Spring 2008 Topics

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Improving Quality through Physician Rankings, P4P and Patient Safety Organizations

Two recent studies on the success of *pay-for-performance* (P4P) programs have shown that there is a correlation between such programs and higher quality of care for patients. The study conducted by CMS and Premier, Inc., called the "Hospital Quality Incentive Demonstration" (HQID), measured cost and quality improvements among P4P providers for five different patient populations: pneumonia, coronary artery bypass graft, congestive heart failure, acute myocardial infarction/heart attack, and hip and knee replacement. The study, which was begun in 2003, has impressively concluded that "*if all* hospitals nationally were to achieve the three-year cost and mortality improvements found among the HOID project participants for [the five different patient populations], they could save an estimated 70,000 lives per year and reduce hospital costs by more than \$4.5 billion annually." [1]

A second study, conducted by researchers from UCLA and supported by the Hawaii Medical Service Association in Honolulu, also showed improved quality of care among P4P providers in *preferred provider organization* (PPO) settings, as well as an increased number of patients going to P4P physicians. [2] The study analyzed 11 quality indicators for patients enrolled in PPOs over six

The Future of Managed Care: Resurgence of IPAs and PHOs

In the wake of two favorable advisory opinions regarding *clinical integration* from the Federal Trade Commission (FTC) over a period of the past six years, it is likely that the near future will see a resurgence of *independent practice* associations (IPAs) and physician hospital organizations (PHOs). According to attorney Gregory Pepe, [1] the 2002 FTC MedSouth Advisory *Opinion* ^[2] and the 2007 Greater **Rochester Independent Practice** Association (GRIPA) Advisory Opinion [3] lead to the conclusion that "*evervone* now believes that there are ways in which these organizations can work collectively with independent physician practices to try to put together programs that will *deliver some sort of clinical integration* that the federal government will allow." [4] Pepe believes that 2008 will be the year that IPAs and PHOs begin to gain traction with clinical integration.

Clinical integration among IPAs and PHOs has traditionally been scrutinized by the FTC as generally being anticompetitive and in violation of antitrust laws. However, since the *MedSouth* and GRIPA advisory opinions, it has now become clear that clinical integration is not considered to be a *per se* violation of antitrust regulations. If the subject transaction is not deemed to be a per se violation, the FTC reviews joint contracting arrangements under a *rule of* reason analysis, determining whether the arrangement would actually lead to procompetitive outcomes. The benefits of clinical integration are that it allows a network of competing providers to participate in both *joint-pricing* and *risk*

Proposed Amendment to New Jersey's "Codey Act" Would Allow Self-Referral to Physician-Owned ASCs

After the November 20, 2007 decision in *Health Net of New* Jersey, Inc. v. Wayne Surgical *Center, LLC*, physicians in New Jersey who referred their patients to an *ambulatory surgery center* (ASC) in which they had an ownership interest were suddenly at risk of being in violation of New Jersey's anti-self-referral law (the "Codey Act").[1] The Health Net decision sparked controversy regarding this practice, which had been common practice and had not previously been adjudged as a violation of the Codev Law. which was enacted in 1992. Most unexpectedly, the *Health Net* decision rejected a widely relied upon 1997 New Jersev Board of *Medical Examiners* (BME) advisory opinion, which held that an "ASC was really an 'extension of the physician's medical office' and therefore the arrangement did not violate Codev."[2]

After the ruling in *Health Net*, the BME immediately adopted emergency rules which declare that doctors who refer patients to physician-owned ASCs are not in danger of violating the law as long as they meet certain conditions. Now, legislators in New Jersey, led by Senate President Richard Codey (the namesake of the original law), have proposed an *amendment* to the Codey Law which would *allow self-referral to physician-owned ASCs*.

In addition to protecting doctors who refer patients to ASCs in which they have financial interest, the amendment would put a *twoyear moratorium* on the construction of new surgery centers, as well as establish a *Practitioner Self Referral Review Task Force* that will review years, and found that the patients who visited only physicians who were participating in the study had significantly higher odds of receiving recommended care as measured by the indicators.

