

# HEALTH CARE LAW: A SURVEY OF 1995 DEVELOPMENTS

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## INTRODUCTION

In company with most recent years, the 1995 Survey period was noteworthy for several important and instructive developments in the area of health care law. As this area of law continues to be affected frequently by swiftly changing judicial, legislative and regulatory pronouncements, this Survey emphasizes those issues of most immediate import or of most significant change to the health care law practitioner. While not all inclusive, this Survey presents a summary of important modifications or additions in areas of Medicare and Medicaid reimbursement, medical malpractice, tax exemption, physician recruitment, and fraud and abuse.

### I. MAJOR INDIANA HEALTH LAW DEVELOPMENTS—GENERAL

#### A. *Statutory Developments*

1. *Tax Exemptions for Hospital-Owned Physician Offices and Other Hospital-Owned Property.*—House Enrolled Act 1598 amended Indiana Code section 6-1.1-10-16 retroactive to March 1, 1995, to allow an exemption from property taxation if the property is owned or occupied by a non-profit hospital already granted tax exempt status. The hospital-owned property must be used for charitable purposes.<sup>1</sup> This law allows hospitals that own physician practices, offices or other hospital-owned property an exemption from property taxes by clarifying requirements for exemption that existed under prior law. However, the physician office, practice or other property must provide or support the provision of charity care or the provision of community benefits. Participation in the Medicaid or Medicare programs alone does not entitle an office, practice or other property described in the new legislation to an exemption from property taxes.<sup>2</sup>

2. *Managed Care Organizations may not Require Health Care Providers to Seek Accreditation in order to Enter into a Managed Care Contract.*—Senate Enrolled Act 560 amended Indiana Code section 27-8-10-3(2) to prohibit managed care organizations from refusing to enter into agreements with health care providers solely because the provider has not obtained accreditation from an accreditation organization. This is of particular significance to hospitals that are not accredited by the Joint Commission on the Accreditation of Healthcare

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1. IND. CODE § 6-1.1-10-16 (Supp. 1995).

2. *Id.* § 6-1.1-10-18.5(a)(1) & (2).

Organizations (JCAHO).<sup>3</sup> While most Indiana hospitals are accredited by the JCAHO, some choose not to seek JCAHO accreditation. Hospitals not accredited by JCAHO are surveyed for compliance with the Medicare and Medicaid Conditions of Participation<sup>4</sup> by the Indiana State Department of Health. However, this Act does not prohibit managed care organizations from implementing performance indicators as quality standards if they are developed by a private organization and do not rely upon a survey process (i.e., an accreditation entity) for which a fee is charged.<sup>5</sup>

3. *Organ and Tissue Donation.*—House Enrolled Act 1090 amended Indiana Code sections 29-2-16-1 to 29-2-16-28 concerning the provision of organ and tissue donation. One amendment provides that the hospital administrator or the hospital administrator's designee may ask any patient who is at least eighteen (18) years of age if the patient is an organ or tissue donor or if the patient desires to become an organ or tissue donor.<sup>6</sup> However, the governing board of the hospital must adopt procedures to determine when the administrator or administrator's designee may inquire of the patient as to organ or tissue donation.<sup>7</sup>

This amendment also states if at or near the time of death of a patient the hospital knows that:

- (1) an organ gift has or will be made;
- (2) the coroner has released a transplantation body part within the coroner's custody; or
- (3) the patient or individual in transit to the hospital is identified as an organ or tissue donor then the hospital shall notify the potential organ donee if the donee has been named and is known to the hospital. If the donee is not known to the hospital, the hospital shall notify an organ procurement organization.<sup>8</sup>

The amended law also requires the hospital, upon admission of an individual at or near the time of death, to make a reasonable search for information identifying whether the individual is an organ or tissue donor.<sup>9</sup> Finally, the hospital must establish agreements or affiliations for the coordination of organ procurement after consultation with other hospitals and organ procurement organizations.<sup>10</sup>

4. *Criminal Background Checks for Certified Nurse Aides and Other Employees of Licensed Health Facilities.*—House Enrolled Act 1752 added a class of health care personnel for which criminal background checks must be obtained

3. JCAHO accredits hospitals on a voluntary basis at the option of the hospital. Hospitals accredited by the JCAHO are deemed to be in compliance with the Medicare Conditions of Participation found at 42 C.F.R. pt. 482 (1994).

4. 42 C.F.R. pt. 482 (1994).

5. IND. CODE § 27-8-10-3(c)(1), (2) (Supp. 1995).

6. *Id.* § 29-2-16-10(b).

7. *Id.* § 29-2-16-10(c).

8. *Id.* § 29-2-16-13.

9. *Id.* § 29-2-16-14(a)(2).

10. *Id.* § 29-2-16-15.

prior to employment in a licensed health facility or hospital-based health facility.<sup>11</sup> Existing Indiana law for home health agencies requires criminal background checks to be obtained on prospective home health aides employed by a home health agency.

House Bill 1752 added a new section, Indiana Code section 16-28-13-4, which requires a health facility or hospital-based health facility to obtain criminal background checks for nurse aides or other unlicensed employees prior to employment in a health facility or a hospital-based health facility.<sup>12</sup> However, this new section of the Indiana Code does not require criminal background checks on health professionals licensed pursuant to Indiana Code section 25-1-9-3, which includes registered dietitians or volunteers who provide nursing or nursing-related services without pay.<sup>13</sup>

The individual may not be employed by the health facility or hospital-based health facility if the criminal background check reveals the nurse aide or unlicensed employee of the health facility or hospital-based health facility has been convicted of rape, criminal deviate conduct, exploitation of an endangered adult, failure to report battery, neglect or exploitation of an endangered adult, theft, conviction less than five years before the individual's employment date, murder, voluntary manslaughter within the previous five years, felony battery within the previous five years or a felony relating to controlled substances within the previous five years.<sup>14</sup> The health facility or hospital-based health facility must apply within three (3) business days from the date the person is employed as a nurse aide or other unlicensed employee for a copy of the prospective employee's limited criminal history from the Indiana Central Repository for Criminal History Information under Indiana Code section 5-2-5-1 or any other source allowed by law.<sup>15</sup>

The health facility or hospital-based health facility may require the nurses aide or other unlicensed employee to pay for the fee to obtain the criminal background history check or to reimburse fees incurred by the facility in obtaining the limited criminal background check.<sup>16</sup> Finally, an individual who is denied employment or is dismissed from employment due to information received pursuant to the limited criminal history background check has no cause of action based upon the denial of employment or dismissal from employment from the health facility or hospital-based health facility.<sup>17</sup>

This new statutory requirement could have a negative effect on health facilities and hospital-based health facilities because it may take a considerable amount of time to obtain the limited criminal background history check from the Indiana Central Repository thus delaying the processing of prospective employees who are

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11. *Id.* § 29-2-16-28.

12. *Id.* § 16-28-13-1(a) & (b).

13. *Id.* § 16-28-13-1(b).

14. *Id.* § 16-28-13-3(a)(1)-(10).

15. *Id.* § 16-28-13-4.

16. *Id.* § 16-28-13-6(b)(1), (2).

17. *Id.* § 16-28-13-8.

in particularly short supply. Although the statute allows for health facilities or hospital-based health facilities to obtain the limited criminal history information from "another source allowed by law," no Indiana law currently allows for alternative sources to retrieve this information.

5. *Affidavits Acknowledging Paternity*.—House Enrolled Act 1006 amended Indiana Code section 16-37-2-2.1 to require all personnel of a public or private hospital who attend the birth of a child born out of wedlock to provide an opportunity for the child's mother and a male who reasonably appears to be the child's biological father to execute an affidavit acknowledging the child's paternity.<sup>18</sup> The affidavit shall be executed on a form provided by the Indiana State Department of Health and is not valid if executed more than seventy-two hours after the child's birth or after the mother of the child has executed a consent for the adoption of the child and an adoption petition has been filed.<sup>19</sup>

6. *Release of Survey Reports by the Indiana State Department of Health*.—House Enrolled Act 1206 added a new provision to the Indiana Code at section 16-19-3-25 regarding health provider survey inspection reports performed by the Indiana State Department of Health. The new law states that the recipient of an inspection report has ten calendar days to respond to the inspection report before it is released to the public.<sup>20</sup> However, the Indiana State Department of Health may release the inspection report and any records relating to the inspection report to the public if such release is necessary to protect the public from an imminent threat to health or safety or to protect a consumer of health services from an imminent threat to health or safety.<sup>21</sup> Finally, after the inspection report is released, the inspection report and the records relating thereto may be inspected and copied by interested parties pursuant to Indiana Code section 5-14-3-3(a) and (b).

This addition to the law could limit the ability of health care providers to respond in a timely manner to an inspection performed by the Indiana State Department of Health. Previously, the Indiana State Department of Health's policy allowed providers up to thirty days to respond to the inspection reports before release to the public. Therefore, this addition gives providers significantly less time in which to respond, especially where it is determined that an imminent threat to the health or safety of patients exists. This is of special concern due to the provider's inability to provide the Indiana State Department of Health with any additional information or an acceptable plan of correction<sup>22</sup> when the provider is cited for an adverse inspection report.

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18. *Id.* § 16-37-2-2.1(a)(1), (2).

19. *Id.* § 16-37-2-2.1(b).

20. *Id.* § 16-19-3-25(b).

21. *Id.* § 16-19-3-25(c) (1), (2).

22. A plan of correction constitutes the provider's response to the inspection report of the Indiana State Department of Health.

## II. REIMBURSEMENT ISSUES

### A. Statutory Developments

1. *Changes in Indiana Medicaid Disproportionate Share Hospital ("DSH") Payment Levels.*—The Indiana legislature has redistributed "basic disproportionate share"<sup>23</sup> monies for the benefit of "small hospitals."<sup>24</sup> House Enrolled Act 1701 increased the amount of the basic disproportionate share hospital ("DSH") pool for these hospitals from \$2,000,000 to an amount not to exceed \$5,000,000.<sup>25</sup> The basic DSH pool for large hospitals remained the same at \$18,000,000.<sup>26</sup> The basic DSH pool for private psychiatric institutions<sup>27</sup> was decreased from \$9,000,000 to \$2,000,000.<sup>28</sup> To offset this steep reduction, the Office of Medicaid Policy and Planning ("OMPP") agreed to increase the Medicaid per diem rates available to private psychiatric institutions from \$346 to an effective rate of \$450.<sup>29</sup> Qualifying state mental health institutions benefited as their DSH pool was increased from

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23. A basic disproportionate share provider is a hospital whose Medicaid inpatient utilization rate is one standard deviation above the mean, or one whose low income utilization rate exceeds 25% or has 20,000 or more Medicaid inpatient days per year. IND. CODE § 12-15-16-1(a) (1993). However, see note 32 *infra* and accompanying text (discussing the additional requirement in the new law that a hospital have a Medicare Utilization Rate of at least 1% to qualify as a DSH). The Indiana Code also provides for "enhanced disproportionate share providers." An enhanced disproportionate share provider is a hospital that as of the cost reporting period for July 1, 1992 had at least 6,000 Medicaid inpatient days and at least 750 Medicaid discharges along with either a Medicaid inpatient utilization rate of one standard deviation above the state mean where the utilization rate for providers whose low income utilization rate exceeds 25% is excluded from calculating the mean Medicaid inpatient utilization rate, or the provider's low income utilization rate exceeds 25%. IND. CODE § 12-15-16-1 (1993). Enhanced disproportionate share hospitals are eligible for additional disproportionate share adjustments under IND. CODE § 12-15-19-1 (1993 & Supp.1995). Total basic and enhanced disproportionate share payments to a hospital are limited to the hospital specific limit provided under 42 U.S.C. 1396r-4(g) (1994). See also IND. CODE § 12-15-19-1(c) (1993).

