry is voluntary.\textsuperscript{97} The core data collected are age, type of dementia, gender, and race.\textsuperscript{98} International Classification of Diseases (ICD-9)\textsuperscript{99} data codes are recorded.\textsuperscript{100} Additional data sets on certain populations include educational status, caregiver contact, and

\begin{itemize}
  \item \textsuperscript{93} See id.
  \item \textsuperscript{94} “In April 1988, the American Health Assistance Foundation in Rockville, Maryland, provided major funding to establish a registry of persons in South Carolina who have been diagnosed with dementia, particularly Alzheimer’s disease. This funding was matched by the state Health and Human Services Finance Commission, and with supplemental funding from the Association of Schools of Public Health, and the Centers for Disease Control.” Macera et al., supra note 85, at 35.
  \item \textsuperscript{95} ANNUAL REPORT OF SOUTH CAROLINA ALZHEIMER’S DISEASE REGISTRY 2012, supra note 91, at 5 fig.1.
  \item \textsuperscript{96} Id. at 1.
  \item \textsuperscript{97} Id. at 6.
  \item \textsuperscript{98} Id. at 8–9.
  \item \textsuperscript{99} The World Health Organization describes ICD as follows: “[t]he International Classification of Diseases (ICD) is the standard diagnostic tool for epidemiology, health management and clinical purposes. This includes the analysis of the general health situation of population groups. It is used to monitor the incidence and prevalence of diseases and other health problems, proving a picture of the general health situation of countries and populations.” \textit{International Classification of Diseases (ICD)}, \textsc{World Health Org.}, http://www.who.int/classifications/icd/en/ (last visited Oct. 2, 2015).
  \item \textsuperscript{100} ANNUAL REPORT OF SOUTH CAROLINA ALZHEIMER’S DISEASE REGISTRY 2012, supra note 91, at 19.
\end{itemize}
marital status. The law has strict confidentiality requirements but does allow [South Carolina] Registry staff to contact the families and physicians of persons diagnosed as having Alzheimer’s disease . . . to collect relevant data and to provide information about public and private health care resources available to them. The South Carolina Registry has been extremely and consistently effective with regard to its data collection function. “Since January 1, 1988, the [South Carolina] Registry has identified a total of 199,279 cases of Alzheimer’s disease.” The robustness and duration of the South Carolina Registry provides useful insights for establishing the Registry in Georgia.

B. WEST VIRGINIA

West Virginia provides another excellent model for Georgia’s new Registry. West Virginia is particularly vulnerable to an increased incidence of Alzheimer’s disease because it has one of the oldest populations in the country, and the risk factors for Alzheimer’s disease such as heart disease, diabetes, high cholesterol, smoking, and high blood pressure are all higher in West Virginia than the national average. Thirty-six thousand people in West Virginia were estimated to have Alzheimer’s disease in 2014. By 2025, there will be an estimated 22.2% increase in Alzheimer’s disease in the state.

“The West Virginia Alzheimer’s Disease Registry [West Virginia Registry] is a state-mandated, population-based

101. Id. at 19; see also S.C. CODE ANN. § 44-36-10 (2014) (describing which data sources the Registry should rely upon).

102. ANNUAL REPORT OF SOUTH CAROLINA ALZHEIMER’S DISEASE REGISTRY 2012, supra note 91, at 6; see also S.C. CODE ANN. § 44-36-30 (2015) (establishing that patient information is confidential).

103. See ANNUAL REPORT OF SOUTH CAROLINA ALZHEIMER’S DISEASE REGISTRY 2012, supra note 91, at 1 (describing the amount of data the Registry has collected since its genesis).

104. Id.


106. 2014 ALZHEIMER’S DISEASE: FACTS AND FIGURES, supra note 5, at 22 tbl.2.

107. Id.
registry of patients with Alzheimer’s.”

It has been in existence since 2006 and is currently located at and maintained by West Virginia University. The West Virginia Registry “is a password-protected, encrypted database requiring annual software costs, as well as personnel, to enter, manage and analyze the data.”

Registry data will populate statistical summaries of demographic, diagnostic and treatment information that will be used to advise physicians, patients, caregivers and policymakers at local and state levels about the medical, social and economic impact of Alzheimer’s in West Virginia. Collaterally, it is anticipated that the collection of this data will improve the diagnosis, treatment and care of patients with Alzheimer’s disease, and it will educate policymakers about the size of the problem and necessity of state funding for care and support.

The West Virginia legislature created the West Virginia Registry under the Alzheimer’s Special Care Standards Act in 2006, based on a similar statute in South Carolina, “and it first received funding in 2009.” Active operation of the West Virginia Registry began in 2010. The statute mandated that “all reporting sources including hospitals, physicians, facilities, clinics or other similar units diagnosing or providing treatment or care for Alzheimer’s disease and related disorders, shall provide a report of each case” to the West Virginia Registry. “This means the Legislature has made reporting mandatory. In practical terms, only a physician can diagnose and treat a patient with dementia so a physician or one of their staff would

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109. See West Virginia Alzheimer’s Disease Registry, supra note 27 (“SB 112 passed on March 11th, 2006, was signed by Governor Joe Manchin and became law on June 11th, 2006.”); W. Va. Code § 16-5R-7(a) (granting the Governing Board of West Virginia University the authority to establish an Alzheimer’s disease registry).

110. See Make a Plan for Alzheimer’s in West Virginia: Final Report and Recommendations, supra note 105, at 3.2.

111. Id.


113. See West Virginia Alzheimer’s Disease Registry, supra note 27.

114. See Make a Plan for Alzheimer’s in West Virginia: Final Report and Recommendations, supra note 105, at 3.2.

115. See id. at The Map Process (“The Make a Plan (MAP) for Alzheimer’s initiative kicked off in February 2011.”).

be required to report patient information to the Registry.”

This reporting requirement “meets the HIPAA exception as a ‘public health authority’ activity,” which will be discussed in greater detail in Section III of this Article. The details of data to be collected and procedures for their collection are further outlined in Section IV below, in which we more closely examine the West Virginia Procedural Rules for guidance for Georgia.

C. GEORGIA FEATURES AND LESSONS LEARNED

The Georgia Registry has many of its own unique features. Some of them bear important distinctions from the other two registries, particularly the South Carolina Registry. For example, the South Carolina Registry is explicitly intended to support Alzheimer’s disease research by monitoring patients closely, testing frequently, and providing researchers with access to de-identified data. The Georgia General Assembly, however, was silent regarding whether the Registry is intended to support research on genetic, environmental, and sociological risk factors for development of Alzheimer’s disease. Rather, the law suggests that the data will be used primarily for purposes of public health statistical gathering and policy planning. In other words, at the legislative level, the Registry is primarily intended to estimate the prevalence of dementia in the general population and help the government make sound public health policies. The Task Force’s 2014 State Plan, however, expressly identified collection and use of

119. See infra Part IV.
123. GA. CODE ANN. § 31-2A-17(b) (2015) (“The purpose of the registry shall be to assist in the development of public policy and planning.”).
124. See GA. CODE ANN. § 31-2A-17(c)(1) (2015) (establishing that the Registry is for “[c]ollecting and evaluating data regarding the prevalence of Alzheimer’s disease and related disorders in Georgia.”).
information for research purposes as one objective of the Registry.\textsuperscript{125}

Other comparisons between existing state registries and Georgia’s Registry merit comment. Both the West Virginia and Georgia legislatures enacted broad statutory authorization for the registries while delegating promulgation of detailed implementation and procedural rules to other entities.\textsuperscript{126} In Georgia, the legislature delegated that authority to a state agency, the Georgia Department of Public Health, whereas in West Virginia and South Carolina, academic institutions house the registries and provide rules for their operation.\textsuperscript{127} Georgia’s approach takes advantage of the institutional knowledge of the Georgia DPH public health administration and comports with the broader policy planning, not merely research, objectives of the Registry.\textsuperscript{128}

Distinct features of the Registry in Georgia suggest that lawmakers have learned important lessons from the other two registries. The experiences of these pioneering states may also be useful for other states considering establishing a similar Alzheimer’s disease registry.\textsuperscript{129} The South Carolina Registry, since its inception in 1988, “relied heavily on statistical and demographic sources by culling information from hospital records, Medicaid documents, memory clinic records, mental health records, vital records and long term care evaluations to help understand the disease more fully.”\textsuperscript{130} Recently, in 2009,

\textsuperscript{125} See GEORGIA ALZHEIMER’S AND RELATED DEMENTIAS STATE PLAN, supra note 45, at 40–42.

\textsuperscript{126} GA. CODE ANN. § 31-2A-17(c) (2015) (“[T]he department shall establish procedures and promulgate rules and regulations for the establishment and operation of the registry.”); W. VA. CODE § 16-5R-7(d) (2015) (“The governing board shall propose rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to implement this section.”).

