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From the Editor - Michael E. Skindrud

Our health care clients are navigating a world of accelerating change and increasing market pressure. They focus our attention on their immediate needs and deadlines. But we periodically take time from immediate pressures to ask our team for ideas and articles on timely topics of interest to our clients and friends, and compile them into an electronic newsletter.

We lead this newsletter with immediate concerns, including the Red Flag Rules that may apply to you beginning May 1, 2009, preparations for your recovery audit contractor later this year, implementation of the HIPAA law changes triggered by the Stimulus Package, and new rules governing labor organizing that we believe will be enacted later this year.

We've included an update on the enforceability of physician noncompete agreements, a review of the revised rule limiting physician billing of purchased diagnostic tests (known as the Anti-Markup Rule), and a review of new OIG limitations on access to the Provider Self-Disclosure Protocol. We make predictions for Medicaid providers in the current economic downturn but with the Stimulus money providing support, and conclude with reminders of Stark deadlines and the ever present regulatory pressure on physician-owned specialty hospitals.

We will issue a special update when CMS releases its much anticipated Stark Law final rule containing one or more exemptions for gain sharing, pay-for-performance, value-based purchasing, and other incentive pay mechanisms. We hope it will open the door for safer and better hospital arrangements with independent physicians that align with each other on quality and efficiency measures...but I am ahead of myself. I hope you find useful one or more articles in this newsletter, and we welcome your comments.

Is Your Organization Subject to the Red Flag Rules?

By Charles G. Vogel

Hospitals, physician groups and other health care providers may be surprised to learn that they could be subject to the Federal Trade Commission's so-called "Red Flag Rules" that become effective May 1, 2009. The Rules are intended to combat identity theft and require implementation of a written program to detect, prevent, and mitigate identity thefts in connection with new and existing accounts.

The Rules apply to any organization that meets the Rules' definition of "creditor" and which offer or maintain "covered accounts."

A "creditor" includes any entity that regularly accepts deferred payments for its goods or services. For example, a hospital or physician group that regularly offers payment plans or allows patients to pay in installment payments would be a "creditor" within the meaning of the Rules.

For the Rules to apply, a "creditor" must also maintain "covered accounts." The Rules define a covered account as an account primarily for personal, family or household purposes and involving a "continuing" relationship between a person and a creditor that includes multiple payments or transactions or in which there is a reasonably foreseeable

risk of identity theft. For example, patient billing accounts could be “covered accounts” if a hospital or physician group permits multiple payments on these accounts. Patient medical records may be “covered accounts” because they may be vulnerable to medical identity thefts. Both billing accounts and medical records are likely to involve “continuing relationships” because patients seek medical care on a recurring basis.

If the Rules apply to an entity, the entity’s Board of Directors must approve a written plan that includes reasonable policies and procedures to (1) identify “red flags,” including relevant patterns, practices and/or activities that potentially suggest possible identity theft, (2) detect the “red flags” that have been incorporated into the program, (3) respond appropriately to “red flag” incidents that are detected in order to prevent and mitigate the effect of identity theft, and (4) ensure that the program is reviewed and updated periodically in order to adjust to changing and developing identity theft risks.

The Federal Trade Commission has not mandated any specific language, policies or procedures that must be included in an identity theft program. The expectation is that each covered entity’s program will be appropriate to the entity’s size and complexity, and the scope and nature of its activities.

If you have any questions regarding the application of the Red Flag Rules to your organization or how to implement the policies and procedures required by them, please contact Charles G. Vogel (cvogel@gkclaw.com or 414-287-9502) or another member of the Godfrey & Kahn Health Care Team.

Recovery Audit Contractors are Coming: Are You Prepared?

By: Thomas N. Shorter

Health Care entities in the Midwest have watched from the sidelines as the Centers for Medicare & Medicaid Services (“CMS”) Recovery Audit Contractor (“RAC”) program has unfolded over the last few years. No more. Health Care entities need to be prepared to handle upcoming RAC reviews and the inevitable repayment/recoupment demand letters that will surely follow.

Started in 2005 as a demonstration project by CMS, the RAC program targeted the three states with the greatest Medicare expenditures: California, Florida and New York. The RAC demonstration project was authorized by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The goal of the RAC demonstration project was to test a new method for recovery of Medicare improper payments, namely the utilization of private companies operating on a contingent fee basis to identify and recoup Medicare overpayments and underpayments. The RAC demonstration project concluded on March 27, 2008, and was declared a success by CMS that resulted in identification of \$1.03 billion dollars in improper payments

(96% of that amount being overpayments) over a three-year period.

As a result of the RAC demonstration project, the Tax Relief and Health Care Act made the RAC program permanent and required it to be fully implemented nationwide by January 10, 2010. A gradual implementation plan has been developed by CMS. It has already begun in several upper midwest states, including Minnesota, Michigan, Indiana, and the Dakotas, and will begin implementation August 1 in Wisconsin, Illinois, Iowa, and the remaining states not already in the program.

Who is the RAC for the Upper Midwest States?

CMS has selected four contractors to fulfill the RAC duties nationwide. Region “B” includes Wisconsin, Illinois, Michigan, Minnesota, Indiana, Ohio and Kentucky. The designated RAC for Region B is **CGI Technologies and Solutions, Inc. (“CGI”)**, located in Fairfax, Virginia. The following description of CGI can be obtained from their website www.cgi.com:

“About CGI-Founded in 1976, CGI Group Inc. is one of the largest independent information technology and business process services firms in the world. CGI and its affiliated companies employ approximately 27,000 professionals in over 100 offices across 16 countries. CGI provides end-to-end IT and business process services to clients worldwide from offices in Canada, the United States, Europe, and Asia Pacific as well as from centers of excellence in North America, Europe and India.”

The contact information for CGI is listed as 1-877-316-7222 or racb@cgi.com.

How is the RAC paid for its audit services?

Each RAC is paid on a contingent fee basis for identified overpayments, thus receiving a percentage of the identified overpayment. For Region B, the contingency fee is **12.5% of the identified overpayment**. For underpayments, however, the RAC receives an amount designated by CMS for the recovery.

Under the RAC demonstration project, each RAC retained the contingency fee regardless of whether the health care entity prevailed on appeal. The permanent RAC program requires the RAC to return any fee if the health care entity prevails on appeal of the alleged improper payments.