24. The statute does not use the term "small hospital" but requires a hospital to have a Medicaid inpatient utilization rate at least one standard deviation above the mean to qualify as a Disproportionate Share Hospital ("DSH"). IND. CODE § 12-15-16-1(a)(1) (1993). Those acute care hospitals with 20,000 or more Medicaid inpatient days are viewed as large hospitals and receive monies from a separate pool. *Id.* § 12-15-16-1(a)(3). See also note 26 *infra* and accompanying text (discussing the large hospital DSH pool).

25. IND. CODE § 12-15-16-6(c)(1) (Supp. 1995).

26. *Id.* § 12-15-16-6(c)(6).

27. A private psychiatric institution is one licensed to treat "psychiatric disorders, developmental disabilities, convulsive disturbances, or other abnormal mental conditions." IND. CODE § 12-25-1-1 (1993).

28. IND. CODE § 12-15-16-6(c)(4) (Supp. 1995).

29. Timothy W. Kennedy, *State Legislative Wrap-Up and Case Law Update*, INDIANA LEGAL FORUM, Aug. 11, 1995, at 77.

\$132,000,000 to \$191,000,000.<sup>30</sup>

The statute was changed to require all providers qualifying under Indiana Code section 12-15-16-1(a) to have an inpatient Medicare Utilization Rate<sup>31</sup> of at least one percent in order to qualify as a DSH.<sup>32</sup> The state also acted to make state law consistent with new federal standards that cap a hospital's DSH reimbursement to the costs the hospital incurred in treating Medicaid patients.<sup>33</sup>

2. *Hospital Care for the Indigent Program.*—House Enrolled Act 1701 also streamlined the process by which hospitals receive payments under Indiana's Hospital Care for the Indigent Program ("HCI"). Under the new law, a total of \$35,000,000 a year is devoted to this program. Payment is in the form of a per diem rate which is added to each hospital's Medicaid base inpatient payment rate.<sup>34</sup> The level of payment for each hospital is determined by dividing HCI payments to the hospital in Fiscal Year 1992 under the program by total Medicaid patient days in the same year.<sup>35</sup> Thus, hospitals with higher than usual levels of Medicaid inpatient days in Fiscal Year 1992 are locked into a more favorable HCI reimbursement rate.<sup>36</sup> The effective result of these provisions is that every year hospitals receive the same amount of base HCI reimbursement as they did in 1992 except for a slight annual increase due to a proportionate increase paid into the HCI fund.<sup>37</sup>

3. *Recovering and Paying Interest on Provider Overpayments Situations.*—The state has authorized the collection of interest against providers that are overpaid under the Medicaid program and the payment to providers for interest when the program erroneously recovers an "overpayment." When an amount paid to a provider is later determined by an audit, settlement, or judicial or administrative proceeding to have been in excess, the state may recover interest at a rate two percentage points to the nearest whole number above the average yield on state money for the prior year (excluding pension fund investments).<sup>38</sup> Providers may now recover interest in the event of an erroneous overpayment recovery by the state but only at the rate of interest to the nearest whole number average investment yield for the state (excluding pension fund investments).<sup>39</sup> Thus, the state imposes a two percent interest penalty when the provider is

30. IND. CODE § 12-15-16-6(c)(5) (Supp. 1995).

31. The Medicaid Utilization Rate is the percentage of inpatient days devoted to the treatment of Medicaid patients. 42 U.S.C. § 1396r(b)(2) (1994).

32. IND. CODE § 12-15-17-1 (Supp. 1995).

33. *Id.* § 12-15-19-1(c); 42 U.S.C. § 1396r-4(g) (1994).

34. IND. CODE § 12-15-15-8(b) (Supp. 1995).

35. *Id.* § 12-15-15-8(a). This rate is updated annually. *Id.* § 12-15-15-8(c).

36. *Id.* § 12-15-15-8(b). The principle also functions in reverse so that hospitals with lower than usual levels of Medicaid inpatient days in 1992 are locked into a lower level of reimbursement until the statute is changed.

37. Thus, regardless of whether a hospital increases or decreases the amount of care it provides to indigents, reimbursement is frozen at the base 1992 level until the law is changed.

38. *Id.* § 12-15-21-3(6). The interest accrues from the date of the overpayment. *Id.*

39. *Id.* § 12-15-21-3(7).

overpaid but does not afford the provider the same benefit when the state underpays.

4. *Reimbursement for Emergency Room Screening Services.*—Under an addition to the Indiana Code, the Office of Medicaid Policy and Planning (“OMPP”) must now pay 100% of the rates payable under the Medicaid fee structure for physician screening services in hospital emergency departments.<sup>40</sup> These payments must be calculated using the same methodology used for all other physicians participating in Medicaid.<sup>41</sup> However, this new payment principle does not apply to persons enrolled in the Medicaid Risk-Based Managed Care Program.<sup>42</sup>

5. *Increased Payments Rates for Long Term Care.*—Payment for staffing intermediate care, skilled care, ventilator care and extensive care has been increased by fifteen minutes per day.<sup>43</sup> In addition, Medicaid payment rates must include an incentive limited to 115% of the average inflatable allowable per resident day costs, calculated statewide for a given level of care.<sup>44</sup>

6. *Medicaid “Anti-Hassle” Program.*—In response to widespread complaints from providers describing unnecessary burdens in dealing with Medicaid, the Indiana General Assembly passed legislation designed to reduce “hassles” faced by providers.

a. *Additional time for hospitals to appeal notice of program reimbursement, determination of final audit findings, and equivalent determinations.*—A hospital now has 180 days from notification to appeal a Notice of Amount of Program Reimbursement (“NPR”) under the state Medicaid program instead of the previous requirement to appeal within fifteen days.<sup>45</sup> This change will significantly relieve the time pressure associated with evaluating issues and formulating such appeals.

b. *Additional time to adapt to non-rulemaking policy changes.*—Other legislation was enacted to give providers better notice of non-rulemaking changes in Medicaid policy. New bulletins or notices concerning a change in the Medicaid program, from OMPP or any contractor of OMPP, are not effective for at least forty-five days after the notice or bulletin is mailed to the affected parties.<sup>46</sup> Additionally, the notice or bulletin must be mailed within five days of the date on the notice or bulletin.<sup>47</sup>

c. *Committee review of proposed new IFSSA rules.*—The Indiana Family and Social Services Administration (“IFSSA”) is now required to obtain approval for

40. *Id.* § 12-15-15-2.5. This provision relates only to payments for physician services and does not affect hospital reimbursement rates. *Id.*

41. *Id.* § 12-15-15-2.5(b).

42. *Id.* § 12-15-15-2.5(e).

43. *Id.* § 12-15-14-4.

44. *Id.* § 12-15-14-3.

45. *Id.* § 4-21.5-3-7(a)(3)(B). This change also applies to appeal of audit findings and other equivalent determinations. *Id.*

46. *Id.* § 12-15-13-6(a). This law refers to notice or bulletins that are not subject to rulemaking. IND. CODE § 4-22-2-2 (1993).

47. IND. CODE § 12-15-13-6(b) (Supp. 1995).

new rules<sup>48</sup> from a newly created "Family and Social Services Committee."<sup>49</sup> The fifteen committee<sup>50</sup> members are appointed by the Governor and the membership is designed to assure a diverse array of representation and perspectives. None of the committee members can be employees of the executive or legislative branch of the state.<sup>51</sup>

Provider representation is ensured by an expressly reserved position for a director, administrator or officer of a disproportionate share hospital and a separate reserved position for a licensed physician.<sup>52</sup> Another position is set aside for an individual "who shall represent the interests of health care providers" and who serves as a provider on the Medicaid Advisory Committee but is neither a physician nor a representative of a hospital.<sup>53</sup> Four positions are reserved for consumer advocates.<sup>54</sup> Members of the committee are entitled to a copy of the agenda at least forty-eight (48) hours prior to any meeting.<sup>55</sup>

The secretary of IFSSA and the chairperson of the committee have the power to jointly determine that a delay in adopting a rule would immediately threaten the health and welfare of citizens, violate state or federal law, have a substantial fiscal impact on the state (greater than \$2,000,000 annually), or result in a forfeiture of federal waivers.<sup>56</sup> In such circumstances, the secretary and the chairperson can proceed with promulgation of the rule, but the rule is still subject to ratification by the committee.<sup>57</sup>

7. *Health Finance Commission and Committee.*—Another new provision to the Indiana Code creates a Health Finance Commission to study health finance in Indiana.<sup>58</sup> The voting members of the commission are composed of the members of the Senate Planning and Public Services Committee and the House Public Health Committee.<sup>59</sup>

To assist the Commission, a Health Finance Advisory Committee is also created.<sup>60</sup> This Committee is to advise the Commission and may perform some duties of the Commission, but members of the Committee may not vote on

48. *Id.* § 12-8-1-9.

49. *Id.* § 12-8-3-2.

50. The committee has 15 voting members. *Id.* § 12-8-3-3(a). There are a variety of non-voting members. *Id.* § 12-8-3-3(b).

51. *Id.* § 12-8-3-3(a).

52. *Id.*

53. *Id.* This provision seems designed to offer a position on the committee to a nursing home representative, chiropractor, optometrist, nurse or other health care provider currently represented on the Medicaid Advisory Committee.

54. *Id.*

55. *Id.* § 12-8-3-3(d).

56. *Id.* § 12-8-3-4.2(a).

57. *Id.* § 12-8-3-4.2(c)-(e).

58. *Id.* § 2-5-23.

59. *Id.* § 2-5-23-5.

60. *Id.* § 2-5-23-6.

Commission matters.<sup>61</sup> Members of the Committee are appointed from the general public, but must consist of representatives from cost accounting, actuary, medical economics, insurance, long-term care, hospital, mental health, pharmacy, physician, nurse, and community health fields.<sup>62</sup> In addition, the Dean of the Medical School at Indiana University or a representative must be appointed to the Committee.<sup>63</sup>

To further assist the Commission, the Health Policy Advisory Committee is established effective May 1, 1997.<sup>64</sup> At the request of the Commission chairman, this Committee provides information and otherwise assists the Commission in performing its duties.<sup>65</sup> The Health Policy Advisory Committee members will be appointed from the general public and will represent a diverse array of interests provided for in the amended statute.<sup>66</sup>

### *B. Major Medicare Judicial Decision Affecting Use of GAAP*

In *Shalala v. Guernsey Memorial Hospital*,<sup>67</sup> the United States Supreme Court handed down a five to four decision of considerable import to many hospital providers nationwide. The issue involved whether Medicare regulations require the Health Care Financing Administration ("HCFA") to reimburse according to generally accepted accounting principles ("GAAP") or to go through the formal rule-making process for any exceptions to GAAP affecting Medicare reimbursement.<sup>68</sup> The plaintiffs in *Guernsey* presented legal arguments identical to those presented through an Indiana Hospital Association sponsored Medicare group appeal on the same issue.<sup>69</sup> The *Guernsey* decision effectively led to the dismissal of this group appeal.<sup>70</sup>

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61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.* § 2-5-23-8.

65. *Id.*

66. *Id.* Interests in each of the following must be represented: public hospitals, community mental health centers, community health centers, the long term care industry, health care professionals, rural hospitals, health maintenance organizations, for-profit health care facilities, a statewide consumer organization, a statewide senior citizens' organization, a statewide organization representing people with disabilities, organized labor, businesses that purchase health insurance policies, businesses that provide self-funded employee benefit plans, a minority community, the uninsured (this member must be "chronically uninsured" and an individual "who is not associated with any organization, business, or profession represented in this subsection other than as a consumer"). *Id.*

67. 115 S. Ct. 1232 (1995).

68. *Id.* at 1234.

69. See Letter From Indiana Hospital Association General Counsel to Chief Executive Officers, *IHA-Sponsored Medicare Group Appeal Loss on Advance Refunding of Bonds* (Nov. 24, 1995) (on file with author).