\textsuperscript{127} See GA. CODE ANN. § 31-2A-17(a) (2015) (“There is established within the Department of Public Health the Alzheimer’s Disease Registry.”); W. VA. CODE, § 16-5R-7(a) (“[T]he Governing Board of the West Virginia University shall establish an Alzheimer’s Disease Registry.”); S.C. CODE ANN. § 44-36-10(B) (2015) (“There is established within the University of South Carolina School of Public Health the Alzheimer’s Disease Registry.”).

\textsuperscript{128} GA. CODE ANN. § 31-2A-17 (2015).

\textsuperscript{129} See GA. CODE ANN. § 31-2A-17(a) (2015).

South Carolina amended the law to allow Registry analysts to have direct contact with families and caregivers who are deeply affected by Alzheimer’s disease and possess unique information about patients. Those analysts directly assess and report the hardships and lifestyle changes that Alzheimer’s patients and their support systems face. Georgia has taken a more proactive approach from the Registry’s inception: “families and physicians of persons who are reported to the registry shall be contacted to gather additional data.”

The Registry also has emphasized, from the outset, the importance of protecting the confidentiality of patient data from secondary uses. According to the Georgia legislation, “all persons to whom the data is released shall maintain patient confidentiality.” For example, when a researcher wants to analyze links between Alzheimer’s disease and socioeconomic characteristics, such as health education, literacy, and alcohol abuse, the researcher has strict obligations to safeguard such information.

Alzheimer’s disease registries operate very differently from typical public health registries. “[G]overnments have often mandated registry and treatment in the case of infectious diseases.” “[S]uch infringement on personal choice and privacy has been justified by the overriding need to protect the public from the spread of dangerous disease.” It is a different

131. 2009 S.C. Acts 728 (“[T]he registry may contact families and physicians of persons reported to the registry for the purpose of gathering additional data and providing information on available public and private resources.”).

132. See S.C. CODE ANN. § 44-36-10(C) (2015) (“The registry is authorized to conduct follow-back studies . . . of the progression and treatment of Alzheimer's disease and related disorders, and research on caregiving for . . . [and] services used by individuals with Alzheimer’s disease.”).


134. Id. at (d) (“The collected data in the registry shall be confidential.”).

135. Id.

136. Compare Amy Fairchild et al., Public Goods, Private Data: HIV and the History, Ethics, and Uses of Identifiable Public Health Information, 122 PUB. HEALTH REP. 1, 8 (2007) (“When deemed appropriate, health officials released the names and addresses of those with contagious diseases in order to fulfill a duty to warn the public.”), with Schreurs, supra note 117, at 45 (“Access to patient’s private health information is restricted to the Director of the [West Virginia] Registry.”).

137. Krent et al., supra note 82, at 11.

138. Id. at 11–12.
story for non-infectious disease registries, such as a cancer, diabetes, or Alzheimer’s disease registry. Existing state-run Alzheimer’s disease registries rely on voluntary reporting to avoid releasing or publishing identifiable individual data. Use of individual data for policy planning and research related to non-infectious diseases, such as Alzheimer’s disease and related dementia, “raises potential legal and ethical concerns that merit thorough discussion.” Therefore, best practices for Registry implementation in Georgia and elsewhere should be attuned to those unique considerations.

III. LEGAL AND ETHICAL CONCERNS OF THE REGISTRY

This Section explores the legal and ethical issues raised by the Registry. An Alzheimer’s disease patient’s diagnosis history, medication history, and personal lifestyle are generally confidential information, known only to the physician and patient himself. Reporting such information to the Registry, however, may lead to wider disclosure of what was previously private information and consequently may arouse constitutional concerns. Furthermore, despite the statutory pledge of confidentiality and HIPAA compliance, the risk of disclosure through cyber invasion or public health officials’ errors remains present. Moreover, some patients may object to secondary use of their information in research projects of which they disapprove. Finally, physicians’ professional ethics may also be undermined if the registry information is disclosed. After considering these areas of concern, we conclude by recommending various best practices for avoiding confidentiality breaches before implementation of the Registry in Georgia or other states.

139. See id. at 12 (“Cancer registries... have been motivated largely by the desire to identify and mitigate environmental and occupational risks.... The few registries that are already in place for diabetes, rather than mandating enrollment, rely on patient and doctor consent.”).
140. See, e.g., ANNUAL REPORT OF SOUTH CAROLINA ALZHEIMER’S DISEASE REGISTRY 2012, supra note 91, at 4, 6.
141. Krent et al., supra note 82 (discussing privacy in the context of a diabetes registry).
A. CONSTITUTIONALITY OF THE REGISTRY

A population-based disease registry is essential to identifying the breadth and impact of the targeted disease.\textsuperscript{142} It facilitates research and policymaking to learn what causes the target disease to develop and how to deal with it.\textsuperscript{143} But even traditional, well-established disease registries have come under constitutional scrutiny. Patients have challenged some state registries of health information as unjustifiable invasions of the right of privacy afforded by the U.S. Constitution\textsuperscript{144} a right that the Supreme Court has interpreted to include confidentiality of medical records.\textsuperscript{145} Specifically, the constitutional challenges alleged that the state registries are unconstitutional due to “1) the vagueness of statutory aims to pursue public health . . . [as compared to the recognized] individual privacy interests of cancer patients, and 2) the alleged indignity of one’s individual medical information being transmitted to government authorities.”\textsuperscript{146} Contrary to the vagueness claims, most enabling statutes of disease registries “define specific aims and activities, categories of data to be gathered, reasons for doing so, and rigorous criteria for access to and release of . . . [disease] data.”\textsuperscript{147} Accordingly, the first theory of unconstitutionality is largely unavailing.

Regarding the second theory, \textit{Whalen v. Roe} has been described as the “seminal case” on the issue of “balancing . . . patient privacy and [the] government[s] need for information”\textsuperscript{148} and establishes precedent for recognizing an

\begin{itemize}
\item \textsuperscript{142} See \textit{Population-Based Registries, supra} note 4.
\item \textsuperscript{143} \textit{Id.}
\item \textsuperscript{145} Each of the courts in the \textit{Schulman} and \textit{Whalen} cases, both \textit{supra} note 144, declined to extend federal constitutional privacy rights to the instant circumstances (pregnancy termination certifications and patient-identification requirements, respectively). In their analyses, however, the courts did identify situations where constitutional privacy protections \textit{might} apply. \textit{Id.}
\item \textsuperscript{146} See Robert H. McLaughlin et al., \textit{Are Cancer Registries Unconstitutional?} 70 SOC. SCI. & MED. 1295, 1295 (2010).
\item \textsuperscript{147} \textit{Id.} at 1296. The studies discussed in the McLaughlin et al. article focus primarily on state cancer registries.
\item \textsuperscript{148} Fort Wayne Women’s Health v. Bd. of Comm’rs, 735 F. Supp. 2d 1045, 1059 (2010).
\end{itemize}
individual’s “right to conceal” his medical information.\textsuperscript{149} In \textit{Whalen}, the United States Supreme Court upheld a statute that required that the names, addresses, and prescription details for all persons receiving Schedule II controlled substances to be reported to the New York State Department of Health.\textsuperscript{150} The Court found that the statutes at issue advanced legitimate state interests and that the registry’s purpose to “aid in the enforcement of laws designed to minimize the misuse of dangerous drugs” amounted to a “reasonable exercise of New York’s broad police powers.”\textsuperscript{151}

The Court also noted that the statute did not interfere with physician-patient decision-making,\textsuperscript{152} and it included explicit confidentiality provisions protecting patient information from public disclosure.\textsuperscript{153} At the time the case was brought, exactly seventeen health workers and twenty-four investigators were authorized to access the data, and willful unauthorized disclosure could result in a $2000 fine and up to a year in prison.\textsuperscript{154} The data were kept in a locked, secure area, and computers were brought offline before the computer tapes could be used, preventing any access to the data by outside terminals.\textsuperscript{155} Finally, the Court noted that during the twenty months in which the law had been in place, there was no evidence that it had deterred patients from seeking needed medications.\textsuperscript{156}