Additionally, CMS recently released a list of 119 "clinical performance measures" designed to improve quality as part of the Physician Quality Reporting Initiative (PQRI), which "creates a *auality reporting system that* includes an incentive payment for satisfactorily reporting data on quality measures for covered professional services delivered to *Medicare beneficiaries*." [3] Under the PORI, participating physicians who report quality data on covered professional services provided in 2007 will receive incentive payments in 2008, amounting to 1.5% of their total charges for covered services during the reporting period. According to CMS, more than half the physicians who reported in 2007 are eligible to receive the 2008 incentive payment, and CMS expects the number of physicians participating in the PQRI to increase in the future. Although the incentive payment is intended to improve quality, the payment encourages physicians to maintain their practices within the scope of the PQRI quality measures, thereby raising the potential for physicans to feel pressure to choose less costly diagnoses.

Although P4P programs and the PQRI are intended to improve quality, it is questionable whether there will still be too much focus on cost being an element of the quality of care. In response to this concern, physicians and national health insurers have developed an external plan to *rank physician performance* that works for both parties, and will hopefully address physicians 'concerns that the previous ranking systems were too focused on cost of care. While *sharing*, thus leading to improved efficiency that will benefit consumers.

The particular goals of the GRIPA integration were to create a *connected community* of physicians, hospitals, labs and imaging facilities which will share electronic access to patient information, thus cutting costs. [5] The plan also allowed the group to negotiate *payer contracts* on behalf of members, and requires physicians to adhere to Clinical Guidelines that apply to the entire IPA.

To avoid violating federal antitrust laws, FTC Commissioner, J. Thomas Rosch, notes that, "a very strong system of rewards and punishment" is absolutely necessary, as well as seamless patient care, ultimately lower costs, rigorous quality control, and physician discipline. [6] It is also important to note that one essential feature of GRIPA's integration scheme is that it is non-exclusive, i.e., it allows payors to negotiate individually with member physicians. It was due to the combination of these elements that the FTC did not challenge GRIPA's clinical integration as being a violation of antitrust laws.

Most notably, the GRIPA clinical integration system provides all members in a patient's care team easy access to that patient's information through a *Health* Information Exchange, with the goal of significantly improving quality. Mr. Pepe predicts that this trend of IPAs helping members create patient registries, as well as to assemble databases and disease management teams, will continue as IPAs and PHOs become more successful with clinical integration. As positive as this trend may seem, however, it is still likely that some payors will not be satisfied with it, thereby increasing the potential for litigation as clinical integration increases. Not withstanding that potential for conflict, because IPAs and PHOs now have a clinical integration system model which avoids FTC enforcement action to refer to, it is likely that more groups will develop successful integration schemes in the coming months and years.§

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practitioner referral patterns as they relate to the law. If the bill, which passed through the Senate on March 17, becomes enacted, the Codey Law will not apply to ASCs that perform surgeries requiring anesthesia if the ASC satisfies three precise conditions: (1) the surgery is performed at an ASC licensed by the New Jersey Department of Health and Seniors Services; (2) the referring physician also performs the surgery: and, (3) the physician's remuneration as an owner of the ASC is *directly proportional* to his *ownership interest* and not the volume of patients referred.[3] The facilities would have six months after the passage of the amendment to comply with this last condition regarding remuneration. These conditions apply regardless of whether the ASC is owned solely by practitioners or in conjunction with non-practitioners.§

2[2]"New Jersey Court Rules that Physician Referrals to Ambulatory Surgical Center In Which They Own an Interest Violates Codey Act," Flaster Greenberg Health Care Alert Newsletter, December 2007, http://www.flastergreenberg.com/home/ publications/legal-alerts.aspx?d=272 (Accessed April 18, 2008) (quoting 1997 BME advisory opinion).

[3] Amendment to Section 2 of P.K. 1989, c. 19 (C.45:9-22.5), subsection c.(1)(a)-(c), http://www.njleg.state.nj.us/ 2008/Bills/S1000/787_U1.HTM (Accessed April 18, 2008).

IRS Publishes Final Regulations Regarding Relationship Between Intermediate Sanctions and Revocation of Exemption under Section 501(c)(3) of IRS Code

Healthcare organizations may be considered "*tax-exempt*" under Section 501(c)(3) of the Internal

insurers say that they will abide by the agreement to rank physicians based on both cost and quality of care, the ranking system has not yet been implemented, so no actual standards have been decided upon. However, to add more *transparency* to the ranking process, the insurance companies will allow the rankings to be reviewed by independent parties. The new standards are intended to allow for *uniformity* in rankings between different insurers, which will allow patients to better review and compare different doctors, thereby further increasing transparency. [4]

The increased focus on quality of care is related to how hospitals and doctors deal with patient safety and adverse events. On the topic of patient safety, federal regulators have issued rules that would finally implement the Patient Safety and Quality Improvement Act of 2005 (PSQIA). This Act authorizes the creation of *patient* safety organizations (PSOs) which would be confidential depositories of information on mistakes and adverse events. AMA Trustee J. James Rohack, M.D., believes that the legislation "will allow health care professionals to report errors voluntarily without fear of legal prosecution and transform the current culture of blame and punishment into one of open communication and prevention." [5] Similarly, to reinforce this positive outlook, the rules would prevent health insurers from becoming PSOs.

