

# SURVEY OF RECENT DEVELOPMENTS IN HEALTH LAW

ICE MILLER LLP\*

## INTRODUCTION

This survey summarizes recent developments in case law, legislation, and administrative actions that affect the health care industry. Not meant to be an exhaustive review, this survey details the “hot” topics in the health care industry this year.

### I. MEDICARE PART D PRESCRIPTION DRUG BENEFIT

In 2003, Congress passed, and the President signed, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), a principal purpose of which was to add a prescription drug benefit to the Medicare program.<sup>1</sup> In 2005, the Centers for Medicare and Medicaid Services (“CMS”) took a number of steps to implement the Part D drug benefit in anticipation of the January 1, 2006, commencement of the benefit. Most notably, on January 28, 2005, CMS issued a Final Rule implementing Part D.<sup>2</sup> The Final Rule is quite complex and the following is merely a summary highlighting some of its major provisions.

#### *A. Overview of Part D Benefit and Sponsors*

The Part D prescription drug benefit is not provided directly through CMS. Instead, CMS contracts with “Part D sponsors” to provide the benefit. Part D sponsors may include Prescription Drug Plan (“PDP”) sponsors, Medicare Advantage organizations that offer a Medicare Advantage Prescription Drug plan, a PACE organization offering a PACE plan, or a cost plan offering prescription drug coverage.<sup>3</sup> The Final Rule sets forth a myriad of requirements

---

\* The following Ice Miller LLP attorneys contributed to the research and drafting of this article: Jamie Brashear, Jenifer Brown, Sarah Cotterill, Tami Earnhart, Margaret Emmert, Sherry Fabina-Abney, Natalie Fierek, Cassandra Giles, Beth Hatfield, Blaire Henley, Gregory Pemberton, Susan Rivas, Chris Sears, Myra Selby, Paul Sinclair, Taryn Smith, Skip Whaley, Brad Williams, and Kevin Woodhouse.

1. Pub. L. 108-173, 117 Stat. 2066 (Dec. 8, 2003).

2. 70 Fed. Reg. 4194 (Jan. 28, 2005) (to be codified at 42 C.F.R. pts. 400, 403, 411, 417, and 423).

3. 42 C.F.R. § 423.4 (2005). A “PDP sponsor” is a nongovernmental entity that is certified by CMS as meeting the requirements and standards of the Part D regulations that apply to entities that offer prescription drug plans. *Id.* A PDP is prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in the Part D regulations and that is offered by a PDP sponsor that has a contract with CMS that meets the requirements of the Part D regulations. *Id.* PACE stands for programs of all-inclusive care for the elderly. 42 C.F.R. § 460.6. A “cost plan” is a plan operated by a Health Maintenance Organization or a Competitive Medical Plan in accordance with a cost-reimbursement contract under section 1876(h) of the Social Security Act. 42 C.F.R. § 423.4. Part D coverage may also be provided through a “fallback” prescription

relating to an annual bid process for prescription drug plans approved by CMS, premium setting, risk retention, application procedures, requirements, and contracts between CMS and Part D plans.<sup>4</sup> In general, a Part D plan applicant must: (1) complete an application; (2) be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Part D plan; (3) adhere to minimum enrollment requirements; (4) maintain administrative arrangements satisfactory to CMS related to management, personnel, bonding, insurance, and compliance; (5) not have non-renewed a contract with CMS within the past two years (subject to certain exceptions); (6) not have submitted a bid or offered a fallback prescription drug plan in accordance with specified rules; (7) agree to CMS audits to detect and prevent fraud and abuse; and (8) agree to certain severability conditions.<sup>5</sup> The Final Rule amplifies these conditions by setting forth detailed provisions relating to the actual terms of contracts between CMS and Part D sponsors, which include details about termination and non-renewal of contracts.<sup>6</sup>

Part D provides coverage for most outpatient drugs that may be dispensed by a prescription for medically accepted indications, as well as insulin and medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.<sup>7</sup> It also includes vaccines licensed under the Public Health Services Act and certain biological products. Part D does not cover drugs for which payment is available under Medicare Parts A or B, and a PDP or MA-PD plan may also exclude coverage if the drug was not prescribed in accordance with the plan or Part D (such as if the drug was not covered under the plan's formulary).<sup>8</sup>

Part D sponsors must provide either "standard prescription drug coverage" or "alternative prescription drug coverage."<sup>9</sup> Standard prescription drug coverage has an annual deductible for enrollees of \$250. After an enrollee meets the deductible, the enrollee's prescription drug costs between \$250 and \$2250 (the "initial coverage limit") are subject to a coinsurance payment by the enrollee

---

drug plan. 42 C.F.R. §§ 423.851 to -.875. Fallback drug plans are those that offer standard or alternative coverage, provide access to negotiated prices, and meet the other requirements for prescription drug plans. CMS, however, has the authority to waive requirements of the Final Rule for fallback prescription drug plans if it is necessary to ensure that each enrollee has the choice of at least two prescription drug plans in the area in which the enrollee resides. However, due to the strong participation of private prescription drug plans in all areas, the fallback provisions are not currently necessary.

4. 42 C.F.R. §§ 423.251 and 423.500 to -.516.

5. 42 C.F.R. § 423.504; *see also* 42 C.F.R. §§ 423.401 to -.440 (setting forth the general requirements for prescription drug plan sponsors and rules related to waiving requirements); 42 C.F.R. §§ 423.641 to -.669 (setting forth the procedures for contract determination, contract non-renewal, and contract termination).

6. 42 C.F.R. §§ 423.505 to -.516.

7. 42 C.F.R. § 423.100.

8. *Id.*

9. 42 C.F.R. § 423.104(d)-(e).

equal to twenty-five percent of the actual cost of the prescription drugs. When an enrollee's actual drug costs exceed \$2250, the enrollee is responsible for paying one hundred percent of actual drug costs up to \$3600 (the "annual out-of-pocket threshold"). After an enrollee's actual incurred drug costs exceed the annual out-of-pocket threshold, Part D's "catastrophic" drug benefit will engage under which the enrollee will be responsible for relatively small cost-sharing requirements. The catastrophic cost-sharing requirements are equal to the greater of: (1) \$2 for a generic drug or preferred drug that is a multiple source drug or \$5 for any other drug; or (2) five percent of the actual drug cost.<sup>10</sup>

Part D's catastrophic benefit will not commence until the enrollee has actually "incurred" \$3600 in actual drug costs. For these purposes, "incurred costs" are costs that are not paid for under the Part D plan as a result of the application of any annual deductible or other cost-sharing rules and that are paid for by the enrollee (or on behalf of the enrollee by another person). These are the enrollee's "true out-of-pocket" costs, or "TrOOP." TrOOP costs may not include any reimbursement to the enrollee through insurance, a group health plan, or other third party payment arrangement, or any payment by another person on behalf of the enrollee who is paying under insurance, a group health plan, or a third party payment arrangement.<sup>11</sup> In other words, with few exceptions, the enrollee must actually have personally paid \$3600 in drug costs before the catastrophic coverage commences. Therefore, any amounts paid by an employer-provided prescription drug benefit or other insurance will not count toward the achievement of the \$3600 threshold.<sup>12</sup>

"Basic Alternative prescription drug coverage" is prescription drug coverage that is actuarially equivalent to the standard prescription drug benefit. However, the basic alternative coverage may not have an annual deductible that exceeds the deductible under standard coverage (\$250 in 2006) and must have the same

---

10. *Id.* § 423.104(d). Note that the deductible, initial coverage limit, and annual out-of-pocket threshold set forth above are for 2006 and are all subject to an annual percentage increase for each year that is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals. The calculation is based on data for the twelve-month period ending in July of the previous year. *Id.* § 423.104(d)(5)(iv). In addition, the Final Rule provides for premium and cost-sharing subsidies for individuals who meet certain low-income thresholds. 42 C.F.R. §§ 423.771 to -.800. The Social Security Administration published a final rule implementing the low-income drug subsidy on December 30, 2005. Medicare Part D Subsidies, 70 Fed. Reg. 77,664 (Dec. 30, 2005) (to be codified at 20 C.F.R. pt. 418). Among other things, the final rule details subsidy amounts, eligibility, and the subsidy application process.

11. 42 C.F.R. § 423.100.

12. Note that an enrollee may still count as "incurred" costs that are reimbursed through an employer-sponsored flexible spending account, a health savings account, or a medical savings account because these vehicles are generally funded with an enrollee's own funds. Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4241-42 (Jan. 28, 2005) (to be codified at 42 C.F.R. pts. 400, 403, 411, 417, and 423).

threshold for catastrophic coverage (\$3600 for 2006).<sup>13</sup> If the basic alternative prescription drug coverage meets these requirements, it may deviate from the standard benefit by, for example, changing the cost sharing structure, implementing different formularies, and modifying benefit limits.

In addition, PDP and MA-PD plans that offer a standard or basic alternative plan may also offer enhanced alternative coverage to their own enrollees that covers drugs that are excluded from the Part D program or that increases the actuarial value of the Part D coverage such as reducing the deductible, cost-sharing, or initial coverage limit.<sup>14</sup> Enhanced alternative coverage may only be offered by a PDP sponsor if the sponsor also offers standard or basic alternative coverage in the service area where it is offering the enhanced alternative coverage.<sup>15</sup>

For both standard and alternative prescription drug coverage, Part D sponsors are required to provide Part D enrollees access to their negotiated prices.<sup>16</sup> "Negotiated prices" are prices for covered Part D drugs that are available to beneficiaries at the point of sale at network pharmacies and that are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale (including any dispensing fees).<sup>17</sup> These negotiated prices must be made available to all enrollees regardless of their applicable deductible, initial coverage limit, out-of-pocket threshold, or amounts in excess of this threshold.<sup>18</sup> Part D plan sponsors must disclose to CMS data related to their negotiated price concessions.<sup>19</sup>

### *B. Eligible Individuals and Enrollment*

An individual is eligible to enroll in Part D if he or she is entitled to Medicare benefits under Part A or enrolled in Medicare Part B and lives in the service area of a Part D plan.<sup>20</sup> If an individual is covered under an MA-PD that offers prescription drug coverage, that individual must obtain their prescription drug coverage through the MA-PD plan and may not receive the coverage through another prescription drug plan.<sup>21</sup> Eligible individuals may begin enrolling in Part D during their "initial enrollment period."<sup>22</sup> An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006 has an initial enrollment period from November 15, 2005 through May 15, 2006. An

---

13. 42 C.F.R. § 423.104(e) (2005).

14. *Id.* § 423.104(f).

15. *Id.* § 423.104(f)(2).

16. *Id.* § 423.104(g).

17. 42 C.F.R. § 423.100.

18. 42 C.F.R. § 423.104(g).

19. *Id.*

20. 42 C.F.R. § 423.30(a).

21. *Id.* § 423.30(b).

22. 42 C.F.R. § 423.38(a).

individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006. An individual who first becomes eligible for Part D in March 2006 or thereafter has the same initial enrollment period as he does under Medicare Part B.<sup>23</sup> Each year, there will be an “annual coordinated election period” during which eligible individuals may enroll in Part D or change their Part D prescription drug plan choices for the following calendar year. That period is from November 15 to December 31 of each year.<sup>24</sup> In addition, an otherwise eligible individual may also enroll or disenroll during mid-year “special enrollment periods” such as when the individual loses other creditable prescription drug coverage, the individual mistakenly enrolled or disenrolled because of misinformation from other prescription drug plans or a Federal employee, or the individual moves out of a region covered by the prescription drug plan in which he or she is enrolled.<sup>25</sup>

If the individual fails to apply for Part D by the end of his or her initial enrollment period for Part D and does not have other prescription drug coverage that is “creditable coverage” for any continuous 63 day period or longer, he or she may be subject to a late penalty paid through increased Part D premiums.<sup>26</sup> The higher premium is based on the number of months the individual does not have creditable coverage. The premium is increased by one percent for each

---

23. *Id.* § 423.38(a)(1)-(3).

24. *Id.* § 423.38(b).

25. *Id.* § 423.38(c).

26. 42 C.F.R. § 423.46. Prescription drug coverage is “creditable coverage” for these purposes if the actuarial value of the plan coverage equals or exceeds the actuarial value of Part D Medicare standard prescription drug coverage. The actuarial value of a plan’s prescription drug benefit is determined through the use of generally accepted actuarial principals and in accordance with CMS actuarial guidelines (and generally looks to expected amount of paid claims). 42 C.F.R. § 423.56(a). The basic actuarial equivalence value test is performed by determining whether the expected plan payout on average is equivalent to or exceeds the expected plan payout of Medicare Part D. This generally means that the prescription drug plan’s expected amount of paid claims is at least as much as the expected amount of paid claims under the standard Medicare prescription drug benefit. *Id.* § 423.56. Prescription drug plans that meet the following requirements are deemed to be “creditable coverage” without further need for actuarial analysis: (1) the plan provides coverage for brand and generic prescriptions; (2) the plan provides reasonable access to retail providers and, optionally, for mail order coverage; (3) the plan is designed to pay on average at least sixty percent of participants’ prescription drug expenses; and (4) the plan (i) has no annual benefit maximum benefit or a maximum annual benefit payable by the plan of at least \$25,000 or (ii) has an actuarial expectation that the amount payable by the plan will be at least \$2000 per Medicare eligible individual in 2006. If a plan has integrated health coverage, the integrated health plan has no more than a \$250 deductible per year, has no annual benefit maximum or a maximum annual benefit payable by the plan of at least \$25,000, and has no less than a \$1 million lifetime combined benefit maximum. See CMS, Creditable Coverage Guidance (Jan. 4, 2006), <http://www.cms.hhs.gov/CreditableCoverage/Downloads/CCGuidance.pdf>; CMS, Creditable Coverage Simplified Determination, <http://www.cms.hhs.gov/CreditableCoverage/Downloads/CCSimplifiedDetermination.pdf> (last visited July 2, 2006) (clarifying the “Creditable Coverage Guidance”).

month without creditable coverage.<sup>27</sup> This increased premium will apply for as long as the person remains enrolled in Part D and the higher premium will increase each year because the increase will be applied to each subsequent year's base premium. If the individual does have creditable coverage and fails to enroll in Medicare Part D when he or she is initially eligible, the individual will not be penalized. However, if the individual loses creditable coverage and experiences a continuous period of sixty-three days or longer without creditable coverage, the individual will be subject to the higher premium for late enrollment commencing with the month his creditable coverage is no longer in effect.

In order for individuals to know whether they may safely waive Part D coverage during their initial enrollment period without incurring the late penalty, entities that offer certain types of prescription drug coverage to Part D eligible individuals must provide written notice to those individuals about whether their coverage is "creditable coverage."<sup>28</sup> Among the most common entities that must provide this disclosure are those that sponsor employer and union group health plans, Medigap policies, military coverage, and individual health insurance coverage.<sup>29</sup> CMS has issued model notices that may be provided to Part D eligible individuals to notify them whether an entity's prescription drug coverage is "creditable" or "non-creditable."<sup>30</sup> The notice must be provided to any Part D eligible individual who is enrolled or is seeking enrollment in the entity's prescription drug coverage. It is permitted to be distributed with other materials sent to the eligible individual (e.g., an employer plan's summary plan description or enrollment and/or renewal materials) or as a separate document. A single notice can be provided to the covered Part D eligible individual and all Part D eligible dependents covered under the entity's prescription drug plan. However, a separate notice must be sent if the entity knows that the spouse and/or dependent who are Part D eligible individuals do not live at the same address as the covered participant. Notices must be provided at a minimum at the following times: (1) prior to an individual's initial enrollment period for Part D; (2) prior to the commencement of the annual coordinated election period that begins on November 15 of each year; (3) prior to the effective date of a Part D eligible individual's enrollment in the entity's prescription drug coverage; (4) when the prescription drug coverage ends or changes so that it is no longer creditable coverage; and (5) upon request by the individual.<sup>31</sup> Specified entities must also

---

27. 42 C.F.R. § 423.286(d)(3).

28. 42 C.F.R. § 423.56(c)-(d).

29. *Id.* § 423.56(b).

30. The model notices are available at CMS, Creditable Coverage Overview, [http://www.cms.hhs.gov/CreditableCoverage/01\\_Overview.asp](http://www.cms.hhs.gov/CreditableCoverage/01_Overview.asp) (last visited July 2, 2006); *see also* Creditable Coverage Guidance (Jan. 4, 2006), <http://www.cms.hhs.gov/CreditableCoverage/Downloads/CCGuidance.pdf>; CMS, Creditable Coverage Simplified Determination, <http://www.cms.hhs.gov/CreditableCoverage/Downloads/CCSimplifiedDetermination.pdf> (last visited July 2, 2006) (clarifying the "Creditable Coverage Guidance").

