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Health Care Law

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HEALTH CARE LAW

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He's the best physician that knows the worthlessness of the most medicines.

–Benjamin Franklin

I. INTRODUCTION

Health Care continues to be in the national spotlight with the new White House administration and its agenda, the debate over universal health care, an increasing number of hospital closures, and the astounding number of personal bankruptcies precipitated by burgeoning health care debt. This year we can expect to see the issue of health care reform take center stage as the lights dim on banking reform and the Big Three automakers (General Motors, Ford, and Chrysler). In May 2009, Senator Edward M. Kennedy (D-Mass.) circulated his broad plan for health care reform legislation through Congress and the debate continued.[1] By the time this article is published, it is expected that both the Senate and the House will have weighed in with their proposed legislation. This article addresses changes to the health care landscape in Virginia this year, which may prove to be the calm before the storm.

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1. *Kennedy Touts Health Bill*, NEWSDAY, May 30, 2009, at A24.

II. LEGISLATIVE FOCUS

With economic turmoil raging across the nation, the 2009 General Assembly increased its focus on the affordability, quality, and efficiency of the health care system in Virginia—particularly with respect to small businesses and individuals. Many statewide changes mirrored federal health policy initiatives, such as strengthening the emphasis on electronic health records and prevention of health care fraud and abuse.[2] With such an overwhelming amount of change occurring in the health care industry, it is both an exciting and uncertain time for health professionals and industry insiders.

A. *Health Insurance Legislation*

The 2009 Session took a step toward the promotion of universal health care when it passed legislation requiring that insurance policies offered by small employers to their employees must include certain state-mandated health benefits.[3] The four policy benefits that must be included are preventative screenings—mammograms, pap smears, prostate specific antigen ("PSA") testing, and colorectal cancer screening.[4] However, while requiring these state-mandated health benefits, the General Assembly enacted Virginia Code section 38.2-3406.2 to clarify that this new legislation does not prohibit the offering of capped benefit plans.[5] Under a capped benefit policy, all health insurance mandates are covered, but the benefit is capped at a specific dollar amount.[6] Fi-

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2. *See, e.g.*, American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, div. A, tit. XIII, 123 Stat. 115, 226–79. Nearly two-thirds of the federal funding to states and localities in the American Recovery and Reinvestment Act of 2009 ("ARRA") will be allocated to the health care field. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-580, RECOVERY ACT: AS INITIAL IMPLEMENTATION UNFOLDS IN STATES AND LOCALITIES, CONTINUED ATTENTION TO ACCOUNTABILITY ISSUES IS ESSENTIAL 7–8 (2009), *available at* http://www.gao.gov/new.items/d09580.pdf.

3. Act of May 6, 2009, ch. 877, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 38.2-3406.1(B) (Cum. Supp. 2009)). For the purposes of this section of the Virginia Code, a "small employer" is defined as "an employer located in the Commonwealth that employed at least two but not more than 50 eligible individuals on business days during the preceding calendar year and who employs at least two eligible individuals on the date a policy under this section becomes effective." VA. CODE ANN. § 38.2-3406.1(A) (Cum. Supp. 2009).

4. VA. CODE ANN. § 38.2-3406.1(B)(1) (Cum. Supp. 2009).

5. Act of May 6, 2009, ch. 877, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 38.2-3406.2 (Cum Supp. 2009)).

6. *See* VA. CODE ANN. § 38.2-3406.2 (Cum. Supp. 2009).

nally, to monitor the impact of the newly required state-mandated benefits, the General Assembly will require health insurers offering plans with these benefits to "report annually to the Bureau of Insurance on the number of small employers and individuals using plans issued pursuant to [section 38.2-3406.1], the coverage provided, and the cost of premiums and out-of-pocket expenses."[7] This information will then be compiled in a report and submitted to the Governor and the General Assembly on August 1, 2010 and August 1, 2011.[8]

Another new health insurance benefit, codified at Virginia Code section 38.2-3541.1, provides the option of continued insurance coverage for employees of small employers who were involuntarily terminated during the period September 1, 2008 to December 31, 2009, and whose group health insurance does not provide for continuation coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA").[9] Employers must notify terminated employees of the availability of continuation within thirty days of termination,[10] and employees must elect continued coverage within sixty days of notification.[11]

The General Assembly also amended Virginia Code section 38.2-3407.1 to provide that the accrued interest paid on actions to recover claims proceeds does not apply to claims proceeds payable to out-of-state providers of pharmacy services for pharmacy ser-

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7. Act of May 6, 2009, ch. 877, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 38.2-3406.1 ed. note (Cum. Supp. 2009)).

8. *Id.*

9. VA. CODE ANN. § 38.2-3541.1 (Cum. Supp. 2009). *See* Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, tit. X, 100 Stat. 82, 222–37 (1986) (codified as amended in scattered sections of 26, 29, and 42 U.S.C.). *See generally* 26 C.F.R. § 54.1-4980B-1 (2009) (describing COBRA continuation coverage requirements). Congress passed COBRA to provide temporary continuation of group health coverage to former employees, retirees, spouses, former spouses, and dependent children. U.S. Dep't of Labor, FAQs for Employees About COBRA Continuation Health Coverage, http://www.dol.gov/ebsa/faqs/faq_consumer_cobra.html (last visited Oct. 11, 2009). Under the ARRA,

> [i]ndividuals who are eligible for COBRA coverage because of their own or a family member's involuntary termination of employment that occurred from September 1, 2008 through December 31, 2009 and who elect COBRA may be eligible to pay a reduced premium amount that is only 35% of the premium costs for . . . COBRA coverage for up to 9 months.

Id. Additionally, terminated employees who were offered federal COBRA continuation coverage during that time period and either declined to take COBRA coverage or elected COBRA and later discontinued it, may have another opportunity to elect COBRA coverage and pay a reduced premium. *Id.*

10. VA. CODE ANN. § 38.2-3541.1(A)(3)(c) (Cum. Supp. 2009).

11. *Id.* § 38.2-3541.1(A)(4) (Cum. Supp. 2009).

vices provided outside Virginia unless the state where the services were rendered failed to pay interest on the claims proceeds.[12] If the other state failed to pay this interest, the interest on the claim proceeds paid to the policy holder is to be computed daily at the legal rate of interest from the thirtieth day after the insurer received the proof of loss until the claim is paid.[13]

Finally, the legislature also extended health insurance coverage to include coverage for the purchase, repair, fitting, and replacement of medically necessary prosthetic devices.[14] This coverage applies to all policies issued, extended, or amended on and after January 1, 2010.[15]

Insurance mandates that became effective on or after July 1, 2009 for accident and health insurance policies also now apply to health insurance plans for state employees, pursuant to Virginia Code section 2.2-2818.2.[16] The Department of Human Resource Management is required to report cost and utilization information for each of the mandated benefits applied to state employees under section 2.2-2818.2 to the Special Advisory Commission on Mandated Health Insurance Benefits.[17]

With many Virginians losing their jobs due to the economic recession, these regulations, combined with expanded federal assistance, will assist unemployed individuals and families in continuing access to health care.

B. *Health Information Technology and Electronic Medical Records*

The American Recovery and Reinvestment Act of 2009 ("ARRA") contains several provisions relating to the promotion of health information technology.[18] Health information technology

12. Act of Mar. 27, 2009, ch. 226, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 38.2-3407.1(F) (Cum. Supp. 2009)).

13. VA. CODE ANN. § 38.2-3407.1(F) (Cum. Supp. 2009).

14. Act of Apr. 8, 2009, ch. 839, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 38.2-3418.15(A) (Cum. Supp. 2009)).

15. VA. CODE ANN. § 38.2-3418.15(B) (Cum. Supp. 2009).

16. *Id.* § 2.2-2818.2(B) (Supp. 2009).

17. *Id.* § 2.2-2818(R) (Supp. 2009).

18. *See* Pub. L. No. 111-5, div. A, tit. XIII, 123 Stat. 115, 226–79 (2009). The ARRA contains more than $19 billion in federal funding to support the adoption and implementation of electronic health records. *See* Lara Cartwright-Smith & Sarah Rosenbaum, *The*

was a cornerstone of President Barack Obama's plan to stimulate the economy and improve the overall health care system.[19] Studies have suggested that widespread adoption and implementation of electronic medical records could significantly decrease medical errors, improve efficiency, and lower health care costs.[20] Following the federal government's lead, the 2009 General Assembly enacted various legislation encouraging the adoption of health information technology.

1. Health Information Technology Standards Advisory Committee

One of the greatest barriers to the adoption and integration of health information systems is the compatibility of various systems in the network.[21] Recognizing the need for uniform health information systems, the General Assembly passed legislation creating the Health Information Technology Standards Advisory Committee, consisting of individuals with expertise in health care and information technology, to advise the Information Technology Investment Board on the adoption of nationally recognized technical and data standards for health information technology.[22]

2. Electronic Prescribing

A study led by David Bates, MD, Chief of General Medicine at Boston's Brigham and Women's Hospital, indicated that compu-

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American Recovery and Reinvestment Act of 2009, LEGAL NOTES, May 2009, at 1, http://www.rwjf.org/files/research/legalnotes1issue2part1.pdf.

19. *See* Remarks of President-elect Barack Obama, Radio Address on the Economy (Dec. 6, 2008), http://change.gov/newsroom/entry/the_key_parts_of_the_jobs_plan/. In this address, then-President-elect Obama stated:

> [W]e must also ensure that our hospitals are connected to each other through the internet. That is why the economic recovery plan I'm proposing will help modernize our health care system—and that won't just save jobs, it will save lives. We will make sure that every doctor's office and hospital in this country is using cutting edge technology and electronic medical records so that we can cut red tape, prevent medical mistakes, and help save billions of dollars each year.

Id.

20. *See* Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs*, 24 HEALTH AFFAIRS 1103, 1114–15 (2005).

21. *See id.* at 1104.

