SURVEY OF RECENT DEVELOPMENTS IN HEALTH LAW

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INTRODUCTION

This Survey summarizes recent developments in case law, legislation, and administrative actions that affect the health care industry. It summarizes a wide range of subjects including, among others, fraud and abuse, tax and reimbursement, and payment issues. Although not an exhaustive review, this Survey details the "hot" topics in the health care industry this year.

I. FRAUD AND ABUSE

A. Stark III

On September 5, 2007, the Centers for Medicare and Medicaid Services ("CMS") published the Stark II Phase III ("Phase III") final rule in the *Federal Register*.[1] Phase III does not create any new exceptions to the Stark Law; however, Phase III provides interpretation of the existing statutory exceptions and modifies some of the existing exceptions to the Stark Law.[2]

As a background, the Stark Law generally prohibits, absent qualifying for an exception, a physician from making a referral to an entity for the furnishing of any designated health services for which Medicare or Medicaid would otherwise pay, if the physician or member of the physician's immediate family has a financial relationship with that entity ("DHS entity").[3] The Stark Law was effective January 1, 1992, for clinical laboratory services ("Stark I")[4] and January 1, 1995, for ten other designated health services ("Stark II").[5]

The Stark Law contains significant civil sanctions for violations, including denial of payment, refunds of amounts collected in violation of the law, civil money penalties of up to $15,000 for each offense, and exclusion from Medicare or Medicaid programs.[6] In addition, if an individual enters into an arrangement or scheme that the person knows has the principal purpose of assuring referrals to an entity which, if the individual directly made to the entity would violate the Stark Law, the person is subject to a civil money penalty of up to $100,000 for

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1. Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51,012 (Sept. 5, 2007) (to be codified at 42 C.F.R. pts. 411 & 424) [hereinafter Phase III].

2. *See id.*

3. 42 U.S.C. § 1395nn (2000 & Supp. V 2005).

4. Pub. L. No. 103-66, § 13562(b), 1993 U.S.C.C.A.N. (107 Stat.) 312, 604 (codified as amended 42 U.S.C. § 1395nn).

5. *Id.*

6. 42 U.S.C. § 1395nn(g).

each such circumvention scheme.[7]

The agencies responsible for implementing the regulatory provisions for the Stark legislation are the CMS and the Office of the Inspector General ("OIG").[8] CMS has been given the responsibility for developing regulations that set forth the specific policies by which conduct prohibited by the Stark Law is defined, while the OIG has maintained responsibility for imposing sanctions for violations of Stark Law.[9] On March 31, 1995, the OIG issued final sanction regulations for the Stark Law, currently codified in 42 C.F.R. § 1003.[10] In such regulations, the OIG incorporated the Omnibus Budget Reconciliation Act of 1993 and the Social Security Act of 1994 expansion to other designated health services into the final regulations for sanctioning improper claims and circumvention schemes.[11] On January 4, 2001, CMS published Phase I of the final Stark Law Regulations.[12] Phase I covers the general prohibition on certain referrals, the general exemption to both ownership and compensation arrangement prohibition, and related definitions.[13] On March 26, 2004, CMS published Phase II of the final Stark Law Regulations.[14] The Phase II Rules became effective July 26, 2004.[15] On September 5, 2007, CMS published Phase III of the final Stark Law Regulations.[16] Phase III became effective December 4, 2007.[17] A brief summary of some of the interpretations and changes contained in Phase III are summarized below.

1. "Stand in the Shoes Concept."—In Phase III, CMS introduces a new concept, the "stand in the shoes" concept.[18] Under this new concept, with respect to indirect compensation arrangements, the relationship between a physician and his or her physician organization is disregarded, and the physician "stands in the shoes" of his or her physician organization.[19] Put another way, a physician associated with a physician organization "is deemed to have a direct

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7. *Id.* § 1395nn(g)(4).

8. *See* HHS-OIG-Fraud Prevention & Detection-Enforcement Actions-Administrative Actions, http://www.oig.hhs.gov/fraud/enforcement/administrative/cmp/cmp.html (explaining that OIG can seek money penalties for statutory violations) (last visited Aug. 3, 2008).

9. *Id.*

10. 42 C.F.R. § 1003 (2007).

11. *Id.* § 1003.100(a) (explaining basis of the regulation).

12. Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) (to be codified at 42 C.F.R. pts. 411 & 424) [hereinafter Phase I].

13. *Id.*

14. Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054 (Mar. 26, 2004) (to be codified at 42 C.F.R. pts. 411 & 424) [hereinafter Phase II].

15. *Id.*

16. Phase III, *supra* note 1.

17. *Id.*

18. *Id.* at 51,028.

19. *Id.*

compensation arrangement with a [designated health services entity] if the only intervening entity between the physician and the [designated health services] entity is [the] physician organization."[20] In effect, this change means that many arrangements that would have constituted an indirect compensation arrangement if analyzed under Phase I and Phase II of the Stark Law are now viewed as direct compensation arrangements and will have to be analyzed under Phase III to determine whether an applicable exception can be met in order for the physician to continue to make referrals to the DHS entity. The "stand in the shoes" provisions are effective as of the effective date of the Phase III final rule.[21] Existing arrangements, however, do not need to be amended during the original or current renewal term of the agreement to comply with Phase III.[22] At the expiration of the original or current renewal term of the existing arrangements, the arrangement must then be structured to comply with the requirements of Phase III.[23]

2. Physician Recruitment Exception.—The physician recruitment exception exempts remuneration provided by a hospital to a physician "to induce the physician to relocate his or her practice to the geographic area served by the hospital in order to be a member of the hospital's medical staff."[24] Phase III expands this exception to cover rural health clinics.[25] Additionally, other significant changes to this exception were implemented through the Phase III regulations and are discussed below.

a. Geographic area.—CMS modified the manner in which hospitals determine the geographic area served by the hospital for purposes of this exception. Phase II provided that the exception required the recruited physician to relocate his or her practice to the area composed of "the lowest number of contiguous zip codes from which the hospital draws at least 75[%] of its inpatients."[26] Phase III has not altered this requirement, but CMS has provided clarification that is beneficial to a hospital in determining its geographic area. The term "contiguous zip codes" includes zip codes that are contiguous to the zip code in which the hospital is located, and the term is also intended to include zip codes that are contiguous to each other.[27] For purposes of determining the geographic area which it serves, a hospital should examine its inpatient data and identify the lowest number of zip codes that touch at least one other zip code in which inpatients reside that comprise at least 75% of its inpatients at the time the parties execute the recruitment agreement.[28] If a hospital can achieve the 75% threshold of inpatient admissions through multiple configurations, it may use any

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20. *Id.*
21. *Id.* at 51,012 (listing the effective date as December 4, 2007).
22. *Id.* at 51,028.
23. *Id.*
24. 42 C.F.R. § 411.357(e) (2007).
25. Phase III, *supra* note 1, at 51,048.
26. *Id.* at 51,049.
27. *Id.* at 51,050.
28. *Id.*

of the configurations.[29] In the event a hospital does not draw at least 75% of its inpatients from all of the contiguous zip codes from which it draws inpatients, then the hospital's geographic area would be all of the contiguous zip codes from which it draws its inpatients.[30] Furthermore, CMS provided that a hospital may recruit a physician to a zip code from which it draws no inpatients if that zip code is entirely surrounded by contiguous zip codes from which the hospital draws at least 75% of its inpatients (i.e., a zip code "hole" in the contiguous area).[31]

In response to commentary urging CMS to provide different requirements for recruiting physicians to outlying areas, CMS has expanded the definition of geographic area served by hospitals located in rural areas. A rural area is defined as an area that does not constitute a metropolitan statistical area.[32] For a hospital located in a rural area, it may determine the geographic area it serves based on "the lowest number of contiguous zip codes from which it draws at least 90[%] of its inpatients."[33] Where a hospital in a rural area "draws fewer than 90% of its inpatients from all of the contiguous zip codes from which it draws inpatients," the hospital's geographic "may include non-contiguous zip codes, beginning with the non-contiguous zip code area in which the highest percentage of the hospital's inpatients reside[], and continuing" the process of adding non-contiguous zip code areas based on the order of descending percentages of inpatients.[34] In addition to this special rule for rural hospitals, such hospitals may also determine the geographic areas in which they serve based on the alternative "methodologies applicable to all hospitals."

Pursuant to Phase III modifications, CMS now permits rural health clinics, rural hospitals, and federally qualified health centers to recruit physicians to areas outside of the geographic area they serve if the facility satisfies all other requirements of the exception and the facility establishes a demonstrable need for the recruited physician's services as determined by the Secretary of the Department of Health and Human Services through the advisory opinion process.[35]

b. Relocation requirement.—The Phase II regulations created some confusion regarding the relocation requirement of the physician recruitment exception, and CMS attempted to clarify this issue through the Phase III comments.[36] The exception requires that the recruited physician relocate his or her practice to the geographic area served by the hospital.[37] In order for a recruited physician to satisfy this requirement, the recruited physician must

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29. *Id.*
30. *Id.*
31. *Id.*
32. *Id.* at 51,042.
33. *Id.* at 51,049-50.
34. *Id.* at 51,050.
35. *Id.* at 51,056.
36. *Id.* at 51,050.
37. *Id.*

comply with both aspects of the requirement.[38] First, the recruited physician must move his or her practice from outside of the hospital's geographic area into the hospital's geographic area.[39] Second, the recruited physician must either move his or her practice at least twenty-five miles or "derive at least 75[%] of his or her practice's revenues from . . . new patients."[40] CMS has exempted certain individuals from the relocation requirement. In Phase II, CMS provided that residents and physicians who have been in practice one year or less would not be considered to have an established medical practice to relocate.[41] Recruitment arrangements with such physicians could qualify for the exception regardless of whether the recruited physician moved his or her practice location, so long as all other requirements of the exception were met.[42] CMS has clarified that for purposes of this exception, the term resident "includes all training, including post-residency fellowships."[43]

c. Recruitment arrangements involving group practices.—Another aspect of the physician recruitment exception in which CMS made significant changes was to arrangements between the recruited physician and a physician practice. The two significant areas that were addressed by CMS were practice restrictions and income guarantees.