31. CMS, Creditable Coverage Overview, [http://www.cms.hhs.gov/CreditableCoverage/01\\_Overview.asp](http://www.cms.hhs.gov/CreditableCoverage/01_Overview.asp) (last visited July 2, 2006).

provide notice to CMS of whether their prescription drug coverage is creditable through an on-line disclosure form.<sup>32</sup>

In general, the effective date of coverage for a newly enrolled individual is the first day of the month that the individual is entitled to Part A or enrolled in Part B, if the Part D enrollment is made *before* the person is entitled to Part A or enrolled in Part B. If Part D enrollment is made *after* that time, then coverage is generally effective on the first day of the month after the Part D enrollment is made.<sup>33</sup> Enrollment made during an annual coordinated election period is effective as of the first day of the next calendar year; however, enrollments made from January 1, 2006, through May 15, 2006, are effective as of the first day of the calendar month following the month in which the Part D enrollment is made.<sup>34</sup>

### C. Access to Pharmacies and Drugs

Part D plans are subject to a number of requirements to ensure that enrollees have adequate access to the drugs they need and pharmacies at which they may obtain the drugs. In general, a Part D plan must establish a network of retail pharmacies sufficient to ensure that ninety percent of enrollees in an urban area served by the Part D plan live within two miles of a network pharmacy, ninety percent of enrollees in a suburban area live within five miles of a network pharmacy, and seventy percent of enrollees in rural areas live within fifteen miles of a network pharmacy.<sup>35</sup> Other regulations require adequate access to non-retail pharmacies (e.g., mail-order and institutional pharmacies); home infusion pharmacies; long-term care pharmacies; and pharmacies operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization.<sup>36</sup> Part D plans must also allow enrollees to obtain any benefit offered under the plan at a retail pharmacy—although the Part D plan may charge higher cost-sharing at the retail pharmacy.<sup>37</sup> This requirement is most significant when an enrollee wants to obtain a ninety-day supply of a drug. In many non-Part D prescription drug plans (such as an employer group health plan), ninety-day drug supplies are only available through a mail-order pharmacy. Part D plans are required to offer these extended supplies through retail outlets also—although the plan may charge more if the prescription is filled at a retail outlet.<sup>38</sup> Plans must also ensure access to Part D drugs at out-of-network pharmacies when an enrollee cannot reasonably be expected to obtain such drugs at a network pharmacy and the enrollee does not access Part D drugs at an out-of-

---

32. See CMS, Disclosure to CMS Guidance (Jan. 10, 2006), <http://www.cms.hhs.gov/CreditableCoverage/Downloads/Disclosure2CMSGdnc.pdf>.

33. 42 C.F.R. § 423.40(a) (2005).

34. *Id.* § 423.40(b).

35. 42 C.F.R. § 423.120(a)(1)(i)-(iii).

36. *Id.* § 423.120(a)(3)-(6).

37. *Id.* § 423.120(a)(10).

38. *Id.*

network pharmacy on a routine basis (including access to vaccines through a physician's office).<sup>39</sup> A plan may require the enrollee to assume a greater financial responsibility for drugs obtained at an out-of-network pharmacy.<sup>40</sup>

Part D plans may also create formularies (selected drugs that are exclusively covered by the plan or that are offered at a lower cost or cost-sharing requirement); however, CMS's Final Rule provides limits on a Part D plan's discretion to limit drugs in the formulary.<sup>41</sup> Formularies may only be developed and revised by a Part D plan's pharmacy and therapeutic committee—the membership of which is prescribed by the Final Rule.<sup>42</sup> A plan's formulary must include, within each therapeutic category and class of Part D drugs, at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs.<sup>43</sup> However, only one Part D drug needs to be included if the particular category or class includes only one Part D drug. In addition, only one Part D drug needs to be included for a particular category or class if the Part D plan can demonstrate (and CMS concurs) that only two drugs are available in that category or class and that one drug is clinically superior to the other drug.<sup>44</sup> Finally, a Part D plan must include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.<sup>45</sup>

A Part D plan may not remove a drug from the formulary without providing notice to CMS and other relevant entities sixty days prior to the removal.<sup>46</sup> In addition, the Part D plan must either: (1) provide direct written notice to affected enrollees at least sixty days before the effective date of the change or (2) provide the affected enrollee with a sixty-day supply of the drug the next time that the enrollee requests a refill and provide the enrollee with the removal notice at that time.<sup>47</sup> The regulation sets forth the content requirements of enrollee notices.<sup>48</sup> Drugs may be removed from the formulary immediately if deemed unsafe by the Food and Drug Administration, as long as retrospective notice is provided to affected enrollees, CMS, and other relevant entities.<sup>49</sup> Except for changes required by the FDA, no changes may be made during the period between November 15 and sixty days after the beginning of the new plan year.<sup>50</sup>

The Part D Final Rule also requires that information be provided to enrollees and that enrollees' information remain confidential. A Part D sponsor must

---

39. 42 C.F.R. § 423.124.

40. *Id.*

41. 42 C.F.R. § 423.120(b).

42. *Id.* § 423.120(b)(1).

43. *Id.* § 423.120(b)(2)(i).

44. *Id.* § 423.120(b)(2)(ii).

45. *Id.* § 423.120(b)(2)(iii).

46. *Id.* § 423.120(b)(5)(i).

47. *Id.*

48. *Id.* § 423.120(b)(5)(ii).

49. *Id.* § 423.120(b)(5)(iii).

50. *Id.* § 423.120(b)(6).

provide enrollees with information about the plan's service area, benefits, cost-sharing, formulary list, procedures to request formulary exceptions, access, out-of-network coverage, grievance and appeals procedures, quality assurance policies, and other information.<sup>51</sup> Pharmacies are required to inform enrollees of the price differential between a brand name Part D drug and its generic equivalent. The notice must be provided at the point of sale when the drug is dispensed (or at the time of the delivery of a mail-order drug).<sup>52</sup> Finally, the regulations require PDP sponsors to ensure that they abide by all applicable medical privacy laws and have procedures that specify for what purposes information will be used within the organization and when it may be disclosed outside of the organization. Enrollee records must be maintained in an accurate and timely manner and enrollees must have timely access to the records and information that pertain to them.<sup>53</sup>

#### *D. Cost and Quality Control*

The Final Rule requires Part D plans to institute certain cost control and quality improvement initiatives. Specifically, Part D plans must institute drug utilization management programs, quality assurance measures, and a medication therapy management program that targets medication use by individuals with chronic diseases who are likely to incur substantial annual drug costs due to use of multiple Part D drugs.<sup>54</sup> Part D sponsors are required to support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees based on standards published by CMS on November 7, 2005.<sup>55</sup> Plan D sponsors may be deemed to comply with a number of the requirements of the Final Rule if they are accredited by a private, national accreditation organization approved by CMS.<sup>56</sup> The requirements for which deemed status can be obtained are the following: those relating to access to covered drugs, drug utilization management programs, quality assurance measurements and systems, medication therapy management programs, programs to control fraud, abuse, and waste, and privacy requirements.<sup>57</sup> CMS may remove deemed status if it determines the sponsor does not actually meet the requirements.<sup>58</sup> Deemed entities must submit

---

51. 42 C.F.R. § 423.128; *see also* 42 C.F.R. §§ 423.560 to -.638 (setting forth detailed provisions related to the grievance, coverage determination, and appeals processes required to be implemented by Part D plan sponsors).

52. 42 C.F.R. § 423.132. Note that certain waiver provisions may apply to this notice requirement. *Id.*

53. 42 C.F.R. § 423.136.

54. 42 C.F.R. § 423.153.

55. 42 C.F.R. § 423.159; *see also* Medicare Program; E-Prescribing and the Prescription Drug Program, 70 Fed. Reg. 67,568 (Nov. 7, 2005) (to be codified at 42 C.F.R. pt. 423).

56. 42 C.F.R. § 423.165 (2005). The standards and procedures for applying for approval to become a recognized accreditation organization are at 42 C.F.R. §§ 423.168 and 423.171.

57. 42 C.F.R. § 423.165(b).

58. *Id.* § 423.165(e).

to CMS their accreditation surveys and authorize the accreditation organization to release survey information to CMS (including the Part D sponsor's corrective action plans).<sup>59</sup>

### *E. Compensation to Part D Plans*

Part D plans are compensated for providing the Part D benefits and incurring the risk of providing those benefits through a number of mechanisms. Subpart G of the Final Rule “sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments.”<sup>60</sup> Payments to sponsors are made from CMS's Medicare Prescription Drug Account.<sup>61</sup> CMS provides Part D plans “advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status,” minus the monthly enrollee premiums.<sup>62</sup> It also provides reinsurance subsidies on a monthly basis “based on either estimated or incurred allowable reinsurance costs . . . and final reconciliation to actual allowable reinsurance costs.”<sup>63</sup> CMS provides “payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain [low-income] individuals.”<sup>64</sup> Lump sum or monthly adjustments may be made “based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year.”<sup>65</sup> Finally, each year “CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs,” and actual allowable reinsurance costs and may make retroactive adjustments if necessary.<sup>66</sup> The Final Rule details the calculation of all of the foregoing payments and prevents any State or local governmental authorities from imposing any premium tax, fee, or other similar assessment on these payments.<sup>67</sup> Any payment to a Part D sponsor is conditioned upon the sponsor providing information to CMS that is necessary to determine payment or that is required by law.<sup>68</sup> The Final Rule provides a payment appeals process for reconsideration of “reconciled health status risk adjustments of the direct

---

59. *Id.* § 423.165(d).

60. 42 C.F.R. § 423.301.

61. 42 C.F.R. § 423.315(a).

62. *Id.* § 423.315(b).

63. *Id.* § 423.315(c).

64. *Id.* § 423.315(d).

65. *Id.* § 423.315(e).

66. *Id.* § 423.315(f).

67. *See* 42 C.F.R. § 423.329 (referring to monthly payments, reinsurance subsidies, and low-income subsidies); 42 C.F.R. § 423.336 (referring to risk-sharing arrangements); 42 C.F.R. § 423.343 (referring to annual retroactive adjustments and reconciliations); *see also* 42 C.F.R. § 423.440(b) (referring to prohibition of state imposition of premium taxes).

68. 42 C.F.R. § 423.322; 42 C.F.R. § 423.159.

subsidy, . . . reconciled reinsurance payments, . . . reconciled final payments made for low-income cost sharing subsidies . . . and [final risk-sharing payments].”<sup>69</sup>

### *F. Sanctions*

CMS may impose defined intermediate sanctions for certain violations committed by Part D sponsors.<sup>70</sup> The following violations may result in sanctions:

(1) fail[ing] substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or . . . contract) to a Part D plan enrollee [when] that failure adversely affects (or is substantially likely to adversely affect) the enrollee[;] (2) impos[ing] on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted [by the Social Security Act and the Final Rule;] (3) act[ing] to expel or refus[ing] to reenroll a beneficiary in violation of the [Final Rule;] (4) engag[ing] in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services[;] (5) misrepresent[ing] or falsify[ing] information furnishe[d to CMS or an] individual or . . . other entity under the Part D drug benefit program[; or] (6) employ[ing] or contract[ing] with an individual or entity who is excluded from participation in Medicare . . . for the provision of . . . [h]ealth care[, u]tilization review[, m]edical social work[, or a]dministrative services.<sup>71</sup>

Sanctions for violations may be imposed only after observing detailed procedures set forth in the Final Rule, and the sanctions may include one or more of the following:

(1) [c]ivil money penalties ranging from \$10,000 to \$100,000 depending upon the violation[;] (2) [s]uspension of enrollment of Medicare beneficiaries[;] (3) [s]uspension of payment to the Part D sponsor for Medicare beneficiaries who enroll[; or] (4) [s]uspension of all Part D plan marketing activities to Medicare beneficiaries for the Part D plan subject to the intermediate sanctions.<sup>72</sup>

The sanctions may remain in place “until CMS is satisfied that the deficiency on

---

69. 42 C.F.R. § 423.350(a). The remainder of 42 C.F.R. § 423.350 provides detailed information regarding the reconsideration process, including the content of a request for reconsideration, an informal written reconsideration process, a hearing right, and a review by the CMS Administrator. *See id.* § 423.350(b)-(d).

70. 42 C.F.R. § 423.752(a).

71. *Id.*

72. 42 C.F.R. § 423.750(a)(1)-(4).

which the determination was based is corrected and is not likely to recur.”<sup>73</sup>

### *G. Retiree Prescription Drug Plan Subsidy*

Recognizing that the implementation of the Part D benefit might encourage employers to terminate their retiree prescription drug plans, the Final Rule allows for the payment of a subsidy to employment-based retiree health plans that provide “qualifying covered retirees” with prescription drug coverage that is “actuarially equivalent” to the standard Part D drug benefit.<sup>74</sup> A “qualifying covered retiree” is a Part D eligible individual who is a participant (or the spouse or dependent of the participant) in the employment-based retiree health plan that provides “actuarially equivalent” prescription drug benefits who is not enrolled in a Part D plan.<sup>75</sup> These plan sponsors may *not* collect a subsidy for retirees who enroll in Part D (regardless of whether the retiree also participates in the retiree plan).<sup>76</sup> For each “qualifying covered retiree” the sponsor of the retiree plan is eligible for a subsidy in the amount of twenty-eight percent of the allowable retiree cost for covered Part D drugs in the plan year for such retiree attributable to the gross retiree costs between the cost threshold (\$250 in 2006) and the cost limit (\$5000 in 2006).<sup>77</sup> Drug costs for qualifying covered retirees incurred by the retiree plan below \$250 and above \$5000 are not considered when calculating the twenty-eight percent subsidy.<sup>78</sup>

To receive the subsidy, the employment-based retiree drug plan must provide prescription drug coverage that is “actuarially equivalent” to the standard Part D prescription drug benefit.<sup>79</sup> In general, actuarial equivalence is a measure of whether the retiree drug plan provides benefits that are on average for all participants at least as valuable as the standard Part D drug benefit.<sup>80</sup> Actuarial

73. *Id.* § 423.750(b).

74. 42 C.F.R. §§ 423.880 to -.894.

75. 42 C.F.R. § 423.882.

76. *Id.*

77. 42 C.F.R. § 423.886.

[G]ross retiree costs means, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan, . . . non-administrative costs incurred under the plan for Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of Part D drugs.

42 C.F.R. § 423.882. The cost threshold and cost limits are adjusted annually in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually.

42 C.F.R. § 423.886(b)(3); *see also supra* note 10.

78. 42 C.F.R. § 423.886(b)(1)-(2).

79. 42 C.F.R. § 423.884(d).

80. Actuarial equivalence is achieved if the retiree plan’s “gross value” and “net value” are “at least equal to the actuarial” gross and net values of the standard Part D drug benefit. *Id.* § 423.884(d)(1)-(2). Gross value under the retiree plan “is determined using the actual claims experience and demographic data for Part D eligible individuals who are participants and beneficiaries in the [retiree] plan.” *Id.* § 423.884(d)(5)(ii)(A). Net value under the retiree plan is

equivalence must be certified “by a qualified actuary who is a member of the American Academy of Actuaries” and submitted through an on-line subsidy application process “no later than ninety days prior to the beginning of the plan year” to which the subsidy will apply.<sup>81</sup> Applicants for the retiree drug subsidy must provide ongoing updates on the participation of qualified covered retirees<sup>82</sup> and may receive subsidy payments on a monthly, quarterly, or annual basis.<sup>83</sup>

## II. FRAUD AND ABUSE

### A. Gainsharing

The debate over hospital-physician gainsharing arrangements revived in 2005.<sup>84</sup> Gainsharing had fallen into disuse following an unequivocally negative 1999 Special Advisory Bulletin of the Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”).<sup>85</sup> In the Bulletin, OIG warned that then-current gainsharing practices violated the Civil Monetary Penalties (“CMP”) statute<sup>86</sup> which prohibits any “payment, directly or indirectly, to a physician as an inducement to reduce or limit services” to Medicare or Medicaid beneficiaries who are under the direct care of the physician.<sup>87</sup> OIG also warned that gainsharing arrangements violated the Anti-Kickback statute<sup>88</sup> which prohibits remuneration in return for patient referrals.<sup>89</sup>

---

“determined by reducing the gross value of the coverage by the expected premiums paid by Part D eligible individuals who are plan participants or their spouses and dependents.” *Id.* § 423.884(d)(5)(ii)(B).

81. *Id.* §§ 423.884(c)(5), (d)(2). Applications for the retiree drug subsidy may be made at CMS, Retiree Drug Subsidy Program, at <http://rds.cms.hhs.gov/> (last visited July 2, 2006).

82. *Id.* § 423.884(c)(6).

83. 42 C.F.R. § 423.888(b)(1).

84. “While there is no fixed definition of a ‘gainsharing’ arrangement, the term typically refers to an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital’s costs for patient care attributable in part to the physicians’ efforts.” Department of Health and Human Services, Office of Inspector General, Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>.

85. *Id.*

86. *Id.*; 42 U.S.C. § 1320a-7a (2000).

87. 42 U.S.C. § 1320a-7a(b)(1).

88. See sources cited *supra* note 84; 42 U.S.C. § 1320a-7b.

89. 42 U.S.C. § 1320a-7b(b)(1)(A). Gainsharing arrangements also potentially implicate the Stark law prohibition on self referrals. 42 U.S.C. § 1395nn. OIG expressed no opinion on this issue, because the law fell outside its advisory opinion authority. See, e.g., Op. Dep’t of Health & Human Servs., OIG No. 05-01, 6-7 (Jan. 28, 2005) [hereinafter Advisory Opinion No. 05-01], available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0501.pdf>. Similarly, OIG expressed no opinion on the application of the Internal Revenue Service’s regulations governing private inurement and private benefit issues for nonprofit hospitals. *Id.* at 7 n.8; see 26 U.S.C. §

Current gainsharing issues arise most frequently in surgical settings. Examples include policies which reward the substitution of less costly surgical items or the opening of sterile supplies only on an “as-needed” basis. A January 18, 2001, advisory opinion, in which OIG declined to take enforcement action against a surgical cost-saving arrangement, attracted little attention at the time.<sup>90</sup>

Beginning on January 28, 2005, OIG issued six advisory opinions concerning various gainsharing proposals. The approved arrangements included policies which rewarded “practices to curb the inappropriate use or waste of medical supplies” in cardiac surgery,<sup>91</sup> and the use of standardized supplies in cardiac catheterization laboratories.<sup>92</sup> The advisory opinions concluded that each proposed arrangement constituted a potential violation of the CMP law and the Anti-Kickback statute. However, since the proposals contained safeguards to minimize the potential for abuse, OIG announced that it would not impose sanctions against the requester of the opinion.<sup>93</sup>

With respect to the CMP law, OIG identified eight factors militating against sanctions.<sup>94</sup> First, each proposed arrangement clearly and separately identified the specific cost saving action to be implemented and the resulting savings.<sup>95</sup> This “allow[ed] for public scrutiny and . . . physician accountability for any adverse effects.”<sup>96</sup> Second, the requesters provided “credible medical support for the position that implementation of the recommendations [would] not adversely affect patient care.”<sup>97</sup> Third, the proposed incentive payments were for services “not disproportionately performed on . . . program beneficiaries [and were] calculated [based] on the hospital’s actual out-of-pocket . . . costs.”<sup>98</sup> Fourth, the proposals used objective data to establish the historical frequency of the

---

501(c)(3), Rev. Rul. 69-383, 1969-2 C.B. 113.