22. Act of Feb. 26, 2009, ch. 134, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 2.2-2458.1 (Supp. 2009)).

terized physician order entry ("CPOE") systems have reduced the occurrence of adverse drug events by eighty-eight percent.[23] These systems improve errors associated with illegibility, drug allergies, interactions, and errant dosing.[24] In response to these encouraging figures, the General Assembly passed legislation designed to accelerate the implementation of electronic prescribing in Virginia.[25] The new statute requires the Secretary of Health and Human Resources, in consultation with the Secretary of Technology, to establish a website with information on electronic prescribing for health practitioners.[26] Specifically, the website must contain information about the electronic prescribing process and the advantages of electronic prescribing products, as well as links to federal and private sector websites containing guidance on selecting the appropriate products and incentive programs for implementing electronic prescribing.[27] Furthermore, beginning on January 1, 2010, any health practitioner who contracts with the Commonwealth for the provision of health services will be required to utilize electronic prescribing to the maximum extent practicable.[28] And finally, the Department of Medical Assistance Services ("DMAS") is required to develop programs and incentives to encourage Medicaid providers to adopt electronic prescribing.[29]

3. Health Information Technology for Economic and Clinical Health Act

The Health Information Technology for Economic and Clinical Health Act ("HITECH"), part of the ARRA, provides guidelines for the implementation of a nationwide health information tech-

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23. *See* David W. Bates et al., *The Impact of Computerized Physician Order Entry on Medication Error Prevention*, 6 J. AM. MED. INFORMATICS ASS'N 313, 320 (1999).

24. *See id.* at 314.

25. *See* Act of Mar. 27, 2009, ch. 479, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 2.2-213.3 (Supp. 2009)).

26. VA. CODE ANN. § 2.2-213.3(A) (Supp. 2009).

27. *See id.*

28. Act of Mar. 27, 2009, ch. 479, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-3303 ed. note (Repl. Vol. 2009)). However, "no health care provider shall be prohibited from contracting with the Commonwealth for not utilizing electronic prescribing." *Id.*

29. Act of Mar. 27, 2009, ch. 479, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 2.2-213.3 ed. note (Supp. 2009)). DMAS is required to report to the Governor and the General Assembly, no later than December 1, 2009, with recommendations concerning electronic prescribing programs and incentives. *Id.* DMAS is also "encouraged to pursue opportunities with the private sector in implementing electronic prescribing programs." *Id.*

nology infrastructure, as well as guidelines on how to strengthen patient privacy regulations.[30] HITECH provides for federal funding in the form of grants, loans, and incentive payments for the adoption and implementation of health information technology.[31] Furthermore, it revises numerous provisions under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")[32] in order to make the implementation of electronic health records more secure and patient-accessible.[33] However, HITECH does not limit the changes to HIPAA regulations to those covered entities utilizing electronic health records.[34] Health care providers should become informed about the upcoming changes to patient privacy and security regardless of the use of electronic records.

C. *Health Care Fraud and Abuse*

The current economic recession has taken its toll on government-funded health care. In the Medicare Annual Trustees' Report, released May 12, 2009, the trustees projected that Medicare's Hospital Insurance ("HI") trust fund will be exhausted by 2017—two years earlier than last year's estimate.[35] In Virginia, DMAS announced numerous cost-saving items in the 2009 Appropriations Act to prevent depletion of the Medicaid program.[36] However, stimulus funds from the ARRA saved several programs

30. *See* Pub. L. No. 111-5, div. A, tit. XIII, 123 Stat. 115, 226–79.

31. *See id.* § 13301, 123 Stat. at 246–58.

32. Pub. L. No. 104-191, 110 Stat. 1936.

33. *See* Health Information Technology for Economic and Clinical Health Act §§ 13401–11, 13421(b), 123 Stat. at 260–76. HITECH creates federal breach notification requirements without including a "risk of harm" threshold. *See id.* § 13402(a)–(b), 123 Stat. at 260. It also increases enforcement. *See id.* § 13410, 123 Stat. at 271–76. The Act creates a tiered penalty structure. *See id.* § 13410(d), 123 Stat. at 272–74. It expands HIPPA requirements to business associates. *See id.* § 13401(a)–(b), 123 Stat. at 260. It also restricts marketing and sale of data for all covered entities. *See id.* § 13405(d), 123 Stat. at 266–67. Further requirements are placed on covered entities utilizing electronic health records, such as requiring an accounting of all disclosures, even for treatment, payment, or health operations. *See id.* § 13405(c), 123 Stat. at 265–66.

34. *See id.* § 13407, 123 Stat. at 269–71 (applying the improved privacy and security provisions to vendors of personal health records and other non-HIPAA covered entities).

35. BOARDS OF TRUSTEES, FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TRUST FUNDS, 2007 ANNUAL REPORT OF THE BOARDS OF TRUSTEES 3 (2009), *available at* http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2009.pdf.

36. *See generally* VA. DEP'T OF PLANNING AND BUDGET, THE 2009 EXECUTIVE BUDGET DOCUMENT: DEP'T OF MEDICAL ASSISTANCE SERVICES (2009), http://dpb.virginia.gov/budget/buddoc09/agency.cfm?agency=602.

and prevented several cost-cutting measures in fiscal years 2009 and 2010.[37]

In an effort to sustain the federal Medicare program, the Centers for Medicare and Medicaid Services ("CMS") implemented the Medical Integrity Program, a recovery strategy to retrieve reimbursements that were incorrectly paid out to providers.[38] The program, which contracts four Recovery Audit Contractors ("RACs") to protect the Medicare Trust Fund, has proven wildly successful during its demonstration phase in California, Florida, New York, Massachusetts, South Carolina, and Arizona.[39] Between 2005 and 2008, the RAC demonstration program returned over $900 million in overpayments to the Medicare Trust Fund and nearly $38 million in underpayments to health care providers.[40] The RAC program will be active in Virginia as early as August 1, 2009.[41] In preparation, providers should increase their internal auditing policies, be cognizant of their documentation and billing methods, designate an individual to respond to RAC requests, and educate themselves on the red flags of billing and the Medicare appeals process for responding to RAC requests.

In addition to the RAC Program, CMS increased its enforcement of health care fraud and abuse by helping to create the Health Care Fraud Prevention and Enforcement Action Team ("HEAT").[42] HEAT will increase site visits to potential suppliers

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37. *See* Staffs of S. Fin. Comm. & H. Appropriations Comm., Summary of 2008–2010 Budget Actions 52–58 (May 21, 2009), http://sfc.state.va.us/2009sessionbudgetdocuments.shtml (follow "2008–2010 Budget Actions, Chapter 781" hyperlink) (summarizing the amended budget for the 2008-2010 biennium).

38. *See* Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Enhances Program Integrity Efforts to Fight Fraud, Waste and Abuse in Medicare (Oct. 6, 2008), *available at* http://www.cms.hhs.gov/apps/media/press_releases.asp (follow "October 06, 2008" hyperlink). The Medicare Integrity Program established the Recovery Audit Contractors Program ("RAC") and required nationwide implementation by January 1, 2010. *See* 42 U.S.C. § 1395ddd(h)(1), (3) (2006). CMS has certified four national RACs, who, in association with chosen subcontractors, are responsible for auditing CMS providers and organizations to identify and retrieve overpayments by CMS. *See* Ctrs. for Medicare & Medicaid Servs., Recovery Audit Contractor Overview, http://www.hhs.gov/RAC/ (last visited Oct. 11, 2009).

39. *See* Ctrs. for Medicare & Medicaid Servs., CMS Announces New Recovery Audit Contractors to Help Identify Improper Medicare Payments (Oct. 6, 2008), http://www.cms.hhs.gov/apps/media/fact_sheets.asp (follow "October 06, 2008" hyperlink).

40. *Id.*

41. Ctrs. for Medicare & Medicaid Servs., RAC Expansion Schedule, http://www.cms.hhs.gov/RAC/ (follow "RAC Expansion Schedule" hyperlink) (last visited Oct. 11, 2009).

42. News Release, U.S. Dep't of Health & Human Servs., Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention and Enforcement Action Team (May 20, 2009), *available at* http://www.hhs.gov/news/

in order to prevent imposters from posing as legitimate durable medical equipment providers, increase training for providers on Medicare compliance, improve data sharing between CMS and law enforcement to help identify patterns that lead to fraud, and strengthen program integrity activities to monitor and ensure Medicare Parts C and D compliance and enforcement.[43]

Virginia followed the lead of CMS in fighting health care fraud by adding additional whistle blower protection during the 2009 General Assembly.[44] Employers are now statutorily prohibited from discharging, threatening, or otherwise discriminating or retaliating against a whistle blower.[45] State employers are required to post notices informing employees of the protections provided to them by this act.[46] Furthermore, the act establishes the Fraud and Abuse Whistle Blower Reward Fund, which provides a monetary incentive equal to one percent of the cost savings to any person who discloses information of wrongdoing or abuse where the disclosure results in a savings of at least $10,000.[47] This whistle blower protection statute joins the Virginia Fraud Against Taxpayers Act,[48] which mirrors federal false claims provisions,[49] and the commonwealth's Medicaid Fraud Control Unit[50] in providing strong state laws for the investigation, prosecution, and recovery of monies paid to providers by DMAS under fraudulent pretenses.

As a result of this recent legislation, both the federal RAC program and Virginia's Medicaid Fraud Control Unit will have plenty of statutory support in their quest to recover funds for government health care programs. Subsequently, providers must be cognizant of their documentation and billing practices in order to prevent prosecution under one of the available fraud and abuse laws.

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press/2009pres/05/20090520a.html.

43. *Id.*

44. *See* Act of Mar. 27, 2009, ch. 340, 2009 Va. Acts ___ (codified at VA. CODE ANN. §§ 2.2-3009 to 2.2-3014 (Supp. 2009)).

45. *See* VA. CODE ANN. § 2.2-3011 (Supp. 2009). A "whistle blower" is generally defined as an employee who reports or provides testimony of wrongdoing or abuse. *See id.* § 2.2-3010 (Supp. 2009).

46. *Id.* § 2.2-3013 (Supp. 2009).

47. *Id.* § 2.2-3014(A) (Supp. 2009). The monetary reward, however, shall not exceed $5,000. *Id.*

48. *See* VA. CODE ANN. § 8.01-216.1 to 8.01-216.19 (Repl. Vol. 2009).