Similarly, in \textit{Schulman v. New York City Health and Hospitals Corporation}, the New York Court of Appeals upheld a statute requiring that patients file a certificate of termination of pregnancy after receiving an abortion.\textsuperscript{157} The court stated that “[c]ourts have generally not found that the privacy interest

\begin{itemize}
\item \textsuperscript{149} Planned Parenthood of Indiana v. Carter, 854 N.E.2d 853, 871 (Ind. Ct. App. 2006).
\item \textsuperscript{150} \textit{Whalen}, 429 U.S. at 592–94.
\item \textsuperscript{151} \textit{Id.} at 598.
\item \textsuperscript{152} \textit{Id.} at 603 (“Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication.”).
\item \textsuperscript{153} \textit{Id.} at 594 n.12 (quoting New York Department of Health regulatory language regarding the duty of confidentiality).
\item \textsuperscript{154} \textit{Id.} at 594–95.
\item \textsuperscript{155} \textit{Id.}
\item \textsuperscript{156} \textit{Id.} at 603.
\item \textsuperscript{157} \textit{Schulman v. N.Y.C. Health & Hosps. Corp.}, 342 N.E.2d 501 (N.Y. 1975).
\end{itemize}
extends to situations in which the government gathers personal information for legitimate purposes." It also found that the statute at issue was narrowly tailored to further legitimate state interests, including providing a broad sampling of data to further research and public policy goals. The court noted that there are restrictions on disclosure of information about patients and found no evidence that this statute would lead to public disclosure of information or have a chilling effect on abortions. Applying the rational basis test, the court found that the statute was "narrowly tailored to [further] the compelling [State] interest in maternal health during the second trimester of pregnancy." The New York case was distinguished by *Hawaii Psychiatric Society, District Branch of the American Psychiatric Association v. Ariyoshi*, where the federal District Court in Hawaii issued a preliminary injunction in favor of a psychiatrist whose records were copied by a representative of the Medicaid Fraud Unit (under the Department of the Attorney General). The relevant statute required providers receiving Medicaid funds to keep records for three years and authorized the issuance of warrants to inspect and copy such records. An administrative inspection warrant was issued for all therapeutic notes, patient history forms, and medical records, reports, and diagnoses based solely upon an affidavit stating that the psychiatrist's office had never been inspected and it was in the public interest to inspect it. After finding that the psychiatric association had standing to assert the rights of its members, the court issued a preliminary

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158. *Id.* at 506.
159. *Id.* at 503 (listing seven public health objectives, and noting the particular need for such information-sharing to provide adequate medical care for indigent women).
160. *See id.* at 504 ("The record is completely devoid of any proof that the name requirement dissuades potential abortion recipients from obtaining abortions in New York City.").
161. *Id.* at 507.
163. *Id.* at 1033–34.
164. *Id.* at 1034–35.
165. *Id.* at 1037. The Court cited, as a comparison, the standing analysis pertaining to the doctor-plaintiffs in *Griswold v. Connecticut*, 381 U.S. 479, 484 (1965). *Id.*
injunction for the psychiatrist. Because the nature of the information revealed in a psychiatric session was of an extremely private nature, and due to the potential effect that disclosure of such communications could have on a patient’s decision to seek medical care, the court found that a compelling interest—rather than lower level rational basis—test was appropriate. It also concluded that while the state was furthering a compelling state interest, it was not doing so in the least restrictive manner possible. The Attorney General’s office did not show any evidence that its need could not be satisfied by looking at records with the personally identifiable information redacted.

B. GEORGIA CONSTITUTIONAL RIGHT TO PRIVACY

The U.S. Supreme Court precedent in Whalen is instructive but not necessarily controlling of similar challenges that could be brought under Georgia’s constitution. In Georgia, “citizens have a ‘liberty of privacy’ guaranteed by the Georgia constitutional provision which declares that no person shall be deprived of liberty except by due process of law.” This right of privacy guaranteed by the Georgia Constitution is far more extensive than analogous protections under the U.S. Constitution. Accordingly, invasion of privacy could potentially be a constitutional pitfall for the Georgia Registry. In addition, the Registry’s purpose is arguably distinguishable and, therefore, less defensible than the state purpose asserted for the prescription registry in Whalen. New York was tracking criminal behavior in the Whalen case; by contrast, the

166.  *Id.* at 1052.
167.  *Id.* at 1039 (“[E]ven a burdensome regulation may be validated by a sufficiently compelling state interest.”).
168.  *Id.*
169.  *Id.* at 1042. This decision was criticized by the Seventh Circuit Court of Appeals. Shields v. Burge, 874 F.2d 1201, 1211 (1989) (“[W]e cannot say that . . . the district court cases clearly established that the privacy right’s autonomy strand protects the decision to seek psychological or psychiatric help.”).
170.  See King v. State, 535 S.E.2d 492, 495 (Ga. 2000) (noting that “Georgia recognizes an even broader concept of privacy” than that under the Federal Constitution).
172.  *King*, 535 S.E.2d at 494.
Registry will be used to monitor the health of private citizens. 174 

Despite these differences, it is likely that the Registry would survive a potential constitutional challenge. 175 Like the statute at issue in Whalen, the enabling statute of the Registry, namely House Bill 966, does not directly interfere with patient or physician decision-making. 176 Additionally, it contains a brief confidentiality provision that limits disclosure to all the people to whom the data is released. 177 Thus, House Bill 966 satisfies the two factors that the court in Whalen considered in determining the constitutionality of those registries. 178 Furthermore, a detailed statement of the basis and purpose of the Registry, which would likely support the rational basis review of the statute, was included in the statute. 179 

Of particular relevance to the Registry, Georgia courts have interpreted the state constitutional “liberty of privacy” right as pertaining to medical information. 180 That position was most clearly outlined in King v. State. 181 There, the Supreme Court of Georgia explained that “medical information . . . is certainly a matter which a reasonable person would consider to be private.” 182 The court further provided that “[m]edical

175. Similar state registries have been upheld as valid exercises of state police powers. See, e.g., Rollins v. Ulmer, 15 P.3d 749, 753–54 (Alaska 2001) (upholding constitutionality of medical marijuana registry on grounds that the scheme assured confidentiality, at least on its face, and assuming that the measure rationally allowed for compliance with rules regulating marijuana use); Ark. Dep’t of Human Serv. v. Heath, 848 S.W.2d 927, 928 (Ark. 1993) (holding that a registry for unsubstantiated allegations of child abuse is permissible).
178. Whalen, 429 U.S. at 599–600 (“The cases sometimes characterized as protecting ‘privacy’ have in fact involved at least two different kinds of interests. One is the individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of important decisions.” (internal footnotes omitted)).
179. See GA. CODE ANN. § 31-2A-17(b) (2015) (“The purpose of the registry shall be to assist in the development of public policy and planning.”).
180. See, e.g., King, 535 S.E.2d at 495. (“[T]he personal medical records of this state’s citizens clearly are protected by that right as guaranteed by our constitution.”).
181. Id. at 492.
182. Id. at 495.
records are entitled to more privacy than bank records and phone records."183 Under the state constitutional protection, such records cannot be disclosed without patient consent unless otherwise required by a law of Georgia.184 *King* further specifies that any statute compelling disclosure of such information must “effectuate[] a compelling state interest and . . . [be] narrowly tailored to promote only that interest.”185

In *King*, the police had issued a subpoena to a hospital in order to gain access to the client’s medical records to prove that she had been driving while intoxicated.186 The prosecution cited Georgia Code § 24-9-40(a), which states that “no physician . . . and no hospital or health care facility . . . shall be required to release any medical information concerning a patient except . . . on appropriate court order or subpoena . . . ,” as the statute implicitly requiring the hospital to release the information.187 Citing *Powell v. State*,188 the court explained that “[b]efore the State is authorized to exercise its police power, it must appear ‘that the means are reasonably necessary for the accomplishment of the purpose, and not unduly oppressive upon the individuals.’”189 The court noted that the Fourth Amendment requires the state to demonstrate probable cause to an impartial arbiter before it is allowed to infringe upon an individual’s expectation of privacy.190 If the state’s interpretation of § 24-9-40(a) was to prevail, such safeguards could be circumvented, and the state could have almost unfettered access to personal records.191 Although this would further the state’s compelling interest in law enforcement, the court found that it would not be “reasonable” and that it would be “highly oppressive.”192

It is worth noting that courts in different states have decided the privacy of medical records issue differently. The
Supreme Court of New Hampshire expressly disagreed with King, arguing that the Supreme Court of Georgia placed greater protection on privacy than that which would be considered “reasonable” by society.\textsuperscript{\textup{193}} On the other hand, in Planned Parenthood of Indiana \textit{v. Carter}, the Supreme Court of Indiana cited King and also found that a right to privacy of medical records exists.\textsuperscript{\textup{194}}

There have been multiple Georgia decisions narrowing King. In another case entitled King \textit{v. State (King II)}, the court found that the defendant’s right to privacy was not violated when his medical records were obtained via a search warrant.\textsuperscript{\textup{195}} Two years later, King II was followed by Ellis \textit{v. State}.\textsuperscript{\textup{196}} In King II and Ellis, the court stated that the need to show probable cause to an impartial arbiter in order to obtain a search warrant sufficiently protected individual privacy rights and made the invasion of privacy reasonable.\textsuperscript{\textup{197}}

In addition, Georgia courts have affirmed substantial civil judgments based on violations of the right to privacy. For example, in Multimedia WMAZ, Inc. \textit{v. Kubach}, the Court of Appeals affirmed a civil judgment against a television station that inadvertently revealed the identity of an HIV positive interviewee to the public.\textsuperscript{\textup{198}} The plaintiff agreed to do an interview about AIDS and drug use on the condition that his identity remain concealed.\textsuperscript{\textup{199}} The court ruled that the plaintiff