90. Op. Dep’t of Health & Human Servs., OIG No. 01-01 (Jan. 11, 2001), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-01.pdf>.

91. Advisory Opinion No. 05-01, *supra* note 89, at 3; *see also* Op. Dep’t of Health & Human Servs., OIG No. 05-03 (Feb. 10, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0503.pdf>; Op. Dep’t of Health & Human Servs., OIG No. 05-06 (Feb. 18, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0506.pdf>.

92. Op. Dep’t of Health & Human Servs., OIG No. 05-02 (Feb. 10, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0502.pdf>; Op. Dep’t of Health & Human Servs., OIG No. 05-04 (Feb. 10, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0504.pdf>; Op. Dep’t of Health & Human Servs., OIG No. 05-05 (Feb. 18, 2005), *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0505.pdf>.

93. Advisory Opinion No. 05-01, *supra* note 89, at 8. OIG did conclude that “open as needed” policies for surgical tray items did not run afoul of the CMP statute because the “insubstantial time” required to open them did not constitute a reduction or limitation of services. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.* at 8-9.

procedures involved.<sup>99</sup> The data were used to establish maximum thresholds beyond which savings would not be shared with the physician.<sup>100</sup> Fifth, in the case of product standardization incentives, the arrangements did not unduly limit the selection of cardiac devices available to the physician.<sup>101</sup> Sixth, the hospital and physician will disclose the arrangement to patients in writing.<sup>102</sup> Seventh, “the financial incentives [were] reasonably limited in duration and amount.”<sup>103</sup> Eighth, payments were to be made by the hospital to the physician or surgeon’s practice group to be distributed on a per capita basis, not to the individual physician.<sup>104</sup>

With respect to the Anti-Kickback statute, OIG concluded that the “safe harbor” for personal services and management contracts<sup>105</sup> did not apply to the arrangements, because the percentage payment did not meet the “set in advance” requirement.<sup>106</sup> However, OIG concluded that the incentive payments did not appear to be based on a prohibited intent to induce referrals, or present a risk of overutilization, for three reasons.<sup>107</sup> First, participation in each program was limited to surgeons or cardiologists already members of the participating practice group, potential savings were capped based on the prior year’s admissions, and the hospital’s contract with the practice group was limited to one year.<sup>108</sup> Second, the participating practice groups did not include other nonparticipating physicians or surgeons.<sup>109</sup> The per capita distribution method “mitigat[ed] any incentive for an individual [participant] to generate disproportionate cost savings.”<sup>110</sup> Third, each proposal specifically set out the particular actions that would generate cost savings.<sup>111</sup> Although the measures appeared to present minimal patient risk, the physician would shoulder any liability burden.<sup>112</sup> The proposals appeared to reasonably compensate the physician for the exposure.<sup>113</sup>

Notwithstanding the tension between the advisory opinions and the 1999 Special Advisory Bulletin, OIG emphasized that the former do not represent a policy change. Each advisory opinion contained such a disclaimer.<sup>114</sup> OIG

---

99. *Id.* at 9.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.* at 8-9.

105. 42 C.F.R. § 1001.952(d) (2005).

106. Advisory Opinion 05-01, *supra* note 89, at 11.

107. *Id.* at 12.

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

114. *See, e.g., id.* at 9-10 (noting that “[t]he Proposed Arrangement is markedly different from many “gainsharing” plans, particularly those that purport to pay physicians a percentage of

further reiterated its position in congressional testimony by OIG Chief Counsel Lewis Morris.<sup>115</sup> However, Morris pointed to a distinction between so-called “black box” gainsharing typical of earlier practices and the arrangements described in the 2005 advisory opinions.<sup>116</sup> Morris characterized “black box” gainsharing as “arrangements that give physicians money for overall cost-savings without knowing what specific actions the physicians are taking to generate those savings.”<sup>117</sup> Morris testified that, in “evaluating a particular . . . program, OIG . . . generally focuse[s] on three areas: accountability, quality controls, and safeguards against payments for referrals.”<sup>118</sup> Morris warned that “any broad reading of the [advisory] opinions should be done with caution. Different cost-saving measures or different payment structures could have produced different results.”<sup>119</sup> Clearly, the 2005 advisory opinions represent only the beginning of the renewed gainsharing debate.<sup>120</sup>

### B. Recent Court Decisions Under the False Claims Act (“FCA”)<sup>121</sup>

1. *Causing the Submission of a False Claim.*—In *United States ex rel. Schmidt v. Zimmer, Inc.*,<sup>122</sup> the Third Circuit applied tort law concepts of intervening and superseding cause to a qui tam action against Zimmer, a manufacturer of orthopedic implants. Zimmer contracted with a purchasing agent to supply implants to a group of participant hospitals.<sup>123</sup> According to the complaint, the contract provided for a discount on each implant once the number of implants ordered by the participant exceeded the number ordered the year

---

generalized cost savings not tied to specific, identifiable cost-lowering activities”).

115. *Gainsharing Arrangements: Hearing on Oct. 7, 2006 Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 109th Cong. 1-4 (2005) (statement of Lewis Morris, Chief Counsel, U.S. Department of Health and Human Services Office of Inspector General), available at <http://oig.hhs.gov/testimony/docs/2005/Gainsharing10-07-05.pdf>.

116. *Id.*

117. *Id.* at 3.

118. *Id.*

119. *Id.* at 4.

120. See Hospital Fair Competition Act of 2005, S. 1002, 109th Cong. (2005) (having been sponsored by Senators Grassley and Baucus and proposing to authorize certain “coordinated care arrangements between hospitals and physicians,” meaning gainsharing arrangements).

121. 31 U.S.C. §§ 3729-3733 (2000). The FCA authorizes the United States to bring a civil action against persons who, among other things, knowingly present a false or fraudulent claim to the government. *Id.* § 3729(a). If found liable, the defendant must pay three times the actual damages suffered by the government, plus a civil penalty of \$5500 to \$11,000 per claim. *Id.* So-called qui tam provisions permit, with certain limitations, a private citizen known as a “relator” to commence an FCA suit on behalf of the government, in which the United States Department of Justice may elect to intervene. *Id.* § 3730(b)(1). If the suit is successful, the relator may receive between fifteen to thirty percent of the government’s recovery. *Id.* § 3730(d).

122. 386 F.3d 235 (3d Cir. 2004).

123. *Id.* at 237.

before. Also, each participant allegedly would receive a two percent bonus on implant purchases if it met preset market share and volume purchase commitments.

The complaint alleged that Medicare cost reports filed by the participants failed to disclose the rewards the participant received from Zimmer. This allegedly violated the certification contained on the cost report form, which required the entity submitting the report to certify that the costs submitted were true and correct. The complaint alleged violations of the Anti-Kickback Statute and the Stark self-referral ban.<sup>124</sup>

Zimmer argued that it did not file cost reports and had no reason to know what the hospitals' reports would contain and thus did not "cause" the hospitals to submit false reports. The district court granted Zimmer's motion to dismiss. The Third Circuit reversed, holding that the complaint sufficiently alleged that Zimmer "pursued a marketing scheme that it knew would, if successful, result in the submission by [the hospitals] of compliance certifications required by Medicare that Zimmer knew would be false."<sup>125</sup> The panel specifically applied

ordinary causation principles from negligence law in determining responsibility under the FCA. Under those principles, the "intervention of a force which is a normal consequence of a situation created by the actor's . . . conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about."<sup>126</sup>

Thus, even if the hospitals' allegedly false certifications were an unlawful act, they did not absolve Zimmer from responsibility as a superseding cause.<sup>127</sup> The doctrine did not apply because the complaint alleged that Zimmer "realized or should have realized the likelihood" that false certifications would be made as a part of the discount arrangement.<sup>128</sup>

2. *Displacement of Common Law Remedies.*—In *United States v. Lahey Clinic Hospital, Inc.*,<sup>129</sup> the United States sued to recover alleged Medicare Part B overpayments. The complaint alleged common law theories of unjust enrichment and payment under mistake of fact. The government invoked subject matter jurisdiction under 28 U.S.C. § 1345, the general "United States as plaintiff" jurisdictional statute.

The First Circuit rejected the defendant's argument that the United States could only recover overpayments through the administrative process established under the Medicare Act.<sup>130</sup> It also rejected the contention that the Act implicitly repealed section 1345 and displaced underlying common law causes of action to

---

124. See *supra* notes 88-90 and accompanying text.

125. *Zimmer*, 386 F.3d at 244.

126. *Id.* (omission in original) (quoting RESTATEMENT (SECOND) OF TORTS § 443).

127. *Id.* at 244-45.

128. See *id.* at 245 n.11.

129. 399 F.3d 1 (1st Cir.), *cert. denied*, 126 S. Ct. 339 (2005).

130. See 42 U.S.C. § 405 (g)-(h) (2000); see also 42 U.S.C. § 1395.

recover overpayments.<sup>131</sup> “In the context of recovery of overpayments, the government has broad power to recover monies wrongly paid from the Treasury, even absent any express statutory authorization to sue.”<sup>132</sup>

3. *Materiality of False Statement*.—In *United States ex rel. A+Homecare, Inc. v. Medshares Management Group, Inc.*,<sup>133</sup> the Sixth Circuit joined other circuits<sup>134</sup> in holding that a false claim or statement must be “material” to support an action under the FCA.<sup>135</sup> The panel adopted the “natural tendency” standard articulated by the Supreme Court.<sup>136</sup> “[A] false statement is material if it has a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed.”<sup>137</sup> Under this standard, a false accrual entry for pension expense on a cost report was material, even though it was disallowed by the fiscal intermediary.<sup>138</sup> “A party cannot file a knowingly false claim on the assumption that the fiscal intermediary will correctly calculate the value in the review process.”<sup>139</sup>

4. *FCA Pleading Requirements*.—FCA claims, being a species of fraud, must be pleaded with particularity.<sup>140</sup> In *United States ex rel. Gross v. AIDS Research Alliance-Chicago*,<sup>141</sup> the relator, a participant in a research study of an off-label investigational new drug for the treatment of AIDS, alleged various acts of negligence, mismanagement, and poor oversight of the study. This allegedly caused the defendants “to be noncompliant with a laundry list of federal regulations . . . , various study protocols, and ‘Good Clinical Practices.’”<sup>142</sup> The complaint alleged that the defendants submitted various study reports to the government, but did not allege what the contents of the reports were, nor what if any, relation the reports bore to grant payments.

The Seventh Circuit observed that the “fraudulent statement’s purpose must

---

131. *Lahey*, 399 F.3d at 15.

132. *Id.* Query whether, in electing to bypass the administrative process and sue on a common law unjust enrichment theory, the government risks exposure to common law-based counterclaims arising out of alleged underpayments. *Cf.* *United States v. Royal Geropsychiatric Servs., Inc.*, 8 F. Supp. 2d 690 (N.D. Ohio 1998) (dismissing provider’s counterclaim for declaratory judgment in FCA suit for failure to exhaust administrative remedies).

133. 400 F.3d 428 (6th Cir.), *cert. denied*, 126 S. Ct. 797 (2005).

134. *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 679 (5th Cir. 2003); *United States ex rel. Costner v. URS Consultants, Inc.*, 317 F.3d 883, 887 (8th Cir. 2003); *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732-33 (7th Cir. 1999); *United States ex rel. Berge v. Bd. of Trs.*, 104 F.3d 1453, 1459 (4th Cir. 1997); *United States v. TDC Mgmt. Corp.*, 24 F.3d 292, 298 (D.C. Cir. 1994).

135. *Medshares*, 400 F.3d at 442.

136. *Id.* at 445; *see also* *Neder v. United States*, 527 U.S. 1, 20-22 (1999).

137. *Medshares*, 400 F.3d at 445 (second alteration in original) (citation omitted).

138. *See id.* at 447 n.13.

139. *Id.* at 447.

140. FED. R. CIV. P. 9(b).

141. 415 F.3d 601 (7th Cir. 2005).

142. *Id.* at 603.

be to coax a payment of money from the government.”<sup>143</sup> The panel held that the complaint alleged nothing more than that all of the reports and filings, taken together, constituted false certifications of compliance with applicable regulations. “These conclusory allegations shed no light on the nature or content of the individual forms or why any particular false statement would have caused the government to keep the funding spigot open, much less when any payments occurred or how much money was involved.”<sup>144</sup> The complaint was also deficient for failing to allege that any particular certification of regulatory compliance was a condition of payment.<sup>145</sup>

5. *FCA Claims Based on Violation of Anti-Kickback Statute.*—In *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc.*,<sup>146</sup> the United States intervened in a qui tam action based upon alleged kickbacks made by various medical services companies to pharmacists, respiratory therapists, and a doctor’s patient representative. The complaint alleged that the defendants disguised the kickbacks as rental payments and commissions.<sup>147</sup> The district court denied a motion to dismiss and certified a very straightforward issue for interlocutory appeal: “[W]hether a violation of the Anti-Kickback statute . . . can form a basis for a[n FCA] claim.”<sup>148</sup> The Eleventh Circuit affirmed. Asserting that compliance with the Anti-Kickback statute was a condition of payment of a Medicare claim, the panel held that a claim arising from a kickback was not eligible for payment. A claim for payment under those circumstances was one “for which payment is known by the claimant not to be owed” and is therefore false.<sup>149</sup>

### C. *New Indiana False Claims and Whistleblower Protection Act*

In 2005 the Indiana General Assembly enacted the False Claims and Whistleblower Act<sup>150</sup> patterned after the federal version<sup>151</sup> and those adopted in other states. Although the Act is too new to have generated precedent, it will clearly affect future enforcement of alleged fraud and abuse violations at the state level.

The Act applies to false claims against the state, defined as “Indiana or any agency of state government.” The term “State” expressly excludes political subdivisions.<sup>152</sup> It specifically “does not apply to a claim, record, or statement

---

143. *Id.* at 604.

144. *Id.* at 605.

145. *Id.*

146. 423 F.3d 1256 (11th Cir. 2005).

147. *Id.* at 1258.

148. *Id.* at 1258-59.

149. *Id.* at 1259.

150. Pub. L. No. 222-2005 § 23; IND. CODE § 5-11-5.5-1 (2005).

151. 31 U.S.C. §§ 3729-3730(h) (2000).

152. IND. CODE § 5-11-5.5-1(6).

concerning income tax” under Indiana Code section 6-3.<sup>153</sup> The Act applies to one

who knowingly or intentionally: (1) presents a false claim to the state for payment or approval; (2) makes or uses a false record or statement to obtain payment or approval of a false claim . . . ; (3) with intent to defraud . . . , delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state; (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true; (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property; (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state; [or] (7) conspires with another person[, or causes another person to violate the statute].<sup>154</sup>

Violators are liable for a “civil penalty of at least five thousand dollars (\$5,000) and for up to three (3) times the amount of damages sustained by the state.”<sup>155</sup>

The Attorney General and Inspector General<sup>156</sup> have concurrent investigative jurisdiction.<sup>157</sup> If the Attorney General discovers a violation, that office may initiate suit. If the Inspector General discovers a violation, that office must first certify the finding to the Attorney General. If the Attorney General declines to act, the Inspector General may proceed.<sup>158</sup>

The Act contains *qui tam* provisions similar to the federal version. A private citizen (referred to in federal parlance as a “relator”) may initiate a civil lawsuit against a violator. Once an action is filed, no person other than the Attorney General or Inspector General may bring another action based on the same facts.<sup>159</sup> The Attorney General or Inspector General may intervene in the action and thereafter control the prosecution.<sup>160</sup>

The Attorney General or Inspector General may move to dismiss the action on motion for cause shown,<sup>161</sup> or may seek dismissal in order to permit pursuit of the claim through an administrative proceeding, “including an administrative proceeding or a proceeding brought in another jurisdiction” which presumably includes a federal proceeding.<sup>162</sup>

If the state prevails, the relator may receive a share of the state’s recovery,

---

153. *Id.* § 5-11-5.5-2(a).

154. *Id.* § 5-11-5.5-2(b).

155. *Id.*

156. The same statute, Pub. L. No. 222-2005, § 14, legislatively created the Office of Inspector General.

157. IND. CODE § 5-11-5.5-3(a).

158. *Id.* § 5-11-5.5-3(b)-(c), (e).

159. *Id.* § 5-11-5.5-4(g).

160. *Id.* § 5-11-5.5-5(a).

161. *Id.* § 5-11-5.5-4(b).

162. *Id.* § 5-11-5.5-5(h).

together with reasonable attorney's fees and an amount to cover the expenses and costs of bringing the action.<sup>163</sup> As with the federal version, if the Attorney General or Inspector General intervened, the relator's share is fifteen to twenty percent of the proceeds.<sup>164</sup> If neither intervenes and the relator proceeds alone, the relator's share becomes twenty-five to thirty percent.<sup>165</sup> If the Attorney General or Inspector General intervenes, and it is determined "that the evidence used to prosecute the action consisted primarily of information contained in: (A) a transcript of a criminal, civil, or legislative hearing; (B) a legislative, and administrative, or other public report, hearing, audit, or investigation; or (C) a news media report," the relator's share is lowered to ten percent.<sup>166</sup>

As with the federal statute, the Act includes a "whistleblower" provision which grants a right of action to "an employee who has been discharged, demoted, suspended, threatened, harassed or otherwise discriminated against in the terms and conditions of employment"<sup>167</sup> because the employee objected to an act in violation of the statute; or initiated, testified, or assisted in the investigation or related proceedings. In addition to reinstatement, the employee may recover up to two times back pay with interest, special damages, reasonable attorney fees, and the costs and expenses of litigation.<sup>168</sup>

The Act grants the Attorney General and Inspector General investigative subpoena power through so-called "civil investigative demands." These may be issued in connection with an investigation involving a false claim. A civil investigative demand may call for the production of documentary material, or may demand testimony or answers to written interrogatories.<sup>169</sup> With a few exceptions set out in the statute, procedures follow the Indiana Trial Rules.<sup>170</sup>

A person who fails to comply with a civil investigative demand is subject to Trial Rule 37 sanctions to the same extent as a person who has failed to cooperate in discovery. However, a person who objects to a civil investigative demand may seek a protective order under Trial Rule 26(C).<sup>171</sup> The Act does not specify the procedure by which such a request is to be brought to a court's attention.