In Phase II, CMS prohibited physician practices from imposing additional practice restrictions in recruiting arrangements with recruited physicians that were not related to quality of care.[44] Specifically, CMS indicated that non-compete restrictions were categorically impermissible.[45] CMS received substantial commentary suggesting that such prohibitions created significant obstacles for recruiting and created confusion for physician practices regarding the type of practice restrictions that were prohibited.[46] Based on these "unintended results," CMS revised the language of the exception to prevent physician practices from imposing only those "restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital."[47] As guidance for this revision, CMS provided examples of restrictions that it would not consider unreasonable restrictions having a substantial effect on the recruited physician's ability to remain and practice medicine in the hospital's geographic area after leaving the practice group: (1) "restrictions on moonlighting"; (2) "[p]rohibitions on soliciting patients and/or employees of the physician practice"; (3) requirements that "the recruited physician not use confidential or proprietary information of the

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38. *Id.*
39. *Id.*
40. *Id.*
41. Phase II, *supra* note 14, at 16,094-95.
42. *Id.*
43. Phase III, *supra* note 1, at 51,051.
44. Phase II, *supra* note 14, at 16,096-97.
45. *Id.*
46. Phase III, *supra* note 1, at 51,053.
47. *Id.* at 51,054.

physician practice"; (4) requirements that "the recruited physician . . . repay losses of his or her practice that are absorbed by the physician practice in excess of any hospital recruitment payments"; and (5) requirements that "the recruited physician pay a predetermined amount of reasonable damages ([i.e.,] liquidated damages) if the physician leaves the physician practice and remains in the community."[48]

The expansion of the regulation to prohibit only those practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital is beneficial in the recruiting process, but the reasonableness standard imposes a burden on hospitals to pass judgment on the reasonableness of the practice restrictions imposed by physician practices. Furthermore, CMS addressed the Phase II prohibition of non-compete clauses in recruitment arrangements.[49] The purpose of the prohibition was to discourage physician practices that recruit physicians using hospital resources from impeding the recruited physician's ability "to remain in the community and fulfill his or her obligations under the recruitment arrangement with the hospital."[50] CMS, however, recognized that unless a physician practice was "able to impose a limited, reasonable non-compete clause," it may face significant difficulty in recruiting or be "reluctant to hire additional physicians" even with financial assistance from hospitals.[51] Although compliance with state and local non-compete laws is not required, CMS cautioned that any practice restrictions that do not satisfy applicable state and local laws "run a significant risk of being considered unreasonable."[52] CMS noted, however, that nothing in this section was intended to prevent a hospital from entering into an agreement with a physician practice that would prohibit the physician practice from imposing a non-compete provision or other practice restrictions on recruited physicians.[53]

The recruitment exception also imposes restrictions on hospital-subsidized income guarantees.[54] Physician practices may not allocate more than "the group's actual additional incremental costs attributable to the recruited physician" under an income guarantee.[55] CMS clarified that this limitation of actual additional incremental costs applies to any type of income guarantee, whether it is based on net income, gross income, revenues, or some other variation.[56] In addition, CMS established a narrow exception for a physician who is recruited to a rural area or Health Professional Shortage Area ("HPSA") to replace a physician who, within the previous twelve months, has retired,

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48. *Id.* at 51,053-54.
49. *See id.*
50. *Id.* at 51,054.
51. *Id.*
52. *Id.*
53. *Id.*
54. *Id.* at 51,052-53.
55. *Id.*
56. *Id.* at 51,052.

relocated outside the geographic area, or has died.[57] For purposes of an income guarantee in such situations, the physician group may "allocate to the recruited physician a per capita allocation of the practice's aggregate overhead and other expenses"; however, this amount shall not "exceed 20[%] of the practice's aggregate costs."[58] CMS noted that this limitation applies only to hospital-subsidized income guarantees.[59] Where a physician practice uses its own funding to recruit physicians, the group is permitted to use any cost allocation method when compensating the recruited physician so long as the arrangement satisfies the requirements of an applicable exception (i.e., bona fide employment relationship exception or in-office ancillary services exception).[60] CMS identified the following examples of expenses that generally qualify as recruiting expenses: (1) "headhunter fees"; (2) "travel . . . and moving expenses associated with . . . recruitment"; (3) "employee benefits, taxes and professional fees attributable to hiring the recruited physician"; and (4) the cost of tail insurance covering the physician's prior practice.[61] CMS noted, however, these expenses are limited to those involved in the recruitment of the physician and do not include costs incurred after the physician is recruited and has joined the physician group.[62] If a hospital pays a physician group for the time its physicians spend recruiting, then such compensation would have to satisfy one of the compensation exceptions (other than the recruitment exception) because such costs do not qualify as recruitment expenses for purposes of this exception.[63] Where compensation is made directly to the physician practice, CMS confirmed the requirement that the recruitment agreement must be signed by the hospital, the recruited physician, and the physician practice.[64] However, nothing in the regulation precludes the recruitment agreement from being executed in counterparts.[65]

d. Other additional clarifications to the recruitment exception.—Following the Phase II regulations, there was confusion regarding the extent of the relocation exception afforded to residents.[66] In Phase III, CMS clarified that the requirement that the recruited physician join the hospital's medical staff is a separate requirement from the relocation requirement.[67] Although residents are exempt from having to relocate their medical practice to the geographic area served by the hospital, residents must satisfy the requirement that they join the

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57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.*
61. *Id.*
62. *Id.*
63. *Id.*
64. *Id.* at 51,051.
65. *Id.*
66. *Id.* at 51,048.
67. *Id.*

hospital's medical staff.[68] Therefore, in order to qualify for the recruitment exception, a "recruited physician cannot already be a member of the hospital's medical staff."[69]

3. Fair Market Value.—In Phase III, CMS revised the fair market value exception to expressly exclude leases for office space.[70] In order to comply with the Stark Law, leases must comply with the rental of space exception located at 42 C.F.R. § 411.357(a).[71] CMS also clarified that the fair market value exception applies to compensation paid by a referring physician to a DHS entity and to compensation paid by a DHS entity to a referring physician.[72] CMS declined to elaborate on what constitutes fair market value or create a rebuttable presumption that all transactions are fair market value.[73] CMS stated,

> The parties to a transaction or an arrangement are in the best position to ensure that the remuneration is at fair market value and to document it contemporaneously. If questioned by the government, the burden would be on the parties to explain how the transaction meets the fair market value compensation exception requirements.[74]

Additionally, Phase III deletes the safe harbor that CMS established for hourly payments to physicians for personal services.[75] The Stark Law previously allowed physicians and hospitals to guarantee that hourly payments did not exceed fair market value by setting the payment at a rate less than or equal to the rate for emergency room physicians in the relevant physician market or the average of the fiftieth percentile of national compensation levels for physicians in the same specialty in at least four of six surveys.[76] In Phase III, CMS recognized that taking advantage of this safe harbor was almost impossible as several of the surveys no longer exist and that "it may be infeasible to obtain information regarding hourly rates for emergency room physicians at competitor hospitals."[77] Without the safe harbor, hospitals and physicians must independently determine whether a payment rate is consistent with fair market value based on the nature of transaction, its location, and other factors.

4. Retention Payments.—In Phase III, CMS provided some additional flexibility in efforts to retain physicians in underserved areas. A hospital, federally qualified health center, or a rural health clinic (all referred to as "hospital" below) may make payments to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by

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68. *Id.*
69. *Id.*
70. *Id.* at 51,059.
71. *Id.*
72. *Id.*
73. *Id.* at 51,060.
74. *Id.*
75. *Id.* at 51,070.
76. *Id.* at 51,015.
77. *Id.*

the hospital if all the following conditions are met: (1) the physician has a bona fide firm, written recruitment offer or offer of employment from a hospital, academic medical center, or physician organization that is not related to the hospital making the payment; (2) the offer must specify the remuneration being offered and "require the physician to move the location of his or her medical practice at least [twenty-five] miles and outside of the geographic area served by the hospital making the retention payment"; (3) any retention payment must meet the requirements for recruitment payments: (i) in writing and signed by both parties; (ii) not conditioned on the physician's referral of patients to the hospital; (iii) does not take into account the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and (iv) the physician is allowed to establish staff privileges at any other hospitals and to refer business to any other entities; (4) "[a]ny retention payment must be subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness" as the written recruitment offer or offer of employment; and (5) the retention payment must not exceed the lower of: (i) "[t]he amount obtained by subtracting the physician's current income from . . . the income the physician would receive from comparable physician" related services in the written recruitment or employment offer, "provided that the respective incomes are determined using a reasonable and consistent methodology and that they are calculated uniformly over no more than a [twenty-four]-month period"; or (ii) "the reasonable costs the hospital . . . would otherwise [incur] to recruit a new physician to the geographic area served by the hospital . . . to join the medical staff of the hospital . . . to replace the retained physician."[78]

