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# HEALTH CARE LAW

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## I. INTRODUCTION

Many changes in health care policy occur at the federal and state levels on an annual basis. Most changes reflect the four guiding health policy principles of cost, quality, access, and equity. These same four principles were important thirty years ago when Virginia and other states implemented Medicaid programs, developed certificate of public need and professional licensing programs, and formalized existing facility licensing programs. Thirty years ago, the overriding goals included concerns over rising costs and assuring access to services of adequate quality for all.<sup>1</sup>

Today, much of the health care law agenda is driven by federal reimbursement legislation, as well as regulations and federal legislation governing relationships between health care providers. This article is not intended to be an exhaustive treatise of the federal laws applicable to health care operations and transactions. It should, however, be of assistance in identifying develop-

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1. See Anne R. Somers, *The Nation's Health: Issues for the Future*, 399 ANNALS AM. ACAD. POL. & SOC. SCI. 160, 168-69 (1972).

ments in the legislature,<sup>2</sup> the courts,<sup>3</sup> and health care agencies<sup>4</sup> of the Commonwealth over the last two years.

## II. STATE LEGISLATIVE DEVELOPMENTS

### A. *Professional Licensure*

Each General Assembly session brings new legislation affecting professional licensure requirements and the scope of practice among individual licensing categories. The 2001 and 2002 General Assembly Sessions were no exception.

#### 1. Practitioner Profiling

Of primary interest to physicians were the changes in physician profiling legislation adopted by the 2001 General Assembly in response to regulations governing physician profiles.<sup>5</sup> The profiling was based on surveys that had been collected over the preceding two years as a requirement of 1998 legislation.<sup>6</sup> Profiles became available at the Department of Health Professions Board of Medicine Web site in July 2001.<sup>7</sup> The profile information includes both licensing actions taken by the Virginia Board of Medicine and other states' boards as well as information in general terms on professional liability judgments and settlements.<sup>8</sup>

Due to its 2001 adoption of physician profile regulations,<sup>9</sup> the Board of Medicine received numerous inquiries and concerns from licensees following the regular 2001 General Assembly Ses-

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2. See discussion *infra* Part II.

3. See discussion *infra* Part III.

4. See discussion *infra* Part IV.

5. VA. CODE ANN. § 54.1-2910.1 (Repl. Vol. 2002).

6. See *id.* (requiring the Virginia Board of Medicine to make certain information on physicians or podiatrists available to the public, including final orders of the Board relating to disciplinary action and other information related to competency).

7. See Virginia Board of Medicine Practitioners Information Web site, at <http://www.vahealthprovider.com> (last visited Oct. 4, 2002).

8. *Id.*; see also 18 VA. ADMIN. CODE § 85-20-280 to -300 (2001) (implementing regulations, including penalties for non-reporting).

9. See 18 VA. ADMIN. CODE § 85-20-290(B) (2001) (requiring the Board to make available, as part of the profile information listed at [www.vahealthprovider.com](http://www.vahealthprovider.com), information regarding disciplinary notices and orders).

sion. During 2001, the General Assembly enacted legislation that was intended to address physician concerns about Web profile access.<sup>10</sup> Unfortunately, the new legislation made things worse. It directed that the Board make complaints of misconduct available upon a consumer's request identifying a specific physician, thereby expanding the potential distribution of complaints prior to Board determinations of any misconduct.<sup>11</sup>

The General Assembly removed all of the language added in 2001 in emergency legislation effective February 28, 2002.<sup>12</sup> The General Assembly further refined the method by which disciplinary actions can be reported online.<sup>13</sup> Reports of pending disciplinary actions are now limited to a statement of pending disciplining proceedings.<sup>14</sup> No further information on the specifically alleged violation is provided until such allegation is investigated and a ruling is made by the Board following an informal conference or full evidentiary hearing.<sup>15</sup>

The 2001 General Assembly also passed health practitioner profiling legislation that requires oral and maxillofacial surgeons to report information to the Board of Dentistry.<sup>16</sup> The Board of Dentistry subsequently promulgated emergency regulations governing mandatory reporting by dentists.<sup>17</sup>

## 2. Nurse Midwives and Chiropractors

Other proposed legislation, seeking to expand the in-home practice of nurse midwifery, failed to get out of the legislative committee. House Bills 889, 890, and 891 would have expanded the limited practice of nurse midwifery in Virginia by one of sev-

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10. VA. CODE ANN. § 54.1-2910 (Repl. Vol. 2002).

11. *Id.*; see also *id.* § 54.1-2914 (Repl. Vol. 2002) (defining unprofessional conduct); *id.* § 54.1-2919 (Repl. Vol. 2002) (setting forth the standard process for Board evaluation of complaints against physicians).

12. VA. CODE ANN. § 54.1-2910.1 (Repl. Vol. 2002); see also Jeannie A. Adams, *Confidentiality of Department of Health Professions Information: Is It All It Is Cracked Up To Be?*, VA. HEALTH LAW. 2 (June 2002), available at <http://www.vsb.vipnet.org/sections/hl/June02Newsletter.pdf> (last visited Oct. 4, 2002).

13. VA. CODE ANN. § 54.1-2910.1 (Repl. Vol. 2002).

14. *Id.*

15. See *id.* Informal conferences and formal hearings are governed by VA. CODE ANN. §§ 2.2-4019, -4020 (Repl. Vol. 2001), respectively.

16. See VA. CODE ANN. § 54.1-2709.2 (Repl. Vol. 2002).

17. See 18 VA. ADMIN. CODE § 60-20-250 (2001).

eral avenues.<sup>18</sup> Specifically, House Bill 889 would have provided for automatic licensure of those midwives who obtained the certified professional midwife credential,<sup>19</sup> while House Bill 891 would have exempted such persons from licensure.<sup>20</sup> House Bill 890 would have opened the door to certain midwives seeking direct entry into practice.<sup>21</sup>

Greater self-regulatory efforts by chiropractors were similarly unsuccessful. Efforts to set up a separate chiropractic board failed in one instance<sup>22</sup> and were carried over to the 2003 session in another.<sup>23</sup>

### 3. Pharmacy Practice

The 2002 General Assembly also amended laws governing the practice of pharmacy. Specifically, amendments to Virginia sections 54.1-3300 and -3412 allow pharmacists to expand practice locations to include clinics and allow pharmacies to maintain a combination of paper and electronic records, as long as the records are retrievable.<sup>24</sup> Other pharmacy legislation was intended to enhance consumer access to needed medications<sup>25</sup> and to improve patient and public safety.<sup>26</sup>

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18. See H.B. 889, Va. Gen. Assembly (Reg. Sess. 2002); H.B. 890, Va. Gen. Assembly (Reg. Sess. 2002); H.B. 891, Va. Gen. Assembly (Reg. Sess. 2002).

19. Va. H.B. 889.

20. Va. H.B. 891.

21. Va. H.B. 890.

22. See H.B. 1360, Va. Gen. Assembly (Reg. Sess. 2002).

23. See S.B. 261, Va. Gen. Assembly (Reg. Sess. 2002).

24. See VA. CODE ANN. §§ 54.1-3300, -3412 (Repl. Vol. 2002). The Board of Pharmacy requires pharmacies to maintain rigorous guidelines for pharmacy safety and security. See, e.g., 18 VA. ADMIN. CODE §§ 110-20-190, -200, -240 (2001).

25. See VA. CODE ANN. § 54.1-3411.1 (Repl. Vol. 2002) (allowing nursing homes to use pharmacists to transfer unused resident medication to indigent patients, free of charge); *id.* § 54.1-3301 (Repl. Vol. 2002) (providing a mechanism for stock bottle donations by practitioners and pharmaceutical manufacturers); *id.* § 54.1-3303 (Repl. Vol. 2002) (allowing authorized professionals to dispense prescriptions); see also REPORT OF THE TECHNICAL ADVISORY PANEL OF THE VA. INDIGENT HEALTH CARE TRUST FUND PURSUANT TO HJR 225, 2000, H. Doc. No. 8, at 3-7 (Va. 2001) (discussing options for expanding prescription drug benefits to low income workers in Virginia).

26. See VA. CODE ANN. § 54.1-2520 (Repl. Vol. 2002) (establishing the Prescription Monitoring Program for OxyContin and other Schedule II drugs, which requires pharmacists to report to central database); *id.* § 8.01-581.17 (Cum. Supp. 2002) (expanding peer review protections for exchange of non-identifying patient prescription information).

## B. *Licensure Requirements for Health Care Facilities*

Regardless of how a health care provider chooses to organize itself, it typically must comply with specific regulatory requirements based on its licensure status. Minimal changes to facility licensure laws were made in 2002.<sup>27</sup> In 2001, the General Assembly required outpatient surgical providers to maintain and report data that had previously gone unreported.<sup>28</sup>

Beginning in 2002, hospitals, outpatient surgical hospitals, and physicians must report data<sup>29</sup> on selected outpatient surgical procedures to the Virginia Patient Level Data System.<sup>30</sup> Before this law was passed, health care providers were only required to submit inpatient data to the Commonwealth. Legislators hope that the additional information collected as a result of this new law will improve consumer choice and support health care provider planning, utilization, and quality improvement activities.<sup>31</sup> The Board of Health subsequently adopted emergency regulations detailing the data submission process<sup>32</sup> for specific outpatient surgi-

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27. 2002 General Assembly actions included changes to the appeal procedures for nursing facilities challenging State Health Department surveyor findings from nursing facility surveys. See VA. CODE ANN. § 32.1-126 (Cum. Supp. 2002). Such surveys are required for the nursing facility's continued Medicare and Medicaid participation. See 42 C.F.R. § 442.12 (2001). Virginia Code section 32.1-126 allows nursing facilities the option to pursue formal evidentiary hearings under VA. CODE ANN. § 2.2-4020 in lieu of the informal dispute resolution ("IDR") process. VA. CODE ANN. § 32.1-126 (Cum. Supp. 2002). Historically, such IDRs have generally excluded counsel. A bill that would set staffing standards in nursing facilities (House Bill 677) was continued to 2003 after legislators were persuaded that funding and staffing availability were significant barriers to facility compliance. H.B. 677, Va. Gen. Assembly (Reg. Sess. 2002).

28. VA. CODE ANN. § 32.1-276.6 (Repl. Vol. 2001).

29. The patient level data elements to be reported for each patient receiving outpatient surgery include hospital identifier, operating physician identifier, payor identifier, employer identifier, patient identifier, patient sex, date of birth, zip code, patient relationship to the insured, employment status code, status at discharge, admission type, date and hour of admission, diagnosis upon admission, discharge status, principal and secondary diagnoses, external cause of injury, co-morbid conditions existing but not treated, procedures and procedure dates, revenue center codes, units and charges, and total charges. *Id.* § 32.1-276.6(B) (Repl. Vol. 2001). See 12 VA. ADMIN. CODE 5-218-40 (Cum. Supp. 2002) for a comprehensive list of patient level data elements.

30. VA. CODE ANN. §§ 32.1-276.3, -276.6, -276.9 (Repl. Vol. 2001). The amended Code provisions are effective until July 1, 2003. *Id.*

31. See *id.* § 32.1-276.2 (Repl. Vol. 2001).

32. Reporting entities performing more than one hundred of the specified outpatient surgical procedures each year are required to submit patient level data in electronic data format. Entities performing fewer than one hundred reportable outpatient procedures on an annual basis have the option of submitting information in electronic data or hard copy format. However, all reporting entities must use electronic format by January 1, 2004. 12

cal procedure groups.<sup>33</sup> These emergency regulations will be effective from November 1, 2001 through October 31, 2002.<sup>34</sup>

House Bills 1153 and 1312, introduced to enhance regulation of the operations of abortion clinics, were defeated and passed by indefinitely during the 2002 session.<sup>35</sup> The 2002 General Assembly also set a timetable and gave a regulatory kick-start to Board of Medicine efforts to set standards governing physician office-based surgery, specifically addressing the conditions for anesthesia administration.<sup>36</sup> The Board of Medicine regulations are due out in final form by late 2002.<sup>37</sup>

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VA. ADMIN. CODE § 5-218-50 (Cum. Supp. 2002).

33. 12 VA. ADMIN. CODE §§ 5-218-10 to -90 (Cum. Supp. 2002). For the full text of the emergency legislation, see Rules and Regulations Governing Outpatient Health Data Reporting, 18 Va. Regs. Reg. 634, 634-37 (Nov. 5, 2001). The emergency regulations set forth three options for data submission. First, the reporting entity may submit the outpatient level data to the Board of Health for processing and verification. 12 VA. ADMIN. CODE 5-218-60 (full text available at Rules and Regulations Governing Outpatient Health Data Reporting, 18 Va. Regs. Reg. at 636). Second, the reporting entity may submit the outpatient level data for processing and verification to the non-profit organization hired by the Commonwealth to compile, store, analyze, and evaluate the reported data. *Id.* Third, the reporting entity may submit already processed and verified data to the non-profit organization. *Id.* Each reporting entity must notify the Board and the non-profit organization in writing of the name, address, telephone number, email address, and fax number of a contact person within the reporting entity's organization. 12 VA. ADMIN. CODE § 5-218-70 (full text available at Rules and Regulations Governing Outpatient Health Data Reporting, 18 Va. Regs. Reg. at 637). Finally, if the data is submitted to the Board or the non-profit organization for processing and verification, the data must be submitted within forty-five days after the end of each calendar year quarter. 12 VA. ADMIN. CODE § 5-218-80 (full text available at Rules and Regulations Governing Outpatient Health Data Reporting, 18 Va. Regs. Reg. at 637). If the data is already processed and verified before it is submitted directly to the non-profit organization, it must be submitted within 120 days after the end of each calendar year quarter. *Id.*

34. 12 VA. ADMIN. CODE § 5-218 (Cum. Supp. 2002) (Editor's note). The Board of Health is required to promulgate permanent regulations to replace the emergency regulations if it wishes to continue to regulate this subject matter. *See* Rules and Regulations Governing Outpatient Health Data Reporting, 18 Va. Regs. Reg. 634 (Nov. 5, 2001). However, when this article was authored, the Board of Health had not yet taken steps to promulgate permanent regulations.