### III. TAX

#### A. *Congressional Hearings on Tax-Exempt Hospitals*

Once again, questions regarding hospital tax exempt status and threats of

---

163. *Id.* § 5-11-5.5-6(a).

164. *Id.*

165. *Id.* § 5-11-5.5-6(a)(3).

166. *Id.* § 5-11-5.5-6(a)(2).

167. *Id.* § 5-11-5-8(a).

168. *Id.* § 5-11-5.5-8(b).

169. *Id.* § 5-11-5.5-10.

170. *Id.* § 5-11-5.5-18.

171. *Id.* § 5-11-5.5-16.

increased enforcement actions have been in the spotlight of tax issues affecting tax-exempt hospitals this year. However, little enforcement action has been taken to date and there has been little change in the basic standards governing health care provider tax exemption at the federal level in the past thirty-six years.<sup>172</sup> However, new critics of hospital tax exempt status are emerging including IRS Commissioner Mark Everson, who has warned of “the gathering storm” of enforcement efforts.<sup>173</sup> Additionally, congressional hearings in 2004 to 2005 have focused on hospital charges to the uninsured, charity care, and tax exemption, claiming that tax-exempt hospitals are not doing enough charity care in return for their tax-exempt status.

Over the past year, both the Senate Finance Committee and the House of Representative Ways and Means Committee have heard extensive debate regarding whether hospitals are sufficiently charitable to warrant continued tax-exempt status. On May 26, 2005, Commissioner Everson testified before the House Ways and Means Committee, at a hearing titled “A Review of the Tax-Exempt Hospital Sector,” and warned that the evolution of the health care industry has “created opportunities for noncompliance” stating that the IRS would vigorously monitor and deter abuse by tax-exempt organizations.<sup>174</sup> Commissioner Everson noted, “[i]t is difficult to differentiate for-profit from nonprofit health care providers . . . [and while the] overwhelming majority of charitable organizations do their utmost to comply with the letter and spirit of the tax law[,] . . . there are increasing indications that the twin cancers of technical manipulation and outright abuse that we saw develop in the profit-making segments of the economy are now spreading to pockets of the nonprofit sector.”<sup>175</sup>

A major discussion at the hearing focused on a report prepared by the U.S. Government Accountability Office at the Committee’s request. The report, titled “Nonprofit, For-profit, and Government Hospitals: Uncompensated Care and Other Community Benefits,” compared the level of charity care provided by for-profit, nonprofit and government hospitals in five states, including Indiana.<sup>176</sup> Generally, the report found that government hospitals devoted substantially larger shares of their patient operating expenses to uncompensated care than did

---

172. Non-profit hospitals and health care organizations are exempt from federal income tax as organizations described in Internal Revenue Code (“IRC”) section 501(c)(3) if they are operated and organized exclusively for charitable purposes within the meaning of the statute. Revenue Ruling 69-545 sets forth the rationale for federal tax exemption, stating that hospitals promote the health of a broad cross-section of the community, operating for “community benefit” and serving a charitable purpose. Rev. Ruling 69-545, 1969-2 C.B. 117.

173. Allison Bennett, *Everson Cautions Exempts Must Work to Fix Problems or Face “Gathering Storm,”* 82 BNA, INC. DAILY TAX REP., Apr. 29, 2005, at G-9.

174. *A Review of the Tax-Exempt Sector Before the H. Comm. on Ways & Means*, 109th Cong. (2005) (statement of Mark Everson, Commissioner, Internal Revenue Service).

175. *Id.*

176. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-05-743T, NONPROFIT, FOR-PROFIT, AND GOVERNMENT HOSPITALS: UNCOMPENSATED CARE AND OTHER COMMUNITY BENEFITS (2005).

nonprofit and for-profit hospitals.<sup>177</sup> The non-profit hospitals' uncompensated care costs, as a percentage of patient operating costs, were higher than those of for-profit hospitals.<sup>178</sup> The burden of uncompensated care costs was not evenly distributed within each hospital group but was concentrated in a small number of hospitals.<sup>179</sup> However, regardless of the ownership status, all of the hospitals reported providing a wide range of other community benefits, including health education and clinic services.<sup>180</sup>

The Senate Finance Committee, lead by Chairman Charles Grassley, is currently conducting its own investigation of tax-exempt hospital systems. On May 25, 2005, Grassley sent a letter to ten large hospitals and health systems requesting information in an effort "to learn whether the benefits they provide to the needy justify the tax breaks they receive."<sup>181</sup> The letter sets forth twenty-five questions regarding charity care and community benefit and twenty-one questions regarding payments, charges, debt collection processes, and tax exempt status.<sup>182</sup> The Senate Finance Committee is expected to introduce charity reform legislation. The legislation will consider recommendations submitted by the Panel on the Nonprofit Sector, formed by the Independent Sector at the request of the Senate Finance Committee.<sup>183</sup>

Although it seems unlikely Congress will make any major changes to federal tax laws governing tax exemption for hospitals, it is likely some changes will occur as pressure from key congressional leaders continues to build and stepped-up enforcement actions continue.

### *B. IRS Examination of Tax-Exempt Organization*

On November 4, 2004, the IRS published guidelines for tax-exempt organizations for 2005.<sup>184</sup> Executive compensation was listed as one of the four critical enforcement initiatives for fiscal year 2005. Scrutiny has focused on two main areas: the reporting or failure to report all forms of compensation and benefits on the organization's annual Form 990 return, and specific types of compensation and benefit practices, including, among others, no-interest or low-interest loans, supplemental retirement plans, spouse travel, gifts to executives

---

177. *Id.* at 3.

178. *Id.*

179. *Id.*

180. *Id.* at 4.

181. Press Release, Senate Fin. Comm., 109th Cong., Grassley Asks Non-Profit Hospitals to Account for Activities Related to Their Tax-Exempt Status (May 25, 2005), available at <http://finance.senate.gov/press/Gpress/2005/prg052505.pdf>.

182. *Id.*

183. SENATE FINANCE COMMITTEE, STAFF DISCUSSION DRAFT (2004), available at <http://www.senate.gov/~finance/hearings/testimony/2004test/062204stfdis.pdf> (proposing a legislative reform for tax-exempt healthcare providers).

184. I.R.S., FISCAL YEAR 2005 EXEMPT ORGANIZATIONS IMPLEMENTING GUIDELINES, available at [http://www.irs.gov/pub/irs-tege/implementing\\_guidelines\\_1104.pdf](http://www.irs.gov/pub/irs-tege/implementing_guidelines_1104.pdf).

and directors, and tax gross-ups.

In response, the IRS has revised two forms, Form 990 and Form 1023, both with a stated objective of helping the IRS monitor potential conflict of interests and uncover possible tax avoidance transactions such as excessive compensation. Required for all applications for tax-exempt status after May 1, 2005, the new Form 1023 asks about payments to third parties who helped create the organization; requests information about compensation and other financial arrangements with officers, directors, trustees, employees, and independent contractors; inquires about how the organization sets compensation that is reasonable; requests information about family and business relationships and the presence of conflict of interest policies within the organization; and asks organizations to describe the benefits of membership, membership requirements, and the relationship between individuals who receive benefits and key individuals within the organization.<sup>185</sup>

The IRS also revised Form 990 and Form 990 Schedule A.<sup>186</sup> Under the revised Form 990 Schedule A, organizations will have to disclose the compensation paid to the five highest paid independent contractors providing “other” services, in addition to the already required disclosure of information on the five highest paid independent contractors providing professional services.<sup>187</sup> Among the changes to revised Form 990: (1) organizations will have to disclose the total compensation paid to directors, officers, and key employees, including compensation from related entities of the organization; (2) directors, officers, and key employees of an organization will have to disclose information regarding family or business relationships; (3) organizations will have to report income to former directors, officers, and key employees including, among others, retirement packages and deferred compensation plans; and (4) organizations will have to disclose whether they have a written conflict of interest policy.<sup>188</sup> The changes to Form 990 and Form 990 Schedule A were only proposed at the time this Article was drafted. The IRS was considering comments as it worked to finalize these forms.

Finally, the IRS has also published proposed regulations clarifying the relationship of the substantive requirements of tax-exempt status under section 501(c)(3) and imposition of intermediate sanctions under IRC section 4958.<sup>189</sup> The proposed regulations provide guidance on the specific factors that the IRS will use in determining whether a section 501(c)(3) organization is jeopardizing

---

185. Revised Form 1023 is available online. I.R.S., Dep’t of the Treas., Form No. 1023, Application for Recognition of Exemption (2004), available at <http://www.irs.gov/pub/irs-pdf/f1023.pdf>.

186. Revised Form 990 is now available online. I.R.S., Dep’t of the Treas., Form No 990, <http://www.irs.gov/pub/irs-pdf/f990.pdf>.

187. *Id.*

188. *Id.*

189. Standards for Recognition of Tax-Exempt Status if Private Benefit Exists or if an Applicable Tax-Exempt Organization Has Engaged in Excess Benefit Transaction(s), 70 Fed. Reg. 53,599 (Sept. 9, 2005) (to be codified at 26 C.F.R. pts. 1 and 53).

its tax exempt status as a result of engaging in one or more excess benefit transactions and sets forth a “facts and circumstances” test to be applied in the determination.<sup>190</sup> In considering whether to revoke tax-exempt status, the IRS will examine all relevant facts and circumstances, including: (1) the size and scope of the organization’s regular exempt activities; (2) the relationship between the size and scope of the excess benefit transaction(s) and the organization’s regular exempt activities; (3) whether the organization has been involved in repeated excess benefit transactions; (4) whether the organization has adopted compliance measures intended to prevent the occurrence of future intermediate sanctions violations; and (5) whether the excess benefit transaction has been corrected or the organization has made a good faith effort to correct.<sup>191</sup>

### C. State and Local Tax Exemption Developments

The federal government is not the only one scrutinizing the practices of tax-exempt organizations, state and local authorities are showing renewed interest in hospital property tax exemptions. Local property tax exemptions are the biggest savings for tax-exempt hospitals, followed by state and federal taxes. Local government and municipalities, squeezed for revenue, have begun to challenge property tax exemptions, either as outright attacks on the hospitals’ exempt status or as demands for payments in lieu of taxes (“PILOTs”).<sup>192</sup>

Recently, the Illinois Department of Revenue revoked the state property tax exemption for Provena Covenant Medical Center at the recommendation of the Champaign County Board of Review.<sup>193</sup> After an ownership change, Provena Covenant Medical Center reapplied for the property tax exemption. Provena was denied the property tax exemption based on a number of factors, including Provena’s community benefit report, which primarily consisted of bad debt write-offs; volunteer work done by hospital employees on their own time; and Provena’s aggressive collection tactics including the use of collection agencies, lawsuits, and even “body attachments,” the legal term for the arrest of debtors who fail to show up in court.<sup>194</sup> Provena appealed the decision and is awaiting an administrative law judge’s decision.

Also, in April, the Champaign County Board of Review recommended that another Illinois non-profit hospital be denied a property tax exemption for five

---

190. *Id.* at 53,602.

191. *Id.*

192. PILOTs have been especially prevalent in Pennsylvania, which recently passed legislation to objectify the standards for tax exemption after a large number of local exemption challenges. 10 PA. CONS. STAT. §§ 371-85 (1999).

193. Lucette Lagnado, *Hospital Found “Not Charitable” Loses Its Status as Tax Exempt*, WALL ST. J., Feb. 19, 2004, at B1; see also Julie Appleby, *Scales Tipping Against Tax-Exempt Hospitals: Critics Challenge Bill Collection, Charity Care, Salaries at Non-Profits*, U.S.A. TODAY, Aug. 24, 2004, at 1B.

194. *Id.*

parcels of land.<sup>195</sup> The board recommended that the Carle Foundation's property tax exemption be denied because of the foundation's inadequate provision of charity care, pointing to the fact that the Carle Foundation only spends one-half of one percent of its revenue on charity care, and its close association with a for-profit physicians group. The board argued that the primary use of the Hospital is to serve as a platform from which the physicians group and individual physicians privately benefit.<sup>196</sup>

#### *D. Charity Care Class Action Litigation*

Since July 2004, class action lawsuits alleging that hospitals have charged uninsured patients fees well in excess of the amounts paid on behalf of insured patients have been initiated in federal courts. However, the judicial consensus is that these cases do not present viable federal claims.<sup>197</sup>

The lawsuits, orchestrated by Richard Scruggs, a plaintiffs' attorney who is credited with developing an aggressive, successful litigation strategy against the tobacco industry in the 1990s, are postured as class actions against a tax-exempt hospital system, the American Hospital Association ("AHA"), and additional defendants including officers, directors, attorneys, and other persons who have participated in the hospitals' decision-making process regarding pricing, billing, and collection practices.<sup>198</sup> The complaints seek monetary damages; ask courts to impose constructive trusts on the defendants' assets; and seek injunctions prohibiting the hospital from charging the uninsured the full undiscounted cost of care, charging the uninsured more than insured patients for the same services, and prohibiting the use of aggressive and abusive collection practices in an

---

195. Text of the Recommendation can be found at <http://www.co.champaign.il.us/BOR/CARLE2004.pdf> (last visited July 2, 2006).

196. *Another Nonprofit Hospital Caught in Move to Revoke Property Tax Break*, BNA, INC. DAILY TAX REP. No. 79, Apr. 26, 2005, at H-3.

197. See *Amato v. UPMC*, 371 F. Supp. 2d 752 (W.D. Pa. 2005); *Lorens v. Catholic Health Care Partners, Inc.*, 356 F. Supp. 2d 827 (N.D. Ohio 2005); *Shriner v. ProMedica Health Sys.*, 2005 WL 139128 (N.D. Ohio Jan. 21, 2005); *Burton v. Beaumont Hosp.*, 373 F. Supp. 2d 707 (E.D. Mich. 2005); *Darr v. Sutter Health*, 2004 WL 2873068 (N.D. Cal. Nov. 30, 2004); *Kizzire v. Baptist Health Sys.*, 343 F. Supp. 2d 1074 (N.D. Ala., 2004); *Ferguson v. Centura Health Corp.*, 358 F. Supp.2d 1014 (D. Colo., 2004); *In re Not-for-Profit Hospital/Uninsured Patients Litigation*, 341 F. Supp. 2d 1354 (Judicial Panel on Multidistrict Litigation 2004).

198. See Non-Profit Litigation Website, <http://www.nfplitigation.com> (last visited Jan. 24, 2006) (providing press releases, fact sheets, background information and copies of the filed complaints). This website has been taken down because most of the federal cases have been dismissed. However, plaintiffs' lawyers have refiled many of the claims in state courts. These claims focus more on "disparate pricing" than "charity care" and allege, among others, breach of contract and state consumer protection claims. See *Sutter Health Files Counterclaim in Class Action over Group's Charity Care Program*, 6 BNA, INC., CLASS ACTION LITIGATION 623 (2005); Matthew Roberts & Mindy Staley, *Hospitals Face Challenges to Tax-Exempt Status*, CHARLOTTE BUS. J., Dec. 2, 2005.

attempt to collect fees from the uninsured.<sup>199</sup> The current lawsuits seem to be a part of the larger, national debate on what “charitable” means and whether nonprofits are deserving of their tax exempt status.

#### IV. QUALITY ASSESSMENT AND IMPROVEMENT

##### A. *Patient Safety and Quality Improvement Act of 2005*

On July 29, 2005, the Patient Safety and Quality Improvement Act of 2005 (“Act”)<sup>200</sup> was signed into law by President George W. Bush. The Act amends the Public Health Service Act<sup>201</sup> by establishing confidentiality and privilege protections for information obtained from the voluntary reporting of medical errors.<sup>202</sup> The Act comes as a response to the recommendations of the Institute of Medicine’s (“IOM”) 1999 report *To Err is Human: Building a Safer Health System*.<sup>203</sup> In the report, the IOM recommended that Congress “extend comprehensive peer review protection to provider-generated quality improvement and patient safety information and create a patient safety reporting system that would allow providers to report medical error in a non-punitive environment.”<sup>204</sup>

The Act protects “patient safety work product” which is defined as

any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements . . . which . . . are assembled or developed by a provider for reporting to a patient safety organization and are . . . reported to a patient safety organization or developed by a patient safety organization for the conduct of patient safety activities . . . .<sup>205</sup>

Medical records, discharge information, and other information maintained or developed separate from the patient safety evaluation system is specifically excluded from the definition of patient safety work product. Pursuant to the Act, the privilege and confidentiality protections are only afforded to information that is actually reported, the mere assembling for the purpose of reporting medical errors or other quality information programs is not enough to trigger protection.<sup>206</sup> Also, unlike HIPAA or state law reporting privileges, patient safety work product continues to be privileged and confidential after disclosure.

Patient safety work product is voluntarily reported to patient safety organizations (“PSOs”), which are to contract with providers of health care

199. *Id.*

200. Pub. L. No. 109-41, 119 Stat. 425 (2005).

201. 42 U.S.C. §§ 2996-21 to -26.