The PSOs would represent national quality review standards, thereby creating uniform protections from state to state. Even though original data existing apart from patient safety reports is in New Haven, Connecticut

[2] Letter from Jeffrey W. Brennan, Assistant Director, Federal Trade Commission Bureau of Competition, to John J. Miles, Law firm of Ober, Kaler, Grimes & Shriver, Staff Advisory Opinion: MedSouth, Inc., February 19, 2002, available at <u>http://www.ftc.gov/bc/adops/medsouth.shtm</u> (last accessed April 18, 2008).

[3] Letter from Markus H. Meier, Assistant Director, Federal Trade Commission Bureau of Competition, to Christi J. Braun and John J. Miles, Law firm of Ober, Kaler, Grimes & Shriver, Greater Rochester Independent Practice Association, Inc., Advisory Opinion, September 17, 2007, available at <u>http://www.ftc.gov/bc/adops/gripa.pdf</u> (last accessed April 18, 2008).

[4] "Resurgence of IPAs and PHOs Predicted for 2008," The Executive Report on Physician Organizations, Vol. XI, No. 2, Feb. 2008, pg 1.

[5] "GRIPA Receives Favorable Advisory Opinion from FTC for Clinical Integration Program," GRIPA website, Sept 18, 2007, <u>http://www.gripa.org/press-release-ftc-reviews-clinicalintegration.asp</u> (Accessed Apr. 11, 2008).

[6] "FTC Gives More Guidance on Clinical Integration," Susan Robinson, Timenews.net website, Oct. 26, 2007, http://www.timesnews.net/community_article.php?id=1871 (Accessed Apr. 11, 2008).

ASC Payment System Update for 2008

Beginning in Calendar Year (CY) 2008, CMS began implementing a revised *payment system* for ambulatory surgery centers (ASCs), which uses the current hospital outpatient prospective payment system (HOPPS) as the framework and guide for the revised payment system for freestanding ASCs. For the new system, CMS has set the payment rates for independent free-standing ASCs at 65% for the 2008 implementation of the HOPPS rates for the same procedures performed in a *hospital outpatient* department (HOPD) setting.[1] The payment rates for procedures subject to the transition for CY 2008 are comprised of a 25/75 blend; specifically twenty-five percent (25%) of the CY 2008 revised ASC rate plus seventy-five percent (75%) of the CY 2007 ASC rate. In CY 2009, the blend will change to 50/50, and for CY 2010, it will be 75/25. [2] Beginning in CY 2011, CMS will fully implement the revised ASC payment rates. The revised payment ASC conversion factor will be updated by the *consumer price* index for urban consumers while the HOPPS conversion factor will be updated by the *hospital market basket*. Geographic adjustments will be made using the most recent hospital wage index.

^{1[1]} New Jersey Code Act, N.J.S.A, 45-922.5, 1992.

Revenue Code if they operate exclusively for *exempt* purposes and no earnings inure to the benefit of any private shareholder or individual, i.e., the tax-exempt organization may not be operated in the pursuit of private interests. Should the IRS become aware that an exempt organization has engaged in an excess benefit transaction with a party who could exert influence with the organization (shareholders or private individuals), the IRS may impose as punishment an excise tax on the individual and/or the organization.