35. The first bill would have established specific licensure requirements by legislation, replacing 12 VA. ADMIN. CODE §§ 5-410-1150 to -1360 (2001), which already regulate abortion clinics per 12 VA. ADMIN. CODE § 5-410-10 (defining "outpatient surgical hospital"). *See* H.B. 1153, Va. Gen. Assembly (Reg. Sess. 2002); *see also* H.B. 2265, Va. Gen. Assembly (Reg. Sess. 2001) (similar failed bill). The latter bill would have set additional reporting and malpractice insurance requirements, again singling out abortion clinics. *See* H.B. 1312, Va. Gen. Assembly (Reg. Sess. 2002); *see also* H.B. 2264, Va. Gen. Assembly (Reg. Sess. 2001) (failing to establish certain reporting requirements).

36. VA. CODE ANN. § 54.1-2912.1 (Repl. Vol. 2002). Physicians are seeking such self-regulation with the hope of obtaining facility-based payments from managed care organizations and even Medicare ambulatory surgery center certification. *See* 42 C.F.R. § 416.1-

The 2001 General Assembly created an incentive<sup>38</sup> for certain hospitals to qualify under federal statutes and regulations for critical access hospital ("CAH") certification by Medicare.<sup>39</sup> The law allows hospitals to regain any beds given up to meet the critical access hospital eligibility criteria.<sup>40</sup> The critical access hospital incentive is intended to address the financial viability of two current, and up to three future, candidates.<sup>41</sup>

The 2001 General Assembly also took steps to ban human cloning in response to success in animal cloning and the national stem cell debate.<sup>42</sup> This state action preceded federal action on the issue.<sup>43</sup>

Another 2001 General Assembly change in response to more flexible federal regulations<sup>44</sup> allowed hospital protocols that give physicians up to seventy-two hours to sign verbal orders.<sup>45</sup> This law extended the period under existing regulations that allowed verbal orders for up to twenty-four hours.<sup>46</sup> The law also gave Virginia physicians, consistent with each hospital's bylaws,<sup>47</sup> the

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.200 (2001) (governing certification requirements).

37. See VA. CODE ANN. § 54.1-2912.1 (Repl. Vol. 2002).

38. *Id.* § 32.1-125.3 (Repl. Vol. 2001) (allowing hospitals that reduce bed capacity to qualify for the enhanced Medicare reimbursement).

39. See 42 U.S.C. § 1820 (2000); 42 C.F.R. § 409.1-.102 (2001) (authorizing critical access hospital designation by Medicare).

40. VA. CODE ANN. § 32.1-125.3 (Repl. Vol. 2001). These eligibility criteria include location, bed size, average length of stay, and certain service requirements. 42 U.S.C. § 1820 (2000).

41. The two current CAH hospitals in Virginia are Bath County Community Hospital and RJ Reynolds-Patrick County Hospital. For more details on the CAH option and Medicaid funding considerations, see REPORT OF THE JOINT COMM'N ON HEALTH CARE, CRITICAL ACCESS HOSP. PROGRAM STUDY (COPN FOLLOW-UP), S. Doc. No. 0F (Va. 2002).

42. See VA. CODE ANN. § 32.1-162.22 (Repl. Vol. 2001) This section bans somatic cell nuclear transfer intended to induce pregnancy or the possession of the product of human cloning and sets civil monetary penalties for violations in addition to any penalty provided by law. However, it does not restrict certain biomedical and agricultural research or practices, including the cloning of molecules or animals other than humans.

43. As of this writing, federal legislation has been debated but has not been adopted by Congress. See, e.g., 148 CONG. REC. S3631 (daily ed. May 1, 2002) (statement of Sen. Spector).

44. See 42 C.F.R. § 482.24 (2001) (allowing "prompt" authentication and dating).

45. See VA. CODE ANN. § 32.1-127(B)(11) (Repl. Vol. 2001).

46. See 12 VA. ADMIN. CODE § 5-410-230(c) (1996).

47. Each hospital is required by Virginia law, and as a condition of receiving Medicare and Medicaid payment under 42 C.F.R. § 482.22(c) (2001), to have an organized medical staff. The medical staff must adopt certain bylaws or rules governing medical practice within the hospital setting. See VA. CODE ANN. § 32.1-134.1 (Repl. Vol. 2001); 12 VA. ADMIN. CODE § 5-410-210(A), (C) (1996); 42 C.F.R. § 482.22(c) (2001); see also Terzis v.



option of relying on another physician or person authorized to issue orders under state law<sup>48</sup> to countersign the order.<sup>49</sup>

### C. *Certificate of Public Need*

Following the 2000 amendment of Virginia Code section 32.1-102.13,<sup>50</sup> the Virginia General Assembly was supposed to provide sufficient funds for indigent care in hospitals as a precondition to deregulation.<sup>51</sup> The additional funding in subsequent years, along with the adoption of new regulations establishing separate licensing requirements for currently unlicensed services subject to Certificate of Public Need ("COPN") review, was supposed to allow the three-phased deregulation plan to proceed.<sup>52</sup> The additional funding was part of a compromise reached by the 2000 General Assembly that included health care facility associations, such as the Virginia Hospital and Healthcare Association, and physician groups, such as the Medical Society of Virginia.<sup>53</sup>

Unfortunately for deregulation advocates, the state budget challenges have postponed the effective date of deregulation for yet another year. In the meantime, new proposed regulations im-

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Med. Ctr. Hosp., 235 Va. 443, 367 S.E.2d 728 (1988) (addressing legality under Virginia law of disciplinary actions against medical staff physicians based upon bylaw requirements in hospitals).

48. See, e.g., VA. CODE ANN. §§ 32.1-134.2, -134.4 (Repl. Vol. 2001) (addressing rights of podiatrists and nurse practitioners to participate on medical staff); 12 VA. ADMIN. CODE §§ 5-410-210(c), -230(c) (1996) (authorizing podiatrist and nurse practitioner privileges under Virginia law and requiring orders by persons authorized under state law).

49. Notably, this change may affect a hospital's compliance with state laws on the timing of physician authorization, but it does not guarantee hospital payment for services where payor rules require a contemporaneous physician signature or payor preauthorization prior to payment for services rendered. See, e.g., 42 C.F.R. § 456.60 (2001) (requiring physician certification of hospital patients at the time of admission in order to receive Medicaid payment).

50. See VA. CODE ANN. § 32.1-102.13 (Repl. Vol. 2001); see also A PLAN TO ELIMINATE THE CERTIFICATE OF PUBLIC NEED PROGRAM, S. Doc. No. 0A (Va. 2001).

51. While an indigent care funding mechanism currently exists under state law, see VA. CODE ANN. §§ 32.1-332 to -342 (Repl. Vol. 2001), the deregulation plan proposal was not approved by the 2001 session. See REPORT OF THE JOINT COMM'N ON HEALTH CARE, SCHIP WAIVER FOR LOW-INCOME ADULT PARENTS STUDY (COPN FOLLOW-UP), S. Doc. No. 0G (Va. 2002) [hereinafter SCHIP STUDY], available at <http://legis.state.va.us/jchc/report.htm#annual> (last updated June 28, 2002).

52. SCHIP STUDY, *supra* note 51, at 1.

53. See Virginia Commonwealth University, State, Local, and Community Relations, Legislative Highlights (Feb. 18, 2000), available at <http://www.vcu.edu/exrel/GA00/hlt1.htm> (last visited Oct. 4, 2002).

plementing the 2000 legislation have been promulgated without the deregulation of services component.<sup>54</sup> The 2002 General Assembly did pass two exceptions to COPN requirements and narrowly defeated two others that would have led to further deregulation prior to increased indigent care funding.<sup>55</sup>

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54. See Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations, 18 Va. Regs. Reg. 2220 (May 20, 2002) (to be codified at 12 VA. ADMIN. CODE §§ 5-220-10 to -500). The proposed regulations establish permanent amended procedures for implementing the 190-day review process that now governs COPN reviews. See Virginia Code section 32.1-102.6(B) and other changes which establish special exceptions to COPN review criteria for rural health care facilities. See VA. CODE ANN. § 32.1-102.6 (B) (Repl. Vol. 2001 & Cum. Supp. 2002). See generally Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations, 18 Va. Regs. Reg. 2220 (May 20, 2002). The proposed regulations were previously enacted in the form of emergency regulations. See Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations, 16 Va. Regs. Reg. 1276 (Jan. 31, 2000). However, permanent regulations were not enacted in the one-year emergency regulation period, leading to some confusion over the applicable regulations and COPN review process to be followed in the period after January 2, 2001.

55. See S.B. 490, Va. Gen. Assembly (Reg. Sess. 2002) (enacted as Act of Mar. 22, ch. 449, 2002 Va. Acts 709) (requiring the State Health Commissioner to reissue a request for application for 180 new nursing facility beds, sixty in PD 11 and 120 in PD 13). The additional nursing facility beds were previously issued in two nursing facility batch cycles in 1998 and 1999 but were not developed due to the financial difficulties of the applicant in each case. The Commissioner officially revoked the certificates in December 2001 for the applicants' failure to make progress towards the completion of the nursing facility beds and previous statement of inability to develop those beds, contrary to Virginia Code section 32.1-102.4 (requiring progress towards construction and licensure of projects approved through the COPN process within a three year period). See Letters from Robert B. Stroube, M.D., Acting State Health Commissioner, to M. Dean Cranwell, Esquire, Director of Legal Services, Heritage Hall (Dec. 20, 2001) (on file with the author) (revoking certificates previously issued to HCMF).

The 2002 General Assembly also approved Senate Bill 643, a bill to allow Lucy Corr Nursing Home to convert sixteen assisted living beds licensed by the Virginia Department of Social Services under Virginia Code section 63.1-175 to nursing facility beds licensed by the Virginia Department of Health under Virginia Code Section 32.1-126, as long as those beds are dedicated to private pay and Medicare. See VA. CODE ANN. § 32.1-102.1 (Repl. Vol. 2001); S.B. 643, Va. Gen. Assembly (Reg. Sess. 2002) (enacted as Act of Mar. 22, 2002, ch. 179, 2002 Va. Acts 162). The General Assembly rejected bills that would have eliminated regional health planning and which would have removed cancer care centers from COPN review. See H.B. 293, Va. Gen. Assembly (Reg. Sess. 2002) (proposing elimination of regional health planning agencies) (continued to 2003). House Bills 883 and 885, continued to 2003 session, proposed deregulation of cancer care centers as specialized clinics defined as projects under Virginia Code section 32.1-102.1. See VA. CODE ANN. § 32.1-102.1 (Repl. Vol. 2001); H.B. 883, Va. Gen. Assembly (Reg. Sess. 2002); H.B. 885, Va. Gen. Assembly (Reg. Sess. 2002); see also S.B. 454, Va. Gen. Assembly (Reg. Sess. 2002) (companion to House Bill 883); S.B. 478, Va. Gen. Assembly (Reg. Sess. 2002) (companion to House Bill 883).

#### D. Medicaid Payment

The 2002 General Assembly faced many challenges in maintaining a balanced budget as required by the Virginia Constitution.<sup>56</sup> To reduce overall budget expenditures, the General Assembly required the Virginia Department of Medical Assistance Services to cut general fund expenditures by \$162 million over the next two years.<sup>57</sup>

In the meantime, the outgoing Gilmore administration took advantage of a loophole in federal statutes and regulations governing intergovernmental transfers to obtain approximately \$259 million dollars in additional Medicaid reimbursement to local nursing facilities.<sup>58</sup> The loophole allowed states to generate extra matching funds by paying nursing homes and hospitals owned by local governments more than they would normally receive and then having them return the bulk of the funds to state coffers.<sup>59</sup> According to the Department of Health and Human Services ("DHHS") Office of the Inspector General, twenty-eight states took advantage of the loophole in 2000, increasing federal match funds by \$5.8 billion dollars.<sup>60</sup> Given that there were no restrictions on how the funds were to be used, many states spent the extra funds on non-health care related projects.<sup>61</sup> After facing a series of negative articles concerning the intergovernmental transfer proposal,<sup>62</sup> Virginia was able to get the assistance of two localities to obtain the federal match before January 12, 2002, the deadline under the January 12, 2001 regulations.<sup>63</sup>

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56. See VA. CONST. Art. X, §§ 7, 8, 9.