Phase III has added another basis on which retention payments can be made to a physician. In addition to a bona fide written offer, a hospital can furnish such payments if it receives a written certification from a physician that the physician has a bona fide opportunity for future employment by a hospital, academic medical center, or a physician organization that requires the physician to move the location of his or her medical practice at least twenty-five miles and outside the geographic area served by the hospital.[79] The written certification must contain at least the following: (1) "details regarding the steps taken by the physician to obtain the employment opportunity; [(2)] details of the physician's employment opportunity, including the identity and location of the physician's future employer and/or employment location, and the . . . anticipated income and benefits (or a range of income and benefits)"; (3) certification "that the future employer is not related to the hospital . . . making the payment[s]; [(4)] the date on which the physician anticipates relocating his or her medical practice; and [(5)] information sufficient for the hospital . . . to verify the information included in the written certification."[80] The hospital must verify that the physician has a bona fide opportunity for future employment that requires the physician to

78. *Id.* at 51,065.
79. *Id.* at 51,066.
80. *Id.*

relocate outside the geographic area served by the hospital.[81] Any retention payment may not exceed the lower of: (1) "an amount equal to 25% of the physician's current annual income" (measured over no more than a twenty-four-month period), "using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs [that] the hospital would otherwise have to expend to recruit a new physician . . . to replace the retained physician."[82]

Any retention payment (whether pursuant to an actual written offer or a physician certification) must also meet the following requirements: "(1) the physician's current medical practice has to be located in a rural area, a HPSA" (regardless of the physician's specialty), in an area with demonstrated need for the physician as determined in an advisory opinion, or "at least 75[%] of the physician's patients [must] reside in a medically underserved area or [be] members of a medically underserved population"; (2) the hospital must not enter into a retention arrangement with a particular referring physician more frequently than once every five years; (3) "the amount and terms of the retention payment must not be altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician"; and (4) the arrangement must not violate the anti-kickback statute or any other applicable federal or state law.[83]

5. Temporary Non-Compliance.—Subject to certain conditions detailed below, there is an exception for temporary noncompliance if: (1) the financial relationship between the entity and the referring physician fully complied with "an applicable exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship become noncompliant; (2) the financial relationship fell out of compliance for reasons beyond" the control of the entity, and the entity promptly took steps to rectify "the noncompliance; and (3) the financial relationship does not violate the anti-kickback statute."[84] This exception only applies to designated health services furnished during the period of "time it takes the entity to rectify the noncompliance, which must not exceed [ninety] consecutive calendar days following the date on which the financial relationship" becomes noncompliant with an exception.[85] In the Phase III preamble, CMS steadfastly rejected suggestions that this time period be extended such as a suggestion that the period run from the date of noncompliance until thirty or ninety days after the date the noncompliance was discovered. CMS stated, "A discovery-based rule is contrary to the statutory scheme. Moreover, such a rule creates a perverse incentive not to diligently monitor and enforce compliance."[86] The temporary non-compliance exception may be used by an entity only "once every three years with respect to the same referring physician."[87] Finally, this exception will not apply if the exception with which

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81. *Id.*
82. *Id.*
83. *Id.* at 51,065-66.
84. *Id.* at 51,024 (citing 42 C.F.R. § 411.353(f) (2007)).
85. *Id.* (citing 42 C.F.R. § 411.353(f) (2007)).
86. *Id.* at 51,025.
87. *Id.* at 51,024.

the financial relationship previously complied related to the non-monetary compensation exception or the medical staff incidental benefits exception.[88]

In the preamble to the Phase III regulations, CMS stated:

> Entities should maintain adequate and contemporaneous documentation of all financial relationships with referring physicians, including: [(1)] [t]he terms of each arrangement; [(2)] [w]hether and how an arrangement fell out of compliance with an exception; [(3)] [t]he reasons for the arrangement falling out of compliance; [(4)] [s]teps taken to bring the arrangement into compliance; [(5)] [r]elevant dates; and [(6)] [s]imilar information.[89]

6. Amendment to Existing Agreements.—In Phase III, CMS addressed the amendment of agreements between a DHS entity and a referring physician.[90] The concept applies to space and equipment leases and personal services agreements.[91] In commentary, CMS stated that

> parties may not change the rental charges at any time during the term of the agreement. Parties wishing to change the rental charges must terminate the agreement and enter into a new agreement with different rental charges and/or terms; however, the new agreement may be entered into only after the first year of the original . . . term.[92]

Other provisions not impacting the rental charges or related provisions may be amended at any time so long as "the rental charges are not changed and [the] other requirements of the exception are satisfied."[93] This concept also applies to terms regarding compensation under personal services agreements.[94]

7. Physicians and Group Practices.—Phase III clarifies that independent contract physicians must furnish patient care services under a direct contract with the group, not between the group and another entity.[95] Additionally, Phase III states that independent contractors must perform services in a group facility in order to be considered a physician in the group practice.[96]

B. OIG Actions

1. Advisory Opinion 07-10: Hospital Payment to Physicians for On-Call and Indigent Care Services.—On September 20, 2007, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued Advisory Opinion

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88. *Id.*
89. *Id.* at 51,026.
90. *Id.* at 51,044.
91. *See id.*
92. *Id.*
93. *Id.*
94. *Id.*
95. *Id.* at 51,082-83.
96. *Id.*

07-10.[97] This was the first advisory opinion addressing a hospital's payment to physicians for providing on-call and indigent care services. Based on the specific facts of the arrangement, the OIG determined that it would not impose sanctions on the facility at issue.[98] Under the facility's arrangement, the physicians were obligated to: participate in call rotation equally within specialties, provide inpatient care to any patient seen in the emergency department while on-call if the patient was admitted to the facility regardless of the patient's ability to pay for the care, respond to calls within a reasonable time and such times would be monitored, collaborate and participate in risk management and performance improvement efforts and committees, and document in the medical records in a timely fashion the services provided for all patients seen.[99] Physicians were paid a per diem rate for each day spent on-call, except for the requirement that each physician was required to provide one and one-half days of on-call services each month without payment.[100] The per diem rate varied based on the specialty and whether call coverage was on a weekend or weekday.[101] The facility engaged an independent health care industry consultant to advise the facility on "the reasonableness of the per diem rates paid under the [a]rrangement."[102]

The OIG emphasized three particular aspects of the arrangement that were influential in its decision to not impose sanctions.[103] First, the payments to the physicians reflected the fair market value of the services provided, and such evaluation was determined by an independent third party analysis without regard to referrals or other business generated between the parties.[104] The payments were tailored to reflect the actual burden on the physicians, the likelihood of actually having to respond, the likelihood of having to provide uncompensated care, and the likely extent of treatment.[105] Beyond actual time spent, the physicians were obligated to provide care to any patient seen while on-call, and the obligation continued until the patient's discharge (meaning the physicians remain at risk of having to furnish additional services for no additional payment).[106] The physicians were required to provide eighteen days per year of uncompensated on-call services as part of the arrangement.[107] The physicians assumed responsibility for medical recordkeeping and for cooperation with the facility relating to risk management and performance improvement efforts.[108]

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97. OIG Advisory Opinion No. 07-10 (Sept. 20, 2007), http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf.

98. *Id.* at 1-2.

99. *Id.* at 2-3.

100. *Id.* at 4.

101. *Id.*

102. *Id.*

103. *See* at 8-10.

104. *Id.* at 8-9.

105. *Id.* at 8.

106. *Id.*

107. *Id.*

108. *Id.*

"The difference in per diem rates among specialties [was] based on the different extent of the uncompensated responsibilities that [would] likely fall on the physicians," and the payments were "administered uniformly for all [physicians] in a given specialty without regard to [an] individual physician's referrals" or other business generated between the parties.[109]

Second, the facility evaluated the circumstances giving rise to the arrangement and determined that the facility "had a legitimate, unmet need for on-call coverage and uncompensated care physician services."[110] The emergency department was understaffed because of a "lack of capable and willing physicians."[111] Because of the on-call physician shortage, the facility was forced to transfer patients to other hospitals for the appropriate care. The OIG indicated that the presence of these factors lowered the risk that the arrangement may lead to federal program and patient abuse.[112]

Finally, the arrangement contained many additional safeguards that "minimize[d] the risk of fraud and abuse."[113] The opportunity to provide on-call services pursuant to the arrangement was "offered . . . to all physicians in relevant specialties."[114] The obligations within the specialties were "divided as equally as possible" to avoid being used selectively to reward the highest referrers.[115] Additionally, the participating physicians were required to provide follow-up care to any patient seen in the emergency department while on-call if the patient was admitted, regardless of patient's ability to pay for care.[116] This requirement decreased the chance for physicians to "cherry-pick" only those patients that were likely to be lucrative.[117] Furthermore, the requirement that physicians document the on-call services promoted "transparency and accountability."[118]

The OIG was careful to tailor its opinion to the specific facts of this arrangement and stated that each on-call coverage arrangement must be evaluated based on the totality of the facts and circumstances surrounding it.[119]

2. Advisory Opinion 07-05: Sale of Ambulatory Surgery Center Ownership Interests.—On June 12, 2007, the OIG issued an advisory opinion relating to the sale of interests in an ambulatory surgery center by physician owners.[120] The proposed arrangement involved an ambulatory surgery center ("ASC") in which

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109. *Id.* at 9.
110. *Id.*
111. *Id.*
112. *See id.*
113. *Id.*
114. *Id.*
115. *Id.*
116. *Id.*
117. *Id.*
118. *Id.*
119. *Id.* at 10.
120. OIG Advisory Opinion No. 07-05 (June 12, 2007), http://oig.hhs.gov/fraud/docs/advisoryopinions/opinions/2007/Advopin07-05C.pdf.

three orthopedic surgeons owned 94%, and two gastroenterologists and two anesthesiologists owned the remaining 6%.[121] "Under the [p]roposed [a]rrangement, the [o]rthopedic [s]urgeons would sell to the [tax-exempt] [h]ospital the number of ownership units necessary for the [h]ospital to own 40[%]."[122] The amount to be paid by the hospital was certified to be fair market value for the units.[123] "The amount paid by the [h]ospital [to the orthopedic surgeons for the units] would exceed the amount originally invested by the [o]rthopedic [s]urgeons for this number of units."[124] The hospital acknowledged it would be a in position to influence referrals; however, it agreed to limit its ability to make referrals by agreeing to a number of requirements found to be sufficient in other advisory opinions issued by the OIG.[125]