In the Final Regulations

published on March 28, 2008, [1] the IRS addressed this prohibition of private benefit, as well as the relationship between intermediate sanctions in contrast to revocation of tax-exempt status. In the newly revised regulations, the IRS presented examples of situations which violate the prohibition of exempt organizations serving private interests, including those situations in which the benefit may be non-economic. Additionally, a prohibited private benefit may occur even in the event that the transaction is conducted at fair market value. While past violations were subject to revocation of exempt status as the sole remedy under the new regulations, an exempt organization which is found to have violated such prohibitions may have to pay intermediate excise taxes, which constitute a penalty short of revocation of exempt status. The IRS has identified five factors to be considered when determining whether the organization should be subject to intermediate excise tax or whether exempt status should be revoked: (1) the size and scope of the organizations ongoing activities; (2) the size and scope of the excess benefit transaction in relation to regular

still discoverable in litigation, anything actually reported to a PSO, or the deliberations taken by hospital administration to decide whether to report a "near miss," would be protected from subpoena. Since providers have been traditionally wary of releasing information about medical errors for fear that it will be used against them in tort actions or disciplinary proceedings, it is still questionable as to whether the new rules would do enough to protect providers from liability. As a result, it is likely that the HHS Agency for Healthcare Research and Quality will extend the comment period on the new provisions from six months to one year.

There is an interesting intersection between the studies of the successes of P4P programs and physician rankings on one hand, and the implementation of the PSOIA on the other. All three represent part of what has been called the "hydra-headed" quality issue.^[6] On the one hand, P4P only works if there is a significant level of transparency between a physician and patient so that the patient may make informed decisions about which doctor to choose based on quality and cost. That transparency, in turn, comes somewhat from physician ranking schemes. On the other hand, the PSOIA makes all information that is reported confidential and preventing potential patients from having access to the information about physician errors. However, ithis type of disclosure is a form of transparency to groups that would eventually advocate for the patient's rights, thereby improving quality through better, even if not complete, transparency.

Above all, as Stephanie W. Kanwit, special counsel to America's Health Insurance Plans in Washington, has stated, "Promoting quality improvement [3]

The new payment system will continue to pay ASCs a *facility fee* designed to cover costs. However, the classifications for ASC payment are now called "*ambulatory* payment classifications" (APC) instead of "groupers". Under the APC-based payment system, outpatient providers will share the risk of treating Medicare patients. If costs exceed the predetermined payment, the provider will suffer the loss. If, however, services are delivered at a lower cost than the defined payment, the provider will realize a profit. [4] The Medicare Payment Advisory Commission (MedPAC) recommended this system to make payments more equitable across settings and services by using a common definition of the unit of payment and common method to calculate relative weights, as well as moving all payments for ambulatory care, including physicians' fees, under a combined volume control and update mechanism. [5]

ASCs and hospitals will use the same APCs, but hospitals will use a greater number of APCs due to the wider variety of services provided. Rates paid for each APC are based on the APCs *relative weight*. Additionally, if procedures require use of a device which costs more than fifty percent of the total APC reimbursement, the rate can be adjusted to equal the hospital rate on the device only, and remain at 65% of the HOPPS rate for the remainder of the reimbursement. ASCs will continue to receive payments for ancillary services such as devices and drugs. [6]

These new rules bring mixed results for ASCs, with those specializing in *orthopedic procedures* likely to benefit substantially under the new system, while ASCs specializing in *gastroenterology procedures* may see a significant revenue decrease of as much as 20%, [7] as ASC payments for gastroenterology and endoscopic procedures are currently paid between 82% and 84% of the HOPPS rate. [8] For example, the 2007 ASC payment for diagnostic colonoscopy is \$446, while the 2008 fully implemented payment is \$373. [9] The HOPPS activities; (3) whether excess benefit transactions had happened in the past; (4) whether the organization has implemented safeguards against this type of transaction; and, (5) whether the excess benefit transaction has been corrected, or there has been a good faith effort to do so. These last two factors are given a greater weight of consideration toward the continuation of exempt status in those cases where the organization has taken steps to remedy the situation.

The final regulations included six examples illustrating how the factors would be applied, including how the IRS considers the manner by which executives are compensated, as well as the role of the board before and after the transaction. These examples illustrate how the implementation of safeguards (especially those which create a presumption of *reasonableness*) is viewed as a factor that would significantly contribute to continued taxexempt status. §

[1]Standards for Recognition of Tax-Exempt Status if Private Benefit Exists of if an Applicable Tax-Exempt Organization Has Engaged in Excess Benefit Transaction(s), 73 Fed. Reg. 61, 16519 (March 28, 2008) (to be codified at 26 C.F.R. pts. 1 and 53), <u>http://www.irs.gov/pub/irs-</u> tege/td9390.pdf (Accessed April 14, 2008).