57. See Patrick W. Finnerty, Address at the Virginia Health Law Legislative Update (May 9, 2002) (on file with author).

58. Gordon Hickey et al., *State Finds \$259 Million Federal Loophole*, RICH. TIMES-DISPATCH, Sept. 29, 2001, at A1.

59. *Id.*

60. Dep't of Health & Human Serv. Office of Inspector Gen., *Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers*, A-03-00-00216, at ii (Sept. 2001) [hereinafter OIG REPORT], available at <http://oig.hhs.gov/oas/reports/region3/30000216.pdf> (last visited Oct. 5, 2002).

61. See OIG REPORT, *supra* note 60, at 3-4.

62. See, e.g., Jennifer L. Berghom et al., *Bedford Backs Medicaid Fund Transfer Agreement*, RICH. TIMES-DISPATCH, Oct. 23, 2001, at B7; Hickey et al., *supra* note 58, at A1.

63. See 42 C.F.R. § 447.272 (2001); see also U.S. GEN. ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTERS: HCFA REVERSED ITS POSITION AND APPROVED ADDITIONAL STATE FINANCING SCHEMES, GAO-02-147 (Oct. 2001).

### E. *Privacy of Health Information*

Acknowledging the many public policy reasons to protect the confidential nature of a patient's health information, legislators pass laws governing the treatment of health information each year. In 2002, the Virginia General Assembly passed three laws relating to health information. Instead of placing restrictions on the sharing of health information, all three laws enhanced the exchange of health information.<sup>64</sup>

The amendment to Virginia Code section 8.01-413 provided "authorized insurers" with new access to health care providers' records and papers for a reasonable charge.<sup>65</sup> This Virginia Code section already required hospitals, nursing facilities, physicians, and other health care providers<sup>66</sup> to furnish copies of health records or papers to patients or their attorneys when such copies were requested in relation to anticipated or ongoing litigation.<sup>67</sup> As amended, Virginia Code section 8.01-413 requires health care providers to respond to a patient's, attorney's, or authorized insurer's written request for documents by supplying the requested copies within fifteen days of the request.<sup>68</sup> Even though this new law allows a greater number of people to access a patient's health information, the law continues to protect the patient's confidentiality by requiring providers to obtain a signed writing from the patient confirming the attorney's or insurer's authority to make the request.<sup>69</sup>

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64. See VA. CODE ANN. §§ 8.01-413, 32.1-116.1, 32.1-127.1:04 (Cum. Supp. 2002).

65. *Id.* § 8.01-413.

66. *Id.* § 8.01-413(E). Virginia Code section 8.01-413 states that "health care provider shall have the same meaning as provided in § 32.1-127.1:03 and shall also include an independent medical copy retrieval service contracted to provide the service of retrieving, reviewing, and preparing such copies for distribution." See *id.* § 32.1-127.1:03 (Repl. Vol. 2001).

67. VA. CODE ANN. § 8.01-413(B). The law only applies to requests that are made in anticipation of litigation or in the course of litigation. *Id.* Furthermore, the law applies to health care providers with offices located within or without the Commonwealth if the records pertain to any patient who is a party to a cause of action in any court of the Commonwealth of Virginia. *Id.*

68. *Id.* § 8.01-413(B) (Cum. Supp. 2002). If the provider fails to comply with the request, the patient, attorney, or authorized insurer may cause a subpoena duces tecum to be issued. *Id.* § 8.01-413(C).

69. *Id.* § 8.01-413(B). The provider "shall accept a photocopy, facsimile, or other copy of the original authorization signed by the patient as if it were an original." *Id.*

The amendments to Virginia Code section 37.1-116 promote the sharing of a crime victim's health information between emergency medical services agencies and law enforcement officials.<sup>70</sup> This Virginia Code section already required all licensed emergency medical services agencies to report prehospital patient care data using the established Emergency Medical Services Patient Care Information System.<sup>71</sup> Under the newly modified law, when a patient is a victim of a crime, emergency medical services agencies "may disclose the prehospital patient care report to law enforcement officials" as long as the disclosure complies with applicable privacy laws.<sup>72</sup>

Finally, Virginia Code section 32.1-127.1:04 provides for the sharing of health information between state agencies.<sup>73</sup> This establishes a secure system for sharing protected health information among the Departments of Health, Medical Assistance Services, Mental Health, Mental Retardation and Substance Abuse Services, and Social Services.<sup>74</sup> According to the new law, the system is established for

sharing protected health information that may be necessary for the coordination of prevention and control of disease, injury, or disability and for the delivery of health care benefits when such protected information concerns individuals who (i) have contracted a reportable disease, including exposure to a toxic substance, as required by the Board of Health pursuant to § 32.1-35 or other disease or disability required to be reported by law; (ii) are the subjects of public health surveillance, public health investigations, or public health interventions or are applicants for or recipients of medical assistance services; (iii) have been or are the victims of child abuse or neglect or domestic violence; or (iv) may present a serious threat to health or safety of a person or the public or may be subject to a serious threat to their health or safety.<sup>75</sup>

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70. *Id.* § 32.1-116.1 (Cum. Supp. 2002).

71. *Id.* § 32.1-116.1(A) (Cum. Supp. 2002). "The minimum data set shall include, but not be limited to, type of medical emergency or nature of the call, the response time, the treatment provided and other items as prescribed by the Board." *Id.*

72. *Id.* The applicable privacy laws include the Virginia's Patient Health Records Privacy Law, VA. CODE ANN. § 32.1-127.1:03 (Cum. Supp. 2002), and the federal privacy regulations promulgated by the Department of Health and Human Services as required by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). See HIPAA, 42 U.S.C. §§ 1320d-1320d-8 (Repl. Vol. 1998 & Cum. Supp. 2002); 45 C.F.R. §§ 164.500-534 (2001).

73. *Id.* § 32.1-127.1:04(B) (Cum. Supp. 2002).

74. *Id.* § 32.1-127.1:04.

75. *Id.* § 32.1-127.1:04(B).

Virginia Code section 32.1-127.1:04 also declares that

[t]he coordination of prevention and control of disease, injury, or disability and the delivery of health care benefits are . . . (i) necessary public health activities; (ii) necessary health oversight activities for the integrity of the health care system; and (iii) necessary to prevent serious harm and serious threats to the health and safety of individuals and the public.<sup>76</sup>

This declaration qualifies the disclosure of protected health information to the secure system as a disclosure that does not require patient consent or authorization under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).<sup>77</sup>

Two of the above new laws reference HIPAA, a federal law passed in 1996 to make it easier for Americans to maintain high quality health insurance coverage while changing jobs and to simplify administrative transactions by increasing the standardized use of Electronic Data Interchange.<sup>78</sup> Virginia health plans, health care clearinghouses, and health care providers who engage in designated electronic billing or claims transactions<sup>79</sup> should be aware of the privacy regulations promulgated by the Department of Health and Human Services pursuant to the requirements of HIPAA.<sup>80</sup> The HIPAA privacy standards<sup>81</sup> become effective on

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76. *Id.* § 32.1-127.1:04(A).

77. *Id.* § 32.1-127.1:04(B). This point is explicitly stated in the new Virginia statute: “Pursuant to the regulations concerning patient privacy promulgated by the federal Department of Health and Human Services, covered entities may disclose protected health information to the secure system without obtaining consent or authorization for such disclosure.” *Id.*

78. 42 U.S.C. §§ 1320d–1320d-8 (2000).

79. These three entities are “covered entities” under the HIPAA privacy standards. 45 C.F.R. § 164.104 (2001).

80. *Id.* §§ 164.102–.106 (2001).

81. Depending on the type of disclosure, the HIPAA privacy standards require covered entities to obtain a patient’s authorization before disclosing the patient’s protected health information. *Id.* § 164.506(A)(2). The HIPAA privacy standards also require covered entities to enter into agreements with “business associates” in which the business associate agrees to abide by the HIPAA privacy standards that are applicable to the covered entity. *Id.* § 164.5-502(d)(1). Finally, the HIPAA privacy standards set forth various patient rights relating to protected health information. *Id.* §§ 164.522, .524, .526, .528. For example, covered entities must provide patients with a notice regarding the covered entity’s information practices. *Id.* § 164.520. Patients must be permitted to access and request amendment to their records. *Id.* §§ 164.524, .526. Covered entities must provide patients with an accounting of disclosures, and patients have the right to request the restricted use or disclosure of their protected information. *See id.* §§ 164.522, .528; *see also* 67 Fed. Reg. 53,182 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160, 164).

April 14, 2003 and, in some instances, may preempt Virginia law relating to the treatment of protected health information.<sup>82</sup>

#### F. *State False Claims Act*

The 2002 General Assembly enacted a civil false claims act, the Virginia Fraud Against Taxpayers Act.<sup>83</sup> The Virginia statute mirrors the federal False Claims Act,<sup>84</sup> in that both statutes are now applicable to billings by health care providers that are known to be false or fraudulent claims at the time a provider requests payment or approval.<sup>85</sup> Under both the federal and state acts, a private party may initiate the lawsuit as a *qui tam* plaintiff.<sup>86</sup> The success of the federal statute in obtaining recoveries for the federal government appear to have the same intent and scope.<sup>87</sup> Under both the federal False Claims Act and the Virginia

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82. *Id.* § 160.203. "A standard requirement, or implementation specification set forth in the HIPAA privacy standards that is contrary to a provision of state law preempts the provision of state law," unless an explicit exception applies. *Id.* One exception states that the HIPAA privacy standards will not preempt the state law if "[t]he provision of State law relates to privacy of health information and is more stringent than a standard, requirement, or implementation specification adopted" under the HIPAA privacy standards. *Id.* § 160.203. "More stringent" means that the state law is more restrictive of uses and disclosures of protected health information than the HIPAA privacy standards, or that the state law permits greater rights of access or amendment to the individual who is the subject of the individually identifiable health information. *Id.* § 160.202; *see also* 15 U.S.C. § 6805 (2000) (requiring states to promulgate regulations to implement Gramm-Leach-Bliley Act for protection of non-public personal information maintained by financial institutions).

83. VA. CODE ANN. §§ 8.01-216.1 to -216.19 (Cum. Supp. 2002).

84. *See* 31 U.S.C. §§ 3729-3733 (2000).

85. *See* 31 U.S.C. § 3729; VA. CODE ANN. § 8.01-216(A) (Cum. Supp. 2002).

86. *See* 31 U.S.C. § 3730(b)-(d); VA. CODE ANN. § 8.01-216.5-7 (Cum. Supp. 2002). A *qui tam* action means "an action brought under a statute that allows a private person to sue for a penalty, part of which the government or some specified public institution will receive." BLACKS LAW DICTIONARY 1262 (7th ed. 1999). The whistleblower or *qui tam* provisions of the federal False Claims Act and, by analogy, the Virginia Fraud Against Taxpayers Act, allow any citizen who has knowledge of a fraud against the government to bring suit in the name of the government and, for his or her efforts, to share in the proceeds. *See* 31 U.S.C. §§ 3729-3733 (2000); VA. CODE ANN. §§ 8.01-216.1 to -216.19 (Cum. Supp. 2002); *see also* Emily W. Greenstreet, *The Health Care Industry and the False Claims Act Whistleblower*, 48 MED. TRIAL TECH. Q. 311, 311-14 (2002) (discussing "*qui tam*" actions and the implementation and enforcement of the Federal False Claims Act). *See generally* David M. Respanti and Marc S. Laigaie, *Current Practice and Procedure Under the Whistleblower Provisions of the Federal False Claims Act*, 71 TEMP. L. REV. 23 (1998) (summarizing history and recent practice and procedures under the federal False Claims Act).

87. Between 1986 and 1998, the federal False Claims Act reportedly recovered over \$2

Fraud Against Virginia Taxpayers Act, a private party initiating a *qui tam* suit files both in their name and the name of the government.<sup>88</sup> Once filed, the lawsuit cannot be voluntarily dismissed without the written consent of the Attorney General and the court.<sup>89</sup>

Complaints filed under both the Federal False Claims Act and the Virginia Fraud Against Taxpayers Act are filed under seal.<sup>90</sup> The federal False Claims Act provides sixty days for the U.S. Attorney to review the claim and to decide whether or not it will intervene.<sup>91</sup> The Virginia statute provides the Attorney General's office 120 days to review the complaint while under seal.<sup>92</sup> The federal and state statutes both require the government to assume primary responsibility for the case upon intervention.<sup>93</sup> Under both the federal and state acts, the *qui tam* relator is entitled to a portion of any settlement or recovery.<sup>94</sup> If the government intervenes, the *qui tam* relator is generally allowed fifteen percent to

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billion for the United States Treasury. See Respanti & Laigaie, *supra* note 86, at 23. More recent estimates based on settlements under the federal False Claims Act suggest that the recoveries are increasing, in part because of implementation of companion statutes, such as the Health Care Fraud And Abuse Control Program. See 18 U.S.C. § 1347 (2000); U.S. DEP'T OF HEALTH & HUM. SERV. & DEP'T OF JUST. HEALTH CARE FRAUD & ABUSE CONTROL ANN. REP. FOR FY2001 (Apr. 2002) [hereinafter FRAUD REPORT 2001] (citing over \$1.7 billion health care fraud cases proceedings with a total of \$1.3 billion collected by the Federal Government), available at <http://www.usdoj.gov/dag/pubdoc/hipaa01fe19.htm> (last visited Oct. 5, 2002). These include over \$100 million in civil claims against Vencor, Inc., \$87.5 million against Quorum Health Group, Inc., \$27 million against National Health Care Corporation, \$4 million against CVS Corporation (partially filled prescription allegations), and \$10.25 million from two California medical practice groups. See *id.*

88. Compare 31 U.S.C. § 3730(b) (2000), with VA. CODE ANN. § 8.01-216.5(A) (Cum. Supp. 2002).

89. See 31 U.S.C. § 3730(b); VA. CODE ANN. § 8.01-216.5(A).

90. See 31 U.S.C. § 3730(b)(2); VA. CODE ANN. § 8.01-216.5(B).

91. 31 U.S.C. § 3730(b)(2).