The OIG, however, found that the proposed arrangement failed to meet all of the criteria under the hospital/physician owned ASC safe harbor.[126] Specifically, the OIG found that the arrangement would not meet the criterion that the amount paid to an investor in return for the investment must be directly proportional to the amount of the capital investment of that investor.[127] The OIG noted that while each investor would receive a return on investment proportional to the investor's ownership share, the return would not be proportional to the capital invested by the original investor.[128] The OIG found relevant the fact that the hospital would buy its shares from the orthopedic surgeons rather than the ASC itself.[129]

The OIG noted that it could not

> conclude that the difference in cost of capital acquisition, which results in financial gain to a subset of the physician investors whose referrals may be particularly valuable, is not related, directly or indirectly, to the value or volume of referrals or other business generated between the parties, including referrals by the selling [o]rthopedic [s]urgeons to the [h]ospital or the ASC.[130]

The OIG found that the arrangement posed "a heightened risk of fraud and abuse" and concluded that the "[a]rrangement could potentially generate prohibited remuneration under the anti-kickback statute."[131]

The opinion focuses on the fact that orthopedic surgeons would realize a gain

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121. *Id.* at 2.
122. *Id.*
123. *Id.*
124. *Id.*
125. *See id.* at 3.
126. *Id.* at 5.
127. *Id.*
128. *Id.*
129. *Id.* at 5.
130. *Id.* at 6.
131. *Id.*

on their original investment.[132] However, as certified by the parties, the fair market value of the interests increased since the orthopedic surgeons' original investment.[133] Thus, the advisory opinion leaves unanswered how to reconcile the fair market value requirement with the return on original investment requirement of the hospital/physician owned ASC safe harbor. If not clarified, the opinion could have a significant impact on the potential resale of interests by physician investors.

3. OIG Compliance Guidance Applies to Medical Device Firms.—On September 6, 2006, the Advanced Medical Technology Association ("AdvaMed") sent a letter to the OIG asking for "confirmation that the 1989 Special Fraud Alert on Joint Ventures" as well as other fraud and abuse "guidance on physician investment issued by the OIG apply to medical device and distribution entities," clarification on "certain factors relevant to analyzing a joint venture under the fraud and abuse law[s]," and a request for publication of additional OIG guidance on physician investment in medical device firms.[134]

On October 6, 2006, the OIG issued a response letter confirming that the OIG's 1989 Special Fraud Alert on Joint Ventures as well as other fraud and abuse guidance applies to medical device and distribution entities.[135] The OIG stated that it believes "all industry stakeholders involved in joint ventures with physicians, including medical device manufacturing and distribution entities, are well-advised to pay close attention to such guidance. Most of our guidance about joint ventures is not sector specific and applies equally to all physician joint ventures."[136] Additionally, the OIG clarified that "the amount of revenues generated directly or indirectly by a physician investor is a relevant factor in analyzing a joint venture under the anti-kickback statute."[137] The OIG noted that the "small entity . . . safe harbor . . . includes a condition that limits safe harbor protection to entities that derive no more than 40% of their gross revenues from investors, such as physicians."[138] The OIG stated, "the fact that a substantial portion of a venture's gross revenues is derived from participant-driven referrals is a potential indicator of a problematic joint venture."[139]

II. TAX

In 2006 and 2007, the major tax developments again surrounded tax-exempt hospitals and the provision of community benefits. Various levels of government

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132. *See id.* at 5-6.

133. *Id.* at 2.

134. Office of Inspector Gen., Dep't of Health & Human Servs., Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2005), http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20(2).pdf.

135. *Id.*

136. *Id.* at 1.

137. *Id.* at 2.

138. *Id.* (citing 42 C.F.R. § 1001.952(a) (2005)).

139. *Id.* (citing 70 Fed. Reg. 4858, 4865 (Jan. 31, 2005)).

undertook investigations and other efforts to clarify, examine, and quantify the community benefit standard and ensure that hospitals are operating in a manner that justifies granting such organizations tax-exempt status.

A. Redesigned Form 990

The most significant healthcare development in the area of tax was the redesign of the Form 990. On June 14, 2007, the Internal Revenue Service ("IRS") released for public comment a discussion draft of a redesigned Form 990 ("Discussion Draft").[140] Form 990 is the annual return filed by many public charities and other exempt organizations and reports information about the organization's operations.[141] The IRS's objectives were to promote transparency to the IRS and the public, accurately portray operational information to ensure effective assessment of noncompliance, and minimize filing burdens.[142] An overarching theme in the Discussion Draft was that the IRS intended to solicit detailed information about an organization's operations and, specifically, how the organization carries out its operations with a focus on areas involving potential abuse.[143] Additionally, the IRS sought to provide organizations with more opportunities to explain the organization's operations and charitable purpose.[144]

The Discussion Draft included a ten-page core form that all organizations would be required to fill out and then a series of fifteen schedules to be completed by organizations engaging in particular activities.[145] One of the major changes made to Form 990 is the creation of a summary page that is intended to reflect a "snapshot" of important aspects of an organization's operations that are addressed in greater detail in the rest of the core form.[146] The summary page includes information regarding the total size of the governing board, the number of "independent" members of the governing board, the amount paid to the highest paid employee, and the total executive compensation paid as a percentage of overall program service expenses.[147] The remainder of the core form requests information regarding composition of the governing board and other governance and financial statement practices, joint venture disclosures, compensation disclosures for disqualified persons and compensation of current and certain former officers, directors, trustees, key employees and the top five highest paid employees, and bond-related disclosures.[148]

The series of schedules focus on particular conduct, including fundraising,

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140. TAX-EXEMPT & GOV'T ENTITIES DIV., IRS, BACKGROUND PAPER—REDESIGNED DRAFT FORM 990 (2007), http://www.irs.gov/pub/irs-tege/form_990_cover_ sheet.pdf.

141. *Id.* at 1.

142. *Id.* at 2.

143. *See generally id.*

144. *See generally id.*

145. *Id.* at 2, 4.

146. *Id.* at 3.

147. *Id.*

148. *Id.* at 3-4.

compensation, hospitals, tax-exempt bonds, and non-cash charitable contributions. Schedule H will be the key schedule for health care organizations and will be the vehicle through which such organizations will explain how they satisfy the community benefit standard for exemption. The Community Benefit Report contained within Schedule H addresses: cost-based data for various community benefits, including charity care (without clarifying whether bad debt is included for this purpose), Medicaid and other government programs (without clarifying whether Medicare shortfalls are included for this purpose), a description of any written charity care policy, a description of how the organization assesses the healthcare needs of its community, information about ER policies and procedures, and how the hospital's operations facilitate exempt purposes. Further, the scope of Schedule H extends beyond the community benefit test and encompasses billing information broken down by categories of healthcare coverage, a description of any written collection policy, including how and when the policy is communicated to patients and how the organization collects patient debts and a description of the patient intake process and the education provided to patients regarding their eligibility for government assistance or charity care.

After the ninety-day comment period, the IRS reviewed the numerous comments provided from tax community regarding the Discussion Draft. The IRS is in the process of making additional revisions in response to the comments received and will release the new Form 990 for organizations to complete for returns filed in 2009 for the 2008 tax year.[149]

B. Congressional Budget Office Report—Nonprofit Hospitals and the Provision of Community Benefits

In December 2006, the Congressional Budget Office ("CBO") published a report comparing the provision of community benefits provided by nonprofit and for-profit hospitals.[150] The report was requested by the Chairman of the House Committee on Ways and Means to examine whether nonprofit hospitals provide community benefits sufficient to justify their tax-exempt status.[151] The results indicated that, "on average, nonprofit hospitals provided higher levels of uncompensated care than did similar for-profit hospitals[;] . . . however, the provision of uncompensated care varied" significantly among nonprofit hospitals.[152] In addition, "[n]onprofit hospitals were more likely than otherwise

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149. In December 2007, the IRS released the final version of the redesigned Form 990. Information about the redesigned Form 990, a copy of the Form 990 and its schedules, and information about transitional relief can be found at http://www.irs.gov/charities/article/0,,id=176613,00.html.

150. CONG. BUDGET OFFICE, NONPROFIT HOSPITALS AND THE PROVISION OF COMMUNITY BENEFITS (2006), http://www.cbo.gov/ftpdocs/76xx/doc7695/12-06-Nonprofit.pdf [hereinafter CBO REPORT].

151. Donald B. Marron, *Preface* to CBO REPORT, *supra* note 150.

152. CBO REPORT, *supra* note 150, at 9.

similar for-profit hospitals to provide certain special[ty] services," but the nonprofit hospitals provided care "to fewer Medicaid-covered patients as a share of their total patient population."[153] Finally, the results showed that, "[o]n average, nonprofit hospitals . . . operate[d] in areas with higher average incomes, lower poverty rates, and lower rates of uninsurance than [similar] for-profit hospitals."[154]

C. Healthcare Financial Management Association Released Revised Accounting Guidelines for Healthcare Providers Regarding Bad Debt and Charity Care

Also in December 2006, the Healthcare Financial Management Association ("HFMA") released the updated Statement No. 15 intended to improve clarity and address congressional and legal questions about the reporting practices of tax-exempt hospitals for charity care and bad debt.[155] Where a hospital provides services to a patient determined to have the financial capacity to pay for the services and the patient later fails to pay the amount, this results in a bad debt.[156] Alternatively, charity care is where a hospital provides services to a patient that has demonstrated an inability to pay for services.[157] The updated statement discusses the determination of patient ability to pay and the amount of services eligible for charity support.[158] While the focus is on tax-exempt hospitals, the guidelines also apply "to all taxable and tax-exempt institutional healthcare providers."[159]

D. IRS Issues Draft Governance Guidelines for Charitable Organizations

On February 7, 2007, the IRS posted on its website an informal discussion draft of recommended guidelines for good governance practices for charitable organizations.[160] The IRS's position was that governing boards of charitable

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153. *Id.*

154. *Id.*

155. HEALTHCARE FIN. MGMT. ASS'N, P&P BOARD STATEMENT 15: VALUATION AND FINANCIAL STATEMENTS PRESENTATION OF CHARITY CARE AND BAD DEBTS BY INSTITUTIONAL HEALTHCARE PROVIDERS 1 (2006), http://www.hfma.org/NR/rdonlyres/B32E0CB5-9AE5-4127-83A3-02FFDE0054D5/0/400530Statement15.pdf.