\textsuperscript{\textup{193}} State v. Davis, 12 A.3d 1271, 1274 (N.H. 2010).
\textsuperscript{\textup{194}} Planned Parenthood of Indiana \textit{v. Carter}, 854 N.E.2d 853, 873 (Ind. Ct. App. 2006) (“Although . . . [a previous decision by this court] did not specifically hold that a federal constitutional right of privacy in medical information exists, today we join our colleagues on the Seventh Circuit and elsewhere in concluding that it does.”).
\textsuperscript{\textup{195}} King \textit{v. State (King II)}, 577 S.E.2d 764, 766–67 (Ga. 2003) (distinguishing on the basis that procedural safeguards when issuing search warrants already provide the kind of privacy protections at issue in the first King case).
\textsuperscript{\textup{197}} \textit{Id.} at 91 (“[E]xisting search warrant procedures provide adequate protections for a defendant’s privacy rights under both the Georgia and United States Constitutions.”); King II, 577 S.E.2d at 764 (“Because a search warrant requires a neutral judicial officer to find probable cause that a crime has been committed, we hold that a defendant’s constitutional right to privacy is not violated . . . .”).
\textsuperscript{\textup{199}} \textit{Id.} at 493.
had not waived his privacy right by doing other television interviews in which his back was visible and his voice was not disguised, or by sharing his HIV status with friends and family.\textsuperscript{200} The court affirmed a $500,000 award of damages but reversed the $100,000 punitive award, finding insufficient evidence of “willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences” to support a punitive damages award.\textsuperscript{201}

In determining the level of access to personal information that should be granted to researchers and policymakers, one must consider whether any potential law is likely to pass this privacy inquiry. Addressing this burgeoning health problem is likely to be deemed a compelling state interest, but any invasion of privacy must be reasonable, narrowly tailored to further that interest, and not unduly oppressive.\textsuperscript{202} In addition, we should be aware of the possibility that the Registry could be subject to civil actions if courts deem Alzheimer’s patients’ privacy rights violated.\textsuperscript{203} Aside from the possible threat of litigation, we recommend adopting practices that uphold individuals’ constitutionally and statutorily protected privacy rights.

C. THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

In addition to federal and state constitutional concerns, Registry implementation should be done in accordance with federal statutory requirements—namely, those required by the Health Insurance Portability and Accountability Act (HIPAA).\textsuperscript{204} HIPAA provides specific guidance for balancing individual privacy concerns with researchers’ need for

\begin{footnotesize}
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  \item \textsuperscript{200} Id. at 493–94.
  \item \textsuperscript{201} Id. at 495–96 (quoting from GA. CODE ANN. § 51-12-5.1(b)).
  \item \textsuperscript{202} See, e.g., King, 535 S.E.2d 492.
  \item \textsuperscript{203} See, e.g., Kubach, 443 S.E.2d 491. To the extent that the Advisory Council or DPH is a state actor, there could be thorny procedural and jurisdictional hurdles, including sovereign immunity, to bringing a privacy action under federal or state law. Those considerations are beyond the scope of this Article.
\end{itemize}
\end{footnotesize}
information.\textsuperscript{205} One of the purposes of the Georgia Registry is to provide Alzheimer’s data to policymakers;\textsuperscript{206} ideally, de-identified data should be widely available in a user-friendly format. On the other hand, the Registry should restrict the disclosure of individual, personally identifiable data in order to respect individual privacy interests.

Congress, in enacting HIPAA, already grappled with balancing those competing concerns, and regulations implementing HIPAA provide detailed requirements concerning the acquisition of personal health information for research. The regulations, set out in the HIPAA Privacy Rule, however, apply only to “covered entities,” defined as “health plans, health care clearinghouses, and ... any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA.”\textsuperscript{207} Because the Georgia Registry is not a covered entity as defined by HIPAA,\textsuperscript{208} the Privacy Rule does not strictly apply.

\textsuperscript{205} Indeed, “[a] major goal of the Privacy Rule [45 C.F.R. §§ 164.500–34] is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public’s health and well being.” U.S. DEPT OF HEALTH & HUMAN SERVS.: OFFICE FOR CIVIL RIGHTS, SUMMARY OF THE HIPAA PRIVACY RULE 1 (2003) [hereinafter SUMMARY OF THE HIPAA PRIVACY RULE], http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf.

\textsuperscript{206} H.R. 966, 152d Gen. Assemb., Reg. Sess. § 1(b) (Ga. 2014) (“The purpose of the registry shall be to assist in the development of public policy and planning relative to Alzheimer’s disease and related disorders. The registry shall provide a central data base of individuals with Alzheimer’s disease or related disorders.”).

\textsuperscript{207} SUMMARY OF THE HIPAA PRIVACY RULE, supra note 205, at 2; see also 45 C.F.R. § 160.102–03 (2015) (listing what entities HIPPA applies to and the definition of “covered entities”).

\textsuperscript{208} See U.S. DEPT OF HEALTH AND HUMAN SERVS., PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH: UNDERSTANDING THE HIPAA PRIVACY RULE 5 (2003) [hereinafter UNDERSTANDING THE HIPAA PRIVACY RULE], http://privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf. A health plan is defined as “an individual or group plan that provides or pays the cost of medical care.” Id. at 25. While this includes some government programs, neither the Georgia Registry nor the Task Force that run it provide or pay for any medical care. A health care clearinghouse includes public and private entities that provide billing services, “repricing,” health information management services, and “value-added” networks that process health information for other entities. Id. The Registry does not provide any such services. Finally, health care provider refers to “a provider of medical or health services . . . and any other person or organization who furnishes,
A health plan is defined as “an individual or group plan that provides or pays the cost of medical care.”209 While this includes some government programs, neither the Georgia Registry nor the Task Force that runs it provides or pays for any medical care.210 A health care clearinghouse includes public and private entities that provide billing services, “repricing,” health information management services, and “value-added” networks that process health information for other entities.211 The Registry does not provide any such services.212 Finally, health care provider refers to “a provider of medical or health services ... and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.”213 The Registry does not perform this service either.214 Although the Registry does not constitute a “covered entity,” we nevertheless suggest that, in order to ensure compliance with the constitutional right to privacy in Georgia and general best practices for patient confidentiality, the Registry adhere to the HIPAA standards for covered entities.

The first step in any HIPAA analysis is to understand the definition of protected health information (PHI). PHI refers to individually identifiable health information.215 Thus, de-

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209. Id.
211. See UNDERSTANDING THE HIPAA PRIVACY RULE, supra note 208, at 25.
213. See UNDERSTANDING THE HIPAA PRIVACY RULE, supra note 208, at 25.
215. See UNDERSTANDING THE HIPAA PRIVACY RULE, supra note 208, at 8. According to the Privacy Rule, PHI also only encompasses such information “created or maintained by a covered entity or its business associates acting for the covered entity.” Id. However, for the purposes of this article, we will define it to include personally identifiable health information held by the Georgia Registry. The Privacy Rule defines “de-identified health information” as information from which the following have been removed:

1. Names.
2. All geographic subdivisions smaller than a state ... except for the initial three digits of a ZIP code, assuming that there are at least 20,000 people who share those digits.
identified data relating to Alzheimer’s rate will not be subject to the restrictions described in the following paragraphs. PHI may always be disclosed with the patient’s written consent in the form of an “authorization.”216 An authorization must be written in plain language, and it must specifically describe (1) the information to be disclosed; (2) the person disclosing the information; (3) the person receiving the information; (4) the authorization expiration; and (5) the right to revoke the authorization in writing.217 Examples of disclosures requiring such authorizations include disclosures to life insurance companies, patients’ employers, or pharmaceutical firms.218

The HIPAA Privacy Rule recognizes that sometimes PHI is required for research and that obtaining authorization for all

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death; and all ages over 89 and all elements of . . . such age, except . . . [to] aggregate[ them] into a single category of ‘90 or older.’
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face . . . [pictures] and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule.

Id. at 10. Alternatively, accepted statistical methods may be used to de-identify data. Id.

216. Id. at 9, 11–12. For more information on the specific requirements of an Authorization, see pp. 11–12 of SUMMARY OF THE HIPAA PRIVACY RULE, supra note 205.

217. See UNDERSTANDING THE HIPAA PRIVACY RULE, supra note 208, at 12.

218. SUMMARY OF THE HIPAA PRIVACY RULE, supra note 205, at 9.
data sought may not be practicable. For that reason, it contains an alternative provision for obtaining a waiver, or alteration of authorization. The waiver or alteration must be approved by an Institutional Review Board (IRB) or a Privacy Board. IRBs were created in the 1960s to ensure the ethical treatment of human subjects of clinical research. They remain responsible for ensuring that informed consent has been given and documented pursuant to the U.S. Department of Health and Human Services (HHS) and U.S. Food and Drug Administration (FDA) Protection of Human Subjects Regulations (HHS and FDA Regulations). Privacy Boards were authorized by the HIPAA Privacy Rule as alternative review boards for waiver or alteration of authorization requests. Both boards must adhere to strict guidelines regarding composition and procedure.