92. VA. CODE ANN. § 8.01-216.5(B). Under both statutes, the U.S. Attorney or the Attorney General may seek an extension of the time to review the complaint and the decision on whether to intervene "for good cause shown." See 31 U.S.C. § 3730(b)(3); VA. CODE ANN. § 8.01-216.5(C).

93. See 31 U.S.C. § 3730(c)(1); VA. CODE ANN. § 8.01-216.6(A) (Cum. Supp. 2002). In both statutes, the government may decide to settle or dismiss the action over the objection of the *qui tam* relator. The *qui tam* relator will have the benefit of an in camera hearing to determine whether the settlement or dismissal is fair and reasonable. 31 U.S.C. § 3730(c)(2)(B); VA. CODE ANN. § 8.01-216.6(B), (C). Unlike the federal False Claims Act, the Virginia statute includes a provision allowing the Commonwealth to petition the court "for a partial lifting of the seal to facilitate the investigative process for settlement." VA. CODE ANN. § 8.01-216.6(C).

94. 31 U.S.C. § 3730(d); VA. CODE ANN. § 8.01-216.7 (Cum. Supp. 2002).



twenty-five percent of the recovery.<sup>95</sup> If the government chooses not to intervene, the relator's share increases from twenty-five percent to thirty-five percent.<sup>96</sup> Implementation of the Virginia statute and its use in fighting health care fraud in the Commonwealth will be determined over the next few years.

### G. *Bioterrorism*

Given the national developments in health care safety and security following the September 2001 terrorist attacks and bioterrorism scares, Virginia's passage of bioterrorism legislation and participation in related federal grant requests is no surprise. The legislation required certain health care providers to report to the State Police information about a patient that may indicate disease caused by exposure to an agent or substance that can be used as a weapon.<sup>97</sup> New statutes require physicians and laboratory directors to make reports to the Commissioner, just as they currently do for communicable diseases.<sup>98</sup> In addition to legislation, Governor Warner recently endorsed two bioterrorism grant requests by the Virginia Department of Health totaling \$23.75

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95. See 31 U.S.C. § 3730(d); VA. CODE ANN. § 8.01-216.7(A). In both cases, the court decides the percentage of recovery based upon the extent to which the person substantially contributed to the prosecution of the action and in cases involving use of public records, the recovery of the proceeds may be limited to ten percent. 31 U.S.C. § 3730(d)(1); VA. CODE ANN. § 8.01-216.7(A). In all cases, the *qui tam* relator will receive an amount for reasonable expenses that have been necessarily incurred, plus reasonable attorneys' fees and costs. 31 U.S.C. § 3730(d)(1); VA. CODE ANN. § 8.01-216.7(A).

96. 31 U.S.C. § 3730(d)(2); VA. CODE ANN. § 8.01-216.7(B). One difference between the federal and state statutes is in the treatment of persons who planned and initiated the violation on which the action was brought who still "materially" advance the government's case. Compare 31 U.S.C. § 3730(d)(3), with VA. CODE ANN. § 8.01-216.7(C). Under the federal statute, some recovery is available. See 31 U.S.C. § 3730(d)(3). Under the state statute, no recovery is available to a "mastermind." See VA. CODE ANN. § 8.01-216.7(C). The Virginia statute also differs from the federal statutes in that it bars recoveries by inmates and by individuals against their past or current employer where it can be shown that they failed to exhaust existing internal procedures. See VA. CODE ANN. § 8.01-216.8 (Cum. Supp. 2002). This would appear to bar a Virginia false claim against health care providers that implement compliance programs. See, e.g., Compliance Program Guidance to Individual and Small Group Physician Practices, 65 Fed. Reg. 59,434 (Oct. 5, 2000); Compliance Program Guidance to Nursing Facilities, 65 Fed. Reg. 14,289 (Mar. 16, 2000); OIG Compliance Program Guidance to Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998).

97. See VA. CODE ANN. §§ 32.1-35 to -38 (Cum. Supp. 2002) (requiring health care providers to report to the Commissioner, who is then to report to the State Police concerning outbreaks or unusual occurrences that may indicate disease caused by exposure to an agent or substance that can be used as a weapon).

98. See VA. CODE ANN. § 32.1-36.

million.<sup>99</sup> The funds will be used for physicians and epidemiologists as well as bioterrorism coordinators, planners, educators, and public information officers.<sup>100</sup>

### III. CASE LAW DEVELOPMENTS

#### A. *Family Medical Leave Act*

##### 1. The United States Supreme Court

In *Ragsdale v. Wolverine World Wide, Inc.*,<sup>101</sup> the Supreme Court resolved an issue involving Labor Department regulations that affected Virginia businesses and which had been interpreted by the Labor Department in a manner contrary to the leave entitlement provisions of the Family Medical Leave Act of 1993 (“FMLA”).<sup>102</sup> This regulation applies to many Virginia businesses.<sup>103</sup> The FMLA guarantees qualifying employees twelve weeks of unpaid leave each year and encourages businesses to adopt more generous leave policies.<sup>104</sup> In *Ragsdale*, Wolverine World Wide, Inc. (“Wolverine”) accepted the FMLA’s encouragement of granting more leave than the minimum requirement and gave Tracy Ragsdale (“Ragsdale”), petitioner, thirty weeks of un-

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99. See Press Release, Governor Mark Warner, Governor Warner Endorses \$23.75 Million Federal Bioterrorism Grant Request (April 16, 2002) (noting Governor Warner’s endorsement of the grant request using the funding approved by the original bioterrorism legislation), available at [http://www.governor.state.va.us/Press\\_Policy/Releases/April2002/Apr1602.htm](http://www.governor.state.va.us/Press_Policy/Releases/April2002/Apr1602.htm) (last visited Oct. 5, 2002).

100. *Id.* Subsequent federal legislation has also been approved to provide grant funds for bioterrorism preparedness and response plans in each state. See 42 U.S.C.A. § 247d-6 (Cum. Supp. 2002). A recent press release from the U.S. Department of Health & Human Services announced that in January 2002 “President Bush signed into law a bioterrorism appropriations bill that sent \$1.1 billion to 62 states, territories and three major cities.” U.S. Dep’t. of Health & Human Services, HHS Approves State Bioterrorism Plans so Building Can Begin (June 6, 2002), available at <http://www.hhs.gov/news/press/2002pres/20020606c.html> (last visited Oct. 5, 2002). Twenty percent of the money for each state or municipality was immediately released. *Id.* The remaining eighty percent will be released upon approval of each state or municipality’s bioterrorism plans. *Id.*

101. 122 S. Ct. 1155 (2002).

102. *Id.* at 1165; see also 29 U.S.C. §§ 2601–2654 (2000). The specific leave provisions implicated by this case are 29 U.S.C. section 2612(a)(1) (granting 12 workweeks of leave per year) and section 2653 (encouraging more generous leave policies).

103. 29 U.S.C. §§ 2601–2654.

104. See *id.* § 2653.

paid medical leave.<sup>105</sup> Ragsdale needed the medical leave when she was unable to work due to surgery and radiation therapy for her Hodgkin's disease.<sup>106</sup> Following the use of thirty weeks of unpaid leave, Ragsdale requested additional leave from Wolverine or permission to work on a part-time basis.<sup>107</sup> Wolverine refused and fired her when she did not return to work.<sup>108</sup>

Ragsdale filed suit in the United States District Court for the Eastern District of Arkansas, claiming that a Labor Department regulation<sup>109</sup> required Wolverine to grant her twelve additional weeks of leave because it had not informed her that the thirty-week absence would count against her FMLA entitlement.<sup>110</sup> While "Wolverine conceded it had not given Ragsdale specific notice that part of her absence would count as FMLA leave," it argued that it had complied with the FMLA by granting her more than thirty weeks of leave.<sup>111</sup> The district court granted Wolverine's motion for summary judgment, finding that the regulation was "in conflict with the [FMLA] and invalid because, in effect, it required Wolverine to grant Ragsdale more than 12 weeks of FMLA-compliant leave in one year."<sup>112</sup> The Court of Appeals for the Eighth Circuit agreed and affirmed the lower court's decision.<sup>113</sup>

The Supreme Court affirmed the Eight Circuit's decision.<sup>114</sup> In reaching this decision, the Court reasoned that the Labor Department's regulation<sup>115</sup> "effects an impermissible alteration of the [FMLA's] statutory framework and cannot be within [the Labor] Secretary's power to issue regulations 'necessary to carry out' the Act under § 2654."<sup>116</sup> Finally, the Court closed the door on any future confusion between the Labor Department's regulation and

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105. *See Ragsdale*, 122 S. Ct. at 1159.

106. *Id.*

107. *Id.*

108. *Id.*

109. 29 C.F.R. § 825.700(a) (2001). The regulation provides that if an employee takes medical leave "and the employer does not designate the leave as FMLA leave, the leave taken does not count against an employee's FMLA entitlement." *Id.*

110. *Ragsdale*, 122 S. Ct. at 1155.

111. *Id.* at 1159.

112. *Id.*

113. *Id.*

114. *Id.*

115. 29 C.F.R. § 825.700(a) (2001).

116. *Ragsdale*, 122 S. Ct. at 1165.

the entitlement provision of the FMLA by stating: “[w]hatever the bounds of the Secretary’s discretion on this matter, they were exceeded here. The FMLA guaranteed Ragsdale 12—not 42—weeks of leave in 1996.”<sup>117</sup>

## 2. The United States Court of Appeals for the Fourth Circuit

In the past year, the United States Court of Appeals for the Fourth Circuit decided two significant cases that interpreted a provision of the FMLA in a new or different manner. These cases were *Miller v. AT&T Corp.*<sup>118</sup> and *Rhoads v. Federal Deposit Insurance Corp.*<sup>119</sup> In *Miller*, from September 1990 until her firing in March 1997, Kimberly Miller (“Miller”) was employed as an account representative by AT&T Corporation (“AT&T”).<sup>120</sup> During the course of her employment, Miller was frequently absent from work.<sup>121</sup> Following a series of discussions from her supervisors concerning her absences and the issuance of several letter warnings, a final letter of warning was issued in June of 1996.<sup>122</sup> This correspondence “specifically warned Miller that her next chargeable absence could result in dismissal.”<sup>123</sup> In December of 1996, Miller became ill and was unable to attend work.<sup>124</sup> Miller sought treatment at an urgent care facility and was diagnosed as being severely dehydrated and suffering from the flu.<sup>125</sup> Subsequently, Miller requested FMLA leave from AT&T for four days.<sup>126</sup> On her FMLA leave request form, the treating doctor from the urgent care center indicated that the “serious medical condition” prompting FMLA leave was “Influenza type ‘A.’”<sup>127</sup> AT&T denied Miller’s request for FMLA leave on February 26, 1997 because “the flu is not generally considered to be the type of condition for which an employee is entitled to FMLA leave.”<sup>128</sup>

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117. *Id.*

118. 250 F.3d 820 (4th Cir. 2001).

119. 257 F.3d 373 (4th Cir. 2001).

120. *Miller*, 250 F.3d. at 827.

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.* at 828.

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.* at 829.

In August 1998, Miller filed suit in federal court alleging, among other things, that AT&T had violated her rights under the FMLA by denying her request for the absences due to her flu.<sup>129</sup> Following extensive discovery, the district court granted summary judgment to Miller, holding that Miller's "particular case of the flu" fit the FMLA definition of a "serious health condition" and Miller had provided the necessary certification of her need for FMLA leave.<sup>130</sup> On appeal, the Fourth Circuit addressed two issues raised by AT&T: (1) whether or not an episode of the flu is a "serious health condition" as defined by the FMLA and implementing regulations; and (2) if the flu is considered a "serious health condition" under the applicable regulations, whether or not those regulations are contrary to congressional intent and are therefore invalid.<sup>131</sup>

In resolving the first issue presented, the Fourth Circuit held that section 825.114(c)<sup>132</sup> "simply does not automatically exclude the flu from coverage under the FMLA."<sup>133</sup> The court further explains that "[r]ather, the provision is best read as clarifying that some common illnesses will not ordinarily meet the regulatory criteria and thus will not be covered under the FMLA."<sup>134</sup> The Fourth Circuit dispensed with the second issue on appeal by noting, contrary to AT&T's argument,<sup>135</sup> "the FMLA defines 'serious health condition' broadly 'and does not include any examples of conditions that either do or do not qualify as FMLA "serious health conditions."<sup>136</sup> Therefore, the court could not say "that the regulations adopted by the Secretary [of Labor] are so manifestly contrary to congressional intent as to be considered arbitrary."<sup>137</sup>

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129. See *Miller v. AT&T*, 60 F. Supp. 2d 574, 577-78 (S.D. W. Va. 1999).

130. *Id.* at 579-80; see also 29 U.S.C. §§ 2611(11), 2612(a)(2)(D), 2613(a)-(b) (2000); 29 C.F.R. § 825.305(a) (2001).