49. *See* 31 U.S.C. §§ 3729–3733 (2006).

50. *See* Office of the Att'y Gen., Medicaid Fraud Control Unit, http://www.oag.state.va.us/consumer/medicaid_fraud/ (last visited Oct. 11, 2009).

D. *Required Disclosure of Patient Information*

In contrast to the numerous federal and state prohibitions on disclosure of patient information, the General Assembly passed three pieces of legislation mandating the disclosure of certain patient information in certain circumstances.

1. Patient Level Data System

The General Assembly amended the required disclosures of patient information by hospitals, facilities, physicians, and oral and maxillofacial surgeons under the Virginia Patient Level Data System ("PLDS").[51] Providers and facilities must now report patient street address and city or county to the PLDS[52] but are no longer required to report the patient relationship to the insured.[53]

2. Death Certificates

The State Registrar, or city or county registrar, is now required to issue certified copies of death certificates to grandchildren and great-grandchildren of a decedent.[54]

3. Charges for Billing Statements

A health care provider must supply to a patient or a patient's attorney, upon request, copies of the patient's account balance or an itemized listing of charges at no cost up to three times every twelve months.[55]

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51. *See* Act of Mar. 30, 2009, ch. 652, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 32.1-276.6 (Repl. Vol. 2009)). The Patient Level Data System establishes and administers an integrated system for "collection and analysis of data which shall be used by consumers, employers, providers, and purchasers of health care and by state government to continuously assess and improve the quality, appropriateness, and accessibility of health care in the Commonwealth and to enhance their ability to make effective health care decisions." VA. CODE ANN. § 32.1-276.6(A) (Repl. Vol. 2009).

52. *Id.* § 32.1-276.6(B)(7) (Repl. Vol. 2009).

53. *See* Act of Mar. 30, 2009, ch. 652, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 32.1-276.6(B)(7) (Repl. Vol. 2009)).

54. VA. CODE ANN. § 32.1-271(F) (Repl. Vol. 2009).

55. *Id.* § 8.01-413(A)–(B) (Cum. Supp. 2009).

E. *Advanced Medical Directives*

The 2009 General Assembly passed legislation that radically changed the need for guardianships for the purposes of making health care decisions for incapacitated patients.[56] Essentially, the legislation turned the advance medical directive ("AMD") into a durable medical power of attorney by removing the terminal illness provision required to implement the AMD.[57]

1. Health Care Decisions Act

The Health Care Decisions Act was revised to: (1) allow an individual to make a written AMD to specify what types of health care the declarant does or does not authorize, appoint someone to make health care decisions for the declarant, and specify an anatomical gift;[58] (2) clarify the process for determining whether a patient is incapable of making an informed decision regarding health care;[59] (3) require that determinations of incapacity be made by either two physicians or a physician and a licensed clinical psychologist, one of whom is not otherwise involved in the care of the patient;[60] (4) allow any physician to declare that a patient has regained his or her capacity to make an informed decision;[61] (5) explain the authority of an agent named in an advance directive, or a person otherwise given authority to make medical decisions for an incompetent patient,[62] including the authority to admit the declarant to a facility for treatment for up to ten days[63]

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56. *See* Act of Mar. 27, 2009, ch. 211, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-2983 (Repl. Vol. 2009)).

57. *See id.*

58. *See* VA. CODE ANN. § 54.1-2983 (Repl. Vol. 2009). Additionally, the definition of "health care" was added to the list of definitions contained in section 54.1-2982:

> "Health care" means the furnishing of services to any individual for the purpose of preventing, alleviating, curing, or healing human illness, injury or physical disability, including but not limited to, medications; surgery; blood transfusions; chemotherapy; radiation therapy; admission to a hospital, nursing home, assisted living facility, or other health care facility; psychiatric or other mental health treatment; and life-prolonging procedures and palliative care.

Id. § 54.1-2982 (Repl. Vol. 2009).

59. *See id.* § 54.1-2983.2 (Repl. Vol. 2009).

60. *See id.* § 54.1-2983.2(B) (Repl. Vol. 2009).

61. *See id.* § 54.1-2983.2(D) (Repl. Vol. 2009).

62. *See id.* § 54.1-2986.1 (Repl. Vol. 2009).

63. *See id.* § 54.1-2983.3(C) (Repl. Vol. 2009); *id.* § 37.2-805.1(A) (Cum. Supp. 2009).

and to authorize the declarant's participation in a health care study approved by an institutional review board or research review committee;[64] and (6) determine when a physician may treat a patient against his will.[65] Additionally, any person who willfully conceals, cancels, defaces, obliterates, damages, falsifies, or forges the AMD or revocation of the AMD of another shall be guilty of a Class 1 misdemeanor.[66] If life-prolonging procedures are utilized against a patient's wishes due to such action, the person committing the action will be guilty of a Class 6 felony.[67] Where such action is taken with the intent to withhold or withdraw life-prolonging procedures in contravention of the previously expressed intent of the declarant, the person shall be guilty of a Class 2 felony.[68]

2. Health Care Decisions in the Event of Patient Protest

The 2009 General Assembly codified Virginia Code section 54.1-2986.2 to provide guidelines for making health care decisions in the event of patient protest.[69] An incapacitated individual's surrogate may authorize treatment for the individual as set forth in the individual's advance directive even if the incapacitated individual is denying treatment.[70] This provision was developed so that an individual's wishes regarding his treatment and care will be followed in accordance with his decisions made while competent.[71] If a patient who is incapable of making an informed decision protests a health care recommendation, his agent may make a decision over the patient's protests only if:

> (1) [t]he decision does not involve withholding or withdrawing life-prolonging procedures; (2) [t]he health care decision is based, to the extent known, on the patient's religious beliefs and basic values and on any preferences previously expressed by the patient regarding such health care, or, if they are unknown, is in the patient's best interests; and (3) [t]he health care that is to be provided, continued, withheld, or withdrawn has been affirmed and documented as being

64. *See id.* § 54.1-2983.1 (Repl. Vol. 2009).
65. *See id.* § 54.1-2986.2 (Repl. Vol. 2009).
66. *Id.* § 54.1-2989(A) (Repl. Vol. 2009).
67. *Id.*
68. *Id.* § 54.1-2989(B) (Repl. Vol. 2009)
69. Act of Mar. 27, 2009, ch. 211, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 54.1-2986.2 (Repl. Vol. 2009)).
70. VA. CODE ANN. § 54.1-2986.2(B)(2) (Repl. Vol. 2009).
71. *See id.*

> ethically acceptable by the health care facility's ethics committee, if one exists, or otherwise by two physicians not currently involved in the patient's care, or in the determination of the patient's capacity to make health care decisions.[72]

3. Physician Compliance

Any attending physician who refuses to comply with a patient's AMD or the health care decision of the patient's agent "shall make a reasonable effort to transfer the patient to another physician," even if the physician determines that the health care requested is medically or ethically inappropriate.[73]

F. *Durable Do Not Resuscitate Orders*

The 2009 General Assembly clarified that a patient's expressed desire to be resuscitated in the event of cardiac or respiratory arrest shall constitute revocation of a previously executed the Durable Do Not Resuscitate Order ("DNR").[74] Only the patient or a person authorized to consent for a minor patient may revoke a DNR.[75] A DNR may be rescinded, in accordance with accepted medical practices, by the provider who issued the order.[76]

Any facility, physician, or health care provider acting under the authority of a physician who provides, continues, withholds, or withdraws health care under authorization or consent obtained in accordance with the Health Care Decisions Act is immune from criminal prosecution and civil liability.[77] Furthermore, any agent who authorizes or consents to the provision, continuation, withholding, or withdrawal of health care is immune from criminal prosecution, civil liability, or cost of health care.[78]

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72. *Id.* § 54.1-2986.2(C) (Repl. Vol. 2009).

73. *Id.* § 54.1-2987 (Repl. Vol. 2009).

74. Act of Mar. 27, 2009, ch. 549, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-2987.1(B) (Repl. Vol. 2009)).

75. VA. CODE ANN. § 54.1-2987.1(B) (Repl. Vol. 2009).

76. *Id.* § 54.1-2987.1(C) (Repl. Vol. 2009).

77. *See id.* § 54.1-2988 (Repl. Vol. 2009).

78. *Id.*

G. *Transportation by Law Enforcement*

A law enforcement officer who is transporting a person who has voluntarily consented to being transported to a facility for assessment or evaluation, and who subsequently revokes consent to be transported, may take such person into emergency custody when the officer determines that the person meets the criteria for emergency custody, even if the officer is beyond the territorial limits of his jurisdiction.[79] This legislation also clarifies that a law-enforcement officer who takes a person into emergency custody based upon his own observations or reliable reports of others may transport such person beyond the territorial boundaries of the jurisdiction in order to obtain the required assessment.[80]

H. *Mental Health*

Following the devastating tragedy of the Virginia Tech shootings on April 16, 2007, the Virginia legislature passed significant legislation to aid in the development and expansion of mental health programs.

1. Changes Made by the 2008 General Assembly

The 2008 General Assembly passed amendments to several regulations focusing on the authority of parents or legal guardians to impose involuntary commitment upon minors and on the application of emergency custody orders, temporary detention orders, and mandatory commitment proceedings.

a. Minors

Parental Application. Minors fourteen years of age or older who are incapable of making an informed decision may be admitted to inpatient treatment upon the application of a parent.[81]

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79. *Id.* § 37.2-808(H) (Cum. Supp. 2009).

80. *Id.* § 37.2-808(G) (Cum. Supp. 2009).