Pursuant to the HHS and FDA Regulations, each IRB must have at least five members with “varying backgrounds.” Specifically, a Board must meet the following requirements:

The IRB must be sufficiently qualified through the experience and expertise of its members, and the diversity of members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect

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219. See UNDERSTANDING THE HIPAA PRIVACY RULE, supra note 208, at 13 (“[I]t may not be feasible for a researcher to obtain a signed Authorization for all PHI the researcher needs to obtain for the research study.”).

220. Id; see also 45 C.F.R. § 164.512 (2015) (discussing the uses and disclosures for which an authorization or opportunity to agree or object is not required).

221. UNDERSTANDING THE HIPAA PRIVACY RULE, supra note 208, at 13 (“[T]he Privacy Rule contains criteria for waiver or alterations of Authorizations by an IRB or another review body called a Privacy Board.”).


223. See UNDERSTANDING THE HIPAA PRIVACY RULE, supra note 208, at 11.

224. Id. at 13.


226. Id. at 6 (offering a comparison of IRBs and Privacy Boards in the Frequently Asked Questions section).
for its advice and counsel in safeguarding the rights and welfare of human subjects.227

The Board must have members from different professions (at least one scientific and one non-scientific) with the capability to analyze proposed research with regard to applicable regulations, laws, and standards of professional conduct and practice.228 Finally, at least one member must be independent from the institution, and any member with a conflicting interest in a decision must recuse himself.229

Privacy Boards were created to supplement the IRBs.230 Like IRBs, Privacy Boards must have members with diverse backgrounds and professional competencies.231 At least one member must not have any association with the covered entity or the researcher, and members must recuse themselves where conflicts of interest arise.232

The procedural rules for both IRBs and Privacy Boards are the same.233 In order to receive a waiver or alteration of the requisite authorization to access PHI, a researcher must demonstrate that the research could not be completed practicably without use of the PHI, and the PHI could not practicably be accessed without the waiver or alteration.234 In addition, the researcher must demonstrate that the patient privacy risk is minimal because there is an adequate plan to

227. Id.
228. Id.
230. See HIPAA PRIVACY BOARDS, supra note 225, at 1 (explaining that authorization can be obtained by an Institutional Review Board “or a new type of review body, a Privacy Board”).
231. See id. at 6.
232. Id.
233. Compare HIPAA PRIVACY BOARDS, supra note 225, at 3–4 (describing Privacy Board approval proceedings), with HIPAA IRBs, supra note 229, at 4–5 (describing IRB review proceedings). HHS has recently issued proposed rules modifying a number of IRB operations and requirements, as governed by the Common Rule, including potentially significant changes to the rules for exempt research, expedited review, and waivers of consent. See Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933 (proposed Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 46).
234. See, e.g., HIPAA IRBs, supra note 229, at 4.
protect the PHI identifiers from improper disclosure or use.\textsuperscript{235} Moreover, unless there is a health or research justification for keeping the identifiers, the identifiers will be destroyed at the earliest possible time, unless otherwise required by law.\textsuperscript{236} Finally, the researcher must provide a written statement that he will not reuse the PHI or disclose it except for permissible oversight of his study, for other studies in which use of the information is authorized, or as required by law.\textsuperscript{237}

Some Alzheimer’s patients may not object to having their personal information disclosed. When they provide information to the Registry (or to individuals required to submit it to the Registry), they should be given the option of signing an authorization to disclose their information to researchers. Some patients may be less protective of their information and elect to choose this option in order to promote Alzheimer’s research. However, if researchers would like PHI of those who elect not to authorize its release, we recommend that they be required to obtain a waiver or alteration of authorization from an IRB or Privacy Board.

Our analysis of HIPAA would not be complete if we did not consider potential repercussions to covered entities, such as hospitals, that may be asked to provide data to the Registry. Such healthcare providers may cite HIPAA and claim that they would run afoul of federal law if they provide information to the Registry without patient consent. As analyzed above, however, we conclude that the Registry constitutes a “public health authority,” and the HIPAA Regulations permit the disclosure of personally identifiable information to public health authorities for disease surveillance, disease prevention, and other public health purposes, such as reporting disease and injury.\textsuperscript{238} HIPAA also permits public health authorities to collect information for public health purposes and to enter this information into their own databases without authorization.\textsuperscript{239} HIPAA defines a “public health authority” as:

\begin{itemize}
\item \textsuperscript{235} Id.
\item \textsuperscript{236} Id.
\item \textsuperscript{237} Id.
\item \textsuperscript{238} See generally, 45 C.F.R. § 164.512 (2015) (listing an exception for public health authorities).
\item \textsuperscript{239} See id. (enumerating standards for various entities which are subject to these exclusions).
\end{itemize}
[A]n agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency...that is responsible for public health matters as part of its official mandate. 240

The Registry is acting under a grant of authority from the State of Georgia, and it is responsible for public health matters as part of its official mandate. 241 Accordingly, hospitals and other health care providers reporting data to the Registry should not be concerned about HIPAA liability.

D. PRIVACY RISKS DESPITE STATUTORY CONFIDENTIALITY REQUIREMENT

Despite federal and state constitutional and statutory protections, it is reasonable for Georgians to fear disclosure of personal information reported to the Registry. Alzheimer’s disease is an expensive and debilitating disease to which public misconceptions still attach. 242 People suffering from Alzheimer’s often face violations of their human rights, abuse and neglect, as well as widespread discrimination. 243 As their autonomy decreases, Alzheimer’s and dementia patients may simultaneously face loss of their political, civil, economic, social, and cultural rights. 244 Discrimination against these patients is often the result of a fear that reduced mental capability poses a safety risk to others. 245

There are a number of ways that personal data may be intentionally or inadvertently disclosed. Confidentiality requirements in Georgia House Bill 966 highly restrict the


241. GA. CODE ANN. § 31-2A-17(b) (2015) (“The purpose of the registry shall be to assist in the development of public policy and planning.” (emphasis added)).


243. Id.

244. See id.

disclosure of Registry data. Bill 966 states, in no uncertain terms, that the collected data in the Registry shall be confidential and that all persons to whom the data is released shall maintain patient confidentiality. The Bill does, however, explicitly allow for disclosure of medical information for use in scientific and medical studies. Accordingly, patients understandably may be concerned with such potential secondary uses of medical information in the Registry, even though the enabling statute of the Registry specifically prescribes that “no publication of information, biotechnical research, or medical data shall be made that identifies any patient by name.”

In addition to the authorized disclosures in House Bill 966, Georgia law otherwise may allow disclosure of medical records as part of criminal or other enforcement proceedings. Registry data also may inadvertently be disclosed to unauthorized individuals and potentially used for discriminatory or otherwise wrongful purposes. Also, because all of the data in the Registry will be transferred and stored electronically, the state must guard against hackers who may break into the registration system. Pharmaceutical companies, in particular, would find the information beneficial in their research and marketing efforts. Keeping electronic

247. See id.
248. See id.
249. Id.
250. See, e.g., King II, 577 S.E.2d 764, at 766 (upholding a procedurally valid subpoena against charge of unconstitutional invasion of privacy).
251. See generally U.S. DEPT OF EDUC., PRIVACY & TECH. ASSISTANCE CTR., FREQUENTLY ASKED QUESTIONS—DISCLOSURE AVOIDANCE 2 (2013), http://ptac.ed.gov/sites/default/files/FAQs_disclosure_avoidance.pdf (“Since the release of any data carries at least some element of risk, it may not [be] possible to entirely eliminate the risk of accidental data disclosure.”).
data secure is a challenge even for government agencies guarding top-secret information.254

Finally, even de-identified data may include other characteristics, such as race, age or occupation, of interest to researchers;255 therefore, disclosure of such data could have the tendency to create harmful presumptions about the capabilities of Alzheimer’s disease patients.256 The potential conclusions of such research studies could lead the public to believe that certain characteristics are always indicative of Alzheimer’s disease, which could then lead to discrimination.257 While that sort of aggregate data created by the Registry could lead to important medical findings and facilitate policy planning, public health officials must weigh potential benefits against the possibility that aggregate data can produce unintended consequences to Alzheimer’s disease patients.

E. ADVERSE EFFECT ON PHYSICIAN-PATIENT RELATIONSHIP

In addition to the privacy concerns with the Registry discussed above, we wish to flag particular issues affecting the physician-patient relationship. The confidentiality provisions that protect Alzheimer’s patients do not apply to physicians.258 In particular, nothing in House Bill 966 prevents the information in the Registry from being used to generate aggregate data about individual physicians’ patient populations.259 Such data may be of interest to insurance companies and potential medical malpractice litigants.260 In

254. Leyden, supra note 252.

255. For the specifics requirements of de-identification under the HIPAA Privacy Rule, see supra text accompanying note 215.