131. *Miller*, 250 F.3d at 824-25.

132. This section reads: "Ordinarily, unless complications arise, the common cold, the flu, ear aches, upset stomach, minor ulcers, headaches other than migraine, routine dental or orthodontia problems, periodontal diseases, etc., are examples of conditions that do not meet the definition of a serious health condition and do not qualify for FMLA leave." 29 C.F.R. § 825.114(c) (2001).

133. *Miller*, 250 F.3d at 832.

134. *Id.*

135. AT&T argued that "the legislative history indicates that in enacting the FMLA, Congress was focused on 'major' illnesses, such as cancer, rather than relatively minor ailments." *Id.* at 835.

136. *Id.* (citing *Thorson v. Gemini, Inc.*, 205 F.3d 370, 380 (8th Cir. 2000)).

137. *Id.*

In *Rhoads v. Federal Deposit Insurance Corp.*,<sup>138</sup> the Fourth Circuit clarified an employer's right to question certification under the FMLA.<sup>139</sup> Under the FMLA, an employer may require that a claim for medical leave, for either the employee's own or a family member's condition, be supported by a medical care provider's certification.<sup>140</sup> In order to comply with federal regulations, "[the] employer must give notice of a requirement for medical certification each time a certification is required."<sup>141</sup> The FMLA establishes standards for the certification.<sup>142</sup> However, a provider representing the employer may contact the employee's health care provider for authentication and clarification of medical certification only with the employee's permission.<sup>143</sup> If the employer doubts the validity of the certification, it may seek a second medical opinion, at its own expense, from a health care provider of its choice.<sup>144</sup> To avoid questions of validity and impartiality, this second opinion cannot be given by a health care provider employed on a regular basis by the employer.<sup>145</sup>

If the first two medical opinions differ, at its own expense, the employer can require a third opinion.<sup>146</sup> This third opinion is final and binding.<sup>147</sup> "The third health care provider [also] must be designated or approved jointly by the employer and the employee."<sup>148</sup> While awaiting the receipt of the second or third medical opinion, the employee is statutorily entitled to the benefits of the FMLA.<sup>149</sup> Finally, upon request, the employer must give the employee a copy of the second or third opinion within two business days of the request.<sup>150</sup>

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138. 257 F.3d 373 (4th Cir. 2001).

139. *Id.* at 385-86.

140. 29 C.F.R. § 825.305(a) (2001).

141. *Id.*

142. *See id.* § 825.306.

143. *Id.* § 825.307(a).

144. *Id.* § 825.307(a)(2). In addition, the employer must reimburse the employee for any incidental travel expenses incurred by the employee in getting additional medical opinions. *Id.* § 825.307(e).

145. *Id.* § 825.307(a)(2).

146. *Id.* § 825.307(c).

147. *Id.*

148. *Id.*

149. *Id.* § 825.307(a)(2).

150. *Id.* § 825.307(d).

In *Rhoads*, Lori Denise Rhoads (“Rhoads”) was a financial analyst for Standard Federal Savings Association (“SFSA”).<sup>151</sup> She “suffer[ed] from asthma and related migraine headaches—conditions exacerbated by exposure to cigarette smoke.”<sup>152</sup> After beginning work at one of SFSA’s banks, “Rhoads [immediately] began feeling the negative effects from breathing co-workers’ secondhand smoke.”<sup>153</sup> Although SFSA requested that their employees stop smoking on company premises “out of professional courtesy and human kindness,” it was still unable to fully control or eliminate smoking by its employees.<sup>154</sup> Due to this fact, Rhoads was forced to seek periodic medical treatment for various medical problems and allowed by SFSA administrators to “take lengthy absences from work.”<sup>155</sup> Finally, SFSA officials “arranged for her to work from home to avoid exposure to secondhand smoke.”<sup>156</sup>

While working at home, Rhoads was transferred to another of SFSA’s operations centers.<sup>157</sup> Shortly after her transfer, SFSA officials discovered that Rhoads was being allowed to work from home and asked her to report to the operations center for work on September 1.<sup>158</sup> On September 1, instead of reporting to work, Rhoads called her immediate supervisor at SFSA and informed him that she could not report to work because she was ill and her doctor had advised her not to report to work for the rest of the week.<sup>159</sup> Following approximately two weeks of discussion between SFSA and Rhoads concerning when she would return to work, a senior official at SFSA threatened her with disciplinary action if she did not report to work by September 13.<sup>160</sup> When Rhoads did not report to work on September 13, she was terminated on September 15 “for refusing to return to work for ten con-

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151. 257 F.3d 373, 377 (4th Cir. 2001).

152. *Id.*

153. *Id.*

154. *See id.* (quoting an internal company memorandum).

155. *Id.* Rhoads “sought medical attention for recurring bouts of bronchitis, pneumonia, severe lung infections, and cluster migraine syndrome.” *Id.*

156. *Id.*

157. *Id.*

158. *Id.* Her retirement was scheduled to conclude with the effective date of a “smoke-free workplace rule.” *Id.*

159. *Id.* at 378.

160. *Id.*

secutive days “[w]ithout supervisory approval and in direct defiance of” [supervisory] instructions.”<sup>161</sup>

Rhoads filed suit in federal court alleging that SFSA had violated her rights under the FMLA.<sup>162</sup> At trial, a jury determined that SFSA had not violated any of her FMLA rights because “she did not suffer from an FMLA-qualifying ‘serious health condition.’”<sup>163</sup> Rhoads appealed the lower court’s decision to the Fourth Circuit claiming that “she should not have been required to prove that she was afflicted with such a condition and, regardless, the FDIC waived any right to contest this issue because SFSA failed to follow the FMLA’s ‘second opinion’<sup>164</sup> procedures upon receipt of her physician’s certification of her ailments.”<sup>165</sup> The Fourth Circuit affirmed the decision of the lower court and held that an employer’s failure to request a second opinion will not preclude the employer from later challenging whether the employee actually suffered from a “serious health condition,” entitling the employee to FMLA leave.<sup>166</sup>

## B. Patient Rights

In 2001, the United States Supreme Court significantly strengthened patient rights in *Ferguson v. City of Charleston*.<sup>167</sup> In *Ferguson*, patients challenged the medical practices used at the Medical University of South Carolina (“MUSC”).<sup>168</sup> In 1989, MUSC, a public hospital, the Charleston police department, and the Charleston prosecutor’s office formed a joint task force and developed a policy requiring MUSC maternity patients meeting certain criteria to submit to urinalysis drug testing for cocaine.<sup>169</sup> This drug testing policy was in response to “an apparent increase in the use of cocaine by patients who were receiving prenatal

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161. *Id.* at 379 (first alteration in original).

162. *Id.*

163. *Id.* at 381.

164. For the second opinion procedures refer to 29 U.S.C. § 2613(c)–(d) (2000).

165. *Rhoads*, 257 F.3d at 381. Rhoads’s doctor wrote a letter certifying her medical condition on September 13, but failed to fax it to SFSA until September 16, one day after her termination. *Id.* at 378–79.

166. *See id.* at 386.

167. 532 U.S. 67 (2001).

168. *Id.* at 73.

169. *Id.* at 70–72. Those criteria can be found at note four of the opinion. *Id.* at 72 n.4.



treatment” and the result of hysteria created by the largely unfounded national “crack baby” epidemic of the late 1980s.<sup>170</sup>

Under this drug testing policy, doctors and other hospital personnel selected, on a discretionary basis, predominately low-income African-American expectant mothers who had not come in earlier for prenatal care or who underwent incomplete prenatal care for testing.<sup>171</sup> These women were then induced to provide urine samples that were tested for cocaine under procedures that would yield admissible evidence at trial.<sup>172</sup> Originally, if a patient tested positive for cocaine, hospital officials coordinated with Charleston police to have the woman arrested at the hospital.<sup>173</sup> However, in 1990, the program was modified to give women who tested positive for cocaine the opportunity to enter a drug treatment program instead of being arrested.<sup>174</sup>

Plaintiffs filed suit against the City of Charleston, hospital officials, and various law enforcement officials involved in the drug-testing program.<sup>175</sup> Plaintiffs were ten women, most of whom were African-American, who tested positive for cocaine use while receiving prenatal care at MUSC.<sup>176</sup> They asserted claims for injunctive relief and damages on a number of theories.<sup>177</sup> Primarily, they challenged the drug testing policy on grounds that “warrantless and nonconsensual drug tests conducted for criminal investigatory purposes were unconstitutional searches” in violation of their rights under the Fourth and Fourteenth Amendments.<sup>178</sup>

The district court found that the petitioners had consented to the searches and upheld the drug testing policy and arrests.<sup>179</sup> On appeal, the United States Court of Appeals for the Fourth Circuit affirmed the lower court’s decision.<sup>180</sup> The Fourth Circuit held

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170. *Id.* at 70, 70 n.1; see also Ellen Goodman, *The Myth of the Crack Babies*, THE BOSTON GLOBE, Jan. 12, 1992, at 69.

171. See Brief for Petitioners at 1–2, *Ferguson v. City of Charleston*, 532 U.S. 67 (2001) (No. 99-936).

172. *Ferguson*, 532 U.S. at 72.

173. *Id.*

174. *Id.*

175. *Id.* at 73.

176. *Id.*

177. *Ferguson v. City of Charleston*, 86 F.3d 469, 475 (4th Cir. 1999).

178. *Ferguson*, 532 U.S. at 73.

179. *Ferguson*, 186 F.3d at 476.

180. *Id.* at 484.

that the hospital's actions were constitutional because they were covered by the "special needs" exception to the Fourth Amendment warrant and probable cause requirements.<sup>181</sup> The Supreme Court granted certiorari to consider the issue of "whether the interest in using the threat of criminal sanctions to deter pregnant women from using cocaine can justify a departure from the general rule that an official nonconsensual search is unconstitutional if not authorized by a valid warrant."<sup>182</sup>

In a majority opinion written by Justice Stevens, the Court overturned the Fourth Circuit's ruling and held that a state hospital's performance of a diagnostic test to obtain evidence of a patient's criminal conduct for law enforcement purposes is an unreasonable search if the patient has not consented to the procedure.<sup>183</sup> The Court further held that the interests in using the threat of criminal sanctions to deter pregnant women from using cocaine cannot justify a departure from the general rule that an official nonconsensual search is unconstitutional if not authorized by a valid warrant.<sup>184</sup> Finally, the Court bolstered patient's rights by noting that when state hospital employees obtain evidence from patients to give to law enforcement for criminal purposes, "they have a special obligation to make sure that the patients are fully informed about their constitutional rights."<sup>185</sup>

On June 20, 2002, the United States Supreme Court affirmed the Seventh Circuit's holding that ERISA<sup>186</sup> does not preempt the

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181. *Id.* at 476–84. The "special needs" exception was first articulated in *New Jersey v. T.L.O.*, 469 U.S. 325, 351 (1985) (Blackmun, J., concurring). The "special needs" exception allows the state to disregard the customary probable cause and warrant requirements of the Fourth Amendment when two criterion are met. *T.L.O.*, 469 U.S. at 351 (Blackmun, J., concurring). First, the state must demonstrate that it has some "special need" beyond normal law enforcement activities that make the search or seizure necessary. *See id.* (Blackmun, J., concurring). Second, the state must show that its "special need" cannot be achieved or would be frustrated if a court forced it to abide by the usual probable cause and warrant requirements. *See id.* at 353 (Blackmun, J., concurring). If these two conditions are met by the state, the court then uses a balancing test to measure the state's interests against the person's privacy rights. *Id.* (Blackmun, J., concurring). If the state's interests outweigh the person's privacy interests, the state's search or seizure will be affirmed as constitutional—even in the absence of probable cause or a warrant. *See, e.g.*, *Nat'l Treasury Union v. Von Raab*, 489 U.S. 656, 665–66 (1989).

182. *Ferguson*, 532 U.S. at 70.

183. *Id.* at 85.

184. *Id.* at 86.

185. *Id.* at 85.

186. The Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001–1461 (2000).

Illinois HMO Act, which provides for independent review of disputes between health plans, such as Health Maintenance Organizations (“HMOs”), and primary care physicians.<sup>187</sup> Consequently, HMOs cannot refuse to cover health care services deemed to be medically necessary by the independent reviewer under the Illinois law.<sup>188</sup> The case, involving services provided by a Virginia physician, should have far-reaching implications for other state laws regulating managed care organizations’ denial of benefit practices.<sup>189</sup>

### C. *Payment Issues*

In early 2001, the United States Court of Appeals for the Fourth Circuit decided two cases involving Medicaid and Medicare payment issues: *HCMF Corp. v. Allen*<sup>190</sup> and *INOVA Alexandria Hospital v. Shalala*.<sup>191</sup> In *HCMF*, several related corporate entities that operate nursing homes in Virginia (collectively, “Plaintiffs”) brought suit under § 1983 against the Virginia Department of Medical Assistance Services (“DMAS”), which administers the Medicaid program in Virginia.<sup>192</sup> The Plaintiffs alleged that DMAS had violated their federal statutory right “to ‘reasonable and adequate’ rates of reimbursement under the Medicaid program.”<sup>193</sup>

The Plaintiffs based this contention on the federal Medicaid requirement contained in the Boren Amendment,<sup>194</sup> which requires each state to assure the federal government that under its Medicaid program the state will reimburse nursing facilities at rates that are “reasonable and adequate.”<sup>195</sup> Although the Plaintiffs acknowledged that the Boren Amendment was repealed by Con-

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187. *Rush Prudential HMO, Inc. v. Moran*, 122 S. Ct. 2151, 2171 (2002).