81. *Id.* § 16.1-339 (Cum. Supp. 2009). "Incapable of making an informed decision" is defined as:

> [U]nable to understand the nature, extent, or probable consequences of a proposed treatment or unable to make a rational evaluation of the risks and

Service of Petition. The petition for involuntary commitment of a minor must be served upon the minor and the minor's parents, unless the petition has been withdrawn or dismissed.[82]

Involuntary Commitment Hearing. The time requirement for holding an involuntary commitment hearing of a minor or the emergency admission of a minor for inpatient treatment was increased from seventy-two hours to ninety-six hours.[83]

b. Emergency Custody Orders, Temporary Detention Orders, and Involuntary Commitment Proceedings

The 2008 General Assembly changed the criteria for and application of emergency custody orders, temporary detention orders, and involuntary commitment proceedings for prisoners and juveniles.[84] A person may now be taken into emergency custody, temporarily detained, or involuntarily committed if the person has a mental illness and there is a

> substantial likelihood that, as a result of mental illness, the person will, in the near future, (a) cause serious physical harm to himself or others as evidenced by recent behavior causing, attempting, or threatening harm and other relevant information, if any, or (b) suffer serious harm due to his lack of capacity to protect himself from harm or to provide for his basic human needs.[85]

2. Changes Made by the 2009 General Assembly

The 2009 General Assembly "amend[ed] mental health statutes to address issues resulting from the overhaul of mental health

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> benefits of the proposed treatment as compared with the risks and benefits of alternatives to the treatment. Persons with dysphasia or other communication disorders who are mentally competent and able to communicate shall not be considered incapable of giving informed consent.

Id. § 16.1-336 (Cum. Supp. 2009).

82. *Id.* § 16.1-341(B) (Cum. Supp. 2009). This provision previously only provided that the petition need not be served if the petition had been dismissed. *See id.* § 16.1-341(B) (Cum. Supp. 2007).

83. *See id.* §§ 16.1-340 to 16.1-341 (Cum. Supp. 2009); *see also id.* §§ 16.1-340 to 16.1-341 (Cum. Supp. 2007).

84. Act of Apr. 23, 2008, ch. 850, 2008 Va. Acts 2180 (codified as amended at VA. CODE ANN. §§ 37.2-808, 37.2-809, 37.2-815, 37.2-816 (Cum. Supp. 2008); *id.* § 53.1-40.2 (Cum. Supp. 2008)).

85. VA. CODE ANN. §§ 37.2-808(A), 37.2-809(B), 37.2-815(C), 37.2-816 (Cum. Supp. 2009); *id.* § 53.1-40.2(B)(4) (Repl. Vol. 2009).

laws during the 2008 Session."[86] Provisions were added or amended to clarify and strengthen patient rights and to clarify the process for involuntary commitment.[87]

a. Clarifying the Involuntary Commitment Process

A law enforcement-initiated emergency custody is now restricted to a four-hour time limit and subject to a two-hour extension.[88] The employee or designee of the community services board attending a commitment hearing does not need to be the person who prepared the prescreening report.[89] Neither the designee of the community services board, nor the independent examiner who attends the commitment hearing shall be excluded pursuant to an order of sequestration of the witnesses.[90] Furthermore, the prescreening report is admissible into evidence at the hearing and will be made part of the case record.[91] In addition, the Central Criminal Records Exchange ("CCRE") reporting requirement must now be satisfied by the close of business on the business day following any hearing resulting in involuntary commitment.[92]

b. Patient Rights

The 2009 General Assembly passed legislation promoting the rights of the mentally ill, including providing a patient in a mental health facility with "the opportunity to have an individual of his choice notified of his general condition, location, and transfer to another facility."[93]

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86. Summary as Introduced, H.B. 2060: Mental Health Law; Amends Statutes to Address Issues Resulting From Overhaul Thereof, http://leg1.state.va.us/ (follow "2009" hyperlink; then follow "Bills & Resolutions" hyperlink; then search "HB2060").

87. *See* Act of Feb. 23, 2009, ch. 21, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 19.2-182.9 (Supp. 2009); *id.* §§ 37.2-808, 37.2-815, 37.2-816, 37.2-817, 37.2-819 (Cum. Supp. 2009)).

88. *See* VA. CODE ANN. § 19.2-182.9 (Supp. 2009); *id.* § 37.2-808(G) (Cum. Supp. 2009).

89. *See id.* § 37.2-817(B) (Cum. Supp. 2009). This provision repeals the previous requirement in section 37.2-817(B) that the community services board member who prepared the prescreening report be present at the hearing or participate via a two-way electronic video and audio communication system. *See id.* § 37.2-817(B) (Cum. Supp. 2008).

90. *See id.* §§ 37.2-815(C), 37.2-817(B) (Cum. Supp. 2009).

91. *Id.* § 37.2-816 (Cum. Supp. 2009).

92. *Id.* § 37.2-819 (Cum. Supp. 2009).

93. Act of Feb. 25, 2009, ch. 111, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 37.2-400(A)(11) (Cum. Supp. 2009)).

Transportation. Individuals who are the subject of an emergency custody order, a temporary detention order, or an involuntary commitment order may be transported to a medical facility by a family member or a friend.[94] Representatives of the community services board or other alternative transportation providers with staff trained to provide safe transportation have also been authorized to transport such individuals.[95]

Minors. A person who meets the criteria for involuntary commitment under the Psychiatric Inpatient Treatment of Minors Act may be ordered to receive mandatory outpatient treatment if less restrictive alternatives to involuntary inpatient treatment are appropriate and available and if the minor and his parents understand and agree to comply with the minor's outpatient treatment plan.[96]

c. Medical Records

The Virginia Code now provides that, upon request, any health care provider rendering services to persons subject to emergency custody orders, temporary detention orders, or involuntary commitment proceedings may disclose to the person's family or personal representative the information necessary and appropriate for such individual to perform their duties in relation to such orders or proceedings.[97] It also provides that health care providers will be immune from any harm resulting from their disclosure of health records unless they disclose the records with the intent to cause harm or act in bad faith.[98]

d. Guardians/Conservators

In proceedings to appoint a guardian or conservator for an incapacitated individual, the court may appoint the spouse of the individual.[99] As with all court appointments, this provision ap-

94. *See* VA. CODE ANN. §§ 37.2-808(C), 37.2-810(B), 37.2-829 (Cum. Supp. 2009).
95. *Id.*
96. *Id.* § 16.1-345.2(A)(3)–(4) (Cum. Supp. 2009).
97. *See id.* § 37.2-804.2 (Cum. Supp. 2009).
98. *Id.*
99. *Id.* § 37.2-1007 (Cum. Supp. 2009).

plies only in cases where there is no objection to the spouse being appointed or where there is no conflict of interest.[100]

e. Waiting Lists

Legislation was passed to require the Governor and the General Assembly to develop and implement a plan to provide funding to DMAS to eliminate waiting lists for the Mental Retardation ("MR") Medicaid Waiver and the Individual and Family Developmental Disabilities and Support ("IFDDS") Medicaid Waiver.[101] Beginning July 1, 2010, and for each year thereafter, DMAS must add at least 400 funded slots for MR waivers and at least sixty-seven funded slots for IFDDS waivers until the waiting lists for both have been eliminated.[102]

I. *Nursing Facilities*

In 2008, the General Assembly passed legislation allowing nursing facilities in continuing care retirement communities in Planning District 8 to participate in the Medical Assistance Program as long as (1) the nursing facility is not operating under an open admissions period, (2) any patients who receive medical assistance have been residents of the community for three years or more, (3) not more than ten percent of the facility receives benefits at one time, and (4) residents who qualify for and receive medical assistance have exhausted any refundable entrance fee they paid on their care.[103] These facilities are also exempt from Certificate of Public Need ("COPN") requirements as long as no resident receives federal or state public assistance funds during an open admissions period.[104]

100. *See id.* § 37.2-1003(C) (Repl. Vol. 2005).

101. Act of Mar. 27, 2009, ch. 228, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 32.1-323.2 (Repl. Vol. 2009)).

102. VA. CODE ANN. § 32.1-323.2 (Repl. Vol. 2009). The act aims to eliminate waiting lists within ten years. *See id.*

103. Act of Apr. 23, 2009, ch. 857, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 32.1-102.3:1) (Repl. Vol. 2009)).

104. VA. CODE ANN. § 32.1-102.3:1 (Repl. Vol. 2009).

J. *Adult Protective Services*

The 2009 General Assembly passed a series of bills addressing adult abuse and neglect.

1. Religious Nonmedical Treatment

The definition of "adult neglect" has been amended by providing that

> no adult shall be considered neglected solely on the basis that such adult is receiving religious nonmedical treatment or religious nonmedical nursing care in lieu of medical care, provided that such treatment or care is performed in good faith and in accordance with the religious practices of the adult and there is a written or oral expression of consent by that adult.[105]

2. Mandatory Reporting of Abuse

Emergency services personnel certified by the Board of Health are now also required to report suspected abuse, neglect, or exploitation of adults to the attending physician at the hospital to which the adult was transported.[106] The attending physician is then required to make the required report.[107]

3. Documentation of Abuse

Local social services departments are now required, with the informed consent of the adult or his legal representative, to take photographs, video recordings, or medical imaging of a suspected victim of adult abuse, neglect, or exploitation.[108] If the adult is incapable of providing informed consent "and either has no legal representative or the legal representative is the suspected perpetrator of the adult abuse, neglect, or exploitation, consent may be given by an agent appointed under an advance medical directive or medical power of attorney."[109] However, if no agent or author-

105. *Id.* § 63.2-100 (Cum. Supp. 2009).
106. *See id.* § 63.2-1606(A)(3) (Cum. Supp. 2009).
107. *Id.*
108. *Id.* § 63.2-1605(E) (Cum. Supp. 2009).
109. *Id.*

ized representative is immediately available, consent will be deemed to have been given.[110]

K. *Certificate of Public Need*

On the heels of several hotly contested COPN applications in recent years, the General Assembly has made some changes to the process and criteria for obtaining COPNs in Virginia.[111]

1. Application and Review Process

The criteria for determining need for the purposes of a COPN have been restructured in order to expedite the application and review process for certain types of projects.[112] An expedited application and review process was established for projects involving a capital expenditure of $15 million or more that are not otherwise defined as reviewable,[113] while a Request for Applications procedure for psychiatric and substance abuse treatment beds and services was established.[114] A review process has also been established for cases where no regional health planning agency has been designated for the region in which a project is proposed to be located.[115]

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110. *Id.*

111. In 2008, the General Assembly passed legislation requiring the Board of Health to appoint and convene a task force of at least fifteen individuals, including representatives from the Department of Health and the Division of Certificate of Public Need, regional health planning agencies, the health care provider community, the academic medical community, experts in advanced medical technology, and health insurers to meet biannually and to complete a review of the State Medical Facilities Plan at least once every four years. Act of Mar. 10, 2008, ch. 501, 2008 Va. Acts 750 (codified at VA. CODE ANN. § 32.1-102.2:1 (Cum. Supp. 2008)). The revised processes for COPNs may have been a product of this task force.