Who is the subject to the RAC program?

Medicare **providers and suppliers** that bill Fee-For-Service programs will be subject to RAC review. The RAC demonstration project identified improper payments related to the following services: inpatient hospital, inpatient rehabilitation, outpatient hospital, skilled nursing facility, physician, ambulance and DME.

How far back can the RAC review claims?

The permanent RAC program limits claim review to a maximum of

a three-year look-back period. In no case may claims paid prior to **October 1, 2007** be reviewed.

What is the RAC review process?

The RAC review is based upon claims post-payment. The RAC uses the same payment policies as fiscal intermediaries, carriers and Medicare administrative contractors. RACs are prohibited from selecting claims at random for review. They must instead use proprietary data techniques to identify improper payments. Two types of reviews may be conducted by the RAC: (1) automated (no medical record review needed); and (2) complex (medical record required).

An **automated review** is triggered when there is certainty that the claim is not covered and there is a Medicare policy, article, or coding guideline that applies to the claim. Other automated reviews include situations involving duplicate claims or pricing errors.

A **complex review** is triggered when the proprietary data technique identifies the situation where the probability of an improper payment is high, but must be confirmed by review of medical records. RACs may review the records on-site or request the health care entity to mail or transmit the requested records. Records must be provided to the RAC within 45 days of request by the RAC, or a determination may be made without the records.

Under the permanent RAC program, each RAC is required to employ a medical director. Further, each RAC is to employ registered nurses, therapists and professional coders. These individuals review the claims and make both coverage and coding determinations. Upon request, the medical director will meet with a health care entity following any claims denials.

In most cases, the RAC review process must be completed within 60 days of the receipt of the requested medical records. Following review, the RAC will determine whether an improper payment has occurred and will issue a demand letter to the health care entity.

What are the medical record limits for an RAC complex review?

The CMS limitation on RAC records requests for fiscal year 2009 depends upon the provider/supplier type as shown below. Failure to timely provide records will permit the RAC to deny claims for insufficient documentation and may mean the loss of appeal rights for those claims.

- Inpatient hospitals, inpatient rehabilitation facilities, skilled nursing facilities and hospices: Up to 10% of the average monthly Medicare claims per 45 days, but no greater than 200.
- Outpatient hospitals, home health and other Medicare Part A billers: 1% of the average monthly Medicare services per 45 days, but no greater than 200.

- Physicians: Solo Practitioner: 10 medical records per 45 days; Partnership of 2-5 individuals: 20 medical records per 45 days; Group of 6-15 individuals: 30 medical records per 45 days; Large Group (16+ individuals): 50 medical records per 45 days.
- Other Part B Billers (DME, Lab): 1% of average monthly Medicare services per 45 days, but no greater than 200.

What options do providers and suppliers have when the RAC identifies improper payments?

Upon receipt of a demand letter from RAC, health care entities must immediately assess whether to challenge (informally, formally, or both) the determination. A decision not to appeal simply requires a determination of whether to pay and avoid interest, or to permit recoupment with interest. An informal appeal, which does not preserve any rights under the formal appeal procedures while it is pending, consists of a request to meet the RAC Medical Director. The formal appeal is governed by the Medicare Part A and Part B appeals process, as set forth below.

The timelines for challenge are short, particularly if the health care entity wants to prevent recoupment pending an appeal. Strategies for appealing prior to recoupment, or appealing following a recoupment are critical questions to be addressed with legal counsel, and the accrual of interest may prove to be a significant factor in such a decision. In any case, to avoid recoupment, a health care entity must file an appeal within 30 days of the demand letter from the RAC. To preserve the right to appeal, the health care entity must appeal within 120 days.

Can an RAC determination of improper payments be challenged?

Yes. As discussed in the previous question, health care entities may appeal an RAC determination through the Medicare Part A and Part B appeals process ("Appeal"). An Appeal has five distinct stages: (1) redetermination; (2) reconsideration; (3) administrative law judge hearing; (4) Medicare Appeals Council review; and (5) federal district court review. Depending upon the facts surrounding the claims, certain defenses (e.g., waiver of liability, provider without fault) may be utilized. Legal counsel should be consulted before filing an Appeal.

How can Health Care entities prepare for the RAC program?

Preparation for the RAC program starts with an effective corporate compliance plan. An effective corporate compliance plan will identify areas of key concern to the Office of Inspector General ("OIG"), including those identified in the annual OIG Work Plan. Further, a corporate compliance plan should call for internal assessments and require corrective actions to avoid RAC overpayment determinations.

Each health care entity should develop an RAC policy, procedure

or plan. It should designate the health care entity's RAC contact person to ensure that the right individual within your entity is notified of any medical record requests by the RAC. The policy or procedure should identify other immediate contacts, such as key administrators and legal counsel. Timelines for response to RAC medical record requests should also be outlined for easy reference. In short, each health care entity should have a plan to reference for the inevitable RAC review.

What should our Board of Directors know about the RAC program?

Effective corporate compliance begins with the Board of Directors. Boards should be made aware of how the health care entity is ensuring compliance with state and federal law, including but not limited to the RAC program. It is advisable for each health care entity to have a routine training with the Board regarding compliance issues and how the health care entity maintains compliance with all requirements. As part of such a training, the Board should be educated regarding the RAC policy, procedure or plan, as well as how the health care entity will respond publicly should such a review become public. This training can be conducted with legal counsel so Board members understand the seriousness and complexity of compliance issues within health care entities.

If you have any questions regarding the RAC program, or need assistance with development of an appropriate RAC policy, procedure or plan, or with Board of Director compliance training, please contact Thomas N. Shorter (tshorter@gklaw.com or 608-284-2239) or another member of the Godfrey & Kahn Health Care Team.

Stimulus Package Brings Sweeping Changes to HIPAA; Here's Your Compliance Checklist

By Choua L. Vang

Introduction

On Tuesday, February 17, 2009, President Obama signed into law a \$787 million economic stimulus package, officially known as the American Recovery and Reinvestment Act of 2009 ("ARRA"). ARRA includes the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"). The HITECH Act contains numerous provisions that significantly expand the scope of the security and privacy rules under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Collectively, these provisions will bring about sweeping changes in the way covered entities ("Covered Entities") and business associates ("Business Associates") maintain, use and disclose "protected health information" ("PHI"). For a detailed analysis of these provisions, see our February 23, 2009 Health Care Team Update on "Health Information Technology and HIPAA under the ARRA" which can be viewed on our firm's website (www.gklaw.com) under News & Publications.