188. *Id.* at 2158. Virginia has its own independent review statute. *See* VA. CODE ANN. §§ 32.1-137.7 to -137.17 (Repl. Vol. 2001 & Cum. Supp. 2002).

189. *Rush Prudential HMO, Inc.*, 122 S. Ct. at 2157.

190. 238 F.3d 273 (4th Cir. 2001).

191. 244 F.3d 342 (4th Cir. 2001).

192. *HCMF*, 238 F.3d at 275.

193. *Id.* The “reasonable and adequate” language is derived from the statute. *See* 42 U.S.C. § 1396a(a)(13)(A) (2000).

194. *HCMF*, 238 F.3d at 276.

195. 42 U.S.C. § 1396a(a)(13)(A) (2000); *see also* *Wilder v. Va. Hosp. Ass’n*, 496 U.S. 498, 524 (1990) (establishing rights of hospitals and nursing homes to sue for inadequate payments prior to Boren Amendment repeal).

gress effective October 1, 1997,<sup>196</sup> they argued that a December 1997 policy letter from the United States Health Care Financing Administration (“HCFA”) continued the “reasonable and adequate” standard from the Boren Amendment.<sup>197</sup> The Plaintiffs pointed out to the court that HCFA’s policy letter stated:

“states are not required to subject their existing rates to a public process to the extent that those existing rates were validly determined in accordance with legal standards in effect prior to October 1, 1997.” [Plaintiffs] urged that because DMAS had not adopted new rates pursuant to a public process since October 1, 1997, HCFA’s letter effectively continued the “reasonable and adequate” standard of the Boren Amendment for DMAS’ rates.<sup>198</sup>

Therefore, “[Plaintiffs] alleged that the letter established a ‘federal policy [that] creates federal rights enforceable’ under § 1983.”<sup>199</sup>

The Fourth Circuit held that the “[Plaintiffs’] claim [was] not cognizable regardless of whether the HCFA letter properly authorize[d] the application of Boren Amendment standards to the payments at issue here.”<sup>200</sup> The court based its holding on the rationale that “a formal regulation cannot by itself give rise to a federal right enforceable under § 1983.”<sup>201</sup> Further, the court noted that “[a] policy letter has even less legal stature than a regulation.”<sup>202</sup>

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196. See Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4711, 111 Stat. 251, 507-08 (amended 1997).

197. See *HCMF*, 238 F.3d at 276; see also *Concourse Rehab. and Nursing Ctr. Inc. v. Whalen*, 249 F.3d 136, 140 (2d Cir. 2001) (applying Boren standards to calculate claims for rehabilitative nursing services costs under rates adopted before effective date of the Balanced Budget Act); *Fla. Ass’n of Rehab. v. Fla. Dept. of Health*, 225 F.3d 1208, 1217 (11th Cir. 2000) (finding that the Boren Amendment continues to govern payment disputes for services furnished before effective date of Balanced Budget Act); *Exeter Mem. Hosp. v. Belshe*, 145 F.3d 1106 (9th Cir. 1998) (recognizing a continuing right of hospitals as of the effective date of the Boren Amendment repeal to bring a section 1983 action to seek declaratory and injunctive relief claiming violation of Boren Amendment standards); *United Hosps. Med. Ctr. v. Waldman*, 793 A.2d 1, 5 (N.J. Super. Ct. App. Div. 2002) (recognizing hospital’s right to challenge hospital rate reductions that took place before the implementation of the Balanced Budget Act for failure to satisfy the Boren Amendment standards).

198. *HCMF*, 238 F.3d at 276 (quoting *Children’s Hosp. & Health Ctr. v. Belshe*, 188 F.3d 1090, 1095 (9th Cir. 1999)).

199. *Id.* (second alteration in original).

200. *Id.* at 277.

201. *Id.*; accord *Smith v. Kirk*, 821 F.2d 980, 984 (4th Cir. 1987).

202. *HCMF*, 238 F.3d at 277; accord *Christensen v. Harris County*, 529 U.S. 576 (2000). Applying the rational basis test under an Equal Protection analysis, the Fourth

In *Inova Alexandria Hospital v. Shalala*,<sup>203</sup> Inova Alexandria Hospital ("the Hospital"), a Medicare provider, belatedly sought reimbursement for the services rendered to Medicare beneficiaries during 1994.<sup>204</sup> In August of 1996, Trigon, the hospital's paying agent, disallowed about \$290,000 of the hospital's requested reimbursement for the fiscal year of 1994.<sup>205</sup> In January 1997, the Hospital filed a timely administrative appeal of Trigon's determination to the Provider Reimbursement Review Board ("the Board") of the U.S. Department of Health and Human Services ("HHS").<sup>206</sup> Upon filing the appeal in July, 1997, the Board sent a letter to the hospital detailing a schedule for submission of "position papers."<sup>207</sup> The Board's letter explicitly stated that "preliminary position papers were due by November 1, 1998, and final papers by February 1, 1999."<sup>208</sup> The Board sent a reminder letter to the Hospital in September 1997 that repeated the briefing schedule and warned that failure to meet the deadlines would result in dismissal of the appeal.<sup>209</sup>

The Hospital did not file either a preliminary or a final position paper.<sup>210</sup> It claimed that these failures were the result of "internal confusion" at the Hospital caused by Inova Health System's acquisition of the Hospital, an event that had occurred "after the appeal was filed but before the position papers were due."<sup>211</sup> The Board dismissed the appeal because the Hospital failed to file the proper papers on time.<sup>212</sup> Following the dismissal of the appeal, the hospital challenged the Board's decision by suing the HHS in federal court.<sup>213</sup> The district court reviewed the Board's decision to dismiss the appeal and granted summary judgment to HHS.<sup>214</sup>

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Circuit also upheld a Virginia rule which provides for the reimbursement of nursing home interest expenses at the reconstruction financing bonds interest rate rather than the higher rates of a mortgage obtained by the nursing home to secure the bonds. *HCMF*, 238 F.3d at 277.

203. 244 F.3d 342 (4th Cir. 2001).

204. *Id.* at 345.

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

209. *Id.*

210. *Id.*

211. *Id.*

212. *Id.*

213. *Id.* at 346.

214. *Id.*

Following the district court's ruling, the Hospital appealed to the Fourth Circuit, arguing that in dismissing the appeal, the Board: (1) "violated the Due Process Clause"; (2) "violated the hospital's right to a hearing under the Medicare Act"; and (3) violated the Administrative Procedure Act ("APA") because the "Boards' dismissal rule is invalid because it was not promulgated under the APA's notice and comment procedure."<sup>215</sup>

On appeal, the Fourth Circuit was faced with two questions: "(1) whether the hospital is entitled to judicial review and (2) whether, if judicial review is available, the Board acted properly in dismissing the hospital's administrative appeal."<sup>216</sup> In regard to the first question, the court held that "there are judicially manageable standards for reviewing each of the Hospital's claims. As a result, there is no bar to judicial review because none of the Hospital's claims are 'committed to agency discretion by law.'"<sup>217</sup> In regard to the second issue, the Fourth Circuit found that the district court correctly determined that the Board can only dismiss an administrative appeal "if the provider cannot show excusable neglect for its failure to file a timely position paper."<sup>218</sup> Therefore, since the hospital failed to show "excusable neglect," no material facts were in dispute and the district court's award of summary judgment to HHS was proper.<sup>219</sup>

#### D. *Certificate of Public Need*

The primary COPN case during 2001–2002 was *Chippenham & Johnston-Willis Hospitals, Inc. v. Peterson*.<sup>220</sup> The case involved a hospital replacement application to replace a 153-bed hospital

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215. *Id.* at 347.

216. *Id.* at 345.

217. *Id.* at 348 (quoting 5 U.S.C. § 701(a) (2000)).

218. *Id.*

219. *Id.* at 351–52.

220. 36 Va. App. 469, 553 S.E.2d 133 (Ct. App. 2001). The Supreme Court of Virginia subsequently denied certiorari in this matter. Bob Rayner, *Hospital Plans Hit Snag: Court Sets Stage for Legal Challenge*, RICH. TIMES-DISPATCH, April 13, 2002 at A1. The case has been remanded for further proceedings not inconsistent with the Virginia Court of Appeals decision. *Id.*

with a 130-bed facility in an adjacent jurisdiction.<sup>221</sup> The existing facility was located in the City of Richmond.<sup>222</sup>

Following regional review, the Central Virginia Health Planning Agency (the "CVHPA") recommended conditional approval of Stuart Circle Hospital's replacement at St. Francis Hospital.<sup>223</sup> The Commissioner's staff recommended against the project, leading to an informal fact-finding conference.<sup>224</sup> Chippenham & Johnston-Willis Hospitals, Inc. ("Chippenham") sought participation in the conference and was denied such participation for lack of good cause standing.<sup>225</sup> Chippenham appealed to the Chesterfield Circuit Court, which held that Chippenham demonstrated no substantial mistake of law on CVHPA's part.<sup>226</sup> Chippenham then appealed to the Virginia Court of Appeals.<sup>227</sup> The court of appeals found that Chippenham demonstrated that the CVHPA had made a material mistake of fact or law in its recommendation, found good cause standing, and remanded the matter for further proceedings.<sup>228</sup>

Upon remand, Chippenham will have an opportunity to have its arguments considered by the new Commissioner.<sup>229</sup> Such arguments will delay, if not reverse, the Commissioner's prior approval decision.

### E. *Access to Medical Records*

Recently in Virginia, courts have decided cases of note involving access to medical records. These cases are *Virmani v. Novant Health, Inc.*,<sup>230</sup> *Green v. Richmond Department of Social Services*,<sup>231</sup> and *United States v. Sutherland*.<sup>232</sup>

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221. *Peterson*, 36 Va. App. at 482, 553 S.E.2d at 139.

222. *Id.* at 474, 553 S.E.2d at 135. The existing hospital at the time of the COPN decision, Stuart Circle Hospital, subsequently closed.

223. *Id.*

224. *Id.* at 474-75, 553 S.E.2d at 135-36.

225. *Id.*

226. *Id.* at 475, 553 S.E.2d at 136.

227. *Id.*

228. *Id.* at 482-83, 553 S.E.2d at 140.

229. *Id.*

230. 259 F.3d 284 (4th Cir. 2001).

231. 35 Va. App. 682, 547 S.E.2d 548 (Ct. App. 2001).

232. 143 F. Supp. 2d 609 (W.D. Va. 2001).

In *Virmani*, the United States Court of Appeals for the Fourth Circuit was faced with the decision of whether or not to recognize a privilege for physician peer review materials.<sup>233</sup> A physician (“Virmani”) alleged that Presbyterian Hospital (“Presbyterian”) discriminated against him when Presbyterian terminated Virmani’s privileges.<sup>234</sup> During discovery, Virmani attempted to obtain “all peer review records related to all reviews of physicians for any reason, during the twenty years preceding his request.”<sup>235</sup> Presbyterian moved for a protective order, arguing that peer review materials were privileged under the Federal Rules of Evidence and North Carolina law.<sup>236</sup> Refusing to recognize a privilege for medical peer review materials, the district court denied Presbyterian’s motion for a protective order.<sup>237</sup>

On appeal to the Fourth Circuit, Presbyterian argued “that the district court erred in refusing to recognize a privilege for documents related to medical peer review proceedings.”<sup>238</sup> The court held “that the interest in obtaining probative evidence in an action for discrimination outweighs the interest that would be furthered by recognition of a privilege for medical peer review materials.”<sup>239</sup> Therefore, in declining to recognize a privilege for medical peer review materials, the court affirmed the district court’s order.<sup>240</sup>

In *Green v. Richmond Department of Social Services*,<sup>241</sup> the Virginia Court of Appeals dealt with the issue of denying a father access to his daughter’s medical records.<sup>242</sup> Robert B. Green, Sr., (“Green”) was serving an eighteen-year sentence in prison for marital assault and several other convictions.<sup>243</sup> Green had one daughter.<sup>244</sup> Pursuant to a court order, Green’s daughter was in the custody of the Department of Social Services (the “Depart-

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233. *Virmani*, 259 F.3d at 286.

234. *Id.* at 284.

235. *Id.* at 286.

236. *Id.*

237. *Id.*

238. *Id.*

239. *Id.* at 293.

240. *Id.*

241. 35 Va. App. 682, 547 S.E.2d 548 (Ct. App. 2001).

242. *Id.* at 683, 547 S.E.2d at 548.