70. See Minutes of IHA-Sponsored Medicare Group Appeals Steering Committee Meeting

In 1972, Guernsey Memorial Hospital ("Hospital") issued bonds for capital improvements and in 1985 spent \$672,581 to refinance the bonds.<sup>71</sup> The Hospital expensed this full amount as a cost in the year it occurred. The Court did not dispute that this treatment of the transaction cost was consistent with GAAP principles.<sup>72</sup> However, the Hospital's treatment was inconsistent with non-regulatory reimbursement guidelines published in the *Medicare Provider Reimbursement Manual* ("PRM") section 233, which requires amortization of refinancing costs associated with bonds.<sup>73</sup> The Hospital argued that this informal guideline was inconsistent with regulations that mandated GAAP be utilized by providers participating in the Medicare program.<sup>74</sup>

The federal regulation applicable to this issue, 42 C.F.R. section 413.20(a), does not specifically mention GAAP, but does mandate that "[s]tandardized definitions, accounting statistics and reporting practices that are widely accepted in the hospital and related fields are followed."<sup>75</sup> The Hospital also argued that part (b) of the regulation mandated an accrual basis of accounting and that this had the effect of requiring the use of GAAP except when directly contradicted by another regulation. The Hospital and the dissenters argued that HCFA was authorized to promulgate a regulation, with appropriate notice and comment, that supplanted GAAP<sup>76</sup> but could not impose, by informal guidelines, a policy that conflicts with regulations without the notice and comment required of a regulatory change.<sup>77</sup> Thus, the issue decided was not the substance of the policy itself, but rather whether such a policy could be adopted by HCFA as a guideline without the public notice or comment required for a properly promulgated regulation.<sup>78</sup>

The five to four majority decision assumed *arguendo* that "the standardized

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(May 19, 1995) (on file with author).

71. *Guernsey Memorial Hosp.*, 115 S. Ct. at 1234.

72. *Id.* at 1235.

73. *Provider Reimbursement Manual* § 233 provides that "[d]ebt issue costs from refunding of debt must be amortized from the date the debt is incurred to the scheduled maturity of the debt." *Allowable Cost (Prov. Reimb. Man., Part I, § 233.3)*, 1 Medicare and Medicaid Guide (CCH) ¶ 5184 (October 20, 1994).

74. *Guernsey Memorial Hosp.*, 115 S. Ct. at 1235.

75. *Id.* (quoting 42 C.F.R. § 413.20(a) (1993)).

76. Justice O'Connor in her dissent was quite clear that the policies and rationale behind PRM § 233 were sound. "I do not doubt that the amortization approach embodied in PRM § 233 'squares with economic reality,' and would likely be upheld as a rational regulation were it properly promulgated." *Id.* at 1244 (O'Connor, J., dissenting) (citation omitted).

77. The Administrative Procedures Act requires that "rule making" procedures include notice and comment opportunities for those affected by the rules. 5 U.S.C. § 553(b) (1994). However, the same section exempts "interpretive rules" from this requirement. *Id.* Interpretive rules merely explain an "'agency's construction of the statutes and rules which it administers.'" *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979) (quoting the ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATION PROCEDURE ACT 30, n.3 (1947)).

78. See *supra* note 76 (discussing the dissent's acknowledgment that a properly promulgated regulation would have been upheld).

definitions, accounting statistics, and reporting practices referred to by the regulations refer to GAAP.”<sup>79</sup> However, the Court determined that the regulations refer to reporting requirements on hospital providers and not to a principle of reimbursement binding on the Secretary of the United States Department of Health and Human Services and HCFA.<sup>80</sup> In addition, the Court found that PRM section 233 was “a prototypical example of an interpretive rule” that is not subject to notice and comment requirements.<sup>81</sup> The Court considered section 233 consistent with statutory provisions and regulations that require Medicare to bear no more than its appropriate costs<sup>82</sup> and forbade “cross subsidization” of expenses related to non-Medicare patients.<sup>83</sup> Finally, the court noted that GAAP is not a “lucid or encyclopedic set of pre-existing rules” but rather, a difficult source of guidance because no single authority for GAAP rules exists.<sup>84</sup>

The Court’s decision in *Shalala v. Guernsey Memorial Hospital* affirmed the efficacy of PRM section 233 for treatment of advance refunding of bond transactions under Medicare and generally deferred to agency discretion to adopt such instructions. The Court’s decision has the effect of strengthening the authority of HCFA to implement informal guidelines without having to go through the formal notice and comment requirements normally associated with a regulatory change. Providers challenging these informal guidelines on grounds that the guidelines contradict regulations or GAAP will find *Guernsey* a serious impediment. Conversely, when program guidelines favor the provider’s

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79. *Guernsey Memorial Hosp.*, 115 S. Ct. at 1235.

80. “The logical conclusion is that the provisions . . . concern record keeping requirements rather than reimbursement . . .” *Id.* at 1236. Justice O’Connor in her dissent found little sense in this claim because 42 C.F.R. § 413.20(a) expressly provides that “the methods of determining costs payable under Medicare” are the standardized methods that the Court accepts means GAAP. *Id.* at 1242. “It would make little sense to tie cost reporting to cost reimbursement in this manner while simultaneously mandating different accounting systems for each.” *Id.*

81. *Guernsey Memorial Hosp.*, 115 S. Ct. at 1239. Justice O’Connor’s dissent dismissed this argument because “PRM § 233 cannot be a valid ‘interpretation’ of the Medicare regulations because it clearly is at odds with the meaning of § 413.20 [the regulation] itself.” *Id.* at 1243. O’Connor argued that the regulation set a “default rule” favoring GAAP that could then only be overcome by an equivalent regulation providing an exception to the default rule. *Id.* at 1241. As O’Connor put it, “interpretive rules . . . must explain existing law and not contradict what the regulations require.” *Id.* at 1244.

82. See 42 U.S.C. § 1395x(v)(1)(A)(i) (1994).

83. *Guernsey Memorial Hosp.*, 115 S. Ct. at 1238. O’Connor’s dissent points out that the Court provides no support for the claim that immediate recognition of the advance refunding losses would violate the ban on cross subsidization in the statute. *Id.* at 1244. In fact, testimony and GAAP may suggest otherwise. *Id.* at 1245. Acknowledging that reasonable people can disagree on the point, O’Connor argues that because the statute is silent on the issue the cross subsidization argument is inappropriate. *Id.*

84. *Id.* at 1239. In dissent, O’Connor pointed out that the Secretary had changed her view which had previously concluded that 42 C.F.R. § 413.20 required Medicare reimbursement according to GAAP when that construction was to the Secretary’s benefit. *Id.* at 1242.

assertions, the provider can cite guidelines with greater certainty knowing that they will be viewed as binding.

### C. Administrative Actions

1. *Medicare Fiscal Intermediary Treatment of Ancillary Outpatient Supplies.*—Indiana's Medicare Fiscal Intermediary, AdminaStar Federal ("AdminaStar"), acted in 1995 to stop hospitals from continuing the long standing practice of separately billing ancillary outpatient supplies. AdminaStar took the position that routine supplies were not separately billable and that only "non-routine" supplies could be separately billed.<sup>85</sup> This action caused considerable confusion among hospitals during 1995 as AdminaStar and the Indiana Hospital Association sought to develop acceptable definitions of "routine" and "non-routine." Previously, hospitals considered "non-routine" to be defined by industry practice or custom.<sup>86</sup> AdminaStar took the position that hospitals had customarily and separately billed for most supplies used in a billable setting no matter how common or routine the use of this supply was. AdminaStar then borrowed nursing home guidelines from the *Provider Reimbursement Manual* to define "routine," although these guidelines had been used to define "routine supplies" in a somewhat different healthcare setting.<sup>87</sup>

On June 1, 1995, AdminaStar published five questions, all of which had to be answered "yes" in order for a supply to be considered non-routine and separately billable.<sup>88</sup> These questions made it virtually impossible for any supply to be viewed as "non-routine" because one question provided that if a supply was available for patients for the diagnosis or procedure involved, it was thereby "routine" and not separately billable.<sup>89</sup> In response, the Indiana Hospital

85. See ADMINASTAR FEDERAL, MEDICARE PART A BULLETIN, NO. 95-05-02 (May 11, 1995).

86. This position was reasonable. The *Provider Reimbursement Manual* defines separately billable ancillary services as "special items and services for which charges are customarily made in addition to a routine service charge." *Ancillary Services (Prov. Reimb. Man., Part 1, § 2202.8)*, 2 Medicare & Medicaid Guide (CCH) ¶ 6105 (Aug 13, 1993).

87. AdminaStar expressly cited PRM § 2203.2 as the basis for its definition of non-routine. This provision defines non-routine supplies as "those that are directly identifiable to individual patients, furnished at the direction of a physician, and . . . not reusable." *Ancillary Services in SNFs (Prov. Reimb. Man., Part 1, § 2203.2)*, 2 Medicare & Medicaid Guide (CCH) ¶ 6157 (June 1, 1993). This section of the PRM is explicitly labeled "Ancillary Services in SNFs." *Id.* In using SNF Guidelines for its definition of "routine" that would apply to hospitals, AdminaStar failed to consider that the same Guidelines in discussing routine services expressly note that "[h]ospitals and most SNF's differ historically in their charging practices and method of providing services." *Routine Services in SNF's (Prov. Reimb. Man., Part 1, § 2203.1)*, 2 Medicare & Medicaid Guide (CCH) ¶ 6155 (Jan. 1990).

88. ADMINASTAR, MEDICARE PART A BULLETIN, NO. 95-06-01 (June 1, 1995).

89. Question Number 4 asked: "Is the item not commonly available for use by patients as needed in the billed setting." *Id.* Thus, because of this question, even an item that was only rarely

Association began a group initiative on behalf of its member Indiana hospitals to negotiate a more reasonable and realistic definition of a “routine” supply.<sup>90</sup> The result was a revised four question test that met many of the objections of Indiana hospitals, provided considerable flexibility for individual institutions, and still gave AdminaStar a meaningful definition of “routine.” However, many hospitals will have to change certain billing practices. The revised four question test requires that all of the following be answered “yes” in order for the supply to be “non-routine” and therefore separately billable:<sup>91</sup>

First, is the item medically necessary and furnished at the direction of a physician? (Not a personal convenience item such as slippers, powder, lotion, etc.) This question merely restates the long standing requirement that care be medically necessary to qualify for reimbursement.<sup>92</sup>

Second, is the item used specifically for or on the patient? (Not gowns, gloves, or masks used by staff or oxygen itself available but not specifically used by the patient.) This question conveys the idea that the supply must be one that is actually used by and consumed by the patient. In addition, the item must be actually used on the patient and cannot be something that was available for use but not actually used. Thus, oxygen or other consumables available but not used cannot be separately billed. However, oxygen actually used by the patient would be billable if otherwise qualified.

Third, is the item not ordinarily used for or on most patients or was the volume or quantity used for or on the patient significantly greater than that used for or on most patients in the billed setting? (Not pressure cuffs, thermometers, patient gowns, soap.) This question is at the heart of defining routine and nonroutine supplies. It leaves considerable flexibility for hospitals to apply the definition to best reflect the practices of their facilities. A nonroutine use can occur either because the use of the item itself in the billed setting is unusual or because the amount used was substantially more than usual. The term “not ordinarily used” is not precisely defined. At a minimum, it means a use common to less than half the patients in the billed setting and probably should only be answered “yes” when substantially fewer than half the patients use the supply (or use it in the quantity ordinarily consumed).<sup>93</sup>

Fourth, is the item not basically a stock (bulk) supply in the billed setting and

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used on patients but was simply available for use would be viewed as routine and not separately billable.

90. See Letter From Indiana Hospital Association General Counsel to Chief Executive Officers, *New Medicare IHA-Sponsored Group Initiatives* (June 7, 1995) (on file with author).

91. ADMINASTAR FEDERAL, MEDICARE PART A BULLETIN, NO. 95-10-12 (Oct. 17, 1995).

92. “[N]o payment may be made under part A or part B of this subchapter for any expenses incurred for items or services—

(1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. § 1395y(a) (1994).