112. *See* VA. CODE ANN. § 32.1-102.2(A)(6) (Repl. Vol. 2009).

113. *See id.* § 32.1-102.2(A)(6) (Repl. Vol. 2009) (citing *id.* § 32.1-102.1 (Repl. Vol. 2009)).

114. *See id.* § 32.1-102.3:2 (Repl. Vol. 2009). The new regulations also allow for the conversion of psychiatric beds to nonpsychiatric beds and the introduction of stereotactic radiosurgery and proton beam therapy. *See id.* § 32.1-102.1 (Repl. Vol. 2009).

115. *See id.* § 32.1-102.6 (Repl. Vol. 2009).

2. Reduction in Criteria

To streamline the COPN application process, the number of criteria considered for the COPN applications was reduced from twenty-one to eight.[116]

3. Satisfaction of Conditions

When a COPN is subject to conditions imposed by the Commissioner, and the certificate holder fails to satisfy these conditions, the Department of Health may approve alternative methods to satisfy the conditions.[117] These alternative methods may include allowing the certificate holder to (1) make direct payments to an organization authorized to receive contributions to satisfy a certificate, (2) make direct payments to a private non-profit foundation that provides basic insurance coverage for individuals, or (3) make other documented efforts to provide underserved populations with medical care.[118] The certificate holder must devise a plan of compliance that identifies the alternative method chosen, a timeframe for satisfying the conditions, and an explanation of how the conditions will be satisfied.[119]

4. Nursing Facility Beds

In 2008, the General Assembly exempted from the definition of "project" any relocation of up to ten beds or ten percent of beds, whichever is less, (1) from one existing facility to another at the same site in a two-year period, or (2) from an existing nursing home facility to another existing nursing home facility owned by the same person in any three-year period.[120]

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116. *See* Act of Mar. 25, 2009, ch. 175, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 32.1-102.3(B) (Repl. Vol. 2009)). Though the number of statutory criteria was reduced, the content of the criteria largely remains the same. Notably absent are the previous criteria relating to health maintenance organizations, biomedical and behavioral research projects, and the need and availability of osteopathic and allopathic services and facilities. Other criteria have been merged to shorten the number of items. *See* VA. CODE ANN. § 32.1-102.3(B) (Repl. Vol. 2009).

117. *See* VA. CODE ANN. § 32.1-102.4(F) (Repl. Vol. 2009).

118. *Id.*

119. *Id.*

120. Act of Mar. 27, 2008, ch. 664, 2008 Va. Acts 1074 (codified as amended at VA. CODE ANN. § 32.1-102.1 (Repl. Vol. 2008)).

In 2009, the General Assembly provided that the Commissioner of Health may accept and approve a request to amend the conditions of a COPN issued for an increase in beds in a nursing care or extended care facility in order "to allow such facility to continue to admit persons . . . to its nursing facility beds through June 30, 2012."[121]

5. Exemptions

Facilities of the Department of Corrections are now exempt from the definition of "medical care facility" for purposes of the COPN process.[122]

L. *Life Expectancy*

Recognizing the increase in life expectancy for both sexes, the 2009 General Assembly passed legislation amending Virginia's continued life expectancy table to increase life expectancy at birth from 71.8 to 74.7 years for males and from 78.8 to 80 years for females.[123]

M. *Infectious Disease*

If any salaried or volunteer firefighter, paramedic, or emergency medical technician becomes exposed to another's bodily fluids in a measure that may transmit HIV or hepatitis, the other person will be deemed to have consented to testing for those viruses.[124] Furthermore, the General Assembly amended this section of the Virginia Code to provide that a law enforcement officer is no longer required to inform a person of this provision prior to exposure to his bodily fluids.[125] The legislature also removed the trans-

121. Act of Mar. 27, 2009, ch. 394, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 32.1-102.3:2 ed. note (Repl. Vol. 2009)). To qualify, the facility must (1) be operated by an association described in Virginia Code section 55-458; (2) have been created in connection with a real estate cooperative; (3) offer its residents nursing services consistent with the definition of "continuing care" in title 38.2, chapter 49 of the Virginia Code; and (4) have been issued a COPN prior to October 3, 1995. VA. CODE ANN. § 32.1-102.3:2 ed. note (Repl. Vol. 2009).

122. VA. CODE ANN. § 32.1-102.1 (Repl. Vol. 2009).

123. Act of Mar. 27, 2009, ch. 454, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 8.01-419 (Cum. Supp. 2009)).

124. VA. CODE ANN. § 32.1-45.1(E) (Repl. Vol. 2009).

125. *See* Act of Feb. 25, 2009, ch. 96, 2009 Va. Acts ___ (codified as amended at VA.

ferring facility of its discretion in deciding if the responder must be notified as to the general condition of a patient with a known communicable disease and any necessary precautions to prevent the spread of the disease.[126] Now, such notice must always be given to the responder.[127]

N. *Charity Care Policies*

All hospitals are now required to provide written information about the hospital's charity care policies in public areas of the hospital, including admissions or registration areas, emergency departments, and waiting rooms.[128] Additionally, information about the eligibility criteria and procedures for applying for charity care must be (1) provided to patients at the time of admission, discharge, or at the time services are provided; (2) included in any billing statements that are sent to uninsured patients; and (3) included on any website of the hospital.[129]

In 2008, the General Assembly amended the criteria that health practitioners must meet in order to provide free health care to an underserved population of Virginia.[130] Practitioners who provide free health care to underserved Virginians are required to notify the Board of Health of the dates and locations of such services at least five business days prior to providing such services.[131] Any health practitioner not licensed in Virginia who volunteers for a non-profit organization is permitted to provide volunteer services for up to three days, without prior notice, as long as the organization verifies that the practitioner has a valid and unrestricted license in another state.[132]

CODE ANN. § 32.1-45.1 (Repl. Vol. 2009)).

126. Act of Mar. 27, 2009, ch. 478, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 32.1-116.3(C) (Repl. Vol. 2009)).

127. VA. CODE ANN. § 32.1-116.3(C) (Repl. Vol. 2009).

128. *Id.* § 32.1-137.01 (Repl. Vol. 2009).

129. *Id.*

130. Act of Mar. 27, 2008, ch. 674, 2008 Va. Acts 1086 (codified as amended at VA. CODE ANN. § 54.1-2901(A)(27) (Cum. Supp. 2008)).

131. VA. CODE ANN. § 54.1-2901(A)(27) (Repl. Vol. 2009).

132. *Id.*

O. *Virginia Birth-Related Neurological Injury Compensation Program*

Effective January 1, 2009, the annual assessment for physicians participating in the Virginia Birth-Related Neurological Injury Compensation Program (the "Program") increased from $5,100 to $5,600.[133] The annual participating hospital assessment increased from $50 per live birth to $52.50 per live birth in 2008 and to $55 per live birth in 2009.[134] Furthermore, payment is to be provided for expenses to cover therapeutic, nursing and attendant care, as well as medications and supplies provided by the claimant's relatives when the services provided are beyond what is normally provided by family members to uninjured children.[135] Additional changes to the Program include (1) the requirement that only one member of the panel of physicians be from the field of obstetrics,[136] (2) the requirement that the Program pay $3,000 per claim reviewed to the medical school that performed the assessment,[137] and (3) the clarification of the method for calculating payments for loss of earnings.[138]

P. *Joint Commission on Health Care*

The General Assembly again extended the Joint Commission on Health Care for another two years, setting a new expiration date of July 1, 2012.[139]

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133. *Id.* § 38.2-5020(A) (Cum. Supp. 2009).
134. *See id.* § 38.2-5020(C) (Cum. Supp. 2009).
135. *See id.* § 38.2-5009(A)(1) (Cum Supp. 2009).
136. *Id.* § 38.2-5008(B) (Cum. Supp. 2009).
137. *Id.*
138. *See id.* § 38.2-5009(A)(2) (Cum. Supp. 2009).
139. Act of Mar. 30, 2009, ch. 707, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 30-170 (Repl. Vol. 2009)).

III. ADMINISTRATIVE CHANGES

A. *The Virginia Department of Health Professions*

1. Administration

a. Address of Record

The Department of Health Professions will collect and keep confidential "an official address of record from each health professional licensed, registered, or certified by a health regulatory board . . . to be used by the Department and relevant health regulatory boards for agency purposes."[140] Health professionals are also given the opportunity to provide a second address for purposes of public dissemination.[141] In the event that an alternative public address is not provided, the address of record may be publicly disclosed.[142] Health professionals will be given the opportunity to update their address information at regular intervals.[143] The Department has also been authorized to collect a fee from each licensed health professional to cover the costs of such updates.[144]

b. Copies of Complaint to be Provided

For every complaint filed against a person licensed, certified, or registered by any of the health regulatory boards, a copy of the complaint must be provided to the person who is the subject of the complaint prior to either an interview of the person or at the time the person is notified in writing of the complaint, unless delivery of the complaint would materially obstruct a criminal or regulatory investigation.[145]

c. Privacy and Confidentiality

In order to protect the privacy and security of licensed health professionals, the Department of Health Professionals may

140. VA. CODE ANN. § 54.1-2400.02(B) (Repl. Vol. 2009).
141. *Id.* § 54.1-2400.02(C) (Repl. Vol. 2009).
142. *Id.*
143. *Id.* § 54.1-2400.02(D) (Repl. Vol. 2009).
144. *Id.*
145. *Id.* § 54.1-2400.2(F) (Repl. Vol. 2009).