202. Pub. L. No. 109-41, 119 Stat. 425 (2005).

203. INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (2000).

204. Deborah A. Datte et. al., *National Peer Review Protection? Understanding the New Patient Safety and Quality Improvement Act of 2005*, 9 HEALTH LAW. NEWS 11 (2005).

205. Pub. L. No. 109-41, 119 Stat. 425 (2005) (adopting new Public Health Service Act § 921(7)).

206. *Id.*

services to receive and review the patient safety work product. PSOs are entities whose “mission and primary activity” are “to conduct activities that are to improve patient safety and the quality of health care delivery.”<sup>207</sup> For recognition as a PSO, the entity needs to provide the Secretary of DHHS with a certification that the entity has policies and procedures in place to perform “patient safety activities” including: (1) “[e]fforts to improve patient safety and the quality of healthcare”; (2) “[t]he collection and analysis of patient safety work product”; (3) “[t]he development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices”; (4) “[t]he utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk”; (5) “[t]he maintenance of procedures to preserve confidentiality with respect to patient safety work product”; and (6) “[t]he provision of appropriate security measures with respect to patient safety work product.”<sup>208</sup> In short, a PSO is more than a repository for patient safety information, “[i]t must have an active staff, function to analyze the work product reported to it, and make recommendations for the improvement of care.”<sup>209</sup>

The Act contains a whistle-blower protection provision which protects the individuals who report medical errors. The provision prohibits providers from taking “adverse employment action,” including the loss of employment, failure to promote, failure to provide any employment related benefit that the individual is otherwise entitled to, and adverse evaluation or decisions relating to the accreditation, certification, credentialing, or licensing of the individual.<sup>210</sup>

### *B. Indiana Medical Error Reporting System*

Indiana recently became the second state to enact mandatory reporting requirements for healthcare providers.<sup>211</sup> Effective January 1, 2006, Indiana hospitals are required to report a delineated number of medical errors to the Indiana Department of Health (“DOH”).<sup>212</sup> The DOH passed the emergency rule in response to Executive Order 05-10, a directive to establish a medical error

---

207. 42 U.S.C. § 299(b)-24(b)(1)(A) (2005) (adopting new Public Health Service Act § 924).

208. *Id.* § 299(b)-21(5) (adopting new Public Health Service Act § 921(8)).

209. Datte et al., *supra* note 204.

210. Pub. L. No. 109-41, 119 Stat. 425 (2005) (adopting new Public Health Service Act § 922(e)).

211. Minnesota was the first state to provide a mandatory medical error reporting mechanism. *See* MINN. STAT. §§ 144.706-144.7069 (2004); *see also* National Academy for State Health Policy, *State Patient Safety Centers: A New Approach to Promote Patient Safety*, [http://www.nashp.org/Files/final\\_web\\_report\\_11.01.04.pdf](http://www.nashp.org/Files/final_web_report_11.01.04.pdf).

212. LSA Document #05-326(E). LSA Document #05-326(E) is an emergency rule effective until proposed rule 05-193 is finalized. Proposed Rule 05-193 will be published in the February 2005 Indiana Register for public comment.

reporting and quality system.<sup>213</sup> Executive Order 05-10 required the DOH to develop minimum standards for medical error reporting, and mandated conferring with various hospitals, physicians, pharmacist representatives, and quality improvement experts while also consulting best practice guides in developing the standards.

The regulations require hospitals to report multiple types of errors and make a lists of mistakes available for public review.<sup>214</sup> The first list of hospital errors is expected to be released in 2007. Governor Mitch Daniels believes that a successfully implemented medical error reporting program will reduce the frequency of medical errors, reveal causes of error, and enable health professions to design methods to prevent or discover errors before patients are harmed.<sup>215</sup> Pursuant to the executive order, the medical error reporting system (“MERS”): (1) should “ensure that patients’ and healthcare professionals’ identities are kept confidential,” (2) “not be used as the basis for punishing any healthcare professional,” (3) “require all healthcare professionals to report medical errors promptly,” (4) “require hospitals to report all MERS data to the DOH,” (5) “require DOH to regularly disseminate medical error data,” (6) “require hospitals to provide patients with easy to understand aggregate data and trends analysis,” and (7) “require hospitals to share successful solutions and improvements with other hospitals.”<sup>216</sup> The DOH is currently accepting comments on proposed regulations.<sup>217</sup> The final regulations are expected to replace the emergency rule in spring 2006.

## V. ANTITRUST

### A. *Post-Consummation Challenge to Hospital Merger*

In 2005, the Federal Trade Commission (“FTC”) successfully challenged a hospital merger post-consummation, resulting in an order of divestiture of the acquired facility. An FTC administrative law judge (“ALJ”) determined that Evanston Northwestern Healthcare Corporation (“ENH”) had consummated an illegal acquisition when it acquired Highland Park Hospital.<sup>218</sup> In *Evanston Northwestern Healthcare Corp.*,<sup>219</sup> the ALJ determined that the transaction lessened competition substantially in the market for acute care inpatient services and ordered that ENH divest Highland Park Hospital (“Highland Park”).<sup>220</sup>

---

213. Ind. Exec. Order No. 05-10 (Jan. 10, 2005), available at [http://www.in.gov/gov/media/eo/EO\\_05-10\\_Medical\\_Error\\_Reporting.pdf](http://www.in.gov/gov/media/eo/EO_05-10_Medical_Error_Reporting.pdf).

214. Indiana Department of Health, 29 Ind. Reg. 1742 (proposed Feb. 1, 2006).

215. Ind. Exec. Order No. 05-10.

216. *Id.*

217. 29 Ind. Reg. 1742.

218. Post-Acquisition Evidence Dooms Deal In Acute Care Inpatient Services Sector, 89 BNA, INC. ANTITRUST & TRADE REG. REP. 443 (2005) [hereinafter Post-Acquisition Evidence].

219. *Evanston N.W. Healthcare Corp.*, 70 Fed. Reg. 18,397 (FTC Apr. 11, 2005).

220. Post-Acquisition Evidence, *supra* note 218.

ENH acquired Highland Park in 2000 for more than \$200 million. The acquisition combined ENH's Evanston and Glenbrook Hospitals, both located in Cook County, Illinois, with Highland Park, the nearest hospital north of the two facilities.<sup>221</sup> The FTC contended that, after the acquisition, ENH raised prices far above the price increases of comparable hospitals.<sup>222</sup> ENH filed a notice of appeal on October 26, 2005.<sup>223</sup>

This case presented a rare opportunity to examine the actual effects of an acquisition on price in the hospital industry. Most antitrust analyses occur premerger and therefore involve projections based upon economic theory. This case also reversed a string of losses by the FTC and the Antitrust Division of the Department of Justice ("DOJ") in their attempts to challenge hospital mergers.

### B. Physician Organizations

In 2005, the FTC entered into consent decrees for violations of Section 5 of the Federal Trade Commission Act ("FTC Act")<sup>224</sup> with physicians groups in Chicago,<sup>225</sup> Cincinnati,<sup>226</sup> New Mexico,<sup>227</sup> and South Carolina.<sup>228</sup>

The Chicago consent decree involved Evanston Health Network Corporation ("EHN") and EHN Medical Group, Inc. ("EHN Medical").<sup>229</sup> EHN is a nonprofit corporation that owns EHN Faculty Practice Associates ("Faculty Practice"). Faculty Practice is a nonprofit corporation that employs about 460 salaried doctors.<sup>230</sup> Faculty Practice is the sole shareholder of EHN Medical, which is a for-profit corporation that represents Faculty Practice and over 400 independent physicians in their contract negotiations with health plans.<sup>231</sup> The FTC alleged in its complaint that EHN Medical had violated Section 5 of the FTC Act by facilitating agreements among competing physicians to fix reimbursement rates.<sup>232</sup> The FTC found no integration among the physicians and alleged that the actions of EHN Medical increased the reimbursement rates paid by payors,

221. *Id.*

222. *Id.*

223. Notice of Appeal, *In re* Evanston N.W. Healthcare Corp., No. 9315 (FTC Oct. 26, 2005), available at <http://www.ftc.gov/os/adjpro/d9315/051026enhnotofappeal.pdf>.

224. 15 U.S.C. § 45 (2005).

225. *See In re* Evanston N.W. Healthcare Corp., 2005 FTC LEXIS 146 (Oct. 20, 2005).

226. *See* New Millennium Orthopaedics, LLC, 70 Fed. Reg. 24,588 (FTC May 10, 2005).

227. *See* San Juan IPA, Inc., 70 Fed. Reg. 30,949 (FTC May 31, 2005).

228. *See* Preferred Health Services, Inc., 70 Fed. Reg. 11,675 (FTC Mar. 9, 2005); Partners Health Network, 70 Fed. Reg. 47,202 (FTC Aug. 12, 2005).

229. *Physicians' Group Settles Cartel Charges, Will Cease Collective Bargaining Activities*, BNA, INC., ANTITRUST & TRADE REG. REP. 362 (2005) [hereinafter *Physicians' Group*]. Counts I and II of the complaint against EHN involved the acquisition of Highland Park Hospital, which was determined to be anticompetitive post-consummation. *See* discussion, *supra* Part V.A.

230. *Physicians' Group*, *supra* note 229.

231. *Id.*

232. *Id.*

employers, and patients.<sup>233</sup>

The South Carolina consent decree involved a physician-hospital organization (“PHO”), Partner’s Health Network, Inc. (“Partner’s Health”). Partner’s Health represented itself as a “messenger model” PHO. A messenger model is a structure through which competing physicians may obtain the efficiencies of price negotiations without coordinating reimbursement rates.<sup>234</sup> The FTC said that Partner’s Health was not a legal messenger model because it enabled and assisted competing physicians in coordinating reimbursement rates and other terms with health plans and orchestrated refusals to deal.<sup>235</sup>

Each of the consent decrees prohibited the physician organizations from entering into agreements to negotiate with payors, other than through “qualified risk-sharing joint arrangements” and “qualified clinically integrated joint arrangements.”<sup>236</sup> In a qualified risk-sharing joint arrangement, all physician participants share financial risk, which would create incentives to control costs jointly.<sup>237</sup> A qualified clinically-integrated joint arrangement would require all physician participants to participate in active and ongoing programs to evaluate and modify their clinical practice patterns to create a high degree of interdependence and cooperation to control costs and ensure quality service.<sup>238</sup> The consent decrees require the physician organizations to notify the FTC prior to engaging in certain actions for twenty years.

### *C. Competition Between Physician-Owned Specialty Hospitals and General Acute-Care Hospitals*

A controversial topic in 2005 was the effect on general acute-care hospitals when physician-owned specialty hospitals enter a market. Physician-owned specialty hospitals have been criticized because they target the most profitable patients, leaving less profitable patients to be served by general acute-care hospitals. Federal law prohibits physicians from investing in general acute-care hospitals.<sup>239</sup> Thus, to retaliate for loss of referrals, some general acute-care hospitals have terminated the privileges of physicians that have an ownership interest in specialty hospitals.<sup>240</sup> Some physician-owners have challenged such terminations in court. Most such cases have been won by the general acute-care

---

233. *Id.*

234. *Id.*

235. *Id.*

236. *Id.*

237. *Id.*

238. *Id.*

239. 42 U.S.C. § 1395nn (2000). The Stark Law prevents physicians from referring Medicare and Medicaid “designated health services,” including inpatient and outpatient hospital services and a number of other items and services, to an entity with which the physician has a financial relationship unless an exception applies.

240. DAVID A. ARGUE, *ECONOMISTS INC., COMPETITION BY PHYSICIAN-OWNED SPECIALITY HOSPITALS: A BRIEF ANALYSIS OF POLICY AND LITIGATION* 3 (2005).

hospitals on the basis that the market at issue was competitive, irrespective of whether or not physician-owners of specialty hospitals were excluded from privileges at a particular hospital.

Similar arguments were used in *Arnett Physician Group, P.C. v. Greater Lafayette Health Services, Inc.*,<sup>241</sup> which addressed the termination of a physician group's exclusive service contract and HMO agreement, allegedly in response to the plaintiffs' attempt to open their own acute-care hospital.<sup>242</sup> A physicians' group and its affiliated clinic, health plan, and HMO brought the claim against the only existing hospital system in town and twenty-one doctors who had left the plaintiff to join a physician group affiliated with the defendant hospital.<sup>243</sup> Plaintiffs claimed that the hospital had conspired with the defendant doctors to violate Section 1 of the Sherman Act in an effort to deny the plaintiffs access to consumers of general acute-care hospital services in the Lafayette, Indiana area.<sup>244</sup> The court determined that staffing decisions at a single hospital cannot violate Section 1 of the Sherman Act and that the plaintiffs did not have antitrust standing or antitrust injury.<sup>245</sup> The court found no evidence that would connect the defendant hospital's terminations to the effort to set up a competing acute-care hospital. It reiterated the principle that "antitrust laws protect competition, not competitors."<sup>246</sup>

#### D. Exclusive Dealing

A rare exclusive-dealing case received considerable publicity in 2005. The Third Circuit court of appeals affirmed a ruling that Dentsply International, Inc. ("Dentsply") had unlawfully maintained its monopoly over prefabricated artificial teeth through an exclusivity policy that prevented dealers from selling the artificial teeth of other manufacturers.<sup>247</sup> In *United States v. Dentsply International, Inc.*,<sup>248</sup> the court affirmed a ruling that Dentsply had monopoly power in a market consisting of the combined sale of artificial teeth to dental laboratories and dealers, and had excluded competitors.<sup>249</sup> Dentsply controlled approximately seventy-five to eighty percent of the market for artificial teeth.<sup>250</sup>

In determining the relevant market, the court included both sales to the

---

241. 382 F. Supp. 2d 1092 (N.D. Ind. 2005).

242. Ashley McKinney Fisher, *Antitrust Health Care Recent Developments*, 2005 A.B.A. HEALTH CARE COMM. 1 (2005); *Arnett*, 382 F. Supp. 2d at 1095. The opinion does not indicate whether such acute care hospital was general or specialty.

243. *Arnett*, 382 F. Supp. 2d at 1095.

244. *Id.*

245. *Id.*

246. *Id.* at 1095, 1096.

247. *Dentsply's Exclusivity Policy Illegally Maintains its Artificial Tooth Monopoly*, 88 BNA, INC., ANTITRUST & TRADE REG. REP. 207 (2005) [hereinafter *Dentsply's Exclusivity*].

248. 399 F.3d 181 (3d Cir. 2005), *cert. denied*, 126 S. Ct. 1023 (2006).

249. *Dentsply's Exclusivity*, *supra* note 247.

250. *Id.* (on a revenue basis).

laboratories and sales to the dental dealers.<sup>251</sup> The court concluded that Dentsply's share of the market was more than adequate to establish a prima facie case of market power and rejected the district court's finding that other manufacturers in the market could compete by marketing directly to dental labs.<sup>252</sup> In addition, Dentsply's actions demonstrated its intent to exclude competitors and maintain monopolistic power by successfully prohibiting dealers from handling competitors' teeth.<sup>253</sup> Another indication of Dentsply's market power was its control of prices, which it was able to set without consideration of its competitors, something that a firm without monopoly power would not be able to do.<sup>254</sup>

In addition to market power, the Third Circuit also found that Dentsply used its power to adversely affect competition in the market.<sup>255</sup> By effectively preventing dealers from carrying competitors' teeth, the ultimate users—the dental labs—also could not purchase teeth of other manufacturers, and thus could not fulfill customer requests for alternative teeth lines.<sup>256</sup> These requests were denied by dealers because of fear of being cutoff by Dentsply. This situation created a barrier to entry to competitors in the market. Furthermore, the court determined that Dentsply's proffered business justification was pretextual and that Dentsply could not successfully show a pro-competitive objective for its exclusivity policy.<sup>257</sup>

Dentsply also involved allegations of resale price maintenance against Dentsply by dental labs. The dental labs purchased artificial teeth via a network of authorized dealers. If a dealer did not have the requested teeth in stock, Dentsply would "drop ship" teeth directly to the labs, but billing and collection services were still handled by the dealers.<sup>258</sup> The plaintiffs alleged, inter alia, that Dentsply and its dealers agreed to allow Dentsply to set dealers' resale prices.<sup>259</sup> Although Dentsply provided a "suggested price" list to dealers, which ordinarily is permissible, Dentsply went a step further by requiring any deviation from the suggested prices to be cleared with Dentsply; such deviations, once permitted, were allowed only when a lab was considering buying a competitor's product for reasons of price.<sup>260</sup> In these instances, Dentsply, not the dealer, negotiated with the lab to determine a price at which the dealer would sell the teeth to the lab.<sup>261</sup> The dental labs alleged that these practices caused them to purchase teeth at

---

251. *Dentsply's Exclusivity*, *supra* note 247; *Dentsply*, 399 F.3d at 188.

252. *Dentsply's Exclusivity*, *supra* note 247.

253. *Id.*

254. *Id.*; *Dentsply*, 399 F.3d at 191.

255. *Dentsply*, 399 F.3d at 191.

256. *Dentsply's Exclusivity*, *supra* note 247.