93. See Letter From Indiana Hospital Association General Counsel to Chief Executive Officers, *Revised Medicare Ancillary Outpatient Supplies Policy* (Nov. 6, 1995) (on file with author).

the amount or volume used not typically measured or traceable to the individual patient for billing purposes? (Not pads, drapes, cotton balls, urinals, bedpans, wipes, irrigation solutions, ice bags, IV tubing, pillows, towels, bed linen, diapers, soap, tourniquets, gauze, prep kits, oxygen masks and oxygen supplies, or syringes.) This question is designed to exclude items that are generally stored in bulk and typically not traceable to an individual patient for billing purposes. For example, hospitals keep quantities of soap on hand but do not generally keep track of how much soap an individual patient uses. This question is primarily directed at relatively inexpensive items that the facility keeps available in large amounts. Such items should be included in the general charge for the billed setting and not separately billed.

All four of these questions must be answered "yes" for the item to be separately billable. Note, however, that just because something cannot be separately billed does not mean that its cost cannot be recovered. Hospitals may bundle the expenses associated with routine supplies into the basic rate for the billed setting or otherwise chargeable procedures. Some facilities may be required to raise billed setting rates as charge masters are changed to reflect the bundling of these supply costs into the general rate for the billed setting.

An important element helping to clarify use of the new criteria is the concept of the "billed setting." AdminaStar has not defined billed settings because individual hospitals must define their own billed settings. This is in recognition of the uniqueness of services at acute care facilities. Generally, a billed setting will be the cost center that is the source of the billing rate. For example, an emergency room with its basic rate for an emergency visit would be a billed setting. The criteria as applied to supplies within the emergency room billed setting may apply differently than in another billed setting of the same hospital. As long as hospitals use common, prudent billing practices, and follow other Medicare cost apportionment principles, they may define "billed setting" in a manner that best describes their facility.<sup>94</sup> Bundling supply charges into the general rate for the billed setting may result in a higher general rate for that billed setting.<sup>95</sup> In addition, AdminaStar has agreed to consider the effects of this new policy when matching costs for the lesser of cost or charges for evaluation purposes.<sup>96</sup> AdminaStar has agreed to consider that the Medicare rate for the general setting may be higher than the private payer rate for the same billed setting as long as the Medicare rate includes routine supply costs while the private payer rate may have such supplies unbundled from the general rate.<sup>97</sup>

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94. *Id.*

95. See Health Financial Managers Association (HFMA), Supply Questions and Answers, Answer to Question No.27, at the Indiana University Conference Place (June 12, 1995) (on file with author).

96. Medicare will only pay the lesser of reasonable costs or customary charges made by the provider for the same services. 42 C.F.R. § 413.13(b) (1994). Thus if a provider is customarily charging private payers less than its Medicare costs, the provider runs the risk of Medicare reimbursing at the lower customary charge rate.

97. Telephone Interview with Dennis Brinker, CFO and Vice President of Intermediary

2. *U.S. Department of Justice Initiatives Under the False Claims Act.*—Two initiatives by the United States Department of Justice (“DOJ”) exemplify a growing enforcement trend to use the Federal False Claims Act in cases involving alleged improper Medicare reimbursements to providers.

a. *Following consultants’ advice can result in government investigation.*—The government has filed a False Claims Act<sup>98</sup> suit against Harry Metzinger and William Ritter, consultants who provided advice on Medicare reimbursement coding for outpatient laboratory services to hospitals.<sup>99</sup> The government claims that the consultants instructed hospitals to submit improper claims, thereby defrauding the Government.<sup>100</sup> The DOJ has sent letters to approximately 200 hospitals nationwide who used the advice of Metzinger and Ritter, threatening these hospitals with False Claims Act actions as well.<sup>101</sup>

b. *DOJ claims Medicare “72-Hour Window Rule” widely violated.*—As broad as the DOJ’s False Claims Act threats against 200 hospitals in the Metzinger case may seem, it pales in comparison to the ongoing DOJ action that threatens nearly every hospital in the nation with False Claims Act violations regarding the so-called “72-Hour Window Rule.” This Medicare rule requires that the costs of all outpatient care related to and within three days of a hospital admission be included in the Diagnostic Related Group payment for the inpatient care if the prior outpatient services were provided by the admitting hospital or by an entity wholly owned or operated by that hospital.<sup>102</sup> The government intends to make allegations that approximately 4,600 hospitals nationwide violated this rule.<sup>103</sup>

Pennsylvania hospitals were the first target of the DOJ’s investigation into this

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Operations, AdminaStar Federal, Inc. (Nov. 28, 1995).

98. The False Claims Act permits a civil action by the government against anyone knowingly presenting a false claim to the government. 31 U.S.C. § 3729(a) (1994). “Knowingly” is broadly defined as actual knowledge, deliberate ignorance of the truth, or reckless disregard for the truth. *Id.* § 3729(b). The Act contains punitive damages for those found liable, including triple actual damages to the government and a minimum of \$5,000 (a maximum of \$10,000) *per claim* in statutory punitive damages. *Id.* § 3729(a). Thus, hospitals with potentially hundreds of small dollar laboratory claims can face enormous penalties even though the dollar figure for actual overpayments may be relatively small.

99. *Government Files False Claims Against Medicare Consultants and Warns Hospitals of Possible Claims Against Them for Following Consultant’s Advice*, REIMBURSEMENT ADVISOR (Dennis Berry ed.), Feb. 1995, at 3.

100. *Id.*

101. *Id.* The Indiana hospitals involved were required by the DOJ to waive any defense under the Statute of Limitations and to conduct extensive audits by an independent auditor in order to avoid immediate legal action by the DOJ. Even so, the DOJ still retains the option of joining the hospitals as defendants depending upon the results of the audit and upon how forthcoming the hospitals are in their cooperation with the DOJ.

102. 42 U.S.C. § 1395ww(a)(4) (1994); 42 C.F.R. § 412.2(c)(5) (1994).

103. *Government offers settlement of “DRG payment window” false claims allegations*, REIMBURSEMENT ADVISOR (Dennis Berry ed.) Sept. 1995, at 1 [hereinafter *Government Offers Settlement*].

practice and the DOJ reached a group settlement with approximately 180 Pennsylvania hospitals that could produce about \$3,400,000 in refunds and penalties to the government for overpayments.<sup>104</sup> The Pennsylvania settlement offer placed hospitals in three tiers of culpability with increased penalties for each tier.<sup>105</sup> The DOJ claims that 113 Indiana hospitals have violated the 72-Hour Window Rule and that application of a settlement agreement similar to the one in Pennsylvania would result in \$2,251,102 in refunds and penalties to the federal government from Indiana alone.<sup>106</sup> The Indiana Hospital Association has reacted by organizing a group initiative to defend against the DOJ action and to negotiate a settlement agreement.<sup>107</sup>

*c. Hospitals should consider implementing a corporate compliance*

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104. OFFICE OF THE INSPECTOR GENERAL, STATUS REPORT—OFFICE OF INSPECTOR GENERAL/DEPARTMENT OF JUSTICE JOINT PROJECT—MEDICARE NONPHYSICIAN OUTPATIENT BILLS SUBMITTED BY HOSPITALS, A-03-94-00021, at 2 (Aug. 1995) [hereinafter STATUS REPORT]. This report justifies the overwhelming DOJ initiative on grounds that prior Inspector General reports found improper billings under the rule and that the problem continues. *Id.* However, the prior Inspector General reports found that the causes of the improper billings were “clerical errors and misinterpretation of regulation” and never suggested that the problem was caused by hospitals intentionally acting in violation of the False Claims Act. OFFICE OF THE INSPECTOR GENERAL, EXPANSION OF THE DIAGNOSIS RELATED GROUP PAYMENT WINDOW, A-01-92-00521, at i (July 1994). This report also noted that there had been improvement over time. *Id.* at 7. The report cited by the DOJ recommended that the HCFA take certain actions to correct the problem that the HCFA refused to adopt. *Id.* at 13-16. Finally, case law indicates that courts are unlikely to find False Claims Act liability where health care providers are merely following industry practice. *See* Michael M. Mustokoff, How to Prevent an Erroneous Hospital Bill From Becoming a Federal Case, Presentation at the Healthcare Financial Management Educational Foundation “Rapid Response Program,” “Settling with the Department of Justice, Pay; Fight; OR . . .” (Oct. 6, 1995) (unpublished, on file with author); *see also* *United States v. Krizek*, 859 F. Supp. 5, 10 (D.D.C. 1994) (refusing to impose False Claims Act liability where the practice in question was a common industry practice and strongly condemning the government’s position as “not rational” and unfair to a medical community “which for the most part is made up of honorable and dedicated professionals”). None of this has stopped the DOJ from vigorous enforcement of the False Claims Act, and the substantial damages that flow from it for small dollar claims violations, to force hospitals into submission and monetary settlements. In fact, even hospitals that paid back claims because of previous OIG audits are being advised by the DOJ that they may still be liable for those same claims as the previous payback did not extinguish liability under the False Claims Act. *Government threatens false claims suits in seeking settlements on alleged DRG payment window violations*, REIMBURSEMENT ADVISOR (Dennis Berry ed.), Feb. 1995, at 1.

105. *See Government Offers Settlement*, *supra* note 103. The tiers range from simple payback with interest for the least culpable to paybacks with a penalty of 100% for the most culpable. *Id.*

106. *See* STATUS REPORT, *supra* note 104, at 7. The DOJ’s estimates of financial exposure also illustrate the enormous risks hospitals face in defending False Claims Act allegations in court. This settlement amount of \$2,251,102 for Indiana hospitals, which includes some penalties, could amount to nearly \$200 million of exposure under the False Claims Act. *Id.*

107. *See* Letter From Indiana Hospital Association General Counsel, *supra* note 90.

*program.*—The ongoing Metzinger and 72-Hour Window Rule initiatives by the DOJ illustrate a new government approach to dealing with alleged improper payments under Medicare. Previously, Medicare overpayments were generally handled by a repayment (sometimes with interest) of the overpayment amount. The government's new approach is to use or threaten to use the False Claims Act and seek not only payback, but substantial monetary penalties against providers. This enforcement approach suggests that hospitals and others should consider implementing a Corporate Compliance Program to reduce exposure to the False Claims Act.<sup>108</sup>

Significantly, the DOJ settlement offer in the 72-Hour Window Rule case includes substantial compliance requirements on hospitals that, if implemented, would provide them with a "safe harbor" against future inadvertent violations.<sup>109</sup> A comprehensive Corporate Compliance Program can serve as evidence that the hospital did not act with the reckless disregard for the truth that is required for liability under the False Claims Act.<sup>110</sup> One approach to corporate compliance is to view the government as another customer. Such an approach would integrate a Corporate Compliance Program, focused on avoiding violations of government requirements that could lead to significant financial liability or even allegations of fraud, into existing Total Quality Management or other quality assurance programs.

### III. PROVIDER LIABILITY

Provider liability cases deal with the statute of limitations for acts of medical malpractice committed on minors, loss of chance, failure to prosecute, intentional torts, roles and responsibilities of physicians, and fraudulent concealment.

#### A. *Judicial Opinions*

1. *Statute of Limitations: Acts of Medical Malpractice Committed on Minors.*—Perhaps the two most important decisions of 1995 in the area of provider liability/medical malpractice were *Cundiff v. Daviess County Hospital*<sup>111</sup> and *Ledbetter v. Hunter*.<sup>112</sup> Both cases involve constitutional challenges to the

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108. See Letter From Indiana Hospital Association General Counsel to Chief Executive Officers, Proposed Settlement of DOJ Outpatient Billing/False Claims Enforcement Action Includes Safe Harbor Protection for Hospitals (Aug. 11, 1995) (on file with author).