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has to be grounded on the concept of an 'informed consumer' There's truly a ground swell, both public and private, for greater transparency." [7] Transparency is clearly one of the most important issue facing providers and hospitals today and it is this transparency that is driving up quality, not only through physician ranking systems, but also through P4P programs and initiatives.§

confidential error reports," By Dave Hansen, *American Medical News*, March 10, 2008, pg 1. [6] BNA Health Law Reporter, "Outlook 2008: Health Care Quality, Fraud and Abuse Top List of Health Law Issues for 2008," Vol. 17, No. 1, Jan. 3, 2008, pg 5 (quoting Thomas W. Mayo, of counsel to the firm of Haynes and Boone LLP, Dallas, Texas).

1[7] BNA Health Law Reporter, "Outlook 2008: Health Care Quality, Fraud and Abuse Top List of Health Law Issues for 2008," Vol. 17, No. 1, Jan. 3, 2008, pg 5.

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developed and implemented hospital and physician driven MSOs and networks involving a wide range of conversion factor is expected to be the 2007 conversion factor multiplied by the 2008 hospital inpatient market basket increase (3.3%), resulting in an expected HOPPS conversion factor of approximately \$63.69.[10] §

[1] "CMS Revises Payment Structure for Ambulatory Surgical Centers and Proposes Policy and Payment Changes for Hospital Outpatient," Centers for Medicare and Medicaid Services, July 16, 2007. [2] "Ambulatory Surgery Center Payment Changes Proposed," McDermott Will & Emory, August 10, 2006, http://www.mwe.com/index.cfm/fuseaction/ publications.nldetail/object id/8cc0c68c-57 1b-4cf3-9b0a-ce476d0a1763.cfm , (Accessed 8/20/2007). [3] "CMS Revises ASC Payment System," PYA Alert, pyapc.com, August 21, 2007. [4]"Preparing for Medicare's APC System," By, Donn G. Duncan, M.D., Healthcare Financial Management, (July 1999), p. 42. [5] Report to the Congress: Medicare Payment Policy, March 1999, p. 101. [6] All information from "Overview of New Payment System," Ambulatory Surgery Center Association, http://www.ascassociation.org/ medicarepayment/overview (Accessed March 20, 2008). [7] "Ambulatory SurgeryCenter Payment Changes Finalized," McDermott Will & Emory, July 19, 2007, http://www.mwe.com/index.cfm/fuseaction/ publications.nldetail/object id/091f18f0-1c09-470f-b681-e0c2080eec75.cfm, (Accessed August 20, 2007) [8] "CMS finalizes 2008 ASC Payments," American Gastroenterological Association, www.gastro.org/wmspage.cfm?parm1=3950, (Accessed August 17, 2007). [9] "Ambulatory Surgery Center Payment Changes Proposed," McDermott Will & Emory, August 10, 2006, http://www.mwe.com/index.cfm/fuseaction/ publications.nldetail/object_id/8cc0c68c-57 1b-4cf3-9b0a-ce476d0a1763.cfm , (Accessed August 20,2007). [10]"CMS Published ASC Final Rule, 2008 OPPS Proposed

Rule," By Sally Hardgrove & Mark Blessing, BKD, LLP,

October 2007.

^{1[1] &}quot;Hospital quality improving, cost, mortality rate trends declining for participants in Medicare pay-for-performance project," Press Release, By Alven Weil, Premier Inc. Website, January 31, 2008, http://premierinc.com/about/news/08jan/performance-pays-2.jsp (Accessed April 25, 2008) [2] "Patient outcomes and evidence-based medicine in a preferred provider organization setting: a six-year evaluation of a physician payfor-performance program," Amanda S. Gilmore, et al, 42 Health Services Research 2140 (Dec. 2007, http://findarticles.com/p/articles/ mi_m4149/is_6_42/ai_n21157693/print (Accessed April 21, 2008). [3] "Quality Reporting Initiative Will Help Improve Health Care for Beneficiaries and Provide Incentives for Eligible Professional," Centers for Medicare and Medicaid Services, Press Release, April 17, 2008, http://www.cms.hhs.gov/apps/media /press/release.asp?Counter=3047 (Accessed April 17, 2008). [4] "Insurers Agree to Develop a Set of Standards in Rating Doctors," By Reed Abelson, The New York Times, April 1, 2008, http://query.nytimes.com/gst/fullpage.html? res=9C05E0D61338F931A35757C0A96E9 C8B63&scp=1&sq= physician+rank&st=nyt (Accessed April 25, 2008). [5] "Rules aim for better patient safety through

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