> promulgate regulations permitting use on identification badges of first name and first letter only of last name and appropriate title when practicing in hospital emergency departments, in psychiatric and mental health units and programs, or in health care facility units offering treatment for patients in custody of state or local law-enforcement agencies.[146]

The requirements related to confidentiality of information obtained during an investigation or disciplinary proceeding "shall not prohibit investigative staff . . . from interviewing fact witnesses, disclosing to fact witnesses the identity of the subject of the complaint or report, or reviewing with fact witnesses any portion of records or other supporting documentation necessary to refresh the fact witnesses' recollection."[147]

The Department, and the Board of Nursing individually,

> may release any information that identifies specific individuals for the purpose of determining shortage designations and to qualified personnel if pertinent to an investigation, research, or study, provided a written agreement between such qualified personnel and the Department, which ensures that any person to whom such identities are divulged shall preserve the confidentiality of those identities, is executed.[148]

2. Medications

a. Tamper-Resistant Prescription Pads

While not a Virginia Board of Pharmacy initiative, a new federal law affecting prescriptions paid for by the Centers for Medicare and Medicaid Services ("CMS") will change the prescribing habits of Virginia's physicians. This law, which became effective April 1, 2008, requires prescriptions to be written on tamper-resistant pads for (1) outpatient enrollees of Medicaid, MEDALLION, FAMIS, and FAMIS Plus fee-for-service and (2) dual eligibles when Medicare Part D is the primary payor and Medicaid the secondary.[149]

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146. *Id.* § 54.1-3005(21) (Repl. Vol. 2009).

147. *Id.* § 54.1-2400.2(H) (Repl. Vol. 2009).

148. *Id.* §§ 54.1-2506.1(A), 54.1-3012.1(A) (Repl. Vol. 2009).

149. U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, Pub. L. No. 110-28, § 7002(b), 121 Stat. 112, 187–88 (2007).

b. Dispensing Medications

Therapeutically Equivalent. The 2009 General Assembly passed legislation requiring pharmacists filling prescriptions for workers' compensation claims to "dispense a therapeutically equivalent drug product for prescribed name-brand drugs."[150] However, pharmacists must fill such prescriptions with the name-brand drug products prescribed if (1) a therapeutically equivalent drug product does not exist, (2) the usual and customary retail price for the equivalent is higher than that of the prescribed name-brand drug,[151] or (3) the prescriber specifies on the prescription "brand medically necessary" and there is a medical reason why the patient should not have the prescription filled with a therapeutically equivalent drug product.[152] The prescriber may also specify to a pharmacist that a prescription is "brand medically necessary" by verbal instructions in a telephone call.[153]

Automated Dispensing. "Drugs in multi-dose packaging, other than those administered orally, may [now] be placed in [an automated drug dispensing] device if approved by the pharmacist-in-charge in consultation with a standing hospital committee comprised of pharmacy, medical, and nursing staff."[154]

Prescription Drug Donation Program. In response to the rising cost of prescription drugs, the General Assembly passed legislation permitting the donation of prescription drugs to participating pharmacies.[155] The legislation further clarified the liability of pharmaceutical manufacturers relating to storage, donation, acceptance, or dispensing of any drug in accordance with the Prescription Drug Donation Program.[156] The new law also provides that "[u]nused prescription drugs dispensed for use by persons eligible for coverage under [the Medicaid program] may be donated . . . unless such donation is prohibited."[157] The General As-

150. Act of Mar. 27, 2009, ch. 559, 2009 Va. Acts ___ (codified at VA. CODE ANN. § 65.2-603.1(B) (Cum. Supp. 2009)).

151. VA. CODE ANN. § 65.2-603.1(B) (Cum. Supp. 2009).

152. *Id.* § 65.2-603.1(C) (Cum. Supp. 2009).

153. *Id.*

154. *Id.* § 54.1-3434.02(B) (Repl. Vol. 2009).

155. *See* Act of Feb. 25, 2009, ch. 109, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-3411.1(A)–(B) (Repl. Vol. 2009)).

156. *See id.* (codified as amended at VA. CODE ANN. § 54.1-3411.1(D)–(E) (Repl. Vol. 2009)).

157. VA. CODE ANN. § 54.1-3411.1(C) (Repl. Vol. 2009).

sembly passed complimentary legislation providing that a pharmacy participating in bulk donation programs "may charge a reasonable dispensing or administrative fee to offset the cost of dispensing [donated medications], not to exceed the actual costs of such dispensing."[158] Hospitals, as well as clinics organized to provide delivery of health care services to the indigent, may dispense donation medications to the indigent.[159]

c. Administration of Medications

Administration of Controlled Substances by Animal Shelters. The Board of Pharmacy may register an animal shelter or pound

> to purchase, possess, and administer certain Schedule II-VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals; and to purchase, possess, and administer certain Schedule VI controlled substances for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound.[160]

Prescribing Authority of Certified Sexual Assault Nurse Examiners. Registered professional nurses certified as sexual assault nurse examiners, "[p]ursuant to an oral or written order or standing protocol issued by a prescriber within the course of his professional practice . . . may . . . possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention."[161]

Influenza Vaccinations. The Board of Health must develop and issue guidelines by August 31, 2009 "for the administration of influenza vaccine to minors by licensed pharmacists, registered

158. Act of Feb. 25, 2009, ch. 101, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-3301(10) (Repl. Vol. 2009)).

159. VA. CODE ANN. § 54.1-3411.1(B) (Repl. Vol. 2009). This regulation, and others found in subsection B, will remain in effect until the Board of Pharmacy Regulations promulgated for the Prescription Drug Donation Program become effective. *Id.* § 54.1-3411.1 ed. note (Repl. Vol. 2009).

160. *Id.* § 54.1-3423(E) (Repl. Vol. 2009). The provisions of this subsection were previously found in Virginia Code section 54.1-3425, which was repealed by the same Act of Assembly that merged the two sections. *See* Act of Mar. 6, 2009, ch. 149, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-3423 (Repl. Vol. 2009)); *see also* VA. CODE ANN. § 54.1-3425 (Repl. Vol. 2005).

161. VA. CODE ANN. § 54.1-3408(K) (Repl. Vol. 2009).

nurses, or licensed practical nurses . . . [with] the consent of the minor's parent, guardian, or person standing in loco parentis."[162]

Prescription Drugs. The 2009 Session expanded the authority of persons who have completed a training course approved by the Board of Nursing to allow administration of prescription drugs, in compliance with the prescriber's instructions, where the drugs would normally be self-administered by an individual receiving services in a program licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services.[163]

3. Prescriptive Authority

a. Physician Assistants

Since July 1, 2007, licensed Physician Assistants ("PAs") have had the authority to prescribe controlled substances and devices for Schedules II–VI.[164] PAs who wish to add Schedules II–VI to their existing protocol must submit a written request to the Board office that includes their name, proof of licensure, and the signature of their primary supervising physician, or complete the Board's prescriptive authority request form.[165]

b. Optometrists

Only licensed optometrists and licensed opticians, upon the valid, written prescription of a licensed physician or optometrist, may sell or dispense contact lenses, and only licensed optometrists may dispense ophthalmic devices that contain medication.[166]

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162. *Id.* § 32.1-46.02 (Repl. Vol. 2009).

163. Act of Feb. 25, 2009, ch. 48, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-3408(L) (Repl. Vol. 2009)). Authority was previously limited to administration of drugs that would normally be self-administered by a resident of a facility licensed or certified by the Department of Mental Health, Mental Retardation and Substance Abuse Services. *See* VA. CODE ANN. § 54.1-3408(K) (Repl. Vol. 2005).

164. VA. CODE ANN. § 54.1-2952.1(A) (Repl. Vol. 2009).

165. VA. BD. OF MED., REQUEST FOR PRESCRIPTIVE AUTHORITY FROM THE PA (2007), *available at* http://www.dhp.state.va.us/medicine/medicine_forms.htm#PA; *see* 18 VA. ADMIN. CODE § 85-50-130 (2007) (Qualifications for approval of prescriptive authority); *id.* § 85-50-150 (2007) (Protocol regarding prescriptive authority).

166. VA. CODE ANN. §§ 54.1-1706, 54.1-3204 (Repl. Vol. 2009).

4. Licensure

a. Occupational Therapy Assistants

All Occupational Therapy Assistants are required to be licensed by the Board of Medicine.[167]

b. Radiologist Assistants

Provided the Board of Medicine requirements are met, Radiologist Assistants may now be licensed as

> an advanced-level radiologic technologist . . . who, under the direct supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology, is authorized to (i) assess and evaluate the physiological and psychological responsiveness of patients undergoing radiologic procedures; (ii) evaluate image quality, make initial observations, and communicate observations to the supervising radiologist; (iii) administer contrast media or other medications prescribed by the supervising radiologist; and (iv) perform, or assist the supervising radiologist to perform, any other procedure consistent with the guidelines adopted by the American College of Radiology, the American Society of Radiologic Technologists, and the American Registry of Radiologic Technologists.[168]

c. Dental Hygienists

Any dental hygienist "who holds a license issued by the Board of Dentistry may provide educational and preventive dental care in the Cumberland Plateau, Southside, and Lenowisco Health Districts."[169] Any dental hygienist providing such educational or preventative services shall practice pursuant to a protocol developed by the Department of Health, Virginia Dental Hygienists' Association, and other oral health care other entities.[170] The medical directors of the Cumberland Plateau, Southside, and Lenowisco Health Districts must prepare and submit a report of services

167. *See id.* § 54.1-2956.5(B) (Repl. Vol. 2009).

168. *Id.* § 54.1-2900 (Repl. Vol. 2009).