While many of the provisions under the HITECH Act will not be effective until February 17, 2010 or later, one significant provision - breach notification - is scheduled to become effective before the end of this year. Moreover, many of the provisions will require significant time and resources in order to implement. For these reasons, Covered Entities and Business Associates must develop and put into place concrete plans of action now to ensure their organizations are fully compliant by each of the applicable deadlines. To assist Covered Entities and Business Associates with this effort, we have prepared the following list of action items that must be completed and the dates by which they must be completed:

A. Covered Entities and Business Associates

1. Breach Notification:

Under the HITECH Act, Covered Entities and Business Associates must report to the U.S. Department of Health and Human Services ("HHS") breaches of "unsecured protected health information," defined as protected health information that is not secured through the use of a technology or methodology specified by HHS.

To comply with this requirement, Covered Entities and Business Associates must create and implement policies and procedures for identifying, tracking and reporting breaches of "unsecured protected health information." Such policies and procedures must comply with the notification requirements specified in the HITECH Act, such as methods of notification and timeliness of the notification.

Due date: HHS must promulgate regulations by August 17, 2009 – due date is 30 days after regulations have been promulgated.

2. Restrictions on Disclosures:

The HITECH Act requires Covered Entities and Business Associates to honor an individual's request to restrict disclosures of PHI to health plans for payment or health care operations purposes if the PHI pertains solely to items and services paid for by the individual in full.

To comply with this requirement, Covered Entities and Business Associates must create and implement policies and procedures for receiving and processing requests from individuals to restrict disclosures of PHI to health plans.

Due date: February 17, 2010.

3. Minimum Necessary:

Under the HITECH Act, Covered Entities and Business Associates must limit their uses, disclosures or requests for PHI to a "limited data set," if practicable, or, if needed, the minimum necessary to accomplish the intended purpose of the use, disclosure or request.

To comply with this requirement, Covered Entities and Business

Associates must educate their workforce members about the new minimum necessary and limited data set standards.

Due date: February 17, 2010.

4. Accounting for Disclosures:

Under the HITECH Act, Covered Entities and Business Associates making disclosures of an individual's PHI from an electronic health record ("EHR") for treatment, payment and health care operations ("TPO") are required to account for such disclosures if requested by the individual. The term "EHR" is defined as "an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff."

To comply with this requirement, Covered Entities and Business Associates must develop policies and procedures for tracking disclosures of PHI from an EHR for TPO. Covered Entities and Business Associates must also develop a system for receiving and processing requests from individuals for an accounting of such disclosures.

Due date: For Covered Entities and Business Associates currently using EHR, the accounting requirement would apply to disclosures made on or after January 1, 2014. For Covered Entities and Business Associates yet to acquire EHR, the accounting requirement would apply to disclosures made on or after January 1, 2011, or the date EHR are acquired, whichever is later.

5. Prohibition on Sale of PHI:

Under the HITECH Act, Covered Entities and Business Associates are prohibited from receiving, directly or indirectly, any remuneration in exchange for PHI, except pursuant to a valid HIPAA authorization signed by the individual or pursuant to one of the exceptions listed in the Act.

To comply with this requirement, Covered Entities and Business Associates must review their exchanges of PHI to determine whether any remuneration is received, and if so, whether the receipt of the remuneration complies with the requirements under the HITECH Act. Covered Entities and Business Associates should also develop policies and procedures to ensure that no PHI is exchanged for remuneration unless the receipt of the remuneration complies with the requirements under the HITECH Act.

Due date: HHS must promulgate final regulations by August 17, 2010 – due date is six months after the date final regulations are promulgated.

6. Individual Access to PHI in EHRs:

Under the HITECH Act, Covered Entities and Business Associates using or maintaining EHRs with respect to PHI of an individual are required to provide the individual with a copy of his information in

electronic format, upon request.

To comply with this requirement, Covered Entities and Business Associates must develop a system for receiving and processing requests from individuals for electronic copies of their PHI.

Due date: February 17, 2010.

7. Use of PHI for Marketing:

The HITECH Act prohibits Covered Entities and Business Associates from receiving remuneration, either directly or indirectly, for disclosing PHI for marketing purposes that previously qualified as "health care operations," unless certain requirements have been met.

To comply with this requirement, Covered Entities and Business Associates must review their disclosures of PHI for marketing purposes and determine whether they receive any remuneration in exchange for such disclosures. If remuneration is received, Covered Entities and Business Associates must determine whether the receipt of the remuneration complies with the requirements under the HITECH Act. Covered Entities and Business Associates should also develop policies and procedures to ensure that no remuneration is received in exchange for the use or disclosure of PHI for marketing purposes, unless the receipt of the remuneration complies with the requirements under the HITECH Act.

Due date: February 17, 2010.

8. Use of PHI for Fund-raising:

Under the HITECH Act, Covered Entities and Business Associates may only use and disclose PHI for fund-raising communications as a permitted "health care operation" if the recipient of the communication is provided with an opportunity to opt-out of receiving further communications. Such opportunity must be provided in a clear and conspicuous manner.

To comply with this requirement, Covered Entities and Business Associates must determine whether they use and disclose PHI for fund-raising purposes, and if so, provide the recipients of the fund-raising communication with the opt-out notice required under the HITECH Act.

Due date: February 17, 2010.

9. Business Associate Agreements:

The HITECH Act requires that each of the new obligations identified above be incorporated into business associate agreements entered into by Covered Entities and Business Associates ("Business Associate Agreements"). In our opinion, this means that Business Associate Agreements must be amended to affirmatively incorporate the new obligations into the old agreements, or that new Business Associate Agreements containing the new obligations must be entered into.

To comply with this requirement, Covered Entities should identify and maintain a list of each of their Business Associates. Business Associates should do the same for its Covered Entities. The parties should then work with each other to negotiate, draft and sign amendments to current Business Associate Agreements or new Business Associate Agreements. Finally, new Business Associate Agreements incorporating the new obligations under the HITECH Act should be drafted for use by Covered Entities and Business Associates on a go-forward basis.

Due date: February 17, 2010.