243. *Id.* at 683–84, 547 S.E.2d at 548. Green will be eligible for parole in 2004. *Id.*

244. *See id.*



ment").<sup>245</sup> From prison, Green requested copies of his daughter's medical records.<sup>246</sup>

In response to Green's request, the Department filed a motion in Juvenile and Domestic Relations District Court.<sup>247</sup> The district court judge found "good cause to deny Green access to his daughter's medical, hospital, and other health records, except to the extent authorized by his daughter's treating physician."<sup>248</sup> Green appealed this decision to the circuit court.<sup>249</sup> In the circuit court, the judge found that Green's access to his daughter's medical records would interfere with her disclosures to her therapist, would be harmful to her, and was "not in her best interests."<sup>250</sup> Therefore, the judge denied Green access to his daughter's hospital, medical, and other health records.<sup>251</sup>

On appeal, the Virginia Court of Appeals noted that a parent can be denied access to his child's medical records for "good cause shown."<sup>252</sup> The court further noted that the "testimony of the therapist and the report of the psychiatrist are unrebutted by any evidence explaining how Green's daughter, who needs psychological treatment, would benefit or progress in resolving issues if Green had access to her medical records."<sup>253</sup> Therefore, the lower court's decision finding good cause in denying Green access to his daughter's medical records, was affirmed.<sup>254</sup>

In *United States v. Sutherland*,<sup>255</sup> the United States District Court for the Western District of Virginia denied a hospital's motion to quash the government's subpoena to compel the production of certain hospital pharmacy records in a case involving a de-

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245. *Id.*

246. *Id.* at 684, 547 S.E.2d at 549.

247. *Id.*

248. *Id.*

249. *Id.*

250. *Id.* at 686, 547 S.E.2d at 550.

251. *See id.* at 686, 547 S.E.2d at 549.

252. *Id.* at 686, 547 S.E.2d at 550. The court quoted from VA. CODE ANN. § 20-124.6 (Repl. Vol. 2000). This section of the Virginia Code reads: "Notwithstanding any other provision of law, neither parent, regardless of whether such parent has custody, shall be denied access to the academic, medical, hospital or other health records of that parent's minor child unless otherwise ordered by the court for *good cause shown.*" VA. CODE ANN. § 20-124.6 (Repl. Vol. 2000) (emphasis added).

253. *Green*, 35 Va. App. at 687, 547 S.E.2d at 551.

254. *Id.*

255. 143 F. Supp. 2d 609 (W.D. Va. 2001).

pendant doctor accused of the unlawful distribution and dispensing of controlled substances.<sup>256</sup> Although the district court judge denied the hospital's motion, the judge recognized a strong federal policy to protect the privacy of patient medical records.<sup>257</sup> The court required the government to provide written notice to each patient involved and to allow each patient the opportunity to object to the medical record disclosure.<sup>258</sup>

#### F. *Tort Claims and Professional Liability Insurance*

Medical malpractice claims and awards in the United States have increased dramatically.<sup>259</sup> Between 1993 and 1999, the average medical malpractice award granted by juries grew eighty-four percent from \$1.9 to \$3.5 million.<sup>260</sup> The medical malpractice plaintiff's bar's overwhelming success has caused insurers that transact professional liability coverage in the medical field to scramble for survival.<sup>261</sup>

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256. *Id.* at 610.

257. *Id.* at 612. The judge held that a Virginia statute, VA. CODE ANN. § 32.1-127.1:03(A) (Cum. Supp. 2000), which recognizes a patient's right of privacy in the content of his/her medical record and sets forth procedural requirements for submitting a subpoena for medical records, was inapplicable. *Sutherland*, 143 F. Supp. 2d at 611. Because this case was a federal criminal matter, state procedural law did not apply. However, the judge explained that the Federal Health Insurance Portability and Accountability Act privacy standards restrict a health care provider's disclosure of a patient's medical records and indicate a strong federal policy to protect the patient's privacy in the content of the patient's health information. *Id.* at 612.

258. *Sutherland*, 143 F. Supp. 2d at 612. The court held that the government [must] provide written notice prior to production of the subpoenaed records to the last known address of each individual whose records are sought under the subpoena. The notice must inform the individual that he or she may object to disclosure within five business days of the date the notice was mailed. If the government objects to giving notice, it must show cause before this court as to why notice would be unduly burdensome or prejudicial in a particular instance. *Id.* at 613.

259. See Joseph B. Treaster, *Malpractice Rates are Rising Sharply; Health Costs Follow*, N.Y. TIMES, Sept. 10, 2001, at A1.

260. *Id.* In Virginia, awards in medical malpractice claims filed against health care providers are capped. VA. CODE ANN. § 8.01-581.15 (Repl. Vol. 2000 & Cum. Supp. 2002). By July 1, 2002, the maximum recovery limit in medical malpractice cases was set at \$1.65 million. *Id.* This amount shall increase on each July 1 thereafter by \$50,000 per year. *Id.* However, the annual increase on July 1, 2007 and the annual increase on July 1, 2008 shall be \$75,000 per year. *Id.*

261. See Treaster, *supra* note 259.

Some insurers have even started to look elsewhere for more commercially viable business.<sup>262</sup> Faced with a 2001 underwriting loss of nearly \$1 billion, the nation's largest malpractice underwriter, St. Paul, announced in December 2001 that it would no longer renew professional liability policies for 42,000 physicians nationwide.<sup>263</sup> In February 2002, MIIX Group Inc., a New Jersey-based insurer, decided to stop writing medical malpractice coverage in five states, including Virginia.<sup>264</sup>

Other insurers have attempted to cope with the financial strain by raising premium prices for health care providers. For example, in July 2001 Virginia's Reciprocal of America asked state Insurance Departments for a single rate increase of 150% for professional liability coverage.<sup>265</sup>

Liability insurance rate increases have been especially difficult for our nation's long-term care industry. Insurance companies that underwrite nursing homes generally provide coverage to facilities nationwide and distribute costs evenly over nursing homes throughout the country. Consequently, the high costs for negligence claims against long-term care providers in one state causes liability insurance premiums to skyrocket for nursing homes in other states.

An ambiguous statute in Florida started an avalanche of resident's rights lawsuits in the late 1980s that continued through the 1990s.<sup>266</sup> Florida's recent surge of settlements and verdicts involving long-term care providers has taken its toll on Virginia nursing homes. For this reason, the Virginia Health Care Asso-

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262. See Terry E. Tyrpin, *Tort Reform Would Cure Med Mal Crisis*, NAT. UNDERWRITER: PROP. & CAS./RISK & BENEFITS MGMT. ED., Jan. 28, 2002, at 25.

263. Tom Gorman, *Physicians Fold Under Malpractice Fee Burden*, L.A. TIMES, Mar. 4, 2002, at A1.

264. Neil Versel, *MIIX to End Some Malpractice Sales*, BUS. INS., Mar. 25, 2002, at 14. MIIX Group, Inc. stopped writing medical malpractice liability coverage in Illinois, Massachusetts, Ohio, Texas, and Virginia. *Id.* This decision came after the New Jersey-based insurer reported a 2001 net loss of \$157.6 million, which was much higher than the net loss of \$36.5 million from the year before. *Id.*

265. Chicago's Continental Casualty Company also asked for a 150% rate increase in July 2001. Jake Bleed, *Arkansas Doctors Feel the Pinch from Medical Rising Malpractice Insurance*, ARKANSAS DEMOCRAT-GAZETTE, Feb. 4, 2002. Professional Advocate Insurance Company in Maryland asked for a 100% increase. *Id.*

266. Karen L. Goldsmith, *Florida Long Term Care Tort Reform 2001: The Good, the Bad, & the Ugly*, HEALTH LAW. NEWS Dec. 2001, at 8. Only ten percent of the nursing home beds in the United States are in Florida. *Id.* However, Florida accounts for twenty-one percent of total nursing home claims. *Id.*

ciation is searching for a creative solution to the crisis. Some Virginia long-term care providers have started to enter into binding arbitration agreements with their residents upon admission to their facilities.<sup>267</sup> The nursing homes hope that this will encourage insurers to lower their liability insurance premiums.

#### IV. REGULATORY DEVELOPMENTS

##### A. Patient Safety

Beginning with the 1999 Institute of Medicine (IOM) study,<sup>268</sup> there has been increased interest at both the national and state levels in patient safety and efforts to support patient safety and medical/health care error reduction. In January 2001, the Joint Commission for the Accreditation of Health Organizations came out with its own manual revisions addressing sentinel events and how to address them in facilities through development of root cause analyses.<sup>269</sup> Other national organizations prepared their own error reduction reports designed to support the IOM study and push patient safety and error reduction efforts into the forefront.<sup>270</sup>

The Commonwealth has established its own organization through the coordination and assistance of health care stakeholders such as the Virginia Hospital and Health Care Association and the Medical Society of Virginia. This organization, the Virginians Improving Patient Care and Safety (VIPCS), has

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267. Agreements to arbitrate medical malpractice claims are valid and enforceable in Virginia. However, a medical malpractice arbitration agreement is only valid if its terms allow the resident to withdraw from the arbitration agreement at any time within a period of at least sixty days after the termination of health care. VA. CODE ANN. § 8.01-581.12 (Repl. Vol. 2000).

268. INSTITUTE OF MEDICINE, COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 1999), available at [http://www.nap.edu/html/to\\_err\\_is\\_human/](http://www.nap.edu/html/to_err_is_human/) (last visited Oct. 3, 2002).

269. See JOINT COMM'N ON THE ACCREDITATION OF HEALTH CARE ORGS., *REVISIONS TO JOINT COMM'N STANDARDS IN SUPPORT OF PATIENT SAFETY AND MED./HEALTH CARE ERROR REDUCTION* (2001), available at <http://www.jcaho.org/accredited+organizations/hospitals/standards/revisions/index.htm> (last visited Oct. 4, 2002).

270. See, e.g., INSTITUTE FOR SAFE MEDICATION PRACTICES, *ISMP MEDICATION SAFETY ALERT!, PLEASE DON'T SLEEP THROUGH THIS WAKE-UP CALL* (May 2, 2001) (addressing handwriting and symbol errors that could lead to potential hazards in treatment), available at <http://www.ismp.org/MSAarticles/wakeupcall.html> (last visited Oct. 4, 2002).

met several times and is working towards collaboration of best practice guidelines drawing from both health care and non-health care sources.<sup>271</sup> The Virginia General Assembly supported the fledgling VIPC&S coalition by expanding confidentiality and immunity protections to patient safety organizations.<sup>272</sup>

### B. *Emergency Medical Treatment and Active Labor Act*

After two years of stricter interpretations of the Emergency Medical Treatment and Active Labor Act ("EMTALA"),<sup>273</sup> the Department of Health and Human Services signaled a change in interpretation that was more favorable to hospitals receiving patients in emergency medical conditions.<sup>274</sup> Proposed regulations modify the standards that apply to the definition of a "hospital" for EMTALA purposes.<sup>275</sup> The new regulations would define a hospital so as to limit the application of EMTALA regulations to outpatient centers.<sup>276</sup>

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271. See <http://www.vipcs.org> for more information regarding VIPC&S collaborations.

272. See VA. CODE ANN. § 8.01-581.17 (Cum. Supp. 2002).

273. See 42 U.S.C. § 1395dd (2000); Special Responsibilities of Medicare Hospitals in Emergency Cases, 42 C.F.R. § 489.24 (2001).

274. Under the statute and regulations, an emergency medical condition is defined as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in (i) placing the health of the individual . . . in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part.

42 U.S.C. § 1395dd(e)(1)(A) (2000). The EMTALA definition also encompasses certain pregnant woman experiencing contractions. *Id.* § 1395dd(e)(1)(B). If an emergency medical condition is found during a routine screening examination in a person who comes to the emergency department seeking treatment, the hospital has a statutory duty to treat, stabilize, and more appropriately transfer the patient. *Id.* § 1395dd(b)(1).

275. See Medicare Program: Changes to the Hospital Inpatient Prospective Payment Systems & Fiscal Year 2003 Rates, 67 Fed. Reg. 31,404 (May 9, 2002) (to be codified at 42 C.F.R. §§ 405, 412, 413, 482, 485, 489) (addressing EMTALA requirements through changes in outpatient prospective payment regulations). The same regulations address some of the concerns about the complex provider-based payment rules that will affect Medicare and Medicaid payment after October 2002 to outpatient centers typically billed as a part of a hospital. *Id.*

276. *Id.* at 31,404, 31,505-07 (limiting application of the EMTALA requirement to dedicated emergency departments); see also 42 C.F.R. § 489.24(a), (c) (2002). The regulations as proposed would also limit the applicability of EMTALA to inpatients only when the individual patient is found to have an emergency medical condition which has not been stabilized. See *id.* § 489.24(d)(2); see also *Smith v. Richmond Mem'l Hosp.*, 243 Va. 445, 416 S.E.2d 689 (1992) (ruling on a similar EMTALA issue).

One question raised by EMTALA legislation is the extent to which it affects the involuntary commitment process in Virginia.<sup>277</sup> A June 2001 Attorney General's opinion confirms that the federal EMTALA legislation does not preempt or conflict with civil commitments.<sup>278</sup> The Attorney General's opinion finds that while community services boards may designate the facility in which the person will be confined, the Board does not require a hospital to admit the person over its objection<sup>279</sup> in cases interpreting EMTALA requirements.<sup>280</sup>

### C. *Fraud and Abuse Issues*

Anti-fraud activities against health care providers are on the rise in Virginia and nationally. The number of fraud and abuse cases that have taken place in Virginia over the past year remains a secret, because the majority of fraud and abuse cases brought against health care organizations are settled quickly and quietly. Three fraud and abuse cases that affected Virginia providers in 2001 were HCMF Corporation,<sup>281</sup> Chippenham Associates, L.P.<sup>282</sup> and the CVS Corporation.<sup>283</sup>

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277. See VA. CODE ANN. §§ 37.1-67.01, -67.1 (Cum. Supp. 2002) (addressing emergency custody and temporary detention order requirements).