169. *Id.* § 54.1-2722(E) (Repl. Vol. 2009). These districts are designated as Virginia Dental Health Professional Shortage Areas. *Id.*

170. *Id.*

provided, detailing their impact on oral health, to the Secretary of Health & Human Resources by November 2010.[171]

d. Estheticians

The grandfather period for licensure as an esthetician or master esthetician has been extended for individuals who applied before July 31, 2009 and who meet certain experience, training, or reciprocity requirements.[172] The grandfather period does not apply to individuals who have previously been denied licensure by the Board for Barbers and Cosmetology.[173]

e. Licensed Marriage and Family Therapists

Licensed marriage and family therapists are now authorized to perform independent examinations of persons who are subject to a hearing for involuntary commitment.[174]

f. Practice of Midwifery

After several highly publicized, tragic outcomes resulting from breech deliveries by midwives outside of a hospital setting,[175] the General Assembly passed legislation that requires midwives and certified nurse midwives to disclose to their patients information on health risks associated with home deliveries, "including but not limited to risks associated with vaginal births after a prior

171. *Id.* Accordingly, the provisions of Virginia Code section 54.1-2722(E) expire on July 1, 2011. *See id.*

172. *See id.* § 54.1-703.3 (Repl. Vol. 2009). To be covered by the grandfather provision, an individual must: (1) have at least three years of documented work experience as an esthetician or a master esthetician prior to July 1, 2008; (2) have completed, prior to July 1, 2008, a training program that the Board for Barbers and Cosmetology deems satisfactory; or (3) hold an unexpired certificate of registration, certification, or license as an esthetician or a master esthetician that was issued to him or her on the basis of comparable requirements. *Id.*

173. *See id.*

174. *Id.* § 37.2-815(A) (Cum. Supp. 2009). Clinical social workers, professional counselors, psychiatric nurse practitioners, and clinical nurse specialists are also authorized to perform an independent examination prior to a commitment hearing. *Id.*

175. *See, e.g.*, Elizabeth Simpson, *Beach Midwife to Give Up License*, VIRGINIAN-PILOT, Oct. 21, 2008, at B6.

cesarean section, breech births, births by women experiencing high-risk pregnancies, and births [of twins or multiples]."[176]

g. Assisted Living Facilities

Any person who successfully completes a training program approved by the Board of Nursing may administer medication that would normally be self-administered to residents of an assisted living facility until August 1, 2009.[177] After August 1, 2009, all medication aides must be registered by the Board of Nursing.[178]

h. Medication Aides

All medication aides are now required to be registered by the Board of Nursing.[179] Enforcement was delayed until August 1, 2009 but will be effective retroactively back to January 1, 2009 for anyone not in compliance by the August 1, 2009 enforcement deadline.[180]

i. Nurses

Licensed nurses, including nurses licensed by a state participating in the Nurse Licensure Compact,[181] are among those persons presumed to know the statewide standard of care in the field in which they are qualified or certified for purposes of medical malpractice actions or proceedings before a medical malpractice review panel.[182]

176. Act of Mar. 30, 2009, ch. 646, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. §§ 54.1-2957.03, 54.1-2957.9 (Repl. Vol. 2009)).

177. *See* VA. CODE ANN. § 54.1-3042 ed. note (Repl. Vol. 2009).

178. *Id.*

179. *Id.* § 54.1-3042 (Rep. Vol. 2009).

180. *Id.* § 54.1-3042 ed. note (Repl. Vol. 2009).

181. *See generally id.* tit. 54.1, art. 6 (Repl. Vol. 2009). Virginia is one of twenty-three states to implement the Nurse Licensure Compact, which allows an individual to obtain licensure in one state and practice in another, provided the individual acknowledges subjection to each state's laws and discipline. *See* NURSE LICENSURE COMPACT ADM'RS, FREQUENTLY ASKED QUESTIONS REGARDING THE NATIONAL COUNCIL OF STATE BOARDS OF NURSING (NCSBN) NURSE LICENSURE COMPANY (NLC) 1 (2009), *available at* https://www.ncsbn.org/NLCA_Faqs_051109.pdf.

182. VA. CODE ANN. § 8.01-581.20(A) (Cum. Supp. 2009).

5. Physician Assistants

A written practice supervision agreement between the supervising physician and a PA, detailing activities delegated to the PA, is required.[183] Treatment may be included in the plan, including establishment of a final diagnosis or treatment plan for the patient as long as it is designated in the written practice supervision agreement.[184]

6. Monitoring

The Board of Dentistry is permitted to "recover from any licensee against whom disciplinary action has been imposed reasonable administrative costs associated with investigating and monitoring such licensee and confirming compliance with any terms and conditions imposed upon the licensee in the order imposing the disciplinary action."[185] Recovery under this provision shall not exceed $5,000 and shall not constitute a fine or penalty.[186]

7. Miscellaneous

An Advisory Board on Massage Therapy was created to assist the Board of Nursing "in carrying out the provisions . . . regarding the qualifications, examination, registration, regulation, and standards of professional conduct of massage therapists."[187]

B. *Health Practitioners Intervention Program*

The General Assembly has clarified that the purpose of the Health Practitioners Intervention Program is to monitor impaired health practitioners as opposed to treating them.[188] In order to highlight this distinction, the name of the Program was changed from the Health Practitioners Intervention Program to the

183. *Id.* § 54.1-2952 (Repl. Vol. 2009); *see* also 18 VA. ADMIN. CODE § 85-50-101 (2007) (requiring a written protocol that spells out the roles and functions of the practitioner's assistant).

184. VA. CODE ANN. § 54.1-2952 (Repl. Vol. 2009).

185. *Id.* § 54.1-2708.2 (Repl. Vol. 2009).

186. *Id.*

187. *Id.* § 54.1-3029.1 (Repl. Vol. 2009).

188. *See* Act of Mar. 27, 2009, ch. 472, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-2516 (Repl. Vol. 2009)).

Health Practitioners' Monitoring Program ("HPMP").[189] The statutory language removed "intervention services" from the list of services performed by the HPMP and added "referral for intervention and treatment" as a designated service.[190] The legislature granted limited liability to agencies providing intervention and treatment services, as long as the Director of the Department of Health Services contracts for those services under the HPMP and the agency discharges its obligations in good faith.[191] The Department of Health Professions is integrally involved with the HPMP in developing contracts necessary for the implementation of monitoring services for enrolled professionals.[192] Due to these additions, the Department of Health Professions will likely refer more professionals to the HPMP and, in turn, the HPMP will report enrolled professionals to the Department of Health Professions.

The HPMP has also expanded its committee membership to include at least one registered nurse engaged in active practice.[193]

C. *The Prescription Monitoring Program*

Physicians are no longer required to obtain informed consent from a patient before utilizing the Prescription Monitoring Program ("PMP") to look up the patient's prescription history.[194] The law also authorizes a prescriber to delegate PMP access to up to two health care professionals who are licensed, registered, or certified by a health regulatory board and employed at the same facility under the direct supervision of the prescriber.[195]

189. *See, e.g.*, VA. CODE ANN. §§ 54.1-2400.2, 54.1-2516 (Repl. Vol. 2009).
190. *Id.* § 54.1-2516(A) (Repl. Vol. 2009).
191. Act of Mar. 27, 2009, ch. 472, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 54.1-2516 (Repl. Vol. 2009)).
192. *See* VA. CODE ANN. § 54.1-2516 (Repl. Vol. 2009).
193. *Id.* § 54.1-2517(A) (Repl. Vol. 2009).
194. *Id.* § 54.1-2523(C)(2) (Repl. Vol. 2009).
195. *Id.* § 54.1-2523.2 (Repl. Vol. 2009).

IV. CIVIL ACTIONS

A. *Admissibility*

1. Medical Examiner Reports

Any statement of fact or opinion in a medical examiner's report concerning the physical or medical cause of death is admissible in a preliminary hearing as evidence of the cause of death, provided it does not allege any conduct by the accused.[196]

2. Expressions of Sympathy

In 2005, Virginia joined the ranks of states excluding expressions of sympathy by health care providers from being admitted at trial.[197] By May 2008, thirty-four states had enacted laws making apologies for medical errors inadmissible in civil actions.[198] The 2009 General Assembly expanded the list of expressions of sympathy that are inadmissible in medical malpractice actions and wrongful death actions brought against health care providers to include commiseration, condolence, compassion, and apologies.[199]

B. *Immunity*

1. Funeral Services

Funeral service establishments, funeral service licensees, and crematories that receive bodies following routine donations of organs, tissues, or eyes, and provide embalming, cremation, or other funeral services are now immune from numerous civil liabilities.[200] For example, they are not civilly liable for any act, decision, or omission related to the handling, processing, or presentation of the decedent including "any failure to restore [the] de-

196. *Id.* § 19.2-188(B) (Supp. 2009).

197. *See* Act of Mar. 23, 2005, ch. 649, 2005 Va. Acts 905 (codified at VA. CODE ANN. § 8.01-581.20:1 (Cum. Supp. 2005)).

198. Kevin Sack, *Doctors Start to Say "I'm Sorry" Long Before "See You In Court,"* N.Y. TIMES, May 18, 2008, at A1.

199. Act of Mar. 27, 2009, ch. 414, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. §§ 8.01-52.1, 8.01-581.20:1 (Cum. Supp. 2009)).

200. VA. CODE ANN. § 54.1-2818.4 (Repl. Vol. 2009).

cedent's form or features in a manner acceptable for viewing prior to the final disposition of the remains,"[201] unless such act, decision, or omission resulted from bad faith or malicious intent.[202]

2. Health Providers Responding to Disaster

In the absence of gross negligence or willful misconduct, health care providers who respond to a disaster are immune from civil liability for any injury or wrongful death arising from the delivery or withholding of health care.[203]

C. *Privilege*

The legislature strengthened the physician-patient privilege in Virginia, providing that communications between physicians and their patients are privileged and cannot be disclosed, except at the request or with the consent of the patient.[204]

D. *Statute of Limitations*

In 2008, the General Assembly extended the statute of limitations for personal injury in malpractice cases arising out of the negligent failure to diagnose a malignant tumor or cancer or to communicate such diagnosis to the patient.[205] The limitations pe-

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201. *Id.* In 2008, the General Assembly passed legislation removing the requirement of obtaining consent from the decedent's next of kin prior to the removal of organs, glands, eyes, or tissue for use in transplants or therapy. Act of Mar. 4, 2008, ch. 287, 2008 Va. Acts 430 (codified as amended at VA. CODE ANN. § 32.1-283(A) (Cum. Supp. 2008)).