156. *Id.* at 2.

157. *Id.*

158. *See generally id.* at 2-12.

159. *Id.* at 2.

160. The IRS removed this posting from its website in response to changes in other related policies. *See* GOVERNANCE OF CHARITABLE ORGANIZATIONS AND RELATED TOPICS, http://www.irs.gov/ charities/article/0,,id=178221,00.html (last visited Aug. 2, 2008). A copy of the original post can be found at IRS, IRS ISSUES DISCUSSION DRAFT OF "GOOD GOVERNMENT PRACTICES" FOR 501(C)(3) ORGANIZATIONS 1 (2007), *available at* http://www.pgdc.com/pgdc/news-story/2007/02/08/irs-issues-draft-good-governance-practices-501-c-3-organizations [hereinafter IRS ISSUES DISCUSSION DRAFT].

organizations should be made up of individuals who are informed and active in overseeing a charity's operations and finances.[161] The guidelines included governance practice recommendations pertaining to an organization's mission statement, code of ethics, due diligence, duty of loyalty, transparency, fundraising policy, financial audits, compensation practices, and document retention policy.[162]

E. IRS Report on Exempt Organizations Executive Compensation Compliance Project

"In 2004, the Internal Revenue Service, through the Exempt Organizations Office of the Tax Exempt and Government Entities Division ('EO'), implemented the Executive Compensation Compliance Initiative (the 'Project')."[163] The IRS intended to "[i]ncrease awareness of compensation as a compliance issue within the charitable sector[,] establish an IRS enforcement presence in this area," examine the "practices and procedures exempt organizations use to determine compensation of their officers, directors, trustees, key employees, and related persons," and "[a]ssess and enhance tax law reporting and compliance with respect to compensation practices of exempt organizations."[164] Part I of the Project involved sending compliance check letters regarding executive compensation to 1223 exempt organizations (both public charities and private foundations) who were selected based on certain Form 990 responses.[165] Then, based in part on the Part I responses, Part II involved 782 examinations conducted "to determine whether the compensation of disqualified persons was reasonable in accordance with" the Internal Revenue Code ("IRC") requirements.[166]

The EO released a report in March 2007 discussing the results of the Project (the "Report").[167] The Phase I compliance checks revealed "significant reporting errors and omissions in [certain] areas, particularly excess benefit transactions and transactions with disqualified persons, as well as potential compliance issues related to loans made to officers."[168] The EO noted that "the findings [were] not based on a statistical sampling," only reflected the organizations selected for the Project, "and are not representative of the entire regulated community."[169] Many of the errors and omissions revealed were corrected when the organizations provided additional clarifying information or filed amended returns; however,

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161. IRS ISSUES DISCUSSION DRAFT, *supra* note 160.

162. *Id.* at 2-3.

163. IRS, REPORT ON EXEMPT ORGANIZATIONS EXECUTIVE COMPENSATION 1 (2007), *available at* http://www.irs.gov/pub/irs-tege/exec._comp._final.pdf.

164. *Id.* at 2.

165. *Id.* at 3.

166. *Id.* at 3-4.

167. *Id.* at 1.

168. *Id.* at 5.

169. *Id.*

5% of Phase I organizations were recommended for examination under Phase II.[170] Of the 782 examinations, twenty-five "resulted in proposed or assessed excise taxes aggregating in excess of $21 million against [forty] disqualified persons or organization managers."[171] The assessments were imposed due to:

> [(a)] excessive salary and incentive compensation; [(b)] payments for vacation homes, personal legal fees, or personal automobiles that were not reported as compensation; [(c)] payments for personal meals and gifts to others on behalf of disqualified persons that were not reported as compensation; and [(d)] payments to an officer's for profit corporation in excess of the value of services provided by the corporation.[172]

The Project results discussed in the Report led the EO to make several statements and recommendations regarding potential abuse in the exempt sector.[173] The EO indicated that the "Form 990 compensation reporting need[ed] to be revised to facilitate accurate and complete reporting" and the "EO needs to revisit . . . when penalties should be assessed for an incomplete Form 990."[174] Additionally, the EO determined that it needed to communicate with the public regarding the most common return preparation errors identified during the Project and "educate the public charity sector [regarding] the section 4958 rebuttable presumption and how to satisfy the requirements."[175] Finally, the EO emphasized that the Project further "illustrate[d] the need for a continued enforcement presence in this area" and that the "EO should continue to review compensation issues."[176]

F. Senator Grassley's Letter Requesting Examination of How Nonprofit Hospitals Fulfill Community Benefit Requirements

In April 2007, Senator Grassley, ranking member of the Committee on Finance, asked the Government Accountability Office ("GAO") to study how nonprofit hospitals meet the community benefit requirement in order to qualify for tax-exempt status.[177] Senator Grassley expressed concerns regarding the broad discretion for designation that hospitals have under the community benefit standard and inconsistent reporting caused by the variation among hospital policies relating to charity care and bad debt.[178] In addition, Senator Grassley

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170. *Id.*

171. *Id.* at 7.

172. *Id.*

173. *Id.* at 10.

174. *Id.*

175. *Id.*

176. *Id.*

177. Press Release, U.S. Senate Comm. on Fin., Grassley Seeks GAO Study of Non Profit Hospitals' Community Benefits (Apr. 5, 2007), http://finance.senate.gov/press/Gpress/2007/prg040507b.pdf.

178. *Id.*

was concerned about nonprofit hospitals' executive and board member compensation and these individuals' involvement with for-profit business ventures with the nonprofit hospitals.[179]

Specifically, Senator Grassley requested that the GAO conduct a study examining the following issues: (1) State and IRS community benefit standards and hospital industry guidelines used to interpret these standards; (2) standards and policies hospitals use pertaining to uncompensated care, charity care, and bad debt and how hospitals interpret and report these categories in practice; (3) standards hospitals use for defining and reporting community benefits other than uncompensated care; and (4) nonprofit hospital executive and board member compensation and these individuals' involvement in for-profit ventures with the nonprofit hospitals.[180]

III. Reimbursement and Payment Issues

A. 2008 Physician Fee Schedule

On July 2, 2007, the Centers for Medicare and Medicaid Services ("CMS") issued Proposed Revisions to Payment Policies under the Physician Fee Schedule for CY2008 ("2008 Proposed Physician Fee Schedule").[181] The 2008 Proposed Physician Fee Schedule contains a number of proposed revisions to the Stark regulations as well as solicitation of comments for a number of other potential revisions to the Stark regulations.[182] Among other things, in the 2008 Proposed Physician Fee Schedule, CMS discusses the anti-mark up provisions for purchased tests, the In-Office Ancillary Services exception, independent diagnostic testing facilities ("IDTFs") performance standards, per click payments, and under arrangements relationships.[183] A brief summary of each of these proposed changes is contained below.

1. The Anti-Markup Rule.—Under the Medicare Anti-Markup Rule, if a physician bills Medicare for the technical component of a diagnostic test performed by an outside supplier, the physician is prohibited from marking up the charges for the technical component submitted to Medicare above what the physician paid to purchase the test from the outside supplier.[184] Currently, the Anti-Markup Rule does not apply to the professional component of a diagnostic test.[185]

In the 2008 Proposed Physician Fee Schedule, CMS proposed to expand the

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179. *Id.*

180. *Id.*

181. Payment and Policies Under the Physician Fee Schedule, 72 Fed. Reg. 38,122 (proposed July 12, 2007) (to be codified at 42 C.F.R. pt. 409, 410, 411, 413, 414, 415, 418, 423, 424, 482, 484, 485, and 491).

182. *Id.* at 38,160.

183. *See id.* at 38,123.

184. *Id.* at 38,179.

185. *Id.*

Anti-Markup Rule to the technical and professional component services whether they are "purchased interpretations" or provided under reassignment of rights, unless the performing supplier is a full-time employee of the billing entity.[186] Thus, the only technical or professional services a medical group can mark-up are those performed by the group's "full-time employees."[187] If adopted, this would limit the ability of IDTFs and group practices with in-office imaging equipment to use independent contractor (or part-time employee) radiologists to perform the interpretations since the group practice would be limited to billing Medicare no more than the amount actually paid to the radiologist. Additionally, CMS has proposed to exclude from the "net charge" that can be passed through to Medicare any amount attributable to rent or similar charges paid by the supplier to the billing entity for space or equipment related to the provision of the interpretations.[188]

Although outside the survey period, on November 27, 2007, the 2008 Physician Fee Schedule final rule was published.[189] The final rule included the anti-markup changes as noted above. However, on January 3, 2008, CMS announced a one-year delay of the application of the anti-markup rule to certain diagnostic services performed in certain locations.[190]

2. In-Office Ancillary Services Exception.—The in-office ancillary services exception permits a physician to order designated health services for his or her Medicare and Medicaid patients and then have the physician's practice perform and bill for the services without violating the Stark law if the physician is able to meet certain supervision, billing, and building requirements.[191]

In the 2008 Proposed Physician Fee Schedule, CMS did not issue any specific revisions to the in-office ancillary exception, but instead requested comments on whether changes to the in-office ancillary exception are necessary and, if so, what changes should be made.[192] CMS specifically requested comments on: (1) whether certain services should not be protected under the exception (for example, any therapy services that are not provided on an incident to basis and service that will not be used at the time of the patient's visit in order to assist the physician with making a diagnosis or plan of treatment during the visit); (2) whether, and, if so, how CMS should change the definition of "same

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186. *Id.* at 38,180.