278. See Op. to Hon. Kenneth Stolle (June 28, 2001) (noting that Congress has stated its intent not to preempt any state law by passage of EMTALA, except where such law directly conflicts with the requirement of the Act); see also 42 U.S.C. § 1395dd(f) (2000).

279. See Op. to Hon. Kenneth Stolle, *supra* note 278. For additional regulations affecting EMTALA, see Medicare and Federal Healthcare Programs: Fraud and Abuse; Revisions & Technical Corrections, 67 Fed. Reg. 11,928, 11,935 (Mar. 18, 2002) (to be codified at 42 C.F.R. pts. 1001, 1003, 1005, 1008) (establishing, under 42 C.F.R. § 1003.106(a)(4)(iii), the possibility of enhanced penalties against health care providers for previous failures to follow EMTALA).

280. See *Williams v. United States*, 242 F.3d 169, 175-76 (4th Cir. 2001) (holding that Indian Hospitals operating under Indian Healthcare Improvement Act do not have the duty to provide emergency medical treatment to non-native Americans under EMTALA or North Carolina common law); *Petty John v. Mission St. Joseph's Health Sys., Inc.*, No. 01-1140, 2001 U.S. App. LEXIS 23423 (4th Cir. Oct. 30, 2001) (holding that testimony by expert witness does not establish that hospital staff actually knew of a patient's emergency medical condition within the meaning of EMTALA); see also *Prosise v. Foster*, 261 Va. 417, 422, 544 S.E.2d 331, 333 (2001) (holding that an on-call attending physician at teaching hospital does not have a duty of care to a patient when the physician is not contacted regarding the patient's condition or treatment).

281. FRAUD REPORT 2001, *supra* note 87. HCMF Corporation is a privately owned nursing home chain. *Id.* (see "Department of Justice: Criminal Division" section).

282. See Motion to Approve Settlement Agreement with Department of Justice, at 1-2, *In re Chippenham Assoc., L.P.*, United States Bankruptcy Court for the Middle District of

HCMF Corporation pled guilty to improperly claiming reimbursement for salaries and benefits paid to thirty HCMF owners, family members, and employees who allegedly performed little or no work or whose duties were unrelated to operating the eighteen nursing facilities.<sup>284</sup> Based on the plea, HCMF admitted to having submitted false and misleading documentation to Medicare and Medicaid auditors in order to justify its claims.<sup>285</sup> As part of its plea agreement, HCMF agreed to pay restitution in the amount of \$1.7 million, the chairman of HCMF's Board of Directors agreed to be jointly and severally liable for the restitution amount, and both the Chairman and Treasurer pled guilty to making false statements in connection with a federal health care program.<sup>286</sup> These pleas by officers will lead to exclusion and possible criminal penalties.<sup>287</sup>

In a recent settlement for its culpable conduct in operating a nursing facility that had poor Medicare and Medicaid survey results, Chippenham Associates, L.P., and its manager agreed to pay \$250,000 and spend another \$250,000 in facility improvements to keep the facility operational despite Chippenham Associates, L.P.'s bankruptcy.<sup>288</sup>

In the CVS case, the federal government alleged that CVS and Revco Drugstores, Inc., violated the federal False Claims Act<sup>289</sup>

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Tennessee, Case No. 301-00353 (Jan. 2002). Chippenham Associates, L.P. operated a single nursing facility in the Richmond area. *Id.* at 1.

283. Revco Drugstores Inc. is a pharmacy chain which was acquired by CVS in 1997. *Government Reaches \$4 Million Agreement With Pharmacy Chains*, 6 HEALTH CARE FRAUD LIT. REP., 2001, at 10 [hereinafter *Pharmacy Chains*].

284. See FRAUD REPORT 2001, *supra* note 87 (see "Department of Justice: Criminal Division" section).

285. *Id.*

286. *Id.*

287. *Id.*

288. See Settlement Agreement, attached as Exhibit A to January 4, 2002 Motion to Approve Settlement Agreement with Department of Justice, *In re* Chippenham Assoc., L.P., United States Bankruptcy Court for the Middle District of Tennessee, Case No. 301-00353 (Jan. 2002).

289. In an action involving the federal False Claims Act, the government or a *qui tam* relator must prove: (1) that the defendant presented, or caused to be presented, a claim to the federal government; (2) that the claim was false or fraudulent; and (3) that the defendant knew the claim was fraudulent. 31 U.S.C. § 3729(a)(1) (2000). According to the statutory definition, a "claim" includes "any request or demand . . . for money or property which is made to a contractor, grantee, or other recipient if the United States Government" either provides any portion or reimburses for any portion of the requested money or property. *Id.* § 3729(c). See also the Virginia Fraud Against Taxpayers Act, discussed *supra* Part II.F (addressing new Virginia laws mirroring Federal False Claims Act).

when the parties billed federal and state health care programs for medications in amounts exceeding what actually was given out to the patients.<sup>290</sup> CVS and Revco allegedly dispensed partial prescriptions to patients and billed the government programs for full prescriptions.<sup>291</sup> CVS agreed to settle the allegations by paying \$4 million to the federal government, the District of Columbia, and several participating states, including Virginia.<sup>292</sup> In addition, CVS was required to enter into an integrity agreement with the Department of Health and Human Services, Office of Inspector General (“OIG”).<sup>293</sup>

To avoid potential criminal actions or civil liabilities in fraud and abuse allegations, health care providers should, at the very least, be aware of the most recent advisory opinions issued by the OIG. Over the past year and a half, the OIG issued twenty-eight advisory opinions.<sup>294</sup> Additional resources are also available on the Office of Inspector General Web site,<sup>295</sup> including links to OIG compliance program advice for various health care providers, lists of persons no longer able to provide services to federal health care programs such as Medicare and Medicaid, and specific reports and information for health care providers and their counsel concerning regulatory activities of the OIG and changes in enforcement policies and practice.<sup>296</sup>

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290. See *Pharmacy Chains*, *supra* note 283, at 10.

291. *Id.*

292. *Id.* Participating states included Virginia, Alabama, Connecticut, Georgia, Illinois, Indiana, Kentucky, Maine, Maryland, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, and West Virginia. *Id.*

293. *Id.* A separate \$9 million settlement agreement with Eckerd Corp. was recently announced. See *Eckerd Settles Partial Fill Claims*, MEDICAL NEWSWIRE, May 31, 2002, at 2, available at <http://www.medicalnewswire.com/archive> (select “Medical Newswire”) (last visited Oct. 4, 2002).

294. The opinions were released between January 2001 and May 2002. They are available at <http://oig.hhs.gov/fraud/advisoryopinions/html> (last visited Oct. 4, 2002).

295. Web site of the Office of the Inspector General, at <http://oig.hhs.gov> (last visited Oct. 3, 2002).

296. See, e.g., Office of the Inspector General, Janet Rehnquist, An Open Letter to Health Care Providers (November 20, 2001) (responding to concerns raised by Congress and by individual health care providers of the False Claims Act enforcement tools and potential abuse and promoting voluntary compliance efforts by health care providers), available at <http://oig.hhs.gov/fraud/docs/openletters/openletter111901.htm> (last visited Oct. 4, 2002); see also U.S. GEN. ACCOUNTING OFFICE, GAO-02-546 DEPARTMENT OF JUSTICE FALSE CLAIMS ACT GUIDANCE (2002) (noting improvements in the efforts by the Department of Justice to ensure observance of guidelines that the DOJ issued to reform False Claims Act enforcement).



#### D. Medicaid Reimbursement

Many regulatory changes in Medicaid payments to providers have occurred in 2001 and 2002. Hospital reimbursement under the Diagnosis Related Group ("DRG")<sup>297</sup> system has been phased in over the last five years, with mixed reviews. A managed care payment system for hospital care has been phased in over the same time period.<sup>298</sup>

Payments to nursing facilities are now based upon the MDS<sup>299</sup> reports that each nursing facility makes on each Medicaid eligible resident.<sup>300</sup> This new system of payment for Medicaid operation costs follows a change in Medicaid payment for plant costs in nursing facilities over the last year.<sup>301</sup> Other changes in Medicaid payment to ambulances and other providers have also occurred over the last year.<sup>302</sup>

#### V. CONCLUSION

There is a joke that follows a late night television sequence on the top ten reasons to be a health care lawyer. One of the top ten reasons is "likes to fall asleep reading the Federal Register." In Virginia over the last two years, the same could be said about

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297. Diagnosis Related Groups, or DRGs, are the current payment methodology used by DMAS for hospitals still subject to fee for service payment. *See* REPORT OF THE JOINT LEGISLATIVE AUDIT & REVIEW COMM'N: MEDICAID INPATIENT HOSPITAL AND REIMBURSEMENT SYSTEM, H.R. Doc. No. 25, at 18 (2000).

298. The Medallion managed care initiative began January 1, 1996, and has expanded over recent years. *See* 12 VA. ADMIN. CODE §§ 30-120-260 to -350 (Cum. Supp. 2002). The program requires mandatory enrollment into a contracted health maintenance organization (HMO) for specific groups of Medicaid beneficiaries in Virginia. *See* 12 VA. ADMIN. CODE §§ 30-120-360 to -440 (Cum. Supp. 2002) (establishing DMAS Medallion II regulations).

299. MDS stands for "Minimum Data Set," a collection of information on each resident's activities of daily living skills at various points during a nursing facility stay.

300. *See* 12 VA. ADMIN. CODE § 30-40-90 to -200 (Cum. Supp. 2002) (proposing regulations to establish new payment system using resource utilization groups, or RUGs, for MDS Data for Medicaid payment purposes). There are recent studies of efforts to monitor use of MDS data for payment purposes in other states. *See* U.S. GEN. ACCOUNTING OFFICE, NURSING HOMES: FEDERAL EFFORTS TO MONITOR RESIDENT ASSESSMENT DATA SHOULD COMPLEMENT STATE ACTIVITIES, GAO-02-312 (2002) [hereinafter NURSING HOMES].

301. *See* 12 VA. ADMIN. CODE 30-90-29 to -120 (Cum. Supp. 2002) (establishing ten-year phase in of new plant cost reimbursement system).

302. *See* 12 VA. ADMIN. CODE 30-50-530 (Cum. Supp. 2002) (establishing ambulance payment regulations).

reading the Virginia Register. Much has occurred in health law, too much to condense into this note. While the authors wished to address new developments in mental health,<sup>303</sup> tax exemption status,<sup>304</sup> patient rights,<sup>305</sup> Durable Do Not Resuscitate Orders,<sup>306</sup> children's health insurance,<sup>307</sup> and the Americans with Disabilities Act (ADA)<sup>308</sup> in more detail, those matters will have to be left to future survey articles. However as this survey demonstrates, there have been significant developments in health care law generated by the Virginia General Assembly, the courts, and administrative agencies. Most of these changes alter at least one of the health policy principles of cost, quality, access, and equity. In addition, the article demonstrates the increasing role that federal reimbursement legislation is playing in health care law.

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303. See Rules and Regulations to Assure the Rights of Individuals Receiving Services from Providers of Mental Health, Mental Retardation and Substance Abuse Services, 12 VA. ADMIN. CODE 35-115-10 (Cum. Supp. 2002).

304. During the 2002 General Assembly Session, Virginia lawmakers passed Senate Bill 676, which amended the Virginia Code by adding section 17.1-513.01. See S.B. 676, Va. Gen. Assembly (Reg. Sess. 2002) (enacted as Act of Apr. 8, 2002, ch. 792, 2002 Va. Acts 332). This new law provides that assets of Virginia charitable corporations, such as a not-for-profit hospital, are deemed to be held in trust for the public, and that the Attorney General has the authority to act on behalf of the public with respect to such assets. *Id.*

305. See *Hospital COPs for Patients' Rights, Questions and Answers*, (Oct. 10, 2001) (providing guidance to hospitals on implementing interim final rule at 64 Fed. Reg. 36,070 (July 2, 1999)), at <http://www.cms.hhs.vo/cop/2bl.asp> (last visited Oct. 4, 2002); see also NURSING HOMES, *supra* note 300.

306. See VA. CODE ANN. § 54.1-2987.1 (Repl. Vol. 2002) (defining Durable Do Not Resuscitate Order ("DDNR")); see also 12 VA. ADMIN. CODE § 5-65-10 to -110 (Cum. Supp. 2002) (creating new regulations governing DDNR).

307. The Family Access to Medical Insurance Security Plan ("FAMIS"), formerly known as Virginia Children's Medical Security Insurance Plan ("VCMSIP"), provides health care coverage assistance for children through the age of eighteen who currently do not have health insurance and who meet the financial criteria set by the state. The program is financed by state and federal governmental funds, and is designed to cover children of working Virginia families that do not qualify for medical assistance under Medicaid and cannot afford private insurance. In recent years, the Commonwealth has made significant efforts to increase enrollment numbers for this program. See Family Access to Medical Insurance Security Plan, 12 VA. ADMIN. CODE 30-141-10 to -650 (Repl. Vol. 1996 & Cum. Supp. 2002); see also 12 VA. ADMIN. CODE 30-140-10 (Cum. Supp. 2002).

308. See *Chevron U.S.A. Inc. v. Echazabal*, 122 S. Ct. 2045 (2002) (defining "direct threat" under Americans with Disabilities Act to include an employer's refusal to hire or retain an employee at a job site due to the direct threat posed to the employee's health).

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