109. *Id.*

110. See DAVID D. QUEEN & ELIZABETH E. FRASHER, DESIGNING A HEALTH CARE CORPORATE COMPLIANCE PROGRAM 29-31 (1995). A Corporate Compliance Program is simply a program that systematically and comprehensively attempts to ensure that an organization is in compliance with the law. See *id.* at 29. See also Mustokoff, *supra* note 104, at 6 (noting that "An internal compliance program may be insurance against a charge of recklessness").

111. 656 N.E.2d 298 (Ind. Ct. App. 1995). *Cundiff* is presently on appeal to the Indiana Supreme Court.

112. 652 N.E.2d 543 (Ind. Ct. App. 1995). *Ledbetter* was reversed and remanded to the trial court for reconsideration in light of recent pronouncement by Indiana Supreme Court that the Equal

Indiana Medical Malpractice Act ("Act")<sup>113</sup> statute of limitations as it applies to minors.<sup>114</sup> Pursuant to the Act, a minor's claim for medical malpractice must be brought within two years of the act of malpractice, or by the minor's eighth birthday, whichever is later.<sup>115</sup> However, Indiana's general legal disability tolling statute<sup>116</sup> provides that causes of action must be brought within two years after the disability is removed. Persons under the age of eighteen in Indiana are considered under a legal disability.<sup>117</sup> Unfortunately, as of the writing of this Article, neither *Cundiff* nor *Ledbetter* provides a definitive answer as to whether this limitation applicable to minors is constitutional under the Indiana Constitution.

a. *Ledbetter v. Hunter*.—In *Ledbetter*,<sup>118</sup> Trena Ledbetter alleged medical malpractice in connection with the birth of her child on November 25, 1974.<sup>119</sup> Almost twenty years later, on April 22, 1994, Ledbetter filed a medical malpractice claim contending it was timely filed within two (2) years of her child's eighteenth birthday as provided by the Indiana general legal disability tolling provision.<sup>120</sup> The defendant health care providers moved to dismiss Ledbetter's claim alleging it was barred by the Act's statute of limitations which was controlling in areas of medical malpractice.<sup>121</sup> The trial court granted defendant's motion.<sup>122</sup>

On appeal, Ledbetter argued that the Act's statute of limitations tolling provision for minors violated her due process rights as guaranteed by the Fourteenth Amendment to the United States Constitution and Article I, Section 12 of the Indiana Constitution<sup>123</sup> and her equal protection rights as guaranteed by the

Protection Clause of the Fourteenth Amendment to the United States Constitution and the Privileges and Immunities Clause of the Indiana Constitution are to be given independent interpretation and application.

113. IND. CODE § 27-12-1-1 (Supp. 1995). The term "Act" as used throughout this section will refer to the Indiana Medical Malpractice Act.

114. *Id.* § 27-12-7-1(b).

115. *Id.* The statute provides:

A claim, whether in contract or tort, may not be brought against a health care provider based upon professional services or health care that was provided unless the claim is filed within two (2) years after the date of the alleged act, omission or neglect, except that a minor less than six (6) years of age has until the minor's eighth birthday to file.

116. IND. CODE § 34-1-2-5 (1993).

117. IND. CODE § 1-1-4-5 (Supp. 1995).

118. 652 N.E.2d 543 (Ind. Ct. App. 1995); *see also supra* note 112 and accompanying text.

119. *Ledbetter*, 652 N.E.2d at 545.

120. IND. CODE § 34-1-2-5 (1993) provides: "Any person being under legal disabilities when the cause of action accrues may bring his action within two (2) years after the disability is removed." The applicable definition of legal disability "includes persons less than eighteen (18) years of age, mentally incompetent, or out of the United States." IND. CODE § 1-1-4-5 (Supp. 1995).

121. *Ledbetter*, 652 N.E.2d at 545.

122. *Id.*

123. The Due Process Clause of the Fourteenth Amendment to the United States Constitution

Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and Article I, Section 32 of the Indiana Constitution.<sup>124</sup>

On appeal, Judge Kirsch, writing for a unanimous court, affirmed the Act's tolling provision against federal due process and equal protection attack on the theory that the Indiana Supreme Court's decision in *Johnson v. St. Vincent Hospital, Inc.*<sup>125</sup> bound the court in its determination of plaintiff's federal due process and equal protection claims.<sup>126</sup>

In *Johnson*, the court found that the purposes of the Act's statute of limitations as to minors are furthered in a rational manner by limiting the legal disability of infants to those under six years and that the classification of those entitled to legal disability by age and type of claim bears a fair and substantial relationship to the same end.<sup>127</sup> *Ledbetter* did not find *Johnson* dispositive on the question of whether the Act's tolling provision as to minors violated the provisions of Article I, Section 32 of the Indiana Constitution. The court found that *Johnson* was no longer dispositive on this issue when read in light of the Indiana Supreme Court's recent holding in *Collins v. Day*.<sup>128</sup> In *Collins*, the court stated that there is no reason why state law "equal protection" claims have to be analyzed under the same framework as those involving the federal constitution.<sup>129</sup> As a result, the *Ledbetter* court elected to remand and reverse the case to the trial court for consideration of the impact of *Collins* on the Indiana Medical Malpractice Act.<sup>130</sup> At the time of this writing, the case is still on remand at the trial level.

*b. Cundiff v. Daviess County Hospital.*—Unfortunately, the constitutional questions left remaining from *Johnson* were not answered by the court's holding in *Cundiff*.<sup>131</sup> Michael Cundiff was born on September 7, 1982. Shortly after his birth, Michael developed pneumonia. Michael's hospital records reflect that he was given an overdose of the antibiotic Kanamycin.<sup>132</sup>

provides in pertinent part: "No state shall . . . deprive any person of life, liberty, or property, without due process of law . . ." U.S. CONST. amend. XIV. Article I, Section 12 of the Indiana Constitution provides: "All courts shall be open; and every person, for injury done to him in his person, property, or reputation, shall have remedy by due course of law. Justice shall be administered freely, and without purchase; completely; and without denial; speedily, and without delay." IND. CONST. art. I, § 12.

124. The Equal Protection Clause of the Fourteenth Amendment provides in relevant part: "No State shall . . . deny to any person within its jurisdiction the equal protection of the laws." U.S. CONST. amend. XIV. Article I, Section 32 of the Indiana Constitution provides: "The General Assembly shall not grant to any citizen, or class of citizens, privileges or immunities, which, upon the same terms, shall not equally belong to all citizens." IND. CONST. art. I, § 32.

125. 404 N.E.2d 585 (Ind. 1980).

126. *Ledbetter*, 652 N.E.2d at 545, 548.

127. *Johnson*, 404 N.E.2d at 604.

128. 644 N.E.2d 72 (Ind. 1994).

129. *Id.* at 78-80.

130. *Ledbetter*, 652 N.E.2d at 544.

131. *Cundiff v. Daviess County Hosp.*, 656 N.E.2d 298 (Ind. Ct. App. 1995).

132. *Id.* at 300.

On August 9, 1993, Michael was adopted by Charles and Betty Cundiff, who noticed, as Michael continued to grow, that he was not developing normally. They later discovered that he was mentally retarded, had high frequency hearing loss, and a speech impediment.<sup>133</sup>

In December of 1990, three months after Michael's eighth birthday, the Cundiffs were advised by Michael's doctors that the overdose of Kanamycin possibly caused Michael's hearing loss.<sup>134</sup> Almost three years later, on September 21, 1993, the Cundiffs filed a proposed complaint for damages before the Indiana Department of Insurance, on Michael's behalf, alleging acts of medical malpractice.<sup>135</sup>

Like the defendant in *Johnson*, the hospital filed a motion for summary judgment alleging the complaint was barred by the Act's statute of limitations. The motion was granted by the trial court.<sup>136</sup> With the benefit of the *Ledbetter* decision, the *Cundiff* court found *Johnson* dispositive as to plaintiffs' federal claims and not dispositive as to plaintiffs' state privileges and immunities claims.<sup>137</sup>

*Cundiff* is noteworthy nonetheless for suggesting what analysis will be used to determine if the Act's tolling statute will withstand the state constitutional challenge.<sup>138</sup> In *Collins*, the court stated that legislation must meet three criteria to survive constitutional challenge.<sup>139</sup> First, the legislation must be reasonably related to "inherent characteristics" that are distinctive in the unequally-treated classes; second, preferential treatment which is extended by the state must be uniform in application and availability; and, third, the court must defer to the discretion exercised by the legislature in adopting the limitation.<sup>140</sup> Presently, *Cundiff* is on transfer to the Indiana Supreme Court.

2. *Loss of Chance*.—The single and most significant pronouncement from the Indiana Supreme Court concerning medical malpractice was made in *Mayhue v. Sparkman*.<sup>141</sup> *Mayhue* involved the alleged failure to timely diagnose cervical cancer. Dr. Mayhue first diagnosed Sparkman with cervical cancer in 1981 and he treated her at that time with a full course of successful radiation therapy.<sup>142</sup> From 1985 until 1989, Sparkman was treated by her family physician, receiving numerous pap smears, none of which indicated the presence of atypical cells.<sup>143</sup>

In May 1989, however, a pap smear indicated the presence of cancer. Sparkman was again referred to Mayhue, who performed a clinical examination

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133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.* at 302.

138. *Id.* at 301-02.

139. *Collins v. Day*, 644 N.E.2d 72, 80 (Ind. 1994).

140. *Id.*

141. 653 N.E.2d 1384 (Ind. 1995).

142. *Id.* at 1385.

143. *Id.*

that revealed the continued presence of a constricting ring within the vagina and atrophic vaginitis.<sup>144</sup> Sparkman informed Mayhue that her family physician told her that her pap smear results were abnormal, but failed to bring a copy of the report to him or to inform him that the test report indicated the returned presence of cancer.<sup>145</sup> Mayhue did perform a pap smear, which reported atypical cells, but did not suggest a recurrent malignancy.<sup>146</sup> Mayhue did not order an additional pap smear or biopsy, believing that the abnormal cells instead were a reaction to her earlier radiation therapy.<sup>147</sup>

In November 1989, Sparkman returned to Mayhue with complaints of pain in the area above the pubic arch and a belief that a lump existed.<sup>148</sup> An ultrasound was ordered and revealed the presence of a uterine tumor.<sup>149</sup> On January 1990, surgery found that the tumor had spread to the point of inoperability. Sparkman died in November 1990.<sup>150</sup>

The medical review panel formed to review this case<sup>151</sup> found that Mayhue did not satisfy the appropriate standard of care, but believed that the care was not the cause of the complained of harm.<sup>152</sup> The evidence submitted revealed that even if Sparkman's cancer would have been diagnosed earlier, she still had less than a fifty percent chance of recovery.<sup>153</sup> Under traditional tort principles, the plaintiff must prove that proper diagnosis and treatment would have prevented the patient's injury or death.<sup>154</sup> In cases such as this one, the court believed that the defendant would always be entitled to summary judgment.<sup>155</sup>

The trial court, however, denied the doctor's motion for summary judgment and a permissive interlocutory appeal was taken to the court of appeals.<sup>156</sup> The appeals court affirmed and adopted a "pure" loss of chance doctrine.<sup>157</sup> The

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144. *Id.* Atrophic vaginitis is the thinning and atrophying of the epithelium (thin skin) of the vagina, usually resulting from diminished endocrine stimulation. It is common in post-menopausal women. *Id.*

145. *Id.*

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.* at 1386.

150. *Id.*

151. IND. CODE § 27-12-9-1 (Supp. 1995). "[N]o action against a health care provider may be commenced in any court of this state before the claimant's proposed complaint has been presented to a medical review panel . . . and an opinion is rendered by the panel . . . ." *Id.*

152. *Mayhue*, 653 N.E.2d at 1385.

153. *Id.* at 1386.