B. Covered Entities

In addition to the action items that apply to both Covered Entities and Business Associates, Covered Entities must do the following:

Notice of Privacy Practices:

The HITECH Act does not impose any requirements with respect to Notice of Privacy Practices. However, because the HITECH Act includes provisions that restrict the way Covered Entities may use and disclose PHI and grant additional rights to individuals with respect to their PHI, we recommend that Covered Entities review and revise their Notice of Privacy Practices to reflect these changes.

Due date: The HITECH Act does not specify a due date, but we recommend February 17, 2010, the earliest date on which some of the provisions governing use and disclosure of PHI and individuals' rights with respect to PHI become effective.

C. Business Associates

In addition to the action items that apply to both Covered Entities and Business Associates, Business Associates must do the following:

Information Safeguards under the Security Rule:

The HITECH Act requires Business Associates to implement each of the three information safeguards under the HIPAA security rule that currently apply to Covered Entities. These safeguards are administrative, physical and technical. The HITECH Act further requires Business Associates to implement and maintain written policies and procedures documenting compliance with the information safeguards.

To comply with this requirement, Business Associates must undertake a detailed analysis of the standards and implementation specifications under each of the three information safeguards and then implement them as appropriate for their organizations. Business Associates must then develop, implement and maintain written policies and procedures that document their compliance with the information safeguards.

Due date: February 17, 2010.

Conclusion

As evidenced by the checklists above, the work required to comply with the new requirements under the HITECH Act is substantial for both Covered Entities and Business Associates. While the predominant deadline, February 17, 2010, seems a long way away, the deadline will arrive all too quickly and Covered Entities and Business Associates must begin developing and implementing concrete plans of action now to ensure they will be compliant.

If you have questions regarding compliance with the new requirements under the HITECH Act, contact Choua Vang (cvang@gklaw.com or 920-831-6351) or any other member of Godfrey & Kahn's Health Care Team.

Employee Free Choice Act Introduced – Are You Prepared?

By Jon E. Anderson

The Employee Free Choice Act (EFCA) is proposed legislation which, if passed, will amend the National Labor Relations Act to streamline the process by which the employees of an employer may unionize. Specifically, it would allow employees to form unions by signing cards authorizing union representation, establish harsher penalties for employers who violate employee rights when workers seek to form a union, and institute new mediation and arbitration processes for first-contract disputes.

The EFCA was introduced during each of the last three congressional sessions. The EFCA passed in the House on March 1, 2007 for the first time but was filibustered by Senate Republicans. The bill was reintroduced in both the House and the Senate on March 10, 2009 and is a major priority of labor organizations. President Obama has indicated his support for the EFCA.

Under current labor law, the National Labor Relations Board (NLRB) will certify a union as the exclusive representative of employees if it is selected by a majority of employees through a signature drive ("card check") process or more commonly by the employees through a secret ballot NLRB election, which is held if more than 30% of employees in an appropriate bargaining unit sign statements asking for representation by a union. If enacted, the EFCA would require the NLRB to certify a bargaining representative without directing an election if a majority of the bargaining unit employees signed authorization cards. The current employer option of rejecting the cards and demanding an election would be eliminated.

Strict timelines imposed by the EFCA will change the face of collective bargaining. Under the EFCA, a union can demand that an employer begin bargaining within ten days of certification of the union as the exclusive bargaining representative. In addition, if the union and employer cannot agree upon the terms of a first

collective bargaining contract within 90 days, either party can request federal mediation, which could lead to binding arbitration if an agreement still cannot be reached after 30 days of mediation. The results of the arbitration would be binding on both parties for two years. The EFCA would also provide enhanced monetary damages if employers were found to have unlawfully terminated pro-union employees. Finally, the EFCA would impose additional penalties upon employers for each employer violation of the proposed legislation if the NLRB and/or a court deem the violation willful or repetitive.

Employers should anticipate that some version of the EFCA will be passed in the current legislative session. Employment policies and employee handbooks should be reviewed. Supervisors and managers will need training to be able to recognize and respond to union organizing efforts and to handle employee questions that typically arise in an organizing situation. Employer communications concerning unions and organizing will need to be fine-tuned. Employers must be ready to respond quickly under the EFCA, so careful planning now is critical.

Watch our website for more information concerning this legislation that will significantly affect many employers. If you have any questions regarding the EFCA, or would like assistance with your preparations for it, including policy development, training, and communication strategies, please contact Jon E. Anderson (janderson@gklaw.com or 608-258-2901) or another member of the Godfrey & Kahn Health Care or Labor and Employment Teams.

Recent Developments in Physician Non-Compete Agreements

By Robert J. Dreps

Restrictive covenants in physician employment agreements are disfavored, both professionally and legally. The American Medical Association has long been hostile to such restrictions for professional reasons, resolving in 1933 that post-employment restrictions on competition that prevent the “free choice of physician” are unethical. The AMA’s Judicial Council revisited the issue in 1960, stating in an opinion that it is not unethical to enforce a “reasonable agreement not to practice within a certain area for a certain time, if it is knowingly made and understood.” The pendulum again swung back in 1980, when the AMA adopted a Judicial Council opinion declaring that physician non-competition agreements are not “in the public interest.”

The AMA’s current position, adopted in 1996, coincides with the public policies of most states:

Opinion 9.03, Restrictive Covenants and the Practice of Medicine

Covenants not to compete restrict competition, disrupt continuity of care, and potentially deprive the public of medical services. The Council on Ethical and Judicial Affairs

discourages any agreement which restricts the right of a physician to practice medicine for a specified period of time or in a specified area upon termination of an employment, partnership or corporate agreement. Restrictive covenants are unethical if they are excessive in geographic scope or duration in the circumstances presented, or if they fail to make reasonable accommodation of patients’ choice of physician.

The AMA’s grudging acceptance of reasonable non-competition agreements in the practice of medicine coincides with Wisconsin law, which held such agreements do not violate public policy in 1971. See *Oudenhoven v. Nishioka, M.D.*, 52 Wis. 2d 503, 190 N.W.2d 920 (1971). But that does not mean such agreements will always be enforced in this state.

Wisconsin law disfavors restrictive covenants for all employees, including physicians.