257. *Id.*

258. *Id.*

259. *Id.*

260. *Id.*

261. *Court Implants Overcharge Claim by Dental Labs Against Dentsply*, 89 BNA, INC., ANTITRUST & TRADE REG. REP. 305 (2005) [hereinafter *Court Implants*].

artificially high prices.<sup>262</sup>

Finally, the court of appeals in *Dentsply* allowed an exception to the *Illinois Brick*<sup>263</sup> indirect purchaser rule by applying a co-conspirator exception in a resale price maintenance case involving the sale of artificial teeth.<sup>264</sup> The indirect purchaser rule denies standing to purchasers suing manufacturers for illegal overcharges that have been “passed on” to the indirect purchasers through distributors or other middlemen,<sup>265</sup> and generally results in end purchasers being denied the ability to recover for price fixing conspiracies of manufacturers. The policy behind this rule is to avoid duplicative recovery from the manufacturer by the middlemen and the ultimate purchaser.<sup>266</sup> The court determined that dental laboratories have standing to sue Dentsply for alleged overcharges so long as the alleged co-conspirators—Dentsply’s dealer-middlemen—are named as defendants in the lawsuit.<sup>267</sup>

#### *E. Rule of Reason Analysis for PBM Price Fixing Cases*

In *North Jackson Pharmacy, Inc. v. Caremark RX, Inc.*,<sup>268</sup> an independent retail pharmacy sued Caremark RX (“Caremark”), a pharmacy benefits manager, under Section 1 of the Sherman Act for Caremark’s efforts to negotiate reduced prices on behalf of its members, as well as for price fixing with other PBMs.<sup>269</sup> The plaintiffs alleged that they and other independent pharmacies were forced into a choice between being included in the network and having to accept “unconscionably low” reimbursement rates or leaving the network and losing access to Caremark’s subscribers.<sup>270</sup> Caremark filed a Rule 16(c) issue-narrowing motion for the limited purpose of seeking an order from the court that Caremark’s efforts in coordinating the purchase price on behalf of independent pharmacies should be analyzed under the rule of reason rather than the per se rule.<sup>271</sup> The question of markets or market power was not before the court due to the procedural issues at this stage in the litigation.<sup>272</sup>

The district court granted Caremark’s motion and ruled that the plaintiff’s claim should be decided under a rule of reason analysis.<sup>273</sup> The district court determined that Caremark’s collective purchases were not a marked restraint of

---

262. *Id.*

263. *Ill. Brick Co. v. Illinois*, 431 U.S. 720 (1977).

264. *Howard Hess Dental Lab. v. Dentsply Int’l, Inc.*, 424 F.3d 363 (3d Cir. 2005), *cert. denied sub nom. Jersey Dental Labs. Inc. v. Dentsply Int’l, Inc.*, 126 S. Ct. 2320 (2006).

265. *Court Implants*, *supra* note 261.

266. *Id.*

267. *Id.*

268. 385 F. Supp. 2d 740 (N.D. Ill. 2005).

269. *Fisher*, *supra* note 242, at 3.

270. *Id.*

271. *Id.*; *North Jackson Pharmacy*, 385 F. Supp. 2d at 743.

272. *Fisher*, *supra* note 242, at 3.

273. *Id.*; *North Jackson Pharmacy*, 385 F. Supp. 2d at 743.

trade but could create efficiencies appropriate for consideration under the rule of reason.<sup>274</sup> The court was influenced by a 2004 report<sup>275</sup> in which the FTC and the Department of Justice discussed the procompetitive benefit of PBMs to consumers.<sup>276</sup> The report stated that consumers who have a prescription drug insurance plan administered by a PBM enjoy substantial cost savings over cash-paying customers.<sup>277</sup>

## VI. HEALTH INFORMATION PRIVACY AND SECURITY

### A. HIPAA Security Rule Effective

In addition to creating regulations for the privacy of protected health information (“PHI”), the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) also mandated the Department of Health and Human Services (“HHS”) to create regulations that govern the security of protected health information (the “Security Standards”).<sup>278</sup> The Security Standards define the administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic health information (“EHI”). The Security Standards require covered entities to implement basic safeguards to protect EHI from unauthorized access, alteration, deletion, and transmission.

The scope of information covered by the Security Standards is more limited than that of the Privacy Rule. The Privacy Rule applies to protected health information in any form, whereas the Security Standards apply only to protected health information in electronic form.<sup>279</sup> The Security Standards’ application is limited to protected health information that is transmitted or maintained by or in electronic media.<sup>280</sup> Electronic media includes computer hard drives, magnetic tapes or disks, optical disks, the internet, extranets, leased lines, dial-up lines, private networks, and moving data on floppy disks. Electronic media neither includes facsimiles, telephone transmissions, nor video teleconferencing or messages left on voicemail.<sup>281</sup>

Covered entities must modify their systems to meet the Security Standards. However, they are able to schedule the implementation of the security standards

---

274. Fisher, *supra* note 242, at 3.

275. DEPARTMENT OF JUSTICE, FEDERAL TRADE COMMISSION, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), available at [http://www.usdoj.gov/atr/public/health\\_care/204694.htm](http://www.usdoj.gov/atr/public/health_care/204694.htm).

276. *North Jackson Pharmacy*, 385 F. Supp. 2d at 750; Fisher, *supra* note 242, at 3.

277. *North Jackson Pharmacy*, 385 F. Supp. 2d at 750.

278. The Centers of Medicare and Medicaid Services within the Department of Health and Human Services promulgated the Security Standards and has enforcement responsibility for the Standards. CMS maintains a website with helpful compliance tools. CMS, Security Materials, [http://new.cms.hhs.gov/educationmaterials/04\\_SecurityMaterials.asp](http://new.cms.hhs.gov/educationmaterials/04_SecurityMaterials.asp)? (last visited July 2, 2006).

279. 45 C.F.R. § 164.302 (2005).

280. *Id.*

281. 45 C.F.R. § 160.103.

in a way that best fits their needs. Health care providers and large health plans were required to be compliant with the Security Standards by April 20, 2005.<sup>282</sup> Small health plans must meet the Security Standards by April 20, 2006.<sup>283</sup>

The Security Standards require covered entities to:

(1) [e]nsure the confidentiality, integrity, and availability of all EPHI the covered entity creates, receives, maintains, or transmits[;] (2) [p]rotect against any reasonably anticipated threats or hazards to the security or integrity of such information[;] (3) [p]rotect against any reasonably anticipated uses or disclosures of such information that are not permitted or required [by the Privacy Rule;] and (4) [e]nsure compliance by workforce members.<sup>284</sup>

To ensure the security of EPHI, the Security Standards require protections in three general categories: administrative safeguards, physical safeguards, and technical safeguards.<sup>285</sup> The Regulations break each of these categories down into various “Standards” that must be achieved.

The administrative safeguard category of the Security Standards details the administrative actions, policies, and procedures to manage the selection, development, implementation, and maintenance of security measures to protect EPHI and to manage the conduct of the covered entity’s workforce in relation to the protection of EPHI.<sup>286</sup> The administrative safeguards are broken down into nine standards that must be met: (i) security management process; (ii) assigned security responsibility; (iii) workforce security; (iv) information access management; (v) security awareness and training; (vi) security incident procedures; (vii) contingency plan; (viii) evaluation; and (ix) business associate contracts.<sup>287</sup>

The second general category under the Security Standards is physical safeguards. “Physical [s]afeguards are [those] physical measures, policies, and procedures to protect a covered entity’s electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.”<sup>288</sup> To comply with the physical safeguards, a covered entity must achieve four separate standards: (i) facility access controls; (ii) workstation use; (iii) workstation security; and (iv) device and media controls.<sup>289</sup>

The final category of safeguards for EPHI under the Security Standards is technical safeguards. These safeguards are the technology and the policy and procedures for its use that protect EPHI and control access to it.<sup>290</sup> This category

---

282. 45 C.F.R. §§ 164.318(a)(1), 164.318(c).

283. *Id.* § 164.318(a)(2).

284. 45 C.F.R. § 164.306(a).

285. 45 C.F.R. §§ 164.308, 164.310, 164.312.

286. 45 C.F.R. § 164.304.

287. 45 C.F.R. § 164.308(a)-(b).

288. 45 C.F.R. § 164.304.

289. 45 C.F.R. § 164.310(a)-(d).

290. 45 C.F.R. § 164.304.

is broken down into five standards: (i) access control; (ii) audit controls; (iii) integrity; (iv) person or entity authentication; and (v) transmission Security.<sup>291</sup>

For covered entities to meet the standards, the Security Standards set forth various “Implementation Specifications” (“IS”). Some of the IS are required and some are merely addressable. If an IS is required, a covered entity must implement it to achieve compliance with the standard to which it relates. If the IS is addressable, a covered entity must assess “whether the IS is a reasonable and appropriate way” for a covered entity to meet the Standard given the covered entity’s environment.<sup>292</sup>

Each covered entity must decide whether it should implement the addressable IS by taking into account its risk analysis, risk mitigation strategy, what security measures are already in place, and the cost of the implementation. If the addressable IS is reasonable, the covered entity must implement it.<sup>293</sup> If the IS is deemed to be inappropriate or unreasonable, the covered entity must determine whether a reasonable alternative can be implemented. If no reasonable alternative is available, then the covered entity may decide not to implement the addressable IS.<sup>294</sup> In both of these latter cases, the entity must document the decision not to implement the addressable specification, the rationale behind the decision, and how the applicable security Standard is otherwise being met.<sup>295</sup>

### *B. HIPAA Civil Enforcement*

On April 18, 2005, HHS issued Proposed Final Regulations that set forth the HHS’ policies and procedures for enforcing HIPAA.<sup>296</sup> HHS’s approach to the Regulations is to provide clear and easy to understand standards that provide consistent results in the interest of fairness and that provide the Secretary of HHS with reasonable discretion. HHS does not intend for the standards to be “overly prescriptive in areas where it would be helpful to gain experience with the practical impact of the HIPAA rule[s] to avoid unintended adverse effects.”<sup>297</sup>

---

291. 45 C.F.R. § 164.312(a)-(e).

292. 45 C.F.R. § 164.306(d).

293. *Id.* § 164.306(d)(3)(i)-(ii).

294. *Id.* § 164.306(d)(3)(ii).

295. *Id.*

296. HIPAA Administrative Simplification; Enforcement, 70 Fed. Reg. 20,224 (proposed Apr. 18, 2005) (to be codified at 45 C.F.R. pts. 160 and 164). On April 17, 2003, HHS had previously published an Interim Final Rule establishing the rules of procedure for the imposition of civil money penalties on entities that violate the HIPAA Administrative Simplification standards. Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings, 68 Fed. Reg. 18,895 (Apr. 17, 2003) (to be codified at 45 C.F.R. pt. 160). The Interim Final Rule addressed the procedural aspects of imposing civil money penalties such as notices of proposed penalty determinations, discovery procedures, hearing procedures, subpoenas, witnesses, and evidence related to civil money penalty enforcement actions. In contrast, the Proposed Rule discussed in the text above addresses HHS’s enforcement philosophy.

297. HIPAA Administrative Simplification; Enforcement, 70 Fed. Reg. at 20,227.

The regulations would apply the same investigation and penalty process to all violations of HIPAA, whether the violation involves privacy, security, portability, or non-discrimination. In its discussion of the Proposed Regulations, HHS confirms that most investigations are the result of complaints filed by individuals, and HHS emphasizes that “covered entities may not threaten, intimidate, coerce, discriminate against, or take any other retaliatory action” against persons who complain to HHS or persons who cooperate in the enforcement process.<sup>298</sup> Although most enforcement actions arise through individual complaints, the Secretary reserves the right to perform random compliance audits.<sup>299</sup>

Under the Proposed Regulations, if an investigation determines that a HIPAA violation has occurred, HHS will attempt to reach an informal resolution with the covered entity. This generally would involve correction of the problem by the covered entity, or a plan of action to correct the violation. Penalties will not be assessed if an informal resolution is reached.<sup>300</sup>

If an informal resolution is not reached, HHS will advise the covered entity of its determination and offer the entity an opportunity to provide written evidence and explain any mitigating factors.<sup>301</sup> If HHS then determines that a penalty is appropriate, it has broad discretion in determining the amount of the penalty. Under the law, penalties may not exceed \$100 per violation, to a maximum of \$25,000 per identical violation per calendar year.<sup>302</sup> Because many violations involve multiple instances of the violation, the proposed rule describes how HHS will bundle multiple transactions.<sup>303</sup> In general, the bundling will be done in a manner favorable to the covered entity. If the covered entity disagrees with the penalty imposed by HHS, it is entitled to two administrative appeals, after which it may file in court.<sup>304</sup> HHS further noted that if it imposes penalties under its jurisdiction, a covered entity may still be subject to other penalties if its acts have also violated other state or federal laws.<sup>305</sup>

HHS will not impose a penalty if the violator demonstrates that (a) it did not have knowledge of the violation and would not have been aware of the violation even with reasonable diligence, or (b) the violation was “due to reasonable cause and not willful neglect” and the violation was corrected within thirty days of uncovering the violation (or it will be promptly corrected).<sup>306</sup> Furthermore, civil penalties will not be assessed if criminal violations are involved.<sup>307</sup> In assessing the penalty, HHS will consider the time period of the violation, the type and

---

298. *Id.* at 20, 227, 20,251.

299. *Id.* at 20,226.

300. *Id.* at 20,250.

301. Proposed 45 C.F.R. § 160.312(a)(3)(i).

302. Proposed 45 C.F.R. § 160.404(b).

303. Proposed 45 C.F.R. § 160.406.

304. Proposed 45 C.F.R. §§ 160.504, 160.548.

305. Proposed 45 C.F.R. § 160.418.

306. Proposed 45 C.F.R. § 160.410(b).

307. *Id.*

degree of harm to the individual, intent, attempts to rectify the violation, cooperation with the investigation, and the existence or absence of other violations.<sup>308</sup>

The proposed regulations make it clear that a covered entity can be held civilly liable for the acts and omissions of its employees. A covered entity will not be held responsible for the acts and omissions of its business associates as long as it has received assurances from the business associate that it will safeguard the information it receives.<sup>309</sup> With such assurances, there is no duty to monitor the actions of one's business associates, although there is a duty to act if the covered entity is actually aware of a pattern of business associate violations.

When HHS finalizes the proposed regulations, it will notify the general public. There currently is no stated time table for finalization.

### *C. HIPAA Criminal Enforcement*

On June 1, 2005, the Office of Legal Counsel of the U.S. Department of Justice wrote a memorandum expressing its opinion as to whether only covered entities may be criminally liable for violations of HIPAA's privacy and security standards, or if employees and others not directly regulated by the statute may be prosecuted as well.<sup>310</sup> The opinion concluded that only those entities that are explicitly covered by HIPAA (health plans, health care providers that engage in standard electronic transactions, and health care clearinghouses) may be prosecuted for criminal violations of HIPAA. Specific individuals may be prosecuted only due to their corporate (generally managerial) position, or under conspiracy or aiding and abetting laws.

The criminal penalties under HIPAA are significant: (1) a fine of up to \$50,000 and/or up to one year imprisonment for knowingly using or causing to be used a unique health identifier, or obtaining or disclosing individually identifiable health information about an individual; (2) a fine of up to \$100,000 and/or up to five years imprisonment for violations committed under false pretenses; and (3) a fine of up to \$250,000 and/or up to ten years' imprisonment for violations committed with intent to sell or use the information for commercial advantage, personal gain, or malicious harm.

The memorandum further held that prosecution merely requires that the offender knowingly used, obtained, or disclosed the individually identifiable health information, and not that the offender also knew that using the information violated HIPAA.

---

308. Proposed 45 C.F.R. § 160.408.

309. 45 C.F.R. § 160.402 (2005).

310. *See* Scope of Criminal Enforcement under 42 U.S.C. § 1320d-6, Memorandum Opinion for the General Counsel Department of Health and Human Services and the Senior Counsel to the Deputy Attorney General (June 1, 2005), [http://www.usdoj.gov/olc/hipaa\\_final.htm](http://www.usdoj.gov/olc/hipaa_final.htm).

#### D. Other HIPAA Guidance and Developments

During 2005, HHS's Office for Civil Rights ("OCR"—the enforcing Office for the HIPAA Privacy Rule) issued a number of pieces of guidance, principally through Questions and Answers on its website, including confirmation that (1) a health plan may disclose protected health information ("PHI") to a state child support enforcement agency in response to a National Medical Child Support Order; (2) a health care provider may disclose PHI to an interpreter without an individual's authorization when using an interpreter to communicate with an individual; (3) a covered entity may disclose PHI without an individual's authorization to a Protection and Advocacy system when the disclosure is required by law; (4) group health plans (or their health insurers) may disclose PHI without an individual's authorization to plan sponsors for the plan sponsor to provide information required by the Centers for Medicare and Medicaid Services for the purposes of applying for and maintaining the retiree drug subsidy under Medicare Part D; and (5) that broad disclosures of PHI are authorized by the Privacy Rule for purposes of treating the victims and evacuees of Hurricane Katrina.<sup>311</sup>

Also, the constitutionality and procedural creation of the Privacy Rule were upheld in a unanimous decision from the United States Court of Appeals for the Third Circuit. In *Citizens for Health v. Leavitt*,<sup>312</sup> the plaintiffs contended that the Privacy Rule's permissive allowance of the use of individuals' protected health information without their consent for purposes of treatment, payment, and health care operations violated the First and Fifth Amendments to the U.S. Constitution.<sup>313</sup> The court disagreed and held that the Privacy Rule (and therefore the government) did not *compel* any disclosure under the Privacy Rule.<sup>314</sup> The Privacy Rule merely makes such disclosures permissive and any decisions to disclose protected health information were made by individual covered entities.<sup>315</sup> Therefore, the plaintiffs could not establish sufficient governmental action to maintain constitutional claims.<sup>316</sup> Further, the court held that the Privacy Rule was legitimately promulgated in compliance with the Administrative Procedures Act and its existence could not be challenged on procedural grounds.<sup>317</sup> It is likely that this will be one of the last major challenges to the creation of the Privacy Rule.

---

311. All OCR Questions and Answers and other Hurricane Katrina Guidance discussed in this section may be found at OCR's website, at <http://www.hhs.gov/ocr/hipaa>.

312. 428 F.3d 167 (3d Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3600 (U.S. Apr. 13, 2006) (No. 05-1311).

313. *Id.* at 175.

314. *Id.* at 184.

315. *Id.* at 177.

316. *Id.* at 186.

317. *Id.* at 186-88.