256. See Krent et al., supra note 82, at 23 (noting similar risks for diabetics under an analogous New York registry).

257. Id.

258. Cf. GA. CODE ANN. § 31-2A-17(d) (2015) (“[A]nd all persons to whom the data is released shall maintain patient confidentiality.” (emphasis added)).


both cases, availability of physician demographics via the Registry could create incentives for doctors to over- or under-diagnose Alzheimer’s disease. On one hand, insurers might be reluctant to include a physician with a high caseload of Alzheimer’s and related dementia patients in their networks. On the other hand, physicians paid on a capitated basis, may be tempted to over-diagnose to ensure that they receive adequate reimbursement.

With respect to litigation risks, under- or over-diagnosis could erode patients’ trust in the physicians and impair the physician-patient relationship. For example, if a physician over-reports the number of Alzheimer’s patients whom he treats, that may inaccurately signal to the public that he has substantial experience or expertise in dealing with such patients. Reasonable reliance on such a misrepresentation could form the basis for a medical malpractice action. Even more importantly, from the perspective of professional ethics, if the Registry requires doctors and hospitals to either report or allow government inspection of patient data, such disclosures, even if permitted by HIPAA and other privacy laws, could still compromise the consent and confidentiality requirements of the physicians, and other healthcare stakeholders identify value and opportunities).


262. See Patrick C. Alguire, Understanding Capitation, AM. COLL. OF PHYSICIANS, https://www.acponline.org/residents_fellows/career_counseling/understandcapit.htm (last visited Oct. 6, 2015), for background on how capitation payments work and how it can shift physician incentives.

263. “While negligence is by far the most common medical malpractice cause of action, other causes of action that may be asserted include . . . misrepresentation (fraud).” Joe R. McFarlane Jr. & Paul Weber, What is Medical Malpractice?, OPTHALMIC MUTUAL INS. CO. (1993), http://www.omic.com/what-is-medical-malpractice/. In Georgia, “[c]onstructive fraud consists of any act of omission or commission, contrary to legal or equitable duty, trust, or confidence justly reposed, which is contrary to good conscience and operates to the injury of another.” GA. CODE ANN. § 23-2-51(a) (2015).
Hippocratic ethic. This could lead patients to be less forthcoming with medical professionals out of concern that their personal information will be disseminated without their consent. Chilling patients’ candor would negatively impact their treatment and, again, invite potential medical malpractice liability for physicians who would be operating without full information.

IV. PROCEDURAL RULES

The enabling statute of Georgia Registry, namely House Bill 966, closely tracks the enabling statute of the West Virginia Registry. Both statutes explicitly call for promulgation of procedural rules by the institution designated to administer the registry. The West Virginia Procedural Rules were written in consultation with the West Virginia University Associate Counsel and the Counsel to West Virginia Senate Health and Human Services Committee. Additionally, the West Virginia Procedural Rules were promulgated through formal notice and comment rulemaking and took effect on December 27, 2007. They established procedures governing the registry including purpose, content, data management, confidentiality, security and protection, and establishment of an advisory board.


265. See id. (discussing how, if patient confidentiality is breached, “[p]atients would be less likely to share sensitive information, which could negatively impact their care.”).

266. See id.

267. See sources cited and discussion supra note 263.


269. See West Virginia Alzheimer’s Disease Registry: Registry History, supra note 86.


Similarly, House Bill 966 mandates that the Georgia DPH shall establish procedures and promulgate rules and regulations for the establishment and operation of the Registry, which shall provide for:

1. Collecting and evaluating data regarding the prevalence of Alzheimer’s disease and related disorders in Georgia, including who shall report the data to the registry;
2. Determining what information shall be maintained in the registry and the length of time such data shall be available;
3. Sharing of data for policy planning purposes;
4. Disclosing non-identifying data to support Alzheimer’s and related disorder research;
5. [Determining] the methodology by which families and physicians of persons who are reported to the registry shall be contacted to gather additional data; and
6. [Gathering and providing] information about public and private resources.\(^{272}\)

In anticipation of the official release of the procedural rules for the Georgia Registry (Procedural Rules), it is helpful to review the West Virginia Procedural Rules for guidance and consider options the Procedural Rules may present to make improvements tailored to the situation of Georgia. We find many features of the West Virginia instructive but also suggest additional considerations and improvements.

A. MANDATORY AND PERMISSIVE REPORTERS

The West Virginia Procedural Rules mandate that healthcare providers and facilities report cases of Alzheimer’s disease that they diagnose or treat.\(^{273}\) Similarly, the Georgia Procedural Rules should define the range of data reporters as broadly as possible, as suggested by the June 2014 Stakeholders’ Conference findings above.\(^{274}\) Based on those recommendations, the list of reporters can be quite extensive,\(^{275}\) and the rules could specify some reporters as permissive and others as mandatory. The rules also should include a detailed definition section to make sure the reporting


\(^{273}\) W. VA. CODE R. § 64-94-8 (2015) (“Health care Providers and Facilities . . . shall provide a report of each case of the disease or condition as required by this rule.”).

\(^{274}\) Sponsored Stakeholder’s Meeting Memorandum, supra note 3, at 2.

\(^{275}\) See id.
duties on various institutions and individuals are unambiguous. For example, if health care providers were required to report, the Georgia Procedural Rules would need to be clear on who is considered to be a health care provider.\textsuperscript{276} Similarly, if a patient’s legal representatives could provide written disclosure authorization for other people to get access to the patient’s confidential information, the Georgia Procedural Rules also would need to be clear on who are legal representatives of a patient in Georgia.\textsuperscript{277}

The Registry should begin by building on Georgia’s Online Analytical Statistical Information System (OASIS), a nationally regarded public health data collection system, with any additional collection efforts linked to OASIS.\textsuperscript{278} Moreover, OASIS has the following benefits:

\begin{quote}
[It] is an important starting place for the collection and evaluation of additional data required for improved prevalence estimates. For example, measuring prevalence of dementia requires reliable denominators (\textit{persons at risk}). The denominator data in OASIS are clean and accountable. The challenge is estimating the strategy and accuracy of the numerators (\textit{cases}).\textsuperscript{279}
\end{quote}

Since one of the long-term goals for the Registry is to develop the capacity of capturing disease incidence, OASIS, given its ability to provide accurate denominators, is a great starting place in achieving that objective.\textsuperscript{280}

\section{Data Content and Retention}

To ensure that the data collected is robust enough to aid future policy planning, the West Virginia Procedural Rules specify that the West Virginia Registry collect not only minimum information necessary to maintain the registry but also the most relevant and complete summary statistics and

\textsuperscript{276} Cf. UNDERSTANDING THE HIPAA PRIVACY RULE, \textit{supra} note 208, at 25 (giving the definition of a health care provider under HIPPA).

\textsuperscript{277} See generally \textit{id.} at 24–27 (providing a list of defined terms useful in correctly interpreting HIPAA rules).


\textsuperscript{279} Commentary for the Stakeholder’s Meeting, \textit{supra} note 278, at 1.

\textsuperscript{280} \textit{Id.}
information required to advise policy development.281 Under the West Virginia Procedural Rules, data collected include:

a. Last name, first name and middle initial;
b. Birth date;
c. Gender;
d. Last four digits of the Social security number;
e. Maiden name (if female),
f. Race/ethnicity;
g. Address, including street, city, county, and zip code;
h. Contact information, including secondary contacts;
i. Brief medical history;
j. History of Alzheimer's disease and related disorders;
k. Physician's name;
l. Physician’s contact information including address, phone, fax numbers, or email; and
m. Other information considered relevant for policy and planning relative to Alzheimer's disease and related disorders.282

The West Virginia Procedural Rules, however, do not specify the length of time data should remain available.283

In addition to the data collected in West Virginia, our Stakeholder Conference suggested that the Georgia Registry collect additional information, including:

1. [P]rimary language;
2. Healthcare utilization history;
3. Community resources used by the individual;
4. Living arrangements, i.e., who else is present in the home;
5. Associated health conditions plus [any special] need for assistive technology like dialysis, oxygen, etc.;
6. Licenses held by the person with dementia: driving, boats, firearms, [and] other professional.284

On the other hand, we recommend that the Registry exclude physician’s name and physician’s contact information from the publicly available database of the Registry due to the concern that the registry will harm the physician-patient

281. See W. VA. CODE R. § 64-94-4, subsec. 4.2 (2015) (“The content and design of all forms for the Registry shall be consistent with the minimum information necessary to maintain the registry . . .”). Similar language appears in W. VA. CODE R. § 64-94-4, subsec. 4.3 (2015) (discussing “[t]he content and design” of reports).
283. See id. (providing a comprehensive list of “[i]nformation to be reported”).
284. Sponsored Stakeholder’s Meeting Memorandum, supra note 3, at 2.
relationship.\textsuperscript{285} Physicians’ names and contact information should only be disclosed for notification purposes, or, alternatively, they should be maintained separately from the publicly available database. Requiring physicians to reveal patient information could harm the physician-patient relationship, but mere inclusion of the physician’s name in the Registry would not seem to have that effect.\textsuperscript{286}