A covenant by an assistant, service or agent not to compete with his or her employer or principal during the term of the employment or agency, or after the termination of that employment or agency, within a specified territory and during a specified time is lawful and enforceable only if the restrictions imposed are reasonably necessary for the protection of the employer or principal. Any covenant, described in this subsection, imposing an unreasonable restraint is illegal, void and unenforceable even as to any part of the covenant or performance that would be a reasonable restraint. Wis. Stat. § 103.465.

This statute recognizes the inequity in bargaining power and discourages employers from overreaching in drafting non-competition agreements for their employees by invalidating the entire covenant if any part of it is later determined to be unreasonable.

Two recent decisions illustrate Wisconsin’s fact-dependent application of this statute to physician agreements. In *Robert Davison, M.D. v. Bay Area Nuclear Medicine, S.C.*, (BANM), the Court of Appeals held a post-employment restraint unenforceable because it was no longer reasonably necessary to protect BANM.

BANM hired Davison in 2003, when it held a contract as the exclusive provider of nuclear medicine services to St. Vincent’s Hospital in Green Bay. BANM terminated Davison’s employment in 2006, however, after it lost its exclusive services contract with St. Vincent’s to a competitor, then refused to release Davison from his non-competition agreement when he was offered employment with the competitor. Davison sought and received a judicial declaration that the restraint was unenforceable, even if its terms were perfectly reasonable when the agreement was signed in 2003, because BANM no longer had any protectable interest justifying enforcement of the restrictive covenant. The Court of Appeals affirmed, holding that whether a restraint is reasonably necessary to protect an employer’s interests must be

determined not at the time of contracting but at the time of the alleged violation.

In another case from the Fox Valley, the Court of Appeals held a geographic restriction in a heart surgeon's non-compete agreement unreasonable and unenforceable because his employer primarily obtained patients by referrals. See *Fox Valley Thoracic Surgical Associates, S.C. v. Ferrante, et al.*, 2008 WI App 51 (unpublished):

Heart Surgeons contends the restriction is reasonable in light of information regarding the zip codes of patients it has served. We disagree because Heart Surgeons obtained these patients via referrals. The patients' addresses, by themselves, do not demonstrate the geographic area in which Heart Surgeons competes for referrals. This is the area that Heart Surgeons arguably needed to protect.

Moreover, most of Heart Surgeons' referrals came from a single source, Cardiology Associates. Yet, Heart Surgeons has not proffered evidence demonstrating how its geographic restriction is necessary to keep Ferrante from unfairly competing for those referrals. Given the lack of relevant evidence, the circuit court was correct to conclude that Heart Surgeons did not meet its burden of establishing the reasonableness of the geographic restriction. *Id.*, ¶¶ 14-15.

These cases illustrate that, although physician non-compete agreements are not against public policy in this state, great care must be exercised in drafting and attempting to enforce them under Wisconsin law. A geographic restraint that may be perfectly reasonable for a family-practice physician could be held unenforceable against a specialist, for example, based on differences in how the doctors obtain patients. Similarly, a narrow restraint that appears reasonable when a physician is hired may become unenforceable over time based on changes in the employer's business. One size definitely does not fit all in physician non-compete agreements.

If you would like more information on physician non-compete agreements in Wisconsin, please contact Robert J. Dreps (rdreps@gklaw.com or 608-284-2606) or another member of our Godfrey & Kahn Health Care Team.

Revised Anti-Markup Rule Limits Physician Billing for Purchased Diagnostic Tests

By Robyn E. Arnold

Introduction

On October 30, 2008, the Centers for Medicaid & Medicare Services (CMS) released its 2009 Final Physician Fee Schedule, which included revised regulations limiting physician billing for purchased diagnostic tests, otherwise known as the Anti-Markup Rule (Final Rule). The Final Rule became effective on January 1, 2009.

The Anti-Markup Rule imposes a significant limitation on the amount a physician or entity may bill for diagnostic tests, including, with limited exceptions, diagnostic x-ray tests, diagnostic laboratory tests and other diagnostic tests, which are performed or supervised by an outside physician or supplier. Specifically, if the physician performing the professional component of a diagnostic test (*i.e.*, interpreting the x-ray) or supervising the technical component of a diagnostic test (*i.e.*, the actual taking of the x-ray) (in either case, the Performing Physician) does not "share a practice" with the physician or other supplier that bills for the test under Medicare Part B (Billing Physician), the amount billed for the diagnostic test may not exceed the lowest of the following amounts:

- the Performing Physician's net charge to the Billing Physician (determined without regard to the cost of equipment or space leased to the Performing Physician by the Billing Physician),
- the Billing Physician's actual charge to Medicare, or
- the fee schedule amount for the test that would be allowed if the Performing Physician billed Medicare directly for the diagnostic test.

The overriding goal of the Anti-Markup Rule is to limit the ability of physicians or other suppliers to profit from diagnostic tests they bill to Medicare but purchase from other physicians or suppliers who do not have a sufficient nexus with them. If, however, a sufficient nexus exists, then what the billing physician or other supplier may bill for the diagnostic test is not limited by the Anti-Markup Rule.

History of the Anti-Markup Rule

CMS initially implemented the Anti-Markup Rule by applying a payment limitation on the technical component of diagnostic tests purchased from an outside supplier. In November 2007, CMS proposed expanding the Anti-Markup Rule to cover both the technical component and the professional component of diagnostic tests if (1) the component was purchased outright from an outside supplier, or (2) the component was performed at a site other than "the office of the Billing Physician." The proposed expansion, and more specifically, confusion over what constituted "the office of the billing physician or supplier," resulted in a great deal of uncertainty. As a result, CMS limited the scope of the expansion to the technical component of diagnostic tests and certain pathology services until further clarification could be provided.

Revised Anti-Markup Rule

Based on its review of public commentary on the proposed amendments to the Anti-Markup Rule, CMS elected to adopt a flexible approach which offers two alternative measures of the nexus between the Performing Physician and the Billing Physician, *i.e.*, when does the Performing Physician "share a practice" with the Billing Physician? Effective as of January 1, 2009, the determination of whether the Performing Physician "shares a practice" with the Billing Physician can be analyzed under two

alternatives: the “substantially all services” approach and the “site of service” approach.

Alternative 1: The “Substantially All” Approach

All diagnostic testing arrangements should initially be analyzed under the “substantially all” approach. Under the “substantially all” approach, if the Performing Physician performs at least 75% of his or her professional services for the Billing Physician, the services performed by the Performing Physician will be exempt from the Anti-Markup Rule.

The Final Rule clarifies that a Performing Physician satisfies the “substantially all” approach if, at the time the Billing Physician submits a claim for a service performed by the Performing Physician, the Billing Physician has a reasonable belief that (i) the Performing Physician has furnished substantially all of his or her professional services through the Billing Physician for the period of 12 months prior to and including the month the service was performed, or (ii) the Performing Physician is expected to furnish substantially all of his or her professional services through the Billing Physician during the following 12 months, including the month the service was performed.

In contrast to the original proposal by CMS, which required the Performing Physician to provide 100% of its professional services to the Billing Physician in order to avoid application of the Anti-Markup Rule, the “substantially all” approach provides physicians with the flexibility to provide services to more than one Billing Physician by allowing for part-time, on-call, *locum tenens* or other similar relationships.

Alternative 2: The “Site of Service” Approach

If the services performed by a physician do not satisfy the “substantially all” approach, the diagnostic testing arrangement should be analyzed under Alternative 2, the “site of service” approach. Under the “site of service” approach, only the technical component conducted and supervised in and the professional component performed in the office of the Billing Physician will be exempt from the Anti-Markup Rule. Specifically, diagnostic tests will be exempt from application of the Anti-Markup Rule if the following two conditions are satisfied:

- First, (i) with respect to the technical component, the Performing Physician must be an owner, employee or independent contractor of the Billing Physician, and (ii) with respect to the professional component, the Performing Physician must be an employee or independent contractor of the Billing Physician; and
- Second, the diagnostic testing service in question must be performed in the office of the Billing Physician. For purposes of the “site of service” approach, “office of the Billing Physician” is defined as space in which the ordering physician performs substantially the full range of patient services that the ordering physician provides generally. If the

Billing Physician is a physician organization, “the office of the Billing Physician” is space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally.

The benefit of the “site of service” approach is two-fold. First, it can be applied to arrangements on a case-by-case basis. Second, a physician or supplier may have one or more “offices of the Billing Physician” assuming they provide their full range of patient services at each office location.

Impact of the Revised Anti-Markup Rule

CMS believes that the introduction of a two-prong approach to diagnostic testing arrangements will limit the overutilization of diagnostic tests by imposing billing limitations on arrangements between physicians and entities that have no real connection other than the referral of diagnostic tests, while exempting from those limitations diagnostic testing relationships with a sufficient nexus. The either/or analysis provided by the “substantially all” approach and the “site of service” approach offers physicians and physician organizations greater latitude in structuring these arrangements.

However, the Anti-Markup Rule will still impact a large number of diagnostic testing arrangements, such as radiologists who provide part-time services to a variety of physician organizations or physician groups that operate at multiple locations but have a single diagnostic testing location. Physicians and physician organizations need to carefully evaluate how their diagnostic testing arrangements are structured and consider whether they fall under the exemptions provided by the Final Rule. If not, they should consider how relationships could be restructured to fall within the “substantially all” or “site of service” approach.

If you have any questions regarding the Anti-Markup Rule or its application to your practice, contact Robyn Arnold (rarnold@gklaw.com or 414-287-9328) or Charles Vogel (cvogel@gklaw.com or 414-287-9502), or any other member of the Godfrey & Kahn Health Care Team.

OIG Limits Access to the Provider Self-Disclosure Protocol

By Hamilton E. Arendsen

Introduction

As the government’s fight against health care fraud escalates, Medicare providers and suppliers (“Health Care Providers”) need to stay informed about self-disclosure protocols and the benefits and drawbacks of voluntarily disclosing conduct that may give rise to liability. On March 24, 2009, the Office of the Inspector General (“OIG”) announced two changes to its Provider Self-Disclosure Protocol (“SDP”). Prior to this date, the SDP could be used for the self-disclosure of conduct that may violate the physician self-referral law (the “Stark Law”), even if this conduct

would not implicate the anti-kickback statute. Now, however, the OIG will no longer accept self-disclosures that only implicate violations of the Stark Law, unless the disclosed conduct *also* reveals a colorable anti-kickback statute violation. Also, for the first time, the OIG has established a minimum settlement amount of \$50,000 to resolve kickback issues in the submission.

In light of these changes, Health Care Providers considering disclosure of their own conduct utilizing the SDP should first answer two questions. First, does their conduct reveal a colorable anti-kickback statute violation (without regard to any additional Stark Law violations)? Second, is their conduct of sufficient concern to them that they are willing to pay a minimum settlement of \$50,000 to resolve their risk of an anti-kickback violation? If the answer to either question is no, the SDP is not appropriate.

History of the OIG's SDP Program

The OIG first introduced the SDP in 1998. The SDP allows Health Care Providers to voluntarily disclose conduct that may violate the anti-kickback law, which conduct may also violate the Stark Law. The benefit of self-disclosure under the SDP is the likely avoidance of the disruptions associated with a Government investigation and with civil, criminal or administrative litigation. In exchange for voluntary disclosures that the OIG believes are thorough and complete, the OIG will consult with the Department of Justice and other agencies to facilitate a reasonable resolution of the problems identified during the SDP process. Health Care Providers will be removed from participation in this initiative if they fail to disclose matters in good faith or to timely perform the required self-assessment, including quantifying the financial benefits conferred upon the physicians and quantifying the full amount of any overpayments.

In addition, a Health Care Provider's existing compliance program may also factor into the OIG's decision to impose Corporate Integrity Agreements, Certification of Compliance Agreements, or other additional compliance measures. Further, utilizing this SDP is "limited to matters that, in the provider's reasonable assessment, involve conduct that subjects the provider to civil monetary penalty ("CMP") liability under the OIG's physician self-referral and anti-kickback authorities – in particular situations involving a financial benefit knowingly conferred by a hospital upon one or more physicians." See *An Open Letter to Health Care Providers*, April 24, 2006.

In its April 24, 2006 Open Letter, the OIG announced an SDP program specifically tailored to resolving CMP liability under the Stark Law and anti-kickback statutes for financial arrangements between hospitals and physicians. In addition to the "Basic Information" that must be provided in connection with an application under the SDP, see http://oig.hhs.gov/authorities/docs/self_disclosure.pdf, the following information must be enclosed in an initial disclosure submission: (1) a complete description of the conduct being disclosed; (2) a description of

the provider's internal investigation or a commitment regarding when it will be complete; (3) an estimate of the damages to the Federal health care program and the methodology used to calculate that figure (or a commitment regarding when the provider will complete such estimate); and (4) a statement of the laws potentially violated by the conduct. See *An Open Letter to Health Care Providers*, April 15, 2008. In addition, a provider must be in a position to complete the investigation and damages assessment within three months after acceptance into the SDP.

With respect to potential penalties, the OIG has the authority to impose CMPs of up to \$15,000 for each service billed in knowing violation of the Stark Law, and assessments of up to three times the amount claimed for such services. In addition, hospitals and physicians may also have liability for these types of arrangements under the OIG's anti-kickback CMP authority. This section authorizes a penalty of \$50,000 for each kickback, plus an assessment of not more than three times the total amount of remuneration offered, paid, solicited, or received. Under the SDP, however, the OIG will generally settle with the Health Care Provider for an amount near the low end of the damages continuum.

Recent Changes to the SDP

As noted above, the OIG just announced that it is narrowing the focus of its SDP initiative. See *An Open Letter to Health Care Providers*, March 24, 2009. First, the OIG will no longer accept disclosure of matters that concern only liability under the Stark Law in the absence of a colorable anti-kickback statute violation. This means simply that the SDP is not the disclosure pathway for conduct representing possible Stark Law violations, unless the same conduct also suggests an anti-kickback violation. Accordingly, Health Care Providers need to conduct thorough investigations at an earlier stage in order to determine if the conduct at issue will even *qualify* for referral using the SDP given the March 24, 2009 change in protocol.

Second, the OIG has now established a minimum settlement amount for submissions concerning potential violations of the anti-kickback statute. Given the first change in the program discussed above, this effectively creates a minimum settlement amount for all submissions under the SDP. Specifically, the OIG will require a minimum settlement amount of \$50,000 to resolve the matters raised by the self-disclosure. The OIG cited its need to better allocate its resources as the primary reason for narrowing the scope of its SDP.

Summary

OIG's recent changes impact a Health Care Provider's decision of whether to use the SDP to disclose conduct representing potential violations. In addition to the substantive analysis that must be performed to ensure that such conduct may violate the anti-kickback statute, Health Care Providers must think critically about whether the conduct at issue is sufficiently egregious to justify a settlement of at least \$50,000. As a practical matter,

these limitations will significantly decrease the number of self-disclosures, a goal of the OIG to control its workload and speed its response time to matters representing significant anti-kickback violations. Given the intent requirements for anti-kickback violations, Health Care Providers must be extremely careful when deciding whether to use the SDP in the anti-kickback context and analyze the potential benefits and drawbacks of such a self-disclosure.

The SDP is only one of several alternatives for self-disclosure. Others include the U.S. Department of Justice, a State Medicaid agency, the Centers for Medicare and Medicaid Services, and the Health Care Provider's payment contractor, the latter being appropriate for mere billing errors and overpayments.

The recent changes will also require Health Care Providers to examine their corporate compliance programs to ensure that they are consistent with the OIG's SDP program. Any matters involving potential Stark Law or anti-kickback violations should be addressed with the assistance of legal counsel given the significant potential criminal and civil penalties. Godfrey & Kahn's White Collar Counseling and Defense Team has significant depth and experience in handling investigations and disclosures, including disclosures that fit within the OIG SDP program.

If you have any questions regarding the OIG's SDP, to whom you should self-disclose, or how your corporate compliance program impacts your self-disclosure decisions, please contact Thomas Shorter (tshorter@gklaw.com or 608-284-2239) or Hamilton Arendsen (harendsen@gklaw.com or 608-284-2629) in our Madison office, or Sean Bosack in our Milwaukee office (sbosack@gklaw.com or 414-287-9431).

Impact of ARRA on State Medicaid Programs; Downturn Opportunities for Providers

By Andrew J. Turner

At first glance, the federal stimulus package enacted earlier this year, the American Recovery and Reinvestment Act of 2009 ("ARRA"), appears to have little practical impact on providers of Medicaid services. After all, ARRA's Medicaid provisions – while enormous from an economic perspective – do not directly fund providers nor change the fundamental regulatory structure in which providers operate. However, by choosing to support states with additional Medicaid spending, the federal government has virtually assured changes in providers' payer mix and in Medicaid patient demographics.

These changes will present opportunities for state Medicaid providers. Wisconsin's new outpatient mental health regulations, combined with ARRA's impact on Medicaid in Wisconsin, is one example of these opportunities.

Medicaid Provisions of the ARRA

The core ARRA Medicaid provisions seek to guarantee citizen access to Medicaid services by relieving budgetary pressure on state governments. The stated goal is to "protect and maintain State Medicaid programs during a period of economic downturn, including by helping to avert cuts to provider payment rates and benefits or services, and to prevent constrictions of income eligibility requirements for such programs..." ARRA. To achieve this goal the federal government boosts spending, conditions the spending on states' maintenance of existing eligibility rules, and extends Medicaid coverage.

Increase in Federal Funding for Medicaid

ARRA supports state Medicaid spending by increasing the Federal Medical Assistance Percentage ("FMAP") – that is, the percentage of state Medicaid expenditures that the federal government will reimburse. States will receive the increased FMAP from October 2, 2008 through December 31, 2010. The FMAP increase will be 6.2% for all states plus a "bonus" amount based on unemployment rates and a "hold-harmless" provision to prevent any reductions when FMAP is calculated. A similar strategy was implemented for 15 months from April 1, 2003 through June 30, 2004, when a temporary 2.95% FMAP increase was enacted. Though much smaller, there will also be a temporary increase in Disproportionate Share Hospital allotments. The increase will be 2.5% in 2009 and an additional 2.5% in 2010.

Maintenance of Existing Eligibility Rules

In order to secure the intended effect, the FMAP increases come with regulatory strings attached. Most importantly, ARRA forestalls eligibility contractions by halting FMAP increases if a state enacts "eligibility standards, methodologies, or procedures... more restrictive than [those]...in effect on July 1, 2008." ARRA also conditions FMAP money on compliance with Medicaid "prompt pay" requirements (states must pay 99% of "clean claims" within 90 days of receipt) and extends prompt pay to nursing facilities and hospitals.

Extension of Medicaid Coverage

Medicaid coverage will also be extended in several ways. First, Transitional Medical Assistance (which provides extended Medicaid coverage for low-income parents who earn their way out of Medicaid eligibility) has been extended through December 31, 2010. Second, there are various provisions whose net effect is to improve American Indians' access to Medicaid. Finally, ARRA extends existing moratoria on several federal regulations which limited federal reimbursement for some Medicaid services, adds a new moratorium on outpatient hospital regulations which were finalized in December of 2008, and gives the Department of Health and Human Services the option to not promulgate three other rule regulations. The overall effect is to enhance the amount of funds available to states under Medicaid.

ARRA's Effect on Medicaid Providers

These changes will likely bring a wave of new enrollees onto

state Medicaid rolls. As the economic downturn continues, unemployment increases and access to private insurance consequently decreases. In the past, states caught between increasing demand and decreasing revenue (and often under a strict balanced budget mandate) have been forced to change eligibility requirements, reduce services, or take other measures to keep new enrollees from overwhelming the system. In fact, “[d]uring the last downturn [in 2001]... every state implemented an array of measures to control Medicaid spending growth to meet state budget shortfalls.” *Headed for a Crunch: An Update on Medicaid Spending, Coverage and Policy Heading into an Economic Downturn*, Kaiser Commission on Medicaid and the Uninsured, 2008. However, the eligibility freeze for FMAP-increase recipients discourages states from making such cuts, even as more and more consumers may need to rely on Medicaid.

Predicting what this will mean for providers is necessarily speculative, but some outcomes seem likely:

Demand for Health Care Services Unlikely to Drop Significantly Due to Unemployment

Due to ARRA, many consumers will be able to rely on Medicaid coverage if they lose private insurance; thus providers are less likely to see a drop in the consumption of health care services. In the absence of ARRA, insurance loss through unemployment would likely lead consumers to forgo medical procedures, be more cost conscious (perhaps shifting health spending to “quick clinics”) or resort to charity care. In fact, to the extent that Medicaid provides broader coverage with fewer co-pays or other end-user costs than some private insurance plans, patients may end up using more medical services or a greater variety of medical services.

While preserving consumer health coverage should help all providers, the net effect may be different depending on provider type. Some experts “expect all not-for-profit hospitals, but especially providers with high Medicaid payer mix, notably academic medical centers, safety-net providers, and children’s hospitals [will] benefit more from the package.” *Moody’s Special Comment, February 2009 as cited by the Governance Institute*.

Payer Mix Likely to Shift from Private Insurance Toward Medicaid

Providers may not see significant attrition of their client population, but as a practical matter ARRA will result in consumers transitioning from private insurance to Medicaid. To the extent that Medicaid services are reimbursed at a lower rate, providers are likely to see a drop in income (though not as significantly as if those same individuals became completely uninsured).

Payer Mix Not Likely to Shift Equally Among Service Areas

Providers can expect the payer mix for some services to remain unchanged while the Medicaid portion surges in others. New Medicaid enrollees will be demographically different and therefore

require different services. Unemployment driven enrollment will likely increase the percentage of non-disabled adults and children, as compared to the elderly and disabled (who currently make up about a quarter of all Medicaid enrollees nationwide and account for 70% of expenditures). *Kaiser Commission on Medicaid and the Uninsured and Urban Institute estimates based on 2005 MSIS data*.

Opportunities for Medicaid Providers

While ARRA makes few direct adjustments to Wisconsin’s regulatory framework, ARRA-created changes in Medicaid demographics may open opportunities for providers to use the existing regulatory framework in new ways.

As one example, consider the new Wisconsin outpatient mental health services regulation. DHS 35 and related regulatory changes will come into effect on approximately June 1, 2009, roughly contemporaneous with the new influx of ARRA funding and expected increase in Medicaid patients. While the new DHS 35 was not triggered by ARRA, its overall impact will be to liberalize how health care providers may provide outpatient mental health services reimbursable by Medicaid. The new regulatory scheme:

- Allows providers to “provide psychotherapy services in the clinic, a branch office, or alternate location.” *DHS 35, Order Of Department Of Health Services To Adopt Rules*.
- Allows “persons other than a physician or psychiatrist to provide mental health services.” *Id*.
- Allows for more flexibility in oversight and quality improvement processes.

While the new regulation in many ways codifies existing “variances,” providers can also consider ways in which ARRA and state regulations may dovetail with economic downturn effects. For instance, because of the liberalized location and staffing requirements of DHS 35, it may be feasible for providers to respond to changing economic and social conditions. Presumably, a provider could respond to an uptick in unemployment in a particular location – and the attendant mental health issues that would likely follow – by opening a temporary outpatient mental health office in the affected area. *DHS 35.07*. Provided that the main clinic is certified, DHS 35 is flexible in that “[a]dditional offices do not require separate certification.” *DHS 35.08*. Meanwhile, ARRA provides the state with financial backstopping, assuring that potential consumers of these services will have access to Medicaid.

There are other potential synergies with ARRA. Wisconsin’s DHS staff has noted that clinics’ ability to use remote locations does not alleviate complex health record privacy and portability issues. However, the expansion of electronic health record technology to providers’ many locations is supported by ARRA’s Medicare incentive payments for “meaningful use” of such systems. (See “Health Information Technology and HIPAA under the American

Recovery and Reinvestment Act of 2009 (the Stimulus Act)" by Michael E. Skindrud and Choua L. Vang within News & Publications at www.gklaw.com.) Thus, ARRA will help solve the health record issues identified as a concern by DHS staff, enabling providers to take advantage of DHS 35's more flexible scheme.

Regulatory changes and adjustments are likely as these laws and regulations are implemented. DHS 35 will inevitably be refined by DHS interpretations. ARRA may undergo similar changes. For instance, note that while ARRA specifically conditions FMAP increases on states maintaining "eligibility standards, methodologies, or procedures" it is not clear what other adjustments states are allowed to make. Despite these uncertainties, the economic downturn will provide meaningful opportunities for Medicaid providers to expand the care they provide in an era of increased need.

If you have any questions regarding Wisconsin's Medicaid Law and the regulations that govern it, or how the ARRA impacts Medicaid, contact Andrew Turner (aturner@gklaw.com or 608-284-2638) or Michael Skindrud (mkindrud@gklaw.com or 608-284-2619), or any other member of the Godfrey & Kahn Health Care Team.

Physician-Owned