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.* at 1387. The "pure" loss of chance doctrine allows the patient to recover for misdiagnosis or mistreatment of a fatal condition by determining that the "compensable injury is not the result, which is usually death, but the reduction in the probability that the patient would recover or obtain better results if the defendant had not been negligent." *Id.*

Indiana Supreme Court granted transfer to review the issue of whether Indiana law recognizes, in medical malpractice claims, a separate loss of chance doctrine.<sup>158</sup>

On review, the supreme court opted for the *Restatement of Torts (Second)*, section 323 view, which reads:

One who undertakes, gratuitously or for consideration, to render services which he should recognize as necessary for the protection of the other's person or things, is subject to liability to the other for the physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if, (a) his failure to exercise such care increases the risk of harm . . . .<sup>159</sup>

While section 323 liability for misdiagnosis of a potentially fatal condition reads very similar to the pure loss of chance doctrine, the supreme court did not view it that way. Instead, the supreme court believed section 323 to be more procedural than substantive.<sup>160</sup> "Specifically," the supreme court stated, "once the plaintiff proves negligence and an increase in the risk of harm, the jury is permitted to decide whether the medical negligence was a substantial factor in causing the harm suffered by plaintiff."<sup>161</sup> This means that if there is sufficient proof of negligence and a resulting increase in the possibility of death or other harm, the jury may then decide the proximate causation question. To the court, "when Section 323 governs a case, it permits the plaintiff to avoid summary judgment on the issue of proximate cause even when there was a less than 50 percent chance of recovery absent the negligence."<sup>162</sup> The measure of damages as between section 323 and pure loss of chance should remain the same: the loss of the chance of recovery, but not the result that ultimately did occur.

3. *Dismissal for Failure to Prosecute*.—In *Rivers v. Methodist Hospitals, Inc.*,<sup>163</sup> the court held that the failure to participate in meaningful discovery or to assist in the formation of the medical review panel or prosecution of the case may

158. *Id.* at 1389.

159. *Id.* at 1388.

160. *Id.*

161. *Id.*

162. *Id.*

We think in those situations where a health care provider deprives a patient of a significant chance for recovery by negligently failing to provide medical treatment, the health care professional should not be allowed to come in after the fact and allege that the result was inevitable inasmuch as that person put the patient's chance beyond the possibility of realization. Health care providers should not be given the benefit of uncertainty created by their own negligent conduct. To hold otherwise would in effect allow care providers to evade liability for their negligent actions or inaction in situations in which patients would not necessarily have survived or recovered, but still had a significant chance of survival or recovery.

*Id.*

163. 654 N.E.2d 811 (Ind. Ct. App. 1995).

warrant dismissal of the action.<sup>164</sup> *Rivers* discusses the plaintiff's obligation to assist in panel formation as one of the factors to be considered in imposing sanctions for delay and nonresponsiveness. In this regard, *Rivers* should probably be seen as an extension of *Galindo v. Christensen*<sup>165</sup> and *Ground v. Methodist Hospital of Indiana, Inc.*,<sup>166</sup> both courts held that the failure to make a timely submission to the medical review panel can subject the plaintiff to dismissal. The *Rivers* court wrote:

Since the Doctors' request for the formation of a medical review panel, *Rivers* has failed to participate in the selection of a panel chair or formation of a review panel. The Doctors twice asked *Rivers* if they could agree upon a panel chair and even delineated various local attorneys they found acceptable to serve as panel chairman. *Rivers* failed to respond to the Doctors. Although *Rivers* correctly notes Indiana Code § 27-12-10-4 allows for either party to file a request with the clerk of the supreme court to randomly draw a list from which a panel chairman is selected if the parties cannot agree, it is not a defendant's duty to prosecute a plaintiff's cause of action.<sup>167</sup>

*Rivers* is important simply to point out that the failure to aggressively prosecute one's suit may result in dismissal.

4. *Intentional Torts and the Medical Malpractice Act.*—In *Doe v. Madison Center Hospital*,<sup>168</sup> the court revisited a problem that occurs often in the area of medical malpractice; that is, whether allegations of an intentional tort fall within the purview of the Medical Malpractice Act.

In *Doe*, a minor psychiatric patient and her mother sued a mental health care facility and a mental health counselor for assault, battery, and intentional infliction of emotional distress, alleging that the counselor coerced sexual intercourse with the patient, resulting in her contracting a venereal disease.<sup>169</sup> The trial court dismissed the action for lack of subject matter jurisdiction<sup>170</sup> on the grounds that the plaintiffs failed to file their complaint with the Indiana Department of Insurance for the acts of medical negligence.<sup>171</sup> Defendant Madison Center Hospital ("Hospital") contended that the claim sounded in medical negligence because the counselor had mishandled the transference phenomenon or that he had acted outside the scope of his employment.<sup>172</sup> The court of appeals reversed, however, finding that the plaintiff's allegations did not fall within the purview of

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164. *Id.* at 811.

165. 569 N.E.2d 702 (Ind. Ct. App. 1991).

166. 576 N.E.2d 611 (Ind. Ct. App. 1991).

167. *Rivers*, 654 N.E.2d at 815.

168. 652 N.E.2d 101 (Ind. Ct. App. 1995).

169. *Id.* at 102.

170. *Id.*

171. *Id.*

172. *Id.*

the Indiana Medical Malpractice Act.<sup>173</sup>

In finding the counselor's actions outside the Medical Malpractice Act, the court, citing *Van Sice v. Sentany*,<sup>174</sup> noted first that the Malpractice Act does not specifically exclude intentional torts from the definition of malpractice.<sup>175</sup> However, the "Act pertains to curative or salutary conduct of a health care provider acting within his or her professional capacity, and is designed to exclude that conduct 'unrelated to the promotion of a patient's health or the provider's exercise of professional expertise, skill or judgment.'"<sup>176</sup> In other words, the benchmarks of a medical malpractice claim (which must go to a medical review panel) are two-fold: first, the conduct of the defendant must be "curative or salutary"; second, it must involve the health care provider's "exercise of professional expertise, skill or judgment."<sup>177</sup>

The hospital attempted to argue that the location of the incident, a hospital, made the case a Medical Malpractice Act case.<sup>178</sup> The court disagreed, saying that there has to be "some causal connection between the conduct and the nature of the patient-health care provider relationship."<sup>179</sup>

The hospital also argued that the counselor's conduct was based upon his professional services as a mental health counselor and the plaintiff's complaint alleged medical negligence of a therapist where the transference phenomenon is an occupational hazard.<sup>180</sup> The *Doe* court concluded however, that the mishandling or misuse of the transference phenomenon is viable only when a therapist-patient relationship has been established.<sup>181</sup> When the court examined the pleadings and weighed the facts of this case, it concluded that there was no therapist-patient relationship between Doe and the counselor.<sup>182</sup> Absent stronger evidence of a therapeutically-based relationship, the court held, the hospital was not entitled to dismissal.<sup>183</sup>

5. *Expert Opinions as to Roles and Responsibilities of Physicians.*—In *Simms*

173. *Id.*

174. 595 N.E.2d 264 (Ind. Ct. App. 1992).

175. Malpractice is a tort based on health care or professional services rendered by a health care provider to a patient. IND. CODE § 27-12-2-18 (Supp. 1995). A tort is "a legal wrong, breach of duty, or negligent or unlawful act or omission proximately causing injury or damage to another." *Id.* § 27-12-2-28.

176. *Doe*, 652 N.E.2d at 104 (citing *Boruff v. Jesseph*, 576 N.E.2d 1297, 1298 (Ind. Ct. App. 1991)) (quoting *Collins v. Thakkar*, 552 N.E.2d 507, 510 (Ind. Ct. App. 1990)). See also IND. CODE § 27-12-2-14 (Supp. 1995) which states: "Coverage for a health care provider qualified under this subdivision is limited to its health care functions and does not extend to other causes of action."

177. *Doe*, 652 N.E.2d at 104.

178. *Id.*

179. *Id.*

180. *Id.* at 105.

181. *Id.* at 106-07.

182. *Id.* at 107. The counselor had previously been employed as a desk clerk, production worker and volunteer at the hospital. *Id.* at 102.

183. *Id.*

*v. Schweikher*,<sup>184</sup> a case involving an amount in controversy of less than \$15,000 and therefore not subjected to review by panel,<sup>185</sup> the patient claimed that a surgical technician placed a hot instrument on her leg causing a third degree burn.<sup>186</sup> Simms filed her claim against Dr. Schweikher alleging vicarious liability for the nurse's act based upon his duty to supervise her.<sup>187</sup> The trial court entered summary judgment in favor of Dr. Schweikher and plaintiff appealed.<sup>188</sup>

"In support of his motion for summary judgment, Dr. Schweikher submitted his own affidavit, stating that his conduct was within the applicable standard of care."<sup>189</sup> Dr. Schweikher also presented an affidavit from the surgical assistant which admitted that her independent act caused plaintiff's injury and that Dr. Schweikher did not control her placement of instruments during the procedure.<sup>190</sup> The plaintiff offered no evidence to rebut these affidavits.<sup>191</sup> In finding for Dr. Schweikher, the court concluded:

We do not believe that the complex roles and responsibilities of surgeons and hospital staff assisting with surgery are within the common knowledge of laypersons. Without testimony from a medical expert indicating that supervision of surgical staff falls within the standard of care of a surgeon in this or a similar locality, we cannot infer that Dr. Schweikher was negligent by failing to prevent the surgical technician's injurious act.<sup>192</sup>

What is important about *Simms*, however, is that the doctor prevailed because the patient did not raise an inference of negligence due to her failure to provide evidence to rebut the evidence submitted by Dr. Schweikher. In other words, the court did not reach the merits of the plaintiff's legal claim and whether a surgeon may be vicariously liable for the negligent acts of hospital staff assisting in surgical procedures.<sup>193</sup> The court emphasized that its decision was based on the fact that the case was a summary judgment case; the court specifically stated that its holding did not announce a new principle on the issue of whether Dr. Schweikher could be held, as a matter of law, "vicariously liable" for the assistant's acts.<sup>194</sup>

*Simms* is also important for Judge Barteau's dissent, which suggests that the case could have been decided on grounds of *res ipsa loquitur* or on the "common

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184. 651 N.E.2d 348 (Ind. Ct. App. 1995), *trans. denied*.

185. IND. CODE § 27-12-8-6 (Supp. 1995).

186. *Simms*, 651 N.E.2d at 349.

187. *Id.*

188. *Id.*

189. *Id.* at 350.

190. *Id.*

191. *Id.*

192. *Id.*

193. *Id.* at n.3.

194. *Id.*

knowledge" exception to the requirement of expert testimony.<sup>195</sup> Judge Barteau also did not perceive favorably the fact that Dr. Schweikher could act as his own expert, labeling his affidavit "self-serving."<sup>196</sup> Perhaps the most troubling aspect about Judge Barteau's dissent, however, is the fact that it assumes the duty of supervision exists in such situations.<sup>197</sup> This leaves unanswered the question whether, in cases involving surgery, the surgeon is always responsible for the acts and omissions of supporting staff irrespective of their respective professional and employment roles.

6. *Tolling the Statute of Limitations—Fraudulent Concealment and the Continuing Relationship.*—The Indiana Court of Appeals' ruling of *Halbe v. Weinberg*<sup>198</sup> undertakes a comprehensive discussion of the medical malpractice statute of limitations as it applies in breast implant cases. It also contains an important advancement in medical malpractice statute of limitations jurisprudence.