187. *Id.*

188. *Id.*

189. Revisions to Payment Policies Under the Physician Fee Schedule, 72 Fed. Reg. 66,222 (Nov. 27, 2007) (to be codified at scattered sections of 42 C.F.R.).

190. Delay of the Date of Applicability of the Revised Anti-Makeup Provisions for Certain Services Furnished in Certain Locations, 73 Fed. Reg. 404 (Jan. 3, 2008) (to be codified at 42 C.F.R. pt. 414).

191. *See* 42 C.F.R. § 411.355(b) (2007); *see also* Revisions to Payment Policies Under the Physician Fee Schedule, 72 Fed. Reg. 66,222 (Nov. 27, 2007) (to be codified at scattered sections of 42 C.F.R.).

192. Revisions to Payment Policies Under the Physician Fee Schedule, 72 Fed. Reg. 66,222 (Nov. 27, 2007) (to be codified at scattered sections of 42 C.F.R.).

building" and "centralized building"; (3) whether non-specialist physicians should be able to use the exception to refer patients for specialized services that will be performed on equipment owned by non-specialist physicians; and (4) suggestions on any other restrictions on ownership or investment in services that would curtail program abuse.[193]

3. IDTF Performance Standards.—In the 2007 Physician Fee Schedule, CMS expanded the conditions of participation for IDTFs to require that at the time of enrollment or re-enrollment, the IDTF must certify that it meets fourteen additional performance standards.[194] In January, CMS issued Transmittal 187 which updated the Program Manual and some of the performance standards.[195] After much controversy, CMS rescinded the transmittal.[196] However, now CMS is proposing, in the 2008 Proposed Physician Fee Schedule, to revise several of the performance standards and add new performance standards.[197]

The most significant change in the IDTF performance standard is that CMS is proposing to add a new performance standard requiring the IDTF to certify that it "[d]oes not share space, equipment, or staff or sublease its operations to another individual or organization."[198] CMS has stated that the purpose of this standard is to ensure that the operations of an IDTF are separate and distinct from the operations of other entities.[199] CMS has also stated that shared facility arrangements raise concerns under Stark and Anti-Kickback. If adopted, this standard would eliminate the ability of an IDTF to enter into a sublease arrangement with a physician practice, hospital, or other entity.

4. "Per Click" Payments.—Section 1877(e)(1) of the Act provides an exception to the prohibition of physician referrals for space and equipment leases provided certain requirements are met.[200] The requirements, contained at sections 411.357(a) and (b), are that the lease be "commercially reasonable even if no referrals were made between the parties" and that the rental charges be "set in advance, [be] consistent with fair market value, and . . . not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties."[201]

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193. *See id.* at 66,306. CMS noted that because it did not make a specific proposal with regard to the in-office ancillary exception, but merely solicited comments, any revisions to the exception would be accomplished through future rulemaking with provisions for public comment.

194. *Id.* at 38,169.

195. CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T HEALTH & HUMAN SERVS., THE CMS QUARTERLY PROVIDER UPDATE (Jan. 2007), http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/January07whatsnew.pdf.

196. *See, e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T HEALTH & HUMAN SERVS., CMS RESCINDS TRANSMITTAL 187 ON INDEPENDENT DIAGNOSTIC TESTING FACILITY (2007), http://www.medicareupdate.typepad.com/medicare_update/2007/02/cms_rescinds_tr.htm.

197. Revisions to Payment Policies Under the Physician Fee Schedule, 72 Fed. Reg. at 66,285.

198. *Id.* at 66,290.

199. *See id.* at 66,290-93.

200. 42 C.F.R. § 411.357(a)-(b) (2007).

201. *Id.*

In the 2001 Stark Phase I final rule, CMS stated:

> [W]e are permitting time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral. We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that the time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals.[202]

In a reversal of this statement in the 2001 Stark Phase I final rule where CMS opened the door to use unit of service or "per click" payments, in the 2008 Proposed Physician Fee Schedule, CMS proposed that "space and equipment leases may not include unit-of-service-based payments to a physician lessor [(or entity in which the physician is an investor)] for services rendered by an entity lessee to patients who are referred by a physician lessor . . . to the entity."[203] CMS noted its concern that such payments are potentially abusive when the physician-lessor is paid every time he/she makes a referral to that location for use of the equipment.[204] CMS believes that in such a situation, the physician has an incentive to profit from referring a high volume of patients to the lessee.[205]

If finalized, this prohibition would adversely affect most equipment leasing arrangements paid on a "per click" basis where the lessor is a physician or an entity that has physician ownership. This prohibition would also affect equipment leasing companies with physician ownership and management companies that manage physician-owned companies that provide equipment on a per-use basis. In addition to prohibiting the use of per click payments to physician-owned leasing entities, CMS is soliciting comments on whether it should also prohibit per click payments by a physician to an entity from which the physician leases space or equipment if that entity refers patients to the leasing physician.[206]

5. Services Furnished "Under Arrangements."—The Stark regulations

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202. Phase I, *supra* note 12, at 876.

203. Revisions to Payment Policies Under the Physician Fee Schedule, 72 Fed. Reg. 38,183. Although the extent Stark exceptions for space and equipment leases currently permit "per click" lease payments, "per click" lease payments do not satisfy the requirements of the corresponding space and equipment rental safe harbors under the federal anti-kickback statute. *Id.*

204. *Id.*

205. *Id.*

206. *See* Revisions to Payment Policies Under the Physician Fee Schedule, 72 Fed. Reg. 66,222, 66,306 (Nov. 27, 2007) (to be codified at scattered sections of 42 C.F.R. pt. 409). CMS noted that it would not finalize any of the proposed changes regarding per click payments in the final rule due to the number of comments received and the significance of the proposed changes. *Id.* However, CMS noted that it had sufficient comments to finalize the revisions at a later date with no new notice and comment period and intends to finalize a rule at a later date regarding "per click" payments. *Id.*

prohibit a physician from making referrals for DHS to an entity with which the physician has a financial relationship and prohibits the entity from billing Medicare for such DHS unless an exception applies.[207] In an "under arrangements" relationship an outside supplier (usually a physician/hospital joint venture) furnishes the services and the hospital bills for the services, thus the outside supplier is not an "entity" for purposes of the Stark Law. This is because the Stark regulations narrowly defines "entity" to mean the entity that submits a claim to the Medicare program.[208] In an "under arrangements" relationship, the only entity submitting a claim to Medicare is the hospital.

CMS has expressed concern with these types of "under arrangements" relationship with physician-owned entities for a number of reasons including that these arrangements (1) encourage overutilization of services; (2) have no legitimate purpose other than to allow referring physicians to make money on referrals; (3) involve services previously provided in the hospital and which could continue to be provided by the hospital; and (4) the services are now furnished in less medically intensive setting than a hospital and billed at the higher HOPPS rates.[209]

Likely due, at least in part, to the recent Medicare payment reductions for imaging services performed in non-hospital settings and surgical services performed in ambulatory surgery centers, "under arrangements" relationships have been proliferating. In an attempt to prohibit these types of relationships, CMS, in the 2008 Proposed Physician Fee Schedule proposed to expand the definition of entity to include the person or entity that performs the Stark DHS, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS.[210] The proposed revision to the definition of "entity" would essentially bar referring physicians from participating in joint ventures that provide services under arrangements to hospitals or others. In the 2008 Proposed Physician Fee Schedule, CMS also solicited comments on a MedPac proposal to prohibit entities in which there is physician investment and that derive a "substantial portion of their revenue" from a DHS entity from providing equipment or services to imaging centers and other providers of DHS.[211] If implemented, physician-owned entities may be prohibited from providing equipment or services to any entity that furnishes DHS.[212]

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207. *Id.* at 38,186.

208. *Id.* at 38,224.

209. *Id.* at 38,186.

210. *Id.* at 38,187.

211. *Id.*

212. CMS noted that it would not finalize any of the proposed changes regarding "under arrangements" relationships in the final rule due to the number of comments received and the significance of the proposed changes. *Id.* However, CMS noted that it had sufficient comments to finalize the revisions at a later date with no new notice and comment period and intends to finalize a rule at a later date regarding "under arrangements" relationships. *Id.*

B. Proposed Changes to LTCH Payments

CMS has long been concerned with the close referral relationships between acute care hospitals and long term acute care hospitals ("LTCHs").[213] LTCHs are defined as hospitals that have an average Medicare inpatient length of stay greater than twenty-five days.[214] The concern regarding these referrals prompted the creation of a special payment provision, often called the 25% rule, which allowed co-located hospitals, hospitals within hospitals, and satellite LTCHs to admit up to 25% of their patients from the host hospital and receive payment under the LTCH prospective payment system.[215] If the limit was violated, the payment for all cases from the host hospital are adjusted to the lower of the amount payable under the LTCH prospective payment system or the equivalent of what Medicare would pay under the inpatient prospective payment system.[216] CMS is proposing changes to the 25% rule. CMS now proposes to extend the payment adjustment to almost all LTCHs for which more than 25% of discharged patients were admitted from a particular hospital regardless of whether it is co-located.[217]

IV. QUALITY

Section 101 of the Tax Relief and Health Care Act of 2006 ("TRHCA") required the Secretary to implement a system for the reporting by eligible professionals of data on certain quality measures.[218] Under this mandate, CMS created the Physician Quality Reporting Initiative ("PQRI") which establishes a financial incentive for eligible professionals (defined as physicians, practitioners, and therapists) to participate in a voluntary quality-reporting program.[219] Eligible professionals who choose to participate and successfully report on a designated set of quality measures for services paid under the Medicare Physician Fee Schedule and provided between July 1 and December 31, 2007, may earn a bonus payment of 1.5% of their charges during that period, subject to a cap.[220]

The statutory description of satisfactory reporting depends on how many quality measures are applicable to the services furnished by the eligible professional during the entire period of July 1, 2007 to December 31, 2007.[221] If there are no more than three quality measures applicable to the services provided by the eligible professional, then each measure must be reported for at

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213. Prospective Payment System for Long-Term Care Hospitals, 72 Fed. Reg. 4776, 4813 (Feb. 1, 2007) (to be codified at 42 C.F.R. pts. 412 & 413).