In addition to collecting enough information to build up a comprehensive database, the Registry also needs to maximize safeguards for data security. We recognize that full implementation of data security will take time to achieve.\textsuperscript{287} At the outset, we advocate that the Registry prioritize public health objectives, organizing any collected data without individual identifiers. For example, issues like healthcare workforce, public safety, transportation, and housing can be emphasized. Public health policy-driven questions, such as correlating the impact of dementia on hospital lengths of stay, could be studied. Answers to such questions are critical for hospital strategic planning and cost containment.\textsuperscript{288} Yet the research does not require identification of specific patients.\textsuperscript{289}

Finally, we would improve upon the West Virginia Procedural Rules by prescribing the length of time that the data will be available, so that obsolete or duplicated data can be identified, updated, or deleted if necessary.\textsuperscript{290} Clear data retention periods would alleviate the burden on reporters and

\begin{footnotesize}
\begin{itemize}
\item[285] See De Bord et al., supra note 264 (discussing the importance of confidentiality in the physician-patient relationship).
\item[286] See id.
\item[287] See Lee A. Kadel, Designing And Implementing An Effective Information Security Program: Protecting The Data Assets Of Individuals, Small And Large Businesses ii (2004), https://www.sans.org/reading-room/whitepapers/hsoffice/designing-implementing-effective-information-security-program-protecting-data-assets-of-1398 (“The need for information security should be apparent, but . . . an effective security program requires substantial research, and often a great investment of time and resources.”).
\item[289] See id.
\item[290] See W. VA. CODE R. §§ 64-94-1 to -13 (2015) (illustrating that the West Virginia Procedure Rules have no provision for disposing of Alzheimer’s data).
\end{itemize}
\end{footnotesize}
reduce the possibility of inadvertent disclosure of antiquated, inactive data sources.\textsuperscript{291}

C. \textsc{Data Sharing}

With attention to the privacy concerns under federal and state law discussed above, we recommend slightly broader data sharing with the Georgia Registry than authorized in West Virginia. The West Virginia Procedural Rules limit disclosure of de-identified information for research purposes only.\textsuperscript{292} Otherwise, the West Virginia Registry may disclose confidential information regarding a patient with Alzheimer’s disease only to:

\begin{itemize}
\item[a.] The individual [patient];
\item[b.] The individual’s [legal] representative;
\item[c.] A physician or other health care provider . . . for the purpose of a medical evaluation or treatment of the individual;
\item[d.] Any individual or entity which provides the Registry with a lawful written authorization for the disclosure of confidential information from the individual [patient] . . . or that individual’s [legal] representative; or
\item[e.] Any individual or entity which provides the Registry with an order from a court of competent jurisdiction ordering the disclosure of confidential information.\textsuperscript{293}
\end{itemize}

The West Virginia Procedural Rules, while recognizing the policy-planning goal of the West Virginia Registry, appear to restrict disclosure for research purposes only.\textsuperscript{294} We recommend that Georgia’s procedural rules expressly recognize policy planning as a purpose of disclosure while remaining cautious not to undermine confidentiality. De-identified information should be clearly available to policymakers, including local and county governments, to enable officials to enact policies responsive to any increased prevalence of Alzheimer’s patients in their areas.\textsuperscript{295} “Each of Georgia’s counties has a unique experience with dementia and its impact


\textsuperscript{292} W. VA. CODE R. § 64-94-10, subsec. 10.2.1 (2015) (“The Registry may disclose non-identifying information for research purposes only.”).

\textsuperscript{293} \textit{Id}. subsec. 10.3.1.

\textsuperscript{294} See id.

\textsuperscript{295} See Commentary for the Stakeholder’s Meeting, \textit{supra} note 278, at 2.
on residents and local institutions[; r]ural communities’ needs differ from urban communities." 296 A more transparent and liberal data-sharing process than West Virginia’s “will promote the needed responsiveness and innovation required to meet the challenge of [Alzheimer’s disease and] dementia.” 297

Moreover, we contemplate a role for public policy, public health, gerontology, and other research institutes and think-tanks. Based on the positions of our current stakeholders, we anticipate that the following organizations will have strong interest in the Registry:

a. The National Institute on Aging
b. [The] National Institutes of Health
c. The Public Health Law Program in the Office for State, Tribal, Local and Territorial Support (OSTLTS) at the Centers for Disease Control [and Prevention]
d. The Robert Wood Johnson Foundation
e. [The] Public Health Law Program
f. The Cooperative Extension Program
g. The Georgia Hospice and Palliative Care Organization
h. Patient Centered Outcomes Research Institute
i. Centers for Medicare and Medicaid, Region IV 298

Given the important role of such organizations, we recommend that the Georgia Procedural Rules include provisions allowing participation and assistance from these and similar organizations and institutions. 299 Moreover, Georgia’s Procedural Rules should formalize and stabilize any existing cooperation between the Registry and the various types of organizations mentioned above.

Like West Virginia, we certainly support data sharing for research purposes, and, as recommended above, would limit such disclosures consistent with HIPAA requirements for covered entities, even though we conclude that the Registry technically is not a covered entity for HIPAA purposes. 300

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296. Id.
297. Id.
298. See id. at 3.
299. See id.
300. See W. Va. Alzheimer’s Disease Registry, supra note 118 and accompanying text.
V. BEST PRACTICE FOR ESTABLISHING THE REGISTRY

In light of the increasingly epidemic nature of Alzheimer’s disease, the detrimental health effects on its sufferers, and the financial burdens on the taxpayers, the Georgia Registry takes an important step on the path toward better understanding and management of Alzheimer’s disease in Georgia.\textsuperscript{301} The information gathered by the Registry may help determine which groups are most at risk, so that resources can be directed to those groups. Information in the Registry also may further current research regarding the overall effects of the disease.\textsuperscript{302} Gathering this wealth of information, however, also could detrimentally affect patients, physicians, and other stakeholders; therefore, we conclude by recommending best practices of establishing and managing the Georgia Registry.

A. PRIVATE REGISTRIES AND STAKEHOLDER ADVISORY BOARD

Before the Georgia General Assembly passed legislation establishing the Registry, many private institutions across the country already had made tremendous efforts to establish their own Alzheimer’s disease registries. For example, “[t]he Alzheimer’s Prevention Registry . . . , launched in October 2012 by the Banner Alzheimer’s Institute, is a new online community of people who want to help scientists find treatments to slow, halt, or prevent the memory-robbing disorder.”\textsuperscript{303} Private registries have attracted large groups of people who personally participate in the combat against Alzheimer’s disease and who are more likely to voluntarily report to the Registry.\textsuperscript{304} Long established, private registries also offer substantial registry management experience to share

\textsuperscript{301} See, e.g., 2014 ALZHEIMER’S DISEASE: FACTS AND FIGURES, supra note 5, at 21–22 (discussing the progression of Alzheimer’s disease within the population from 2000 to 2050).

\textsuperscript{302} Cf. Population-Based Registries, supra note 4 (“Cancer research programs benefit greatly from the cancer data collected by population-based cancer registries.”).


\textsuperscript{304} See id. (Just six months after the registry was established, “more than 9,300 members ha[d] already joined the effort.”).
with newcomers.\textsuperscript{305} Policymakers and others involved in establishing the Registry would benefit from their assistance.

In the future, policymakers may also want to consider creating a special advisory board for the Registry consisting of diverse stakeholders in Georgia, including faculty from higher education institutions (e.g. University of Georgia College of Public Health), law enforcement officials (e.g. police officers), and local non-profit institutions (e.g. the Archway Program). The advisory board, which is not a feature of the West Virginia Registry,\textsuperscript{306} would supervise the operation of the Registry and monitor the authorization procedure to ensure the disclosure of the Registry information or data to third parties is appropriate, confidential, and legal. The expertise and experience of the members of the advisory board with regard to medical data management is necessary to the successful operation of the Registry.\textsuperscript{307}

**B. DUAL DATA-SHARING PROCEDURE**

In order to weigh the Georgia Registry’s confidentiality compliance against its designated function to collect and share data for policy planning and research purposes, it is important to distinguish aggregate data from personally identifiable information. In statistics, aggregate data are data combined from several measurements.\textsuperscript{308} When data are aggregated, groups of observations are replaced with summary statistics based on those observations.\textsuperscript{309} On the other hand, personally identifiable information is any data that could potentially

\textsuperscript{305} See generally REGISTRIES FOR EVALUATING PATIENT OUTCOMES: A USER’S GUIDE ch. 2. (Gliklich RE, Dreyer NA, Leavy MB eds., 2014). http://www.ncbi.nlm.nih.gov/books/NBK208631/ (showing the difficulty of registry management); New Alzheimer’s Prevention Registry Recruiting 250,000 Volunteers, supra note 303 (explaining how private registries have already gone through this process).