In 1982, Sharon Halbe consulted Dr. Weinberg and was diagnosed with bilateral fibrocystic disease that necessitated a bilateral reduction mammoplasty with subcutaneous mastectomy.<sup>199</sup> The procedure was performed by Dr. Weinberg.<sup>200</sup> From 1982 through 1988, Halbe continued under the care of Dr. Weinberg for various procedures including insertion of two new saline breast implants, resection of a mass, and removal of a lesion on her eyelid.<sup>201</sup> The plaintiff's last visit to Dr. Weinberg was in November 1988.<sup>202</sup>

In January 1992, the plaintiff became aware of media coverage regarding symptoms of other women who had silicone breast implants and attempted to resurrect her relationship with Dr. Weinberg by requesting, and receiving, an order for a xeromammogram.<sup>203</sup> The xeromammogram, although ordered by Dr. Weinberg, was not performed by Dr. Weinberg.<sup>204</sup> The xeromammogram revealed the plaintiff's breast implants contained silicone gel.<sup>205</sup>

In April 1992, the plaintiff instituted legal action against Dr. Weinberg and various manufacturers of breast implants and component parts.<sup>206</sup> In August 1992, the plaintiff amended her complaint and filed a proposed complaint for medical

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195. *Id.* at 350-51 (Barteau, J., dissenting). "[J]uries do not need an expert to help them conclude, say, that it is malpractice to operate by mistake on the wrong limb." *Id.* (quoting *Wright v. Carter*, 622 N.E.2d 170, 171 (Ind. 1993)).

196. *Id.* at 351.

197. *Id.*

198. 646 N.E.2d 995 (Ind. Ct. App. 1995).

199. *Id.* at 996.

200. *Id.*

201. *Id.* Regarding the implants, Halbe was shown samples of "saline" and "silicone" versions. She chose the saline type implant and the doctor indicated he would use these. *Id.*

202. *Id.*

203. *Id.* A xeromammogram could reveal a leak in the implants.

204. *Id.*

205. *Id.*

206. *Id.*

negligence before the Indiana Department of Insurance.<sup>207</sup> Dr. Weinberg filed his motion for summary judgment including the affirmative defense of the statute of limitations.<sup>208</sup>

On appeal, the court of appeals held that the plaintiff's actions were insufficient to reinstate the doctor-patient relationship.<sup>209</sup> Citing *Weinberg v. Bess*,<sup>210</sup> the court stated "[t]he physician's failure to disclose that which he knows, or in the exercise of reasonable care should have known, constitutes constructive fraud. This constructive fraud terminates at the conclusion of the physician-patient relationship."<sup>211</sup> Noting that although the physician-patient relationship does not necessarily end with the patient's last office visit, Halbe's contention that she continued to rely on Dr. Weinberg for medical care did not create a genuine factual issue.<sup>212</sup>

#### IV. FEDERAL DEVELOPMENTS

Numerous significant developments in the health care field occurred at the federal level during the 1995 Survey period. Most significantly, the Internal Revenue Service issued proposed guidance with respect to physician recruitment activities by charitable institutions. Other highlights included long awaited regulations implementing the "Stark" legislation<sup>213</sup> and an important case interpreting the Medicare/Medicaid Anti-Kickback statute.<sup>214</sup>

##### A. Tax

On April 3, 1995, the Internal Revenue Service issued a proposed revenue ruling relating to physician recruitment incentives provided by hospitals exempt from federal taxation under section 501(c)(3) of the Internal Revenue Code.<sup>215</sup> The proposed revenue ruling, issued in the form of Announcement 95-25, details five factual situations of physician recruitment, four of which are not deemed to result in private inurement or excess private benefit, and one of which would result in the hospital losing its tax exempt status.<sup>216</sup>

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207. *Id.*

208. *Id.*

209. *Id.* at 997.

210. 638 N.E.2d 841 (Ind. Ct. App. 1994).

211. *Halbe*, 646 N.E.2d at 997.

212. *Id.* "A patient's bare assertion that she continued to rely upon a physician for medical care is insufficient as a matter of law to create a factual issue." *Id.* (citation omitted).

213. 42 U.S.C. § 1395nn (1994).

214. 42 U.S.C. § 1320a-7b(7) (1994).

215. DEPARTMENT OF THE TREASURY, INTERNAL REVENUE SERVICE, BULLETIN NO. 1995-14, INTERNAL REVENUE BULLETIN, ANNOUNCEMENT 95-25, TAX CONSEQUENCES OF PHYSICIAN RECRUITMENT INCENTIVES PROVIDED BY HOSPITALS DESCRIBED IN SECTION 501(C)(3) OF THE INTERNAL REVENUE CODE 11 (Apr. 13, 1995) [hereinafter I.R.S. ANN. 95-25].

216. *Id.* at 11. Of note is that in October 1994, the IRS entered into a "closing agreement" with Hermann Hospital of Houston, Texas, in lieu of revocation of the hospital's tax exempt status.

In describing the five situations, the specific issue at hand is whether under the facts as described in the proposed revenue ruling a "hospital violates the requirements for exemption from federal income tax as an organization described in Section 501(c)(3) of the Internal Revenue Code when it provides incentives to recruit private practice physicians to join its non-employee medical staff or to provide services on behalf of the hospital."<sup>217</sup> The five scenarios detailed in Announcement 95-25 are summarized as follows:

(1) A rural hospital located in an area in need of primary medical care professionals (which includes obstetricians and gynecologists) recruits a physician who recently completed an ob/gyn residency to become a non-employee member of the hospital's medical staff. Under a recruitment agreement that is properly documented and bears commercially reasonable terms, the hospital pays the physician a one-time bonus of \$5,000, pays the physician's malpractice insurance premium for one year, provides office space at below market rent for three years, a guarantee of a home mortgage and provides start-up financial assistance.

(2) A hospital located in an economically depressed inner city area conducts a community needs assessment indicating a shortage of pediatricians, especially for Medicaid patients. The hospital recruits a pediatrician to relocate to the hospital's city, join the medical staff and treat a reasonable number of Medicaid patients. Pursuant to a recruitment agreement negotiated at arm's length, the hospital reimburses the physician for moving expenses and professional liability "tail" coverage for the physician's former practice and guarantees that the physician's private practice income will meet a certain level for three years.

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This closing agreement arose as a result of the hospital disclosing to the IRS certain physician recruitment and retention arrangements that raised questions as to whether prohibited inurement and private benefit were conferred upon individuals in violation of the proscriptions contained in section 501(c)(3) of the Internal Revenue Code. This closing agreement set forth guidelines for the hospital to follow when structuring recruitment arrangements that were to be followed for 10 years.

These guidelines are very specific in nature and detail the types of physicians who may be recruited by Hermann Hospital, the types of recruitment incentives which may and may not be offered, and the maximum length of such arrangements. Although not binding on any hospital or other institution except Hermann Hospital, this closing agreement has been closely scrutinized because of the rigid detail found in the recruitment guidelines as well as the IRS' decision to publish the document. In Announcement 95-25, the IRS appears to take a much more flexible approach to physician recruitment. If finalized, the proposed revenue ruling may also benefit Hermann Hospital as the closing agreement states that the recruitment guidelines outlined in the agreement shall be modified to the extent that Congress or the IRS legislatively or administratively, as the case may be, establish different physician recruitment standards for tax-exempt hospitals.

*Id.*  
217. *Id.*

(3) A hospital located in an economically depressed inner city area conducts a community needs assessment that indicates a shortage of obstetricians for Medicaid and charity care patients. The hospital recruits an obstetrician currently on its medical staff to provide these services and enters into such an agreement. Under the agreement, the hospital agrees to reimburse the physician for the cost of one year's malpractice insurance in return for an agreement by the physician to treat a reasonable number of Medicaid and charity care patients for that year.

(4) A hospital located in a medium to large size metropolitan area operates a neonatal intensive care unit that requires a minimum of four perinatologists to ensure adequate coverage and a high quality of care in the unit. Two of the current four physicians providing such coverage are relocating to other areas. The hospital initiates a search for perinatologists and determines that one of the top two candidates is a physician who is currently practicing at another hospital in the same city. The hospital recruits this physician to join its medical staff and provide coverage for its neonatal intensive care unit pursuant to an agreement negotiated at arm's-length. Under the agreement, the hospital guarantees that the physician's private practice income will meet a certain level for three years.

(5) A hospital located in a medium to large metropolitan area is convicted of violating the Medicare/Medicaid Anti-Kickback statute<sup>218</sup> because it provided recruitment incentives that constituted payments for referrals. The activities resulting in the violations were substantial.

In the proposed revenue ruling, the IRS stated that in order to meet the requirements of section 501(c)(3), a hospital or other tax-exempt organization that provides recruitment incentives to non-employee private practitioners must provide those incentives in a manner that does not cause the organization to violate certain organizational and operational tests outlined in Internal Revenue Code regulations supporting section 501(c)(3).<sup>219</sup> Whether the hospital provides such incentives in a manner that does not cause the organization to violate these tests is determined by evaluating all relevant facts and circumstances. A violation will result from a failure to comply with any of the four requirements described below.

First, the hospital is not to engage in substantial activities that do not further the hospital's exempt purposes or that do not bear a reasonable relationship to the accomplishment of such purposes. In determining whether an organization meets this operational test, the issue is whether the particular activity undertaken by the organization is appropriately in furtherance of the hospital's exempt purpose.<sup>220</sup>

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218. 42 U.S.C. § 1320a-7b(b) (1994).

219. I.R.S. ANN. 95-25, *supra* note 215. See Treas. Reg. § 1.501(c)(3)-1 (1995).

220. I.R.S. ANN. 95-25, *supra* note 215. See also Rev. Rul. 80-278, 1980-2 C.B. 175; Rev. Rul. 80-279, 1980-2 C.B. 176.

Second, the hospital may not engage in activities that result in inurement of the hospital's net earnings to a private shareholder or individual. An activity may result in such inurement if it is structured as a device to distribute the net earnings of the hospital.<sup>221</sup>

Third, the hospital shall not engage in substantial activities that cause the hospital to be operated for the benefit of a private interest rather than a public one, which would result in a substantial non-exempt purpose.

Fourth and finally, the organization should not engage in substantial unlawful activities, which are inconsistent with charitable purposes.<sup>222</sup>

In reviewing the five recruitment situations, the IRS held in Announcement 95-25 that the hospitals in situations 1, 2, 3 and 4 do not violate the requirements for exemption from federal income taxation as organizations described in section 501(c)(3) as a result of the physician recruitment incentive agreements because the transactions further charitable purposes, do not result in inurement, do not result in the hospitals serving a private rather than a public purpose, and are lawful.<sup>223</sup> In the fifth situation, however, the hospital is not deemed to qualify as a section 501(c)(3) organization because its unlawful physician recruitment activities are inconsistent with charitable purposes.<sup>224</sup>

Overall, it is encouraging that the IRS is issuing guidance for physician recruitment so that tax exempt providers will have greater certainty as to what activities will not jeopardize their exempt status. However, although Announcement 95-25 appears to incorporate some flexibility with respect to physician recruitment activities, the proposed revenue ruling also contains many uncertainties, such as how much a provider may rely on the authority if it has a recruitment situation that varies slightly from one of the favored situations or if it has such a situation that varies greatly but is truly beneficial to the provider's community. Hopefully, the final revenue ruling will answer some of these outstanding issues.

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221. I.R.S. ANN. 95-25, *supra* note 215. See also *Lorain Avenue Clinic v. Commissioner*, 31 T.C. 141 (1958); *Birmingham Business College v. Commissioner*, 276 F.2d 476 (5th Cir. 1960).

222. I.R.S. ANN. 95-25, *supra* note 215. See also Rev. Rul. 75-384, 1975-2 C.B. 204; Rev. Rul. 80-278, 1980-2 C.B. 175; Rev. Rul. 80-279, 1980-2 C.B. 176.

223. I.R.S. ANN. 95-25, *supra* note 215.

224. I.R.S. ANN. 95-25, *supra* note 215. Of note is that in this fifth situation, the hospital in question is located in a medium to large metropolitan area. Under the Medicare/Medicaid Anti-Kickback statute at 42 U.S.C. § 1320a-7b(b), it is not relevant where a person is located for purposes of making illegal inducements for referrals. However, Congress and the United States Department of Health and Human Services have recognized the need for health care providers to locate in rural areas and have issued statutory exceptions and proposed "safe harbor" regulations, respectively, that would allow certain activity, specifically including physician recruitment, to be deemed safe from prosecution under this statute if such activity occurs in a rural area. See 42 U.S.C. § 1320a-7(b)(3) (1994); 42 C.F.R. § 1001.952 (1994).