214. *See id.*

215. *See id.*

216. *See id.*

217. *Id.*

218. Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432, § 101, 120 Stat. 2922, 2975-81.

219. *Id.*

220. *Id.* at 2977-78.

221. *Id.* at 2978.

least 80% of the cases in which the measure was reportable.[222] If there are four or more quality measures applicable to the services provided by the eligible professional, then at least three measures, selected by the eligible professional, must be reported for at least 80% of the cases in which measure was reportable.[223]

Eligible professionals select the quality measures that are applicable to their practices. If an eligible professional submits data for a quality measure, then that measure is presumed to be applicable for the purposes of determining satisfactory reporting.[224] CMS recommends that eligible professionals report on every quality measure that is applicable to their patient populations to: (1) increase the likelihood that they will reach the 80% satisfactory reporting requirement for the requisite number of measures; and (2) increase the likelihood that they will not be affected by the bonus payment cap.[225]

Participating eligible professionals who successfully report as prescribed by TRHCA Section 101 may earn a 1.5% bonus, subject to a cap.[226] The bonus will apply to allowed charges for all covered professional services, not just those charges associated with reported quality measures.[227] The term "allowed charges" refers to total charges, including the beneficiary deductible and copayment, not just the 80% paid by Medicare or the portion covered by Medicare where Medicare is the secondary payor.[228]

A payment cap that would reduce the potential bonus below 1.5% of allowed charges may apply in situations where an eligible professional reports relatively few instances of quality measure data.[229] Eligible professional's caps are calculated by multiplying: (1) their total instances of reporting quality data for all measures (not limited only to measures meeting the 80% threshold), by (2) a constant of 300%, and by (3) the national average per measure payment amount.[230] The national average per measure payment is one value for all measures and all participants that is calculated by dividing: (1) the total amount of allowed charges under the Physician Fee Schedule for all covered professional services furnished during the reporting period on claims for which quality measures were reported by all participants in the program by (2) the total number of instances for which data were reported by all participants in the program for all measures during the reporting period.[231]

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222. *Id.*

223. *Id.*

224. *Id.* at 2979.

225. Proposed Revisions to Payment Policies Under the Physician Fee Schedule, 72 Fed. Reg. 38,210.

226. Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432, § 101, 120 Stat. 2922, 2977-78 (to be codified at 42 U.S.C. § 1395).

227. *Id.* at 2978.

228. *Id.*

229. *Id.*

230. *Id.*

231. *Id.*

CMS will do sampling to test the reporting.[232] CMS plans to focus on situations where eligible professionals have successfully reported fewer than three quality measures.[233] If CMS finds that eligible professionals who have reported fewer than three quality measures have not reported additional measures that are also applicable to the services they furnished during the reporting period, then CMS cannot pay those eligible professionals the bonus incentive payment.[234]

V. PEER REVIEW AND CREDENTIALING: JCAHO STANDARD MS. 1.20

The Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") revised its Hospital Accreditation Standards 2007 ("Revised Standards") to include three new concepts.[235] First, organizations must now incorporate into their bylaws six new areas of general competency in order to comply with MS. 1.20. The six new areas in which practitioners are expected to be competent are: (1) patient care that is compassionate, appropriate, and effective for the promotion of health, prevention of illness, treatment of disease, and care at the end of life, (2) knowledge of established and evolving biomedical, clinical and social sciences, and the application of that knowledge to patient care and education of others; (3) use of scientific evidence and methods to investigate, evaluate, and improve patient care practices; (4) interpersonal and communication skills that enable them to establish and maintain professional relationships with patients, families and other members of health care teams; (5) behaviors that reflect a commitment to continuous professional development, ethical practice, and understanding and sensitivity to diversity, and a responsible attitude toward their patients, their profession and society; and (6) an understanding of both the context and systems in which health care is provided and the ability to apply this knowledge to improve and optimize health care.[236] The additional two concepts established by the revised standards require the medical staff to focus practitioner evaluations on the individual's professional performance and to evaluate practitioners on an ongoing basis, rather than waiting for reappointment to the medical staff.

Additionally, JCAHO made significant revisions to Standard MS. 1.20 pertaining to medical staff bylaws, regulations, and policies.[237] The revisions were intended to support and reinforce the relationship between the medical staff and the governing body.[238] The revised MS. 1.20 contains thirty-three discrete items that must be incorporated in an accredited hospital's medical staff

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232. *Id.* at 2979.

233. *Id.* at 2978.

234. *Id.*

235. *See generally* KATHY L. POPPITT, CREDENTIALS AND PEER REVIEW CHALLENGES AND STRATEGIES (2008).

236. *Id.*

237. The revisions to MS. 1.20 are effective July 1, 2009. The text of MS. 1.20 can be found at http://www.jcrinc.com/fpdf/pubs/pdfs/JCReqs/JCP-09-07-S3.pdf.

238. *Id.*

bylaws.[239] The revised MS. 1.20 "addresses situations in which a medical staff believes that its medical staff executive committee is not [adequately] representing its views . . . [regarding] patient safety and quality of care."[240] "[T]he medical staff bylaws must [now] indicate what authority the medical staff has delegated to the medical staff executive committee, and how [such] authority [can be] delegated and removed."[241] The revisions state "that the medical staff has the ability to adopt medical staff bylaws, rules and regulations, and policies and to propose them directly to the governing body, even if the subject matter had been delegated to the medical staff executive committee."[242]

It is important to note that since the JCAHO adopted the revisions to MS. 1.20, there has been significant criticism of the new standards leading to the appointment of a JCAHO task force that will undertake an investigation of the revisions.[243]

VI. Changes to the Hospital Conditions of Participation, Informed Consent Guidelines, and Hospital Discharge Requirements

A. Hospital Conditions of Participation

On November 27, 2006, CMS issued a final rule revising certain requirements of the hospital conditions of participation ("CoPs").[244] The revisions made changes to the hospital CoPs for completion of history and physical examination, authentication of verbal orders, securing medication, and completion of postanesthesia evaluations.[245]

First, the changes regarding the completion of the history and physical examination are contained in the medical staff CoP located at 42 C.F.R. § 482.22(c)(5). The revised requirement expands the timeframe for completion of the history and physical examination to "no more than [thirty] days before or [twenty-four] hours after admission," and documentation must be placed in the patient's medical record within twenty-four hours of admission.[246] When a history and physical examination is recorded within thirty days before admission, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is completed and

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239. *Id.*

240. *Id.*

241. *Id.*

242. *Id.*

243. The task force must report its findings at the end of February 2008. News Release, Joint Comm'n, Joint Commission Announces Task Force on Implementation of MS. 1.20 (Jan. 3, 2008), http://www.jointcommission.org/NewsRoom/NewsReleases/nr_1_3_08.htm.

244. Hospital Conditions of Participation: Requirements for History and Physical Examinations: Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations, 71 Fed. Reg. 68,672 (Nov. 27, 2006) (codified at 42 C.F.R. pt. 482).

245. *Id.* at 68,672.

246. 42 C.F.R. § 482.22(c)(5) (2008).

documented in the patient's medical record within twenty-four hours after admission.[247] Additionally, the requirement no longer requires that practitioners must be granted the privilege to conduct a medical history and physical examination by the medical staff, rather the individual completing the medical history and physical examination must be qualified to do so "in accordance with [s]tate law and hospital policy."[248]

Second, the changes regarding the authentication of verbal orders are contained in the nursing services CoP[249] and the medical record services CoP.[250] The changes emphasize that hospitals must continue to prohibit the routine use of verbal orders and that verbal orders only be accepted when authorized "by hospital policy and procedures consistent with [f]ederal and [s]tate law."[251] Additionally, the time must now be noted in all patient medical record entries in addition to the requirements that the entry be legible, complete, dated, and authenticated by the person for providing or evaluation the service provided.[252] A temporary exception to the requirement that all orders, including verbal orders, be dated, timed, and authenticated by the ordering practitioner is permitted.[253] For a period of five years from the effective date of the final rule, verbal orders will not need to be signed by the ordering practitioner, but could be authenticated by another practitioner responsible for the care of the patient.[254] Additionally, "[a]ll verbal orders must be authenticated based [on] [f]ederal and [s]tate law. If there is no [s]tate law that designates a specific timeframe . . . , [then] verbal orders must be authenticated within [forty-eight] hours."[255]

Third, the changes regarding the securing of medication are contained in the pharmaceutical services CoP.[256] "All drugs . . . must be kept in . . . secure area[s] and locked when appropriate."[257] This change provides hospitals with greater flexibility in the storage of drugs and biologicals as the previous CoP required that all drugs and biologicals be kept in a locked storage area. However, all scheduled drugs (II, III, IV, and V) "must be . . . locked within a secure area," and "[o]nly authorized personnel may have access to locked areas."[258]