## VII. REIMBURSEMENT

### A. *New Medicare Claims Appeal Process*

On March 8, 2005, the Centers for Medicare and Medicaid Services issued its interim final rule regarding changes to the Medicare appeal procedures.<sup>318</sup> Changes to the Medicare claims appeal process were required by two recent laws, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (“BIPA”)<sup>319</sup> and the MMA.<sup>320</sup> The rules set forth the administrative appeal requirements for Medicare carriers, fiscal intermediaries, Qualified Independent Contractors (“QIC”), Administrative Law Judges (“ALJ”), and the Medicare Appeals Council (“MAC”).<sup>321</sup>

The new Medicare claims appeal process consists of five levels of appeal. First, the Medicare contractor makes an initial determination of the submitted Part A or Part B claim.<sup>322</sup> If a party is dissatisfied with the initial determination, the party may request a redetermination of the claim within 120 days.<sup>323</sup> The Medicare contractor must issue a decision within sixty days after receiving the request for redetermination.<sup>324</sup> Second, following the Medicare contractor’s redetermination, the party may request reconsideration within 180 days from the date of redetermination with a QIC.<sup>325</sup> The QIC must issue a decision within sixty days.<sup>326</sup> Third, the party may request a hearing with an ALJ.<sup>327</sup> The ALJ will conduct a hearing if the amount in controversy is greater than or equal to \$100 and the request is filed within sixty days of the reconsideration decision. The ALJ must issue a decision within ninety days. Fourth, the party may request the MAC to review the case if the request is filed within sixty days.<sup>328</sup> The MAC must issue a decision within ninety days. Finally, the party may file in federal district court if the amount in controversy is greater than or equal to \$1000 and the request is filed within sixty days of the MAC’s decision.<sup>329</sup> The new Medicare claims appeal process is effective May 1, 2005, for Part A claims and January 1, 2006, for Part B claims.

---

318. Medicare Program: Changes to Medicare Claims Appeal Procedures, 70 Fed. Reg. 11,420 (Mar. 8, 2005) (to be codified at 42 C.F.R. pts. 401 and 405).

319. Pub. L. 106-554 § 521 (2000).

320. Pub. L. 108-173, 117 Stat. 2066 (Dec. 8, 2003).

321. Medicare Program: Changes to Medicare Claims Appeal Procedures, 70 Fed. Reg. at 11,420-11,467.

322. 42 C.F.R. § 405.921 (2005).

323. 42 C.F.R. § 940-942.

324. 42 C.F.R. § 405.940-958.

325. 42 C.F.R. §§ 405.960-978.

326. 42 C.F.R. § 405.966.

327. 42 C.F.R. §§ 405.1000-1054.

328. 42 C.F.R. § 405.1102.

329. 42 C.F.R. § 405.1136(e).

### B. Pay for Performance (“P4P”) Initiatives

Medicare is developing various initiatives to encourage quality improvement in the care of Medicare beneficiaries. Pay for Performance (“P4P”) Initiatives are targeted at all health care settings where Medicare beneficiaries receive their health care, including hospitals, physicians’ offices, ambulatory care facilities, nursing homes, home health care agencies, and dialysis facilities.<sup>330</sup> P4P initiatives reward health care providers through incentive payments for, among other things, improving the quality, efficiency, and coordination of care. Pilot P4P Initiatives are currently being tested, including the Hospital Quality Initiative, the Physician Group Practice Demonstration, and the Chronic Care Improvement Program.<sup>331</sup>

### C. Emergency Health Services for Undocumented Aliens

Undocumented aliens’ use of medical services and the resulting unreimbursed costs associated with furnishing emergency health services to undocumented aliens has been a long-standing issue for hospitals and other emergency providers.<sup>332</sup> Pursuant to the Emergency Medical Treatment and Labor Act (“EMTALA”), hospitals participating in Medicare are required to medically screen all persons seeking emergency care and provide the treatment necessary to stabilize those who have an emergency condition, regardless of payment method or insurance status.<sup>333</sup> Furnishing care to undocumented aliens has left hospitals and other emergency providers, especially those on border states or with high populations of undocumented aliens, with large amounts of unreimbursable care costs.

Recognizing this problem, Section 1011 of the MMA provides \$1 billion through 2008 to help hospitals and other emergency health care providers recoup some of the unreimbursed cost.<sup>334</sup> Section 1011 provides \$250 million per year for fiscal years 2005 through 2008.<sup>335</sup> Two-thirds of the funds will be divided among the fifty states and the District of Columbia. The remaining one-third will be divided among the six states with the largest number of undocumented alien apprehensions. Payments will be made directly to hospitals, certain physicians, and ambulance providers for the unreimbursed costs of providing services under EMTALA. Section 1011 funds can be used to cover all medically necessary and appropriate services furnished to undocumented aliens who received emergency services required by EMTALA and any related hospital inpatient, outpatient, and ambulance services.<sup>336</sup>

---

330. CMS, Fact Sheet: Medicare “Pay for Performance (P4P)” Initiatives (Jan. 31, 2005), available at <http://www.cms.hhs.gov/media/press/release.asp?Counter=1343>.

331. *Id.*

332. *Cf.* Pub. L. 108-173, § 1011, 117 Stat. 2066 (Dec. 8, 2003).

333. 42 U.S.C. § 1395dd (2000).

334. Pub. L. 108-173, § 1011, 117 Stat. 2066 (Dec. 8, 2003).

335. *Id.*

336. *Id.*

#### *D. Medicare Payment System Changes*

Over the past year there have been a few significant changes to the Medicare payment system. First, on November 3, 2004, CMS announced a new Medicare prospective payment system (“PPS”) final rule for inpatient psychiatric facilities (“IPFs”), which will replace the cost-based payment system on or after January 1, 2005.<sup>337</sup> Next, on May 19, 2005, CMS proposed a payment increase for inpatient rehabilitation facilities to more accurately reflect the costs of rehabilitation services.<sup>338</sup> Finally, on August 26, 2005, CMS published a final rule regarding Medicare coverage of power mobility devices (“PMDs”), which include power wheelchairs and power operated vehicles, to address inflated and falsified billing.<sup>339</sup> The final rule sets forth revised conditions for Medicare payment of PMDs, denying payment for motorized or power wheelchair unless a physician or a physician assistant, nurse practitioner, or clinical nurse specialist has conducted a face-to-face examination of the beneficiary and has written a prescription for the item.<sup>340</sup>

#### *E. Medicaid DSH Payments*

On August 26, 2005, CMS published a proposed rule which would implement section 1001(d) of the MMA, which requires states to report additional information about their Disproportionate Share Hospital (“DSH”) programs.<sup>341</sup> Under the proposed rule, each state must submit an annual report that includes: (1) hospital name; (2) Medicare provider number; (3) Medicaid provider number; (4) type of hospital; (5) type of hospital ownership; (6) Medicaid inpatient utilization rate; (7) low income utilization rate; (8) disproportionate share hospital payments; (9) regular Medicaid rate payments; (10) Medicaid managed care organization payments; (11) supplemental/enhanced Medicaid payments; (12) indigent care revenue; (13) transfers; (14) total cost of care; (15) uncompensated care costs; and (16) Medicaid eligible and uninsured individuals receiving services.<sup>342</sup>

The proposed rule also requires each state to have its DSH payment program independently audited. The audit must verify:

---

337. CMS, Medicare Announces New Payment System for Inpatient Facilities (Nov. 3, 2004), <http://www.cms.hhs.gov/media/press/release.asp?Counter=1252>.

338. CMS, CMS Proposes Payment Increases, Policy Refinements for Inpatient Rehabilitation Facilities (May 19, 2005), <http://www.cms.hhs.gov/media/press/release.asp?Counter=1464>.

339. Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles, 70 Fed. Reg. 50,940 (Aug. 26, 2005) (to be codified at 45 C.F.R. pt. 410).

340. *Id.* at 50,946.

341. Medicaid Program; Disproportionate Share Hospital Payments, 70 Fed. Reg. 50,262 (Aug. 26, 2005) (to be codified at 42 C.F.R. pts. 447 and 455).

342. *Id.* at 50,267-50,268.

[(1) t]he extent to which hospitals in the [s]tate have reduced uncompensated care costs to reflect the total amount of claimed expenditures made under Section 1923 of the Act, . . . [(2)] DSH payments to each hospital comply with the applicable hospital-specific DSH payment limit[; (3) o]nly the uncompensated care costs of providing inpatient and outpatient hospital services to Medicaid eligible individuals and uninsured individuals as described in Section 1923(g)(1)(A) of the Act are included in the calculation of the hospital-specific limits[; (4)] the [s]tate included all Medicaid payments, including supplemental payments, in the calculation of such hospital-specific limits[; and (5) t]he [s]tate has separately documented and retained a record of all its costs under the Medicaid program, claimed expenditures under the Medicaid program, uninsured costs in determining payment adjustments under Section 1923 of the Act, and any payments made on behalf of the uninsured from payment adjustments under Section 1923 of the Act.<sup>343</sup>

“Federal matching payments are contingent upon a state’s annual submission of both the annual DSH report and the independent certified audit.”<sup>344</sup>

## VIII. LABOR AND EMPLOYMENT

### A. *Fair Labor Standards Act (“FLSA”)*

The Department of Labor (“DOL”) has issued numerous opinion letters in the past year in an attempt to clarify the FLSA overtime regulations issued in 2004, a couple of which involve hospitals and health care systems.

1. *Overtime for “Joint Employees” of Health Care System—FLSA Opinion Letter 2005-15.*—On April 11, 2005, the DOL issued an opinion letter in response to a question from a health care system about its obligation to pay overtime under the FLSA.<sup>345</sup> The health care system had a nurse who held positions at two different companies within the system. Based on a review of the facts provided, the DOL determined that the health care system had to pay overtime to the nurse if the nurse’s *combined* hours at the two employers exceeded forty hours in a workweek.<sup>346</sup>

The DOL’s determination was based on its interpretation of the joint employer regulations, which state that “an employee who performs work that simultaneously benefits two or more employers, or works for two or more employers at different times during the workweek,” generally will be jointly employed “where the employers are not completely disassociated with respect

---

343. *Id.* at 50,268.

344. *Id.*

345. U.S. Department of Labor, FLSA Opinion Letter 2005-12 (Apr. 12, 2005) [hereinafter FLSA 2005-12].

346. *Id.*

to the employment of the particular employee and may be deemed to share control of the employee, directly or indirectly, by reason that one employer controls, is controlled by, or is under common control with the other employer.”<sup>347</sup> Pursuant to these regulations, if the companies have common control, especially in personnel matters, the DOL will treat them as the same company for employment-related purposes.

The DOL’s recent opinion highlights the fact that separating personnel functions may not be enough to avoid being joint employers. Each entity within the health care system that requested the opinion had its own human resources department, employee handbook, payroll system, and retirement plan. There was no regular interchange of employees between the entities. In addition, each entity had its own federal identification number.<sup>348</sup> Nonetheless, the DOL still found that they were joint employers.

The DOL looked at the fact that the two entities shared a common president and board of directors. It also noted that one human resources department occasionally provided administrative support to the other, the Senior Vice President of Human Resources and several other senior executives and managers had responsibility for more than one entity within the system, non-union employees had common health care plans, and job openings were posted within the system. Additionally, the DOL considered the fact that some of the personnel policies were the same (although apparently in different handbooks), such as the FMLA, anti-harassment, and anti-nepotism policies. Because of these “multiple associations,” the DOL found that both employers were responsible for combining the hours an employee worked at both entities for purposes of calculating overtime.<sup>349</sup>

The joint employer analysis is extremely fact-sensitive—several factors need to be considered and each relationship has to be reviewed separately. To avoid being a joint employer, companies need to remain as separate as possible, and stay away from “multiple associations,” similar to those found by the DOL in this recent opinion letter. If related companies wish to take advantage of each other’s expertise or the cost effectiveness of combined insurance plans, they should understand the legal consequences, which may reach far beyond the calculation of hours worked by an employee who works for both companies.

2. *Exempt Status of Nurse Practitioners—FLSA Opinion Letter 2005-20.*—The DOL issued another opinion letter on August 19, 2005, that is directly applicable to the health care industry.<sup>350</sup> FLSA Opinion Letter 2005-20 addressed two issues. The first issue was whether having some Nurse Practitioners who were treated as non-exempt because they worked on an as-needed basis and were paid hourly for their work would invalidate the exemption from overtime for the remainder of the Nurse Practitioners who performed the

---

347. 29 C.F.R. § 791.2(b)-(b)(3) (2005).

348. FLSA 2005-12, *supra* note 345.

349. *Id.*

350. U.S. Dep’t of Labor, FLSA Opinion Letter 2005-20 (Aug. 19, 2005) [hereinafter FLSA 2005-20].

same duties as the PRN Nurse Practitioners, but were paid on a salaried basis.<sup>351</sup> The DOL took the position that having some employees who are treated as exempt within the same job classification, and performing the same duties, as others who are paid on an hourly basis does *not* affect the exempt status of the other employees.<sup>352</sup> This assumes that those who are considered exempt truly meet the duty and salary basis requirements necessary for the exemption.<sup>353</sup>

The second issue addressed by the Opinion Letter was whether paying otherwise exempt employees a shift differential for working evenings and weekends affects their salary basis, and therefore invalidates the exemption. The DOL's opinion is that the predetermined amount of salary necessary to support an exemption need not include *all* of the compensation that the employee will be paid.<sup>354</sup> Further, the exemption is not lost if an employee who is paid the proper salary also receives additional compensation based on hours worked for work beyond the normal workweek. Such additional amounts of compensation may be paid on any basis (e.g., flat amount, bonus, straight-time hourly amount, time and one-half of a calculated hourly amount, paid time off, etc.).<sup>355</sup> Accordingly, the DOL opinion was that an otherwise exempt employee may be paid an "overtime premium" or a shift differential without invalidating the otherwise exempt status.<sup>356</sup>

*B. Exclusive Remedy of Worker's Compensation:  
Jennings v. St. Vincent Hospital and Health Care Center*

The Indiana Court of Appeals issued a decision in 2005 reaffirming that employees working for health care facilities through a staffing agency will be considered employees of both entities and will be subject to the exclusive remedies provisions in the Worker's Compensation Act.<sup>357</sup> Jennings was a registered nurse who specialized in emergency room care.<sup>358</sup> He was employed by StarMed, a company that assigned healthcare workers to hospital facilities on

---

351. Although the Opinion Letter did not specifically state, it was presumed that the exemption for the Nurse Practitioners was the professional exemption. The DOL regulations regarding the professional exemption can be found at 29 C.F.R. § 541.300 (2005).

352. See 29 C.F.R. § 541.2 (stating that exemptions are not based on job title or classification, but rather upon the salary and duties of the individual employee).

353. See 29 C.F.R. pt. 541.

354. The DOL relied on 29 C.F.R. § 541.602, which states that an employee is compensated on an salaried basis "if the employee regularly receives each pay period on a weekly, or less frequent basis, a predetermined amount constituting *all or part* of the employee's compensation, which amount is not subject to reduction because of variations in the quality or quantity of the work performed." 29 C.F.R. § 541.602 (emphasis added).

355. See 29 C.F.R. § 541.604(a) (2005).

356. FLSA 2005-20, *supra* note 350.

357. IND. CODE § 22-3-2-2 (2005).

358. *Jennings v. St. Vincent Hosp. & Health Care Ctr.*, 832 N.E.2d 1044, 1048 (Ind. Ct. App.), *reh'g denied* (Ind. Ct. App. 2005), *trans. denied* (Ind. 2006).

a temporary basis. In 1992, StarMed contracted with St. Vincent to provide St. Vincent with nurses for temporary staffing needs. Jennings was assigned by StarMed to work at St. Vincent from December 11, 1999, to March 9, 2000.<sup>359</sup>

On March 7, 2000, Jennings allegedly contracted Hepatitis C after being stuck by an angiocatheter while performing nursing duties at the emergency room at St. Vincent Hospital.<sup>360</sup> Jennings filed a claim for worker's compensation benefits against StarMed. He also filed a civil suit against St. Vincent claiming negligence. St. Vincent responded with a motion to dismiss based on lack of subject matter jurisdiction, claiming that Jennings was a co-employee of St. Vincent and StarMed, thus invoking the protection of the exclusive remedy provision of the Worker's Compensation Act.<sup>361</sup> Under this provision, an injured employee is entitled to worker's compensation benefits only, and may not sue the employer for damages. The trial court granted St. Vincent's motion, and Jennings appealed that determination.<sup>362</sup>

In upholding the trial court's decision, the court begrudgingly<sup>363</sup> determined that Jennings was a co-employee of St. Vincent and StarMed.<sup>364</sup> The Worker's Compensation Act explicitly recognizes that a worker may have more than one employer at a given moment.<sup>365</sup> To determine whether a worker was engaged in a joint employment situation, seven factors must be evaluated and weighed as a balancing test.<sup>366</sup> The factors include: "(1) the right to discharge; (2) mode of payment; (3) supplying tools or equipment; (4) belief of the parties in the existence of an employer-employee relationship; (5) control over the means used in the results reached; (6) length of employment; and (7) establishment of the work boundaries."<sup>367</sup>

After analyzing each factor, the court determined that St. Vincent's right to discharge Jennings, the tools and equipment that St. Vincent supplied Jennings, and, most importantly, its control over Jennings's performance of his duties led to the conclusion that Jennings was a co-employee of St. Vincent and StarMed.<sup>368</sup> Weighing against this determination were the belief of the parties in the existence

---

359. *Id.*

360. *Id.* at 1049.

361. IND. CODE § 22-3-2-2.

362. *Jennings*, 832 N.E.2d at 1049.