202. VA. CODE ANN. § 54.1-2818.4 (Rep. Vol. 2009).

203. *Id.* § 8.01-225.02(A) (Cum. Supp. 2009). This immunity only applies if

> (i) a state or local emergency has been or is subsequently declared in response to such a disaster, and (ii) the emergency and subsequent conditions caused a lack of resources, attributable to the disaster, rendering the health care provider unable to provide the level or manner of care that otherwise would have been required in the absence of the emergency.

Id. Licensed health care providers will now receive reimbursement for their actual and necessary expenses and enjoy immunity from suit if required to abandon patients in order to respond to a disaster. *See id.* § 44-146.23(C) (Cum. Supp. 2009).

204. *See* Act of Mar. 30, 2009, ch. 714, 2009 Va. Acts ___ (codified as amended at VA. CODE ANN. § 8.01-399(A) (Cum. Supp. 2009)). Previously, the law stated that physicians could not be *required* to disclose such communications but could have done so voluntarily. *See* VA. CODE ANN. § 8.01-399(A) (Repl. Vol. 2007).

205. Act of Mar. 3, 2008, ch. 175, 2008 Va. Acts 254 (codified as amended at VA. CODE ANN. § 8.01-243 (Supp. 2008)).

riod is now one year from the date the existence of a malignant tumor or cancer is communicated to the patient.[206]

E. *Medical Malpractice Act*

The cap on recovery in medical malpractice actions increased to $2 million, the maximum allowed by statute.[207] While there was some discussion early in this year's General Assembly Session about raising the cap or instituting an indexed annual increase, the issue was tabled to the 2010 legislative agenda.[208] Going forward, we can expect much attention to be paid to the medical malpractice cap by all interested parties, including the Medical Society of Virginia, the Virginia Trial Lawyers Association, the Virginia Hospital and Healthcare Association, and professional liability carriers who do business in the Commonwealth.

F. *Medicare Secondary Payor Rule*

The Centers for Medicare and Medicaid Services ("CMS") are responsible for the oversight of the Medicare program nationally.[209] As of July 1, 2009, CMS—in an effort to protect Medicare's interest in the event of a settlement of a claim in litigation—will implement set-aside provisions in accordance with the Medicare Secondary Payer Act ("MSP").[210] There are two circumstances that trigger Medicare approval: (1) the injured party has been both Medicare-eligible since the time of injury and is sixty-five years of age or older, and (2) the gross settlement exceeds $250,000 and the injured party has a reasonable expectation of being Medicare eligible within thirty months.[211] The MSP, first enacted in 1980, was designed to save Medicare resources and requires that when a primary payer exists for an injured person's medical care and

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206. VA. CODE ANN. § 8.01-243(c)(3) (Cum. Supp. 2009).

207. *See id.* § 8.01-581.15 (Repl. Vol. 2007 & Cum. Supp. 2009). The relevant Virginia Code section provides for annual increases in the maximum recovery limit, with an upper cap of $2 million, which was reached in July 2008. *Id.*

208. *See* Peter Vieth, *Med-Mal Damages Cap Fight Held Over Until 2010 Legislative Session*, VA. LAW. WKLY., Jan. 12, 2009, at 1, 22.

209. *See generally* 42 U.S.C. § 1302 (2006); 42 C.F.R. pts. 400–413 (2008).

210. *See* 42 U.S.C. § 1395y; 42 C.F.R. pt. 411. Under the Medicare Secondary Payer Act, certain case settlements should include a Medicare Set Aside to account for future medical costs and tort-related expenses. *See* 42 U.S.C. § 1395y.

211. *See* Robert S. Dampf, *Mediations Settlements: Applicability of the Medicare Secondary Payer Act*, 54 LA. B.J. 173, 173 (2006).

associated expenses, Medicare must be protected as a secondary payer.[212] A primary payer includes liability insurers and self-insured entities,[213] and this federal statute preempts state law and the contractual language of private insurance policies.[214] It applies in three situations: where there are Workers' Compensation benefits,[215] where there is liability insurance,[216] or where there is an employer's large group health plan.[217]

The purpose of the MSP is to protect Medicare's interests in settlements and judgments so that Medicare remains the *secondary* payer and not the *primary* payer.[218] To that end, insurers must take steps to ensure that Medicare is reimbursed for amounts it reasonably expended. These obligations include the reporting of settlements to Medicare once they occur.[219] If an insured party is a qualified Medicare beneficiary, the primary payer must protect Medicare as the secondary payer and the primary payer need only have constructive knowledge of the insured party's Medicare status.[220] That is, a primary payer who should be aware of an insured party's Medicare status has constructive knowledge and must protect Medicare's interests.[221]

In the event that Medicare is not protected as the secondary payer, CMS has the right to seek recovery against any entity that has received a third-party payment or that is responsible for making such a payment.[222] These entities include: the plaintiff, the plaintiff's attorney, a structured settlement broker, a liability insurer, and a self-insured entity.[223]

CMS may not collect directly from a wrongdoer unless that entity is self-insured, and it will not be subject to language in a set-

212. *See* 42 U.S.C. § 1395y(b)(2).
213. 42 C.F.R. § 411.21.
214. *Id.* § 411.32.
215. *See id.* §§ 411.40 to 411.47.
216. *See id.* §§ 411.50 to 411.54.
217. *See id.* §§ 411.100 to 411.130.
218. Mark Popolizio & Carrie T. Taylor, *Workers' Compensation & Liability Lawyers Beware: Section III of the MMSEA Imposes Significant New Penalties for Failing to Protect Medicare's Interests*, UTAH B.J., Jan.-Feb. 2009, at 17.
219. *Id.* at 20.
220. *See id.* at 18.
221. *See* United States v. Baxter Int'l, Inc., 345 F.3d 866, 900 (11th Cir. 2003).
222. *See* 42. C.F.R. §§ 411.24, 411.26; Popolizio, *supra* note 218, at 18.
223. 42 C.F.R. § 411.24(g).

tlement agreement or release that abrogates the primary payer's responsibility to protect Medicare's interests.[224]

While Medicare is generally permitted to recover the full amount of any Medicare payment for injuries covered under the liability policy, there are several ways in which the amount recovered by Medicare may be reduced.[225] First, CMS's recovery is reduced by the amount expended to recover the settlement or judgment, such as attorney's fees and expenses.[226] Second, recovery is limited to money paid for injuries related to the accident, negligence, or other incident that forms the basis of liability.[227] A beneficiary may also request that the amount claimed by Medicare be reduced before a settlement is reached.[228] This compromise of the lien amount may be appropriate in the event that the potential recovery is too small to warrant pursuit of the claim.[229] Finally, a beneficiary may request that Medicare waive its right to recovery of some or all of the claim on the basis of hardship.[230]

The penalties for failing to report a settlement or judgment to CMS are serious. Medicare can initiate recovery at any time after the payment has been made by a primary insurer.[231] If a Responsible Reporting Entity[232] does not timely report claims, lawsuits, or judgments, CMS can require that the plaintiff pay a portion of his settlement directly to Medicare and can require the primary insurer to reimburse Medicare in the event of non-payment.[233] It

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224. *See* OAST & HOOK, MEDICARE SET-ASIDE ARRANGEMENTS IN THIRD PARTY LIABILITY CASES (2009), http://www.oasthook.com/legal_information/MSA_Arrangements_in_Third_Party_liability_Cases.pdf.

225. *See* 42 C.F.R. § 411.24(c).

226. *See id.* § 411.37.

227. *See id.* §§ 411.22, 411.24, 411.54.

228. *See id.* § 411.28(b) (citing 42 C.F.R. §§ 401.601 to 401.625, 405.376). CMS may employ various statutory authorities to waive, compromise, terminate or suspend its right to recovery. For instance, the Federal Claims Collection Act of 1966 gives CMS the right to compromise claims for less than the full amount on behalf of the United States Government. *See* 31 U.S.C. § 3711 (2006).

229. *See* 42 U.S.C. § 1395y(b)(2)(B)(v); 42 C.F.R. § 411.28(a).

230. *See* 42 U.S.C. § 1395y(b)(2)(B)(v); 42 C.F.R. § 411.28; *see also* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE SECONDARY PAYER MANUAL § 50.5.4.4.2, http://www.cms.hhs.gov/manuals/downloads/msp105c07.pdf (last visited Oct. 11, 2009).

231. 42 C.F.R. § 411.24(b).

232. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., SUPPORTING STATEMENT FOR THE MEDICARE SECONDARY PAYER (MSP) MANDATORY INSURER REPORTING REQUIREMENTS OF SECTION 111 OF THE MEDICARE, MEDICAID, AND SCHIP EXTENSION ACT OF 2007, at 13–15 (2008), http://www.cms.hhs.gov/MandatoryInsRep/Downloads/SupportingStatement082808.pdf (CMS's definition of a "Responsible Reporting Entity").

233. *See* 42 C.F.R. § 411.24(g).

can also require a penalty of double payment or interest.[234] Failure to comply with the statute can also result in a $1,000 per day penalty until compliance is documented.[235] Once Medicare is notified of settlement, CMS will send a formal demand letter and expect payment within sixty days of the date of the letter.[236]

V. CONCLUSION

With our nation's attention focused on access to, privacy of, and costs associated with health care, we can expect to see even more sweeping changes in the coming years. The universal health care debate is in full swing, with much time and attention being paid to the impact of rising health care costs on the newly unemployed and other victims of the economic recession. We can expect to see the pharmaceutical and medical device industries enter the debate, as well as other special interest groups, including the American Medical Association, AFL-CIO, and the health insurance industry. The Obama administration's effort to revamp the United States health care system has renewed the nation's fervor for finding a solution to this longstanding dilemma. While it is doubtful that universal health care will be the law of the land in the near future, we can expect to see the beginnings of a more equitable and accessible system going forward, as necessity is the mother of invention.

234. *See id.* §§ 411.24(c), 411.24(m).

235. 42 U.S.C.A. § 1395y (b)(8)(E) (West Supp. 2009); *see also* Popalizio, *supra* note 218, at 17.

236. *See* 42 U.S.C. § 1395y (b)(2)(B).