\textsuperscript{306} See W. VA. CODE § 16-5R-7 (2015) (establishing the Governing Board of West Virginia University as the supervisor of the registry).

\textsuperscript{307} See Gliklich RE et al., supra note 305 (stating that experts are necessary to establish a registry).


\textsuperscript{309} See id. at 4.
identify a specific individual, either directly or by implication.310

Since the Registry aims to provide information to policymakers, aggregate data is more suitable to be presented to the public.311 “[A] regular newsletter to a list serve of interested parties on specific registry related topics” could be an option for the Registry to share aggregate data.312 On the other hand, disclosure of personally identifiable data should be restricted to “researchers and budget planners with a well-developed application process.”313

The application process should be designed to protect data that can identify an individual and potentially harm the patient. The existing OASIS software and infrastructure can be used, and a small application fee should be charged.314 We recommend a data collection review board be established. The application will be submitted to a data protection review board (Board) established within the Registry. Through the detailed application document, the Board will be supplied with the information necessary to determine whether:

[T]he purpose of the request is consistent with the uses of the data as defined by regulation, the applicant is qualified to undertake the study, the proposed study/research is technically feasible, the applicant needs all the data requested[,] and [the applicant] is able to ensure that patient privacy is protected.315

This system of checks and balances, applied to all identifying data requests, guards the rights of individuals while providing access to needed registry information.

The dual data-sharing procedure, as we strongly suggest, recognizes the need for data to be accessible so that there is a more effective, efficient, and responsive registry. Basically, the dual data-sharing procedure balances the need to know with the need to protect the confidentiality of patient records. In all cases, however, the Registry-specific data sharing procedures

310. See id.
311. Cf. id. (discussing the importance of protecting personal identifiable information).
312. See Sponsored Stakeholder’s Meeting Memorandum, supra note 3, at 2.
313. Id.
314. See id.
should be consistent with HIPAA privacy standards under federal law.\textsuperscript{316}

\section*{C. State Medicaid Incentive Program and Other Rewarding Mechanisms}

We also envision opportunities through electronic health records (EHR) to encourage reporting to the Registry. EHR is being used nationwide\textsuperscript{317} to “improve the quality, safety, and efficiency of patient care.”\textsuperscript{318} Under Georgia’s Medicaid program, there is already a useful demonstration project underway for incentivizing providers that utilize EHR in meaningful ways.\textsuperscript{319}

The [Georgia] Medicaid EHR Incentive Program is a voluntary, multi-year, multi-stage program administered by the Georgia Department of Community Health. [It] … is limited to eligible Medicaid professionals for six years of participation, and eligible Medicaid hospitals for three years as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology.\textsuperscript{320}

For those meeting all program requirements, eligible professionals (excluding pediatricians) and eligible Medicaid hospitals may receive various amounts of incentive payments based on a number of factors, beginning with a base payment.\textsuperscript{321}

We suggest adopting a similar state incentive program for Registry implementation. For example, if an eligible physician or hospital provides information to the Registry in accordance with the Procedural Rules, the physician may earn incentive


\textsuperscript{319} See id. (“Georgia is leading the way to incentivize providers that utilize electronic health records . . . .”).

\textsuperscript{320} Id.

\textsuperscript{321} Id.
payments in the form of enhanced reimbursement.\(^{322}\) We acknowledge that tying an incentive to Medicaid reaches only the portion of the Alzheimer’s population that is Medicaid-eligible and that any call for additional payments would be controversial under existing state budgetary challenges.\(^{323}\) Nevertheless, we wish to identify novel ways to ensure robust data reporting to the Registry for maximum effectiveness.

D. MEDICAL-LEGAL PARTNERSHIP

We also perceive opportunities to support the Registry through Georgia’s recent commitment to the medical-legal partnership (MLP) model.

On April 21, 2014, Governor Nathan Deal signed SB 352, a bill codifying MLPs in the state of Georgia. The new law gives Georgia Department of Community Health authorization to approve medical-legal partnerships that comply with standards and guidelines for the purpose of determining eligibility for grants. Georgia is the second state after New York to endorse medical-legal partnerships and create a process for certifying programs within the state.\(^{324}\)

MLPs operate on the recognition that patients’ health care needs may be amenable to not only medical, but also legal, interventions.\(^{325}\) By including legal services providers on patients’ overall treatment team, MLPs may identify and address causes or contributors to poor health,\(^{326}\) such as stress


\(^{326}\) See id. (implying that use of legal remedies to help patients where both legal and medical implications arise may also help the patient with their underlying medial issues, e.g. helping a patient obtain access to disability benefits via a legal remedy will better prepare that patient to battle their medical issues).
and anxiety. Accordingly, MLPs may assist with a wide range of legal needs that Alzheimer’s and related dementia patients face, including estate planning, guardianship, advance care planning, medical powers of attorney, public entitlements, insurance, housing, and disability accommodations. Moreover, MLPs may represent patients in resolving Registry-related legal matters, including privacy concerns with Registry reporting, data sharing, and record retention.

E. DISPARATE REPORTING

To address the concern that Alzheimer’s disease unequally burdens some populations, including racial and ethnic minorities and people with intellectual disabilities, we recommend the Registry be attuned to disparate reporting methods. Disparate reporting means applying a different, but reasonable, reporting mechanism to capture data on race, sex, and disability as reported by different sources. Racial and ethnic minorities are at greater risk for developing Alzheimer’s disease and facing barriers to obtaining a diagnosis and services after onset. In addition, because Alzheimer’s disease primarily affects older adults, the population with younger-onset Alzheimer’s disease faces unique challenges with diagnosis, care, and stigma. Ideally, the Registry will assist researchers and policymakers to better understand the unique challenges faced by these particular groups and create a plan

327. See generally HARVARD HEALTH PUBL’NS, ANXIETY AND PHYSICAL ILLNESS (July 1, 2008), http://www.health.harvard.edu/staying-healthy/anxiety_and_physical_illness (discussing the link between anxiety and physical illness).


330. See Patoine, supra, note 51 (quoting Dr. Patrick A. Griffith, a Professor of Clinical Medicine at the Morehouse School of Medicine: “African-Americans and Hispanics tend to come to the attention of physicians only in the middle or later stages of the illness, . . . . [which] is a much more difficult stage to treat.”).

for improving Alzheimer’s disease reporting from these groups. Lessons learned in this context may then be integrated with the broader efforts to improve reporting for all people with Alzheimer’s disease. Disparate reporting, which considers the special needs of different interest groups, can be a viable approach to close the reporting gap in Georgia.

F. EDUCATION AND OUTREACH

Despite the statutory and regulatory provisions allowing for enforcement of reporting requirements, stakeholders agree that a voluntary outreach and information-driven approach is the most effective way to increase the number of people participating in the Registry. Continuing Medical Education presentations are a key method to reach physicians with information about the Registry’s reporting expectations. Public service announcements and other educational campaigns about the existence, purpose, and value of the Registry directed toward people with Alzheimer’s disease and their families also may empower people with Alzheimer’s disease and their families to report or encourage their physicians to report.

With the costs of providing care for patients with Alzheimer’s approaching thirty billion annually in Georgia, reporting to the Registry is a relatively low-cost tool to address the problem. When paired with outreach to physicians, patients, and families about the diagnosis and treatment of Alzheimer’s disease, the Registry can assist in attacking the encumbrance of Alzheimer’s disease in Georgia.

332. See Sponsored Stakeholder’s Meeting Memorandum, supra note 3, at 2 (listing a variety of ways in which the information should be distributed for both policy planning and research, including the OASIS database and a regular newsletter).
334. See generally New Alzheimer’s Prevention Registry Recruiting 250,000 Volunteers, supra note 303 (illustrating how private registries use public outreach to encourage reporting).
335. See supra note 30 and accompanying text.
VI. CONCLUSION

This article offers a unique window into one state’s experience establishing an Alzheimer’s disease and related dementia registry. Georgia is the most recent of a handful of states to adopt such a registry and, in doing so, has already committed to robust data collection practices along with a clear commitment to protecting patients’ privacy. The authors were privileged to convene a group of stakeholders to brainstorm and submit rulemaking comments on Registry implementation to the Georgia Department of Public Health. In addition, through further consultation with state leaders in gerontology and building on our own health law, public health, and legal services expertise, we offer additional recommended best practices for the Registry. We anticipate that Georgia is leading a nationwide trend in addressing the rapidly rising incidence of Alzheimer’s disease and related dementia with the aging population. Accordingly, our recommendations will be valuable not only for Georgia, but also for other states that may decide to establish similar Alzheimer’s registries.