Finally, the changes regarding the completion of post-anesthesia evaluations are contained in the anesthesia services CoP.[259] The revision provides that a post-anesthesia evaluation for inpatients may be completed and documented by

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247. *Id.*
248. *Id.*
249. *Id.* § 482.23(c)(2)(i)-(ii).
250. *Id.* § 482.24(c)(1)(i).
251. *Id.* § 482.23(c)(2)(i)-(ii).
252. *Id.* § 482.24(c)(1).
253. *Id.* § 482.24(c)(1)(ii).
254. *Id.*
255. *Id.* § 482.24(c)(1)(iii).
256. *Id.* § 482.25(b)(2).
257. *Id.* § 482.25(b)(2)(i).
258. 42 C.F.R. § 482.25(b)(2)(ii)-(iii) (2007).
259. 42 C.F.R. § 482.52(b)(3) (2008).

any individual qualified to administer anesthesia instead of only by the individual that administered the anesthesia.[260]

B. Hospital Informed Consent Guidelines

The requirements related to informed consent for hospitals are found in the Patient's Rights CoP,[261] the medical records CoP,[262] and the surgical services CoP.[263] On April 13, 2007, CMS issued new interpretative guidelines on informed consent in a letter to state survey agency directors.[264] The interpretative guidelines discuss the applicable requirements for each CoP relating to informed decision-making and informed consent and the survey procedure to be used to determine compliance for that CoP.[265]

Specifically, the interpretative guidelines modify or supplement the following areas. "Tag A-0049 . . . in the Patients' Rights CoP discusses the patient's or patient's representative's right to make informed decisions regarding the patient's care."[266] "Tag A-0238 . . . in the medical records CoP discusses the requirement that the hospital must ensure that patient medical records contain properly executed informed consent forms for procedures or treatments specified by the hospital [m]edical [s]taff, or by [f]ederal or [s]tate law if applicable, to require written patient consent."[267] "Tag A-0392 . . . in the [s]urgical [s]ervices CoP discusses the requirement that the hospital must ensure that a properly executed informed consent form is in the patient's medical record before surgery, except in emergencies."[268]

C. Hospital Discharge Requirements

On November 27, 2006, CMS issued a final rule providing new requirements for hospital discharge notices under Medicare and the Medicare Advantage ("MA") program.[269] The final rule contains requirements on how hospitals must notify Medicare beneficiaries who are inpatients about their discharge rights.[270] Notice regarding hospital discharge "is required . . . for . . . Medicare

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260. *Id.*

261. 42 C.F.R. § 482.13(b)(2) (2007).

262. 42 C.F.R. § 482.24(c)(2)(v) (2008).

263. *Id.* § 482.51(b)(2).

264. Memorandum from the Survey & Certification Group of the Ctr. for Medicaid and State Operations to State Survey Agency Dirs., Revisions to the Hospital Interpretive Guidelines for Informed Consent (Apr. 13, 2007), http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/scletter07-17.pdf.

265. *See generally id.*

266. *Id.* at 1.

267. *Id.*

268. *Id.*

269. Medicare Program; Notification of Hospital Discharge Appeal Rights, 71 Fed. Reg. 68,708 (Nov. 27, 2006) (codified at 42 C.F.R. pts. 405, 422 & 489).

270. *Id.*

beneficiaries and for beneficiaries enrolled in . . . MA plans and other Medicare health plans subject to MA regulations."[271]

Hospitals are required to use "a revised version of the Important Message from Medicare ('IM') . . . to explain the discharge rights."[272] The IM will include "a statement of patients' rights, information about when a beneficiary will and will not be liable for charges for continued stay . . . . , [and] a more detailed description of . . . appeal rights."[273]

> Hospitals must issue the IM within [two] days of admission, and must obtain the signature of the [Medicare] beneficiary or his or her representative. Hospitals [must] also deliver a copy of the signed notice prior to discharge, but not more than [two] days before the discharge. For beneficiaries [that] request an appeal, the hospital [must] deliver a more detailed notice.[274]

VII. ANTITRUST

In a unanimous ruling, the Federal Trade Commission ("FTC") found that Evanston Northwestern Healthcare Corp. ("ENH") substantially lessened competition in violation of section 7 of the Clayton Act when it acquired Highland Park Hospital ("HPH") resulting in higher prices for insurers and consumers for general acute care inpatient services, but declined to order divestiture of the acquired hospital.[275] The FTC instead ordered ENH to create two independent negotiating teams, one for ENH and one for HPH, to negotiate separately and independently with purchasers of inpatient hospital services.[276] The FTC did state in its opinion that

> [d]ivestiture is the preferred remedy for challenges to unlawful mergers, regardless of whether the challenge occurs before or after consummation. Thus, where it is relatively clear that the unwinding of a hospital merger would be unlikely to involve substantial costs, all else being equal, the Commission likely would select divestiture as the remedy.[277]

VIII. DMEPOS COMPETITIVE BIDDING PROGRAM

On April 2, 2007, CMS issued a final rule establishing a competitive bidding process to set Medicare payment amounts for certain items of durable medical

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271. *Id.*

272. *Id.*

273. *Id.* at 68,710-11.

274. *Id.* at 68,708.

275. *See In re* Evanston Northwestern Healthcare Corp., FTC No. 9315, 2007 WL 2286195 (Aug. 6, 2007).

276. *Id.*

277. *Id.*

equipment, prosthetics, orthotics, and supplies ("DMEPOS").[278] The final rule requires suppliers to be successful bidders and meet program standards to be selected to supply DMEPOS items to Medicare beneficiaries in ten competitive bidding areas ("CBAs").[279] With few exceptions, suppliers that do not bid or are unsuccessful in their bids will not be able to bill Medicare for items in the CBAs.[280]

CMS will phase in competitive bidding by DMEPOs product category.[281] For 2007, the items include: (1) oxygen supplies and equipment; (2) standard power wheelchairs, scooters, and related accessories; (3) complex rehabilitative power wheelchairs and related accessories; (4) mail order diabetic supplies; (5) enteral nutrients, equipment, and supplies; (6) continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories; (7) hospital beds and related supplies; (8) negative pressure wound therapy pumps and related supplies and accessories; (9) walkers and related accessories; and (10) support surfaces (group two mattresses and overlays) in Miami and San Juan only.[282]

Competitive bidding will impact Medicare DMEPOs pricing. The bids will be used to set a single payment amount for each item in the particular CBA.[283] Payment under the competitive bidding process was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA")[284] and will be effective April 1, 2008. CMS expects that the competitive bidding process will save the Medicare program $1 billion annually once fully implemented.[285]

IX. Food and Drug Law

The Institute of Medicine ("IOM") of the National Academies issued a report, *The Future of Drug Safety: Action Steps for Congress*, which includes recommendations for strengthening the FDA's post-market drug surveillance capabilities.[286] Among the recommendations are expanding the agency's regulatory authority, additional labeling requirements for new drugs, and restrictions on direct-to-consumer advertising.[287] In response to the IOM report,

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278. Medicare Program; Competitive Acquisition, 72 Fed. Reg. 17,992 (Apr. 10, 2007) (to be codified at 42 C.F.R. pts. 411 & 414).

279. *See id.* at 18,010.

280. *Id.* at 18,006-08.

281. *Id.* at 17,992.

282. *Id.* at 18,021.

283. *Id.* at 17,998.

284. *Id.* at 18,070.

285. *See id.* at 18,080.

286. Inst. of Med., Report Brief—The Future of Drug Safety: Action Steps for Congress (2006), http://www.iom.edu/Object.File/Master/37/331/11750_report_brief_Congress.pdf.

287. *Id.*

the FDA issued additional plans for post-market drug monitoring, including a pilot program to profile the safety of newly approved drugs.[288]

On December 14, 2006, the FDA issued two proposed rules which would significantly impact the area of food and drug law regarding investigational drugs. The first proposed rule deals with expanded access for investigational drugs for treatment use.[289] Under the proposed rule, "expanded access to investigational drugs . . . would be available to individual patients, including in emergencies; intermediate-size patient populations; and larger populations under a treatment protocol or treatment investigational new drug application."[290] The intent of the proposed rule is "to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions, who lack other" treatment options.[291] The second proposed rule deals with charging for investigational drugs.[292] In the proposed rule, the "FDA is proposing to revise the . . . charging regulation to clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, to set forth criteria for charging for an investigational drug for the different types of expanded access" to the investigational drugs in the first proposed rule discussed above, "and to clarify what costs can be recovered for an investigational drug."[293]

On May 9, 2007, the Senate passed the Food and Drug Administration Revitalization Act reauthorizing the user fee programs and adding sections to reform the FDA's post-market drug surveillance function.[294] The bill requires the Secretary to assess and collect fees for review of direct-to-consumer television advertisements for prescription drugs.[295] The bill also increases the civil monetary penalties for companies that fail to comply with FDA directives.[296]

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288. FDA, THE FUTURE OF DRUG SAFETY—PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC: FDA'S RESPONSE TO THE INSTITUTE OF MEDICINE'S 2006 REPORT (2007).

289. Expanded Access to Investigational Drugs for Treatment Use, 71 Fed. Reg. 75,147 (Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312).

290. *Id.* at 75,147.

291. *Id.*

292. Charging for Investigational Drugs, 71 Fed. Reg. 75,168 (Dec. 14, 2006) (to be codified at 21 C.F.R. pt. 312).

293. *Id.*

294. Food and Drug Administration Revitalization Act, S. 1082, 110th Cong. (2007).

295. *Id.*

296. *Id.*