*B. Physician Self-Referral/Fraud and Abuse*

1. *Stark I Final Regulations.*—During the 1995 Survey period, the federal Health Care Financing Administration (“HCFA”) issued substantive final regulations<sup>225</sup> implementing section 1877 of the Social Security Act, known as the Ethics in Patient Referrals Act of 1989, or better known as the “Stark I” legislation.<sup>226</sup> Stark I became effective January 1, 1992 and applies to physician referrals for clinical laboratory services to entities in which the physician or one of his or her immediate family members has a financial interest.<sup>227</sup> A separate notice of proposed rulemaking will be published to address the provisions of the Comprehensive Physician Ownership and Referral Act of 1993, or “Stark II,” that relate to physician referrals for “designated health services”<sup>228</sup> (including clinical laboratory services) that became effective January 1, 1995. However, in the preamble to the final regulations, HCFA advised that generally the prohibitions and exceptions found in the Stark legislation are drafted so that they apply equally to situations involving referrals for any of the designated health services.<sup>229</sup> Therefore, HCFA will currently rely upon its language and interpretations in the Stark I final regulations when reviewing referrals involving any of the other designated health services under Stark II.<sup>230</sup>

The two pieces of Stark legislation read together with certain amendments to the Social Security Act provide that, with certain exceptions, if a physician or member of a physician’s immediate family<sup>231</sup> has a financial relationship with an entity, the physician may not make referrals to the entity for the furnishing of designated health services for which payment may be made under the Medicare/Medicaid programs, and the entity may not present a claim to Medicare/Medicaid or bill any third party payor for such services furnished

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225. 60 Fed. Reg. 41,914 (1995). On March 31, 1995, the United States Department of Health & Human Services Office of Inspector General published a final rule relating to civil money penalties, assessments and exclusions for persons who make a claim for payment for a service rendered pursuant to a referral prohibited by the Stark legislation and for persons who enter into schemes to circumvent the basic statutory prohibitions. See 60 Fed. Reg. 16,580 (1995).

226. 42 U.S.C. § 1395nn (1994).

227. *Id.* § 1395nn(a)(1).

228. Under the Stark II legislation, the term “designated health services” includes clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including MRI, CAT scans and ultrasound; radiation therapy services; durable medical equipment; parental and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. *Id.* § 1395nn(h)(6).

229. 60 Fed. Reg. 41,916 (1995).

230. *Id.*

231. The regulations define “immediate family member” to mean husband or wife; natural or adoptive parent, child or sibling; step relatives (parent, child, brother, sister); in-laws (father, mother, son, daughter, brother, sister); grandparent or grandchild; and spouse of a grandparent or grandchild. 60 Fed. Reg. 41,979 (1995).

pursuant to a prohibited referral.<sup>232</sup>

Under the final Stark I regulations, the term "financial relationship" refers to a physician's (or immediate family member's) ownership or investment interest in an entity or compensation arrangement with an entity.<sup>233</sup> Such financial relationships may be held directly or indirectly.<sup>234</sup> However, there are numerous exceptions found in the Stark legislation applicable to such financial relationships.<sup>235</sup> These exceptions apply to (1) both an ownership/investment interest and a compensation arrangement, (2) only an ownership/investment interest, or (3) only a compensation arrangement.<sup>236</sup>

HCFA views the Stark legislation as, for the most part, self implementing.<sup>237</sup> Thus, the final Stark I regulations do not delay any potential enforcement of either Stark I or Stark II except for sanctions that can only be applied as a result of these regulations.<sup>238</sup> In these final Stark I regulations, HCFA essentially incorporates the statutory requirements that are already in effect and attempts to clarify or interpret certain provisions. A few additional exceptions have also been added. Significant developments from the final regulations are described below.

First and foremost, the group practice definition incorporates a percentage threshold for the requirement that "substantially all" of the patient care services provided by the physicians who are members of the group be furnished through the group. This threshold is, in the aggregate, seventy-five percent of the total "patient care services" of the "members of the group." The term "members of the group" is defined to include physician partners, full-time and part-time physician contractors and employees. "Patient care services" are measured by the total patient care time each member spends on these services. For example, if a physician practices forty hours a week and spends thirty hours on patient care services for a group practice, the physician has spent seventy-five percent of his or her time providing countable patient care services.<sup>239</sup>

For purposes of determining whether this threshold is met, a patient care services percentage must be determined for each group member; these percentages are then added together and divided by the number of physicians. Further, group practices will be required to submit written statements to their fiscal intermediaries annually that attest to meeting the seventy-five percent threshold. However, the "substantially all" test does not apply to any group practice located solely in a Health Professional Shortage Area ("HPSA").<sup>240</sup>

Of final note with respect to group practices is that although not explicit in the regulations, HCFA advises in the preamble to the regulations that an entity owned

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232. 42 U.S.C. § 1395nn(a)(1) (1994).

233. 60 Fed. Reg. 41,978 (1995).

234. *Id.*

235. 42 U.S.C. § 1395nn(b)-(d) (1994).

236. *Id.*

237. 60 Fed. Reg. 41,924 (1995).

238. *Id.*

239. 60 Fed. Reg. 41,978 (1995).

240. *Id.*

and operated by physicians and non-physicians may be able to qualify as a group practice, presuming the above described threshold and other requirements are met.<sup>241</sup>

Other important developments from the final regulations pertain to a transaction that involves long-term or installment payments; such an arrangement is not considered an “isolated transaction” for purposes of the isolated transaction compensation arrangement exception.<sup>242</sup> In order to take advantage of this exception, there can be no additional transactions between the parties for six months after the isolated transaction.<sup>243</sup> Thus, it may be necessary to examine other Stark exceptions if an arrangement with a physician or immediate family member of a physician involves installment payments.

In the final regulations, it is important to note that HCFA created a new exception applying to both an ownership/investment interest and a compensation arrangement for services furnished in an ambulatory surgical center (“ASC”), end stage renal disease (“ESRD”) facility, or by a hospice, if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.<sup>244</sup> Further, ownership in a laboratory located in a rural area is excepted if substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. “Substantially all” means no less than seventy-five percent.<sup>245</sup>

An ownership or investment interest in a hospital will not implicate Stark if the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.<sup>246</sup> The regulations define “hospital” as any separate legally organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital’s patients and for which the hospital bills. A “hospital” does not include entities that perform services for hospital patients “under arrangement” with the hospital.<sup>247</sup>

A significant exception in the Stark legislation was clarified by the regulations. This exception for both ownership/investment interests and compensation arrangements applies to certain in-office ancillary services and includes three requirements that apply to the performance, location and billing of such services.<sup>248</sup> Regarding the performance component, certain in-office ancillary services may be performed by an individual who is directly supervised by the referring physician or another physician in the same group practice as the referring physician.<sup>249</sup> The regulations define “direct supervision” as supervision by a

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241. 60 Fed. Reg. 41,937 (1995).

242. See 42 U.S.C. § 1395nn(e)(6) (1994).

243. 60 Fed. Reg. 41,981 (1995).

244. 60 Fed. Reg. 41,980 (1995).

245. *Id.*

246. *Id.*

247. 60 Fed. Reg. 41,979 (1995).

248. 42 U.S.C. § 1395nn(b)(2) (1994).

249. *Id.*

physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.<sup>250</sup>

Because Stark applies to indirect financial relationships, HCFA advises that joint ventures with physicians and hospitals should be structured in such a way that remuneration does not pass from the hospital to the physicians unless a specific Stark exception applies to the arrangement. Otherwise such remuneration may result in prohibited referrals by the physicians to the hospital.<sup>251</sup>

Finally, the regulations require all entities furnishing items or services for which payment may be made under Medicare to submit information to HCFA concerning their financial relationships as defined under Stark. This information must be submitted on a HCFA-prescribed form within the time period specified by the servicing carrier or intermediary. Thereafter, an entity must provide updated information within sixty days from the date of any change in the submitted documentation.<sup>252</sup> Consequently, hospitals and other health care organizations will have to implement processes to track such financial relationships in order to meet this ongoing reporting requirement. The sanctions for failure to meet this reporting requirement include civil money penalties of up to \$10,000.00 for each day a report is not properly made after the provider's applicable deadline.<sup>253</sup>

2. *Hanlester Network v. Shalala*.—In April 1995, the Ninth Circuit Court of Appeals issued a potentially landmark decision in *Hanlester Network v. Shalala*.<sup>254</sup> In *Hanlester* the court reversed in part and affirmed in part the lower court's grant of summary judgment in favor of the government. Most importantly, the court made a number of significant holdings concerning the Medicare/Medicaid Anti-Kickback statute.<sup>255</sup>

First, the court held that the mere encouragement of referrals would not violate the statute. Instead, the court held an "inducement" is necessary. The court noted that the term "induce" is broader than terms like influence or encourage. The term "induce" has been defined as to bring on or about, to affect, cause to influence an act or course of conduct, lead by persuasion or reasoning, incite by motives, or to prevail on.<sup>256</sup> "To induce," according to the court, connotes an intent to exercise influence over the reason or judgment of another in an effort to cause the referral

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250. 60 Fed. Reg. 41,978 (1995).

251. 60 Fed. Reg. 41,956 (1995).

252. 60 Fed. Reg. 41,982 (1995).

253. *Id.*

254. 51 F.3d 1390 (9th Cir. 1995).

255. 42 U.S.C. § 1320a-7b(b) (1994). The Anti-Kickback statute provides in general that whoever knowingly and willfully offers, pays, solicits or receives any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce the referral of patients or business for which payment may be made in whole or in part by Medicare, Medicaid or certain other state health programs is guilty of a felony. Violation of the statute can result in a fine of up to \$25,000 or imprisonment for up to five years, or both.

256. *Hanlester*, 51 F.3d at 1398 (citing BLACK'S LAW DICTIONARY 697 (6th ed. 1990)).

of program-related business.<sup>257</sup>

In addition, the court reaffirmed prior holdings that the Anti-Kickback statute is not unconstitutionally vague, citing the statute's "knowing and willful" language.<sup>258</sup> Further, the "in return for" language in the law does not necessitate proof of an agreement to refer Medicare related business.<sup>259</sup>

Finally and most importantly, the court held that a specific intent to disobey the law must be shown in order to prove a violation. The court construed the language "knowingly and willfully" in the Anti-Kickback statute as requiring the defendants to (1) know that the law prohibits offering or paying the remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law.<sup>260</sup> The court advised in a footnote that the legislative history behind the statute demonstrated that the phrase "knowingly and willfully" was intended to shield from prosecution only those whose conduct "while improper, was inadvertent."<sup>261</sup>

This case is significant from the perspective that should *Hanlester* become the standard for prosecution under the Anti-Kickback statute, it may be difficult for the government to prove a person acted with the requisite intent to disobey the statute. Accordingly, efforts to make anti-kickback prosecution easier may rest with Congress.

#### CONCLUSION

As the demand for accessible, affordable and high quality health care continues to be a focal point of public discourse and debate, legal issues attendant to implementing this important objective will abound. Current national legislative initiatives suggest a forthcoming limitation on the amount of future resources available to meet public expectation in providing health care to all citizens. Many practitioners will undoubtedly have a role in seeking a resolution of the various legal issues to come, including ethical allocations of services, collaboration or competition in providing services, and maintenance of ongoing quality of care. It is in these areas that health law developments will be most prevalent in the next years.

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257. *Id.*

258. *Id.*

259. *Id.* at 1397.

260. *Id.* at 1400.

261. *Id.* at 1399. Of significance is that the Third Circuit Court of Appeals held in *United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985), that if one purpose of the remuneration was to induce referrals, the statute was violated. This broad interpretation has long been cited as the standard with respect to violating the Anti-Kickback statute, and it will be interesting to review future decisions regarding this law in light of the *Hanlester* decision.