363. The court urged the legislature to act to address the given situation stating that a "deficiency in our current system of worker's compensation" exists. *Id.* at 1047. The court did not note that in 2001, the Indiana General Assembly amended IND. CODE § 22-3-6-1(a), the definition of an "employer" to state, "Both a lessor and a lessee of employees shall each be considered joint employers of the employees provided by the lessor to the lessee for purposes of [IND. CODE §] 22-3-2-6 and [IND. CODE §] 22-3-3-31." See *Jennings*, 832 N.E.2d at 1050; IND. CODE §3-6-1(2).

364. *Jennings*, 832 N.E.2d at 1055.

365. IND. CODE § 22-3-3-31; *Jennings*, 832 N.E.2d at 1050.

366. *Jennings*, 832 N.E.2d at 1050-51.

367. *Id.*

368. *Id.* at 1051-54.

of an employer-employee relationship and length of employment factors.<sup>369</sup> The court found that the mode of payment factor was not determinative.<sup>370</sup> Because the more significant factors weighed in favor of an employer-employee relationship, the court concluded that both StarMed and St. Vincent were employers protected by the exclusive remedy provision.

### C. Immigration

1. *J-1 Waivers for Foreign Medical Graduates.*—Routinely, foreign medical graduates (“FMGs”) enter the United States on temporary J-1 exchange visitor visas to complete graduate medical education and/or training in this country. Upon completion of such programs (often medical residency and fellowship training), the FMG must return home to satisfy a two-year home residency requirement before becoming eligible for any other visa category or lawful permanent residence.<sup>371</sup> Not surprisingly, many FMGs seek a waiver of their home residency requirement to pursue employment opportunities in the United States.<sup>372</sup> One waiver option is the “Conrad 30” program which allows each state health department to grant thirty such waivers to FMGs.<sup>373</sup> In exchange, the FMG must agree to practice medicine for three years in a designated healthcare shortage area. Once the two-year home residency requirement of the J-1 visa status is waived, the physician is able to pursue other immigration options, including sponsorship for H-1B visa status and eventually lawful permanent residence.<sup>374</sup> On December 3, 2004, the President signed legislation that extended the “Conrad 30” J-1 waiver program for foreign-born physicians to June 1, 2006.<sup>375</sup> The Act also included a number of other important changes related to J-1 waivers, such as permitting doctors to practice in either primary care or specialty medicine. Historically, such waivers were targeted for physicians practicing primary care only. Under the new law, a specialist may qualify if there is a demonstrated shortage of doctors able to provide the medical specialty in the designated geographical area.<sup>376</sup> Additionally, five of each state’s thirty waivers may be granted to a doctor who practices in areas not designated as underserved if the doctor receiving the waiver practices in facilities that serve

---

369. *Id.* at 1052.

370. *Id.* at 1051.

371. 8 U.S.C. §1182(e) (2000).

372. Per 8 U.S.C. § 1184(l), any federal agency or state health department may serve as an interested government agency and request a waiver on behalf of a FMG.

373. The “Conrad” program was originally enacted as a part of The Immigration and Nationality Technical Corrections Act of 1994 at § 220, Pub. L. No. 103-416, 108 Stat. 4305 (codified at 8 U.S.C. § 1184(l)).

374. 8 U.S.C. § 1182(e).

375. Pub. L. No. 108-441, 118 Stat. 2630 (codified at 8 U.S.C. §§ 1182 and 1184) (improving access to physicians in medically underserved areas).

376. *Id.*

patients who reside in shortage areas.<sup>377</sup> This may permit providers in counties with less than a “whole county” Health Professional Shortage Area (“HPSA”) or Medically Underserved Area (“MUA”) designation to qualify as a waiver sponsor. Finally, physicians sponsored for a waiver by either a federal or state agency are exempt from the H-1B cap, discussed more thoroughly below.<sup>378</sup> Under the prior law, only physicians receiving a waiver under the Conrad program were exempt from the cap.<sup>379</sup>

2. *H-1B Annual Quota*.—Although not exclusively affecting the healthcare industry, the current annual quota of 65,000 on the number of H-1B visas<sup>380</sup> has caused considerable difficulty for many employers. Employers in the healthcare industry regularly utilize the H-1B visa category to sponsor foreign physicians and other health care workers.<sup>381</sup> The Fiscal Year 2006 H-1B cap was reached weeks prior to the start of the fiscal year on October 1, 2005.<sup>382</sup> Enacted December 3, 2004, the H-1B Visa Reform Act of 2004 did not directly raise the annual cap, however, additional foreign nationals are now exempt from the 65,000 annual limitation.<sup>383</sup> For instance, 20,000 visas have been set aside for foreign nationals with a Master’s or higher degree from a U.S. institution of higher education.<sup>384</sup> Foreign nationals with offers to work at institutions of higher education or related or affiliated non-profit entities<sup>385</sup> and those who already have been counted against the cap continue to be exempt from the numerical cap.<sup>386</sup> Unfortunately, the current quota still has not been sufficient to meet the demand for H-1B professionals, and new legislation to further increase and extend the quota will be the subject of continuing debate.

3. *Lawful Permanent Residence*.—Frequently employers, including those in the healthcare industry, choose to sponsor valued foreign national employees for lawful permanent residence or green card status. An important change affecting

---

377. *Id.*

378. *Id.*

379. 8 U.S.C. §1184(l)(2)(A).

380. *Id.* § 1184(g)(1)(A).

381. The H-1B visa category is only available to individuals working in “specialty occupations” which is generally interpreted to mean the position must require a minimum of baccalaureate level education in a particular discipline and the applicant must meet that degree requirement. *Id.* § 1184(i)(1). As such, most nursing positions do not qualify for H-1B classification.

382. Press Release, U.S. Dep’t of Homeland Sec., Citizenship and Immigration Servs., USCIS Reaches H-1B Cap (Aug. 12, 2005) (on file with author).

383. L-1 Visa and H-1B Visa Reform Act, Pub. L. No. 108-447, 118 Stat. 2809 (codified at 8 U.S.C. §§ 1182, 1184, 1356 and 42 U.S.C. § 1869 (2005)). In addition, the \$1000 fee has been made permanent and raised to \$1500 along with the creation of a new \$500 Fraud Prevention and Detection Fee. *Id.*

384. *Id.*

385. Non-profit health care entities with formal affiliations with institutions of higher education may qualify for an exemption from the cap.

386. 8 U.S.C. § 1184(g).

this process is the publication of the Department of Labor's Final Regulations on the Labor Certification for the Permanent Employment of Aliens in the United States and Implementation of a New "PERM" System.<sup>387</sup> Effective March 28, 2005, this new system has dramatically affected the labor certification process which is often the initial requirement for permanent residence based on an offer of employment.<sup>388</sup> Most significantly, it has altered the prevailing wage system utilized by the Department of Labor, transitioned the labor certification application to an electronic, on-line filing process, and provided a clear sequence of recruitment requirements for the testing of the U.S. labor market in determining whether any qualified U.S. workers are available for the work offered to the foreign national.<sup>389</sup>

### IX. LONG-TERM CARE

The Centers for Medicare and Medicaid Services implemented a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 regarding hospital discharge planning for patients who require post-hospital extended care services.<sup>390</sup> The portions of the rule that most affect long-term care facilities require that hospitals include in a patient's discharge plan lists of Home Health Agencies ("HHAs") or skilled nursing facilities ("SNFs") that are available to the patient, in the appropriate geographic area, and participate in the

---

387. Labor Certification for the Permanent Employment of Aliens in the United States; Implementation of New System, 69 Fed. Reg. 77,326 (Dec. 27, 2004) (codified at 20 C.F.R. pts. 655 and 656).

388. Importantly, the Department of Labor has long recognized nursing and physical therapy as job shortage areas. These occupations are designated as Schedule A, Group 1 at 20 C.F.R. § 656.5 and are exempt from the rigors of labor market testing. However, these labor certifications must be filed with Citizenship and Immigration Services (not DOL) and follow the labor certification requirements outlined in the amended PERM rule at 20 C.F.R. § 656.15. For Schedule A, Group I filings, the principal changes concern filing of the new form ETA 9089, Application for Permanent Employment Certification, and complying with the changes in the prevailing wage system and internal posting notice obligations. Additionally, in response to the new PERM regulations, Citizenship and Immigration Services also revised their internal policy memoranda with respect to Schedule A applications received before and after the effective date of the PERM regulation. Interoffice Memorandum from William R. Yates to Regional Directors, et. al., USCIS Revises Guidance Memorandum Describing New Schedule A Requirements, Doc. No. 05101267 (Sept. 23, 2005) (available through the American Immigration Lawyers Association, [www.aila.org](http://www.aila.org)). Recently, CIS announced that it is considering additional revisions to the posting notice requirements for roving employees or employees whose work site is not yet defined. AILA-SCOPS Q&A Regarding Schedule A Posting Requirements, Doc. No. 05122162 (Dec. 19, 2005) (available through the American Immigration Lawyers Association, [www.aila.org](http://www.aila.org)).

389. Labor Certification for the Permanent Employment of Aliens in the United States; Implementation of New System, 69 Fed. Reg. 77,326.

390. 42 C.F.R. § 482.43 (2005).

Medicare program.<sup>391</sup> The patient or the patient's family must be informed of their right to choose from among the providers listed, and the discharging hospital must not favor particular providers or limit the patient's choice.<sup>392</sup> If the patient is enrolled in a managed care organization, the lists must indicate what providers or services have a contract with the organization.<sup>393</sup> Finally, the hospital must disclose those providers in which it has a disclosable financial interest, and providers that have such an interest in the hospital.<sup>394</sup>

The Drug Enforcement Agency ("DEA") issued a regulation designed to address the accumulation of surplus controlled substances at long term care facilities.<sup>395</sup> The DEA recognized that many long term care facilities ("LTCFs"), which are not DEA registrants, receive a resident's entire dosage of a controlled substance, dispense it daily, and must dispose of excess when residents leave the facility or change their medication.<sup>396</sup> To alleviate this problem, the DEA issued a final rule permitting pharmacies to establish automated dispensing systems ("ADS") in LTCFs.<sup>397</sup> "The pharmacy stores bulk drugs in the machine . . . and controls the ADS remotely. . . . Only authorized staff of the LTCF would have access to [the machine's] contents."<sup>398</sup> Drugs "are not considered dispensed until the system provides them, [so] drugs in the ADS are counted as pharmacy stock. . . . If patients do not take all of the drugs prescribed, the excess can be dispensed to other patients."<sup>399</sup>

The Department of Health and Human Services issued a regulation addressing the notice given to residents and visitors of a nursing facility ("NF") or skilled nursing facility regarding nursing levels.<sup>400</sup> This regulation requires NFs and SNFs to post the "number of hours worked by . . . licensed and unlicensed nursing staff who are directly responsible for resident care[.]" reflecting the number and type of staff per shift and calculating the total number of hours worked.<sup>401</sup> Licensed staff includes registered nurses ("RNs"), licensed practical nurses ("LPNs"), or licensed vocational nurses.<sup>402</sup> Certified nurses

391. *Id.* § 482.43(c)(6).

392. *Id.* § 482.43(c)(7).

393. *Id.* § 482.43(c)(6)(ii).

394. *Id.* § 482.43(c)(8).

395. Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities, 70 Fed. Reg. 25,462 (May 13, 2005) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1307).

396. *Id.*

397. *Id.* at 25,462-25,464.

398. *Id.* at 25,462.

399. *Id.*

400. Medicare and Medicaid Programs; Requirements for Long Term Care Facilities; Nursing Services; Posting of Nurse Staffing Information, 70 Fed. Reg. 62,065 (Oct. 28, 2005) (to be codified at 42 C.F.R. pt. 483).

401. *Id.* at 62,072.

402. *Id.*

aides (“CNAs”), as defined by state law, would constitute unlicensed staff.<sup>403</sup> “Direct resident care includes, but is not limited to . . . assisting with activities of daily living, performing gastro-intestinal feeds, giving medications, supervising the care given by CNAs, and performing nursing assessments to admit residents or notify physicians about a change in condition.”<sup>404</sup>

## X. INDIANA LEGISLATIVE CHANGES

### A. *Physician Disclosure of Financial Interests*

House Bill 1306, effective July 1, 2005, requires a physician to provide certain information to an individual before referring the individual to a health care entity in which the physician has a financial interest.<sup>405</sup> Specifically, a physician must disclose in writing to the individual that the physician has a financial interest in the health care entity and inform the individual in writing that the individual may choose to be referred to another health care entity, before the physician may refer an individual to a health care entity in which the physician has a financial interest.<sup>406</sup> The physician must keep a copy of the notice signed by the individual.<sup>407</sup> However, the above does not apply if a delay in treatment caused by compliance with the requirements would reasonably be excepted by the referring physician to jeopardize the individual’s health, impair the individual’s bodily functions, or cause dysfunction of a bodily organ or part of an individual.<sup>408</sup> Compliance with these requirements is a condition of physician licensure under Indiana Code section 25-22.5.<sup>409</sup>

### B. *Health Entity Construction Projects*

Under House Bill 1330, before the owner of a hospital or proposed hospital may begin a construction project that is estimated by the hospital to cost at least \$10 million or an ambulatory or proposed outpatient center may begin construction that is estimated to cost at least \$3 million the owner must hold at least two public hearings concerning the construction project and publish notice of each hearing at least ten days before the hearing is held.<sup>410</sup>

This Bill does not apply to any construction project begun prior to July 1, 2005.<sup>411</sup> Additionally, notwithstanding the hearing, a statement or question regarding a construction project or an objection to a construction project that

---

403. *Id.*

404. *Id.*

405. H.B. 1306, 2005 Reg. Sess., 114th Gen. Assemb. (Ind. 2005) (codified at IND. CODE § 25-22.5-11-5).

406. IND. CODE § 25-22.5-11-3(a) (2005).

407. *Id.* § 25-22.5-11-3(a).

408. *Id.* § 25-22.5-11-3(b).

409. *Id.* § 25-22.5-11-4.

410. *Id.* § 16-21-2-11.5(d).

411. *Id.* § 16-21-2-11.5(c)(2).

arises during a hearing may not cause a delay in or a denial of the issuance of a license.<sup>412</sup>

### *C. Health Related Information Disclosure*

Under Senate Bill 293, a covered entity may disclose certain “protected health information” to a law enforcement official who requests the protected health information for the purpose of identifying or locating a missing person.<sup>413</sup> The protected health information allowed to be disclosed includes contact information and previous addresses of the individual’s family, personal representative, and friends.<sup>414</sup>

### *D. Health and Hospital Corporation*

Several sections of House Bill 1553 made changes to various duties of the Health and Hospital Corporation of Marion County and the Corporation’s Board, including removing certain residency requirements of the Board members and allowing Board members to waive compensation.<sup>415</sup> Moreover, this bill also provided the division of public health with the powers and duties of a local department of health.<sup>416</sup>

### *E. Home and Community Based Services*

House Bill 1069 voided rules adopted by the Division of Disability, Aging, and Rehabilitative Services (“DDARS”) for home and community based services (“HCBS”).<sup>417</sup> The bill required DDARS to adopt new rules implementing the caretaker support program and standards for continuum of care providers by January 1, 2006.<sup>418</sup> DDARS, in adopting the new rules, must consult with certain interested persons to ensure that the new rules protect consumers of HCBS, address the specific needs of distinct populations of consumers, do not create barriers to HCBS by imposing certain costs and requirements on providers, and comply with the requirements of the statutes establishing long term care services and the community and home options to institutional care for the elderly and disabled (“CHOICE”) program.<sup>419</sup>

### *F. Personal Service Agencies, Prescription Drugs, and Health Professions*

Sections of House Bill 1098 made changes to several different statutes. First, House Bill 1098 established a program for the licensing and regulation of

---

412. *Id.* § 16-21-2-11.5(h).

413. *Id.* § 16-39-10-4.

414. *Id.*

415. *Id.* § 16-22-8-9; *id.* § 16-22-8-15.

416. *Id.* § 16-22-8-28.

417. H.B. 1069.1.5, 2005 Reg. Sess., 114th Gen. Assemb. (Ind. 2005) (voiding 460 IAC 1.1).

418. IND. CODE § 12-10.5-1-4(b).

419. *Id.* § 12-10.5-1-9; *id.* § 12-10.5-2-3.

personal service agencies.<sup>420</sup> The Bill required “a personal services agency[] to obtain a license from the state health commissioner” in order to operate a personal services agency.<sup>421</sup> Operating a personal services agency without a license is a Class A misdemeanor.<sup>422</sup> The Bill also established an act governing home care services and required a placement agency to provide the home care services consumer with certain information when a home care services worker is placed in the consumer’s home, including the worker’s criminal history report.<sup>423</sup> The State Department of Labor may impose a civil penalty against a placement agency for failing to provide a consumer with the required consumer notice or worker notice at the times required by the statute.<sup>424</sup>

Additionally, House Bill 1098 amended the statute governing the regulation of pharmacists and pharmacies to require the Board of Pharmacy to establish procedures to ensure that pharmacies may return expired prescription drugs to wholesalers and manufacturers and specified the information that the Board must consider in establishing such procedures.<sup>425</sup> Moreover, the Bill expanded the requirements that must be met by a wholesale drug distributor for eligibility for licensure and specified prohibited acts, including certain criminal acts related to wholesale drug distribution and legend drugs.<sup>426</sup>

Finally, House Bill 1098 substantially revised the statute governing speech pathologists and audiologists by, among other things, requiring licensure of speech-language pathology aides, associates, and assistants and amending the licensure requirements of speech-language pathologists and audiologists.<sup>427</sup>

---

420. *Id.* §§ 16-27-4-1 to -23.

421. *Id.* § 16-27-4-6(a).

422. *Id.* § 16-27-4-23.

423. *Id.* §§ 22-1-5-1 to -19.

424. *Id.* § 22-1-5-19.

425. *Id.* § 25-26-13-4(b)(3).

426. *Id.* § 25-26-14.

427. *Id.* § 25-35.6-1-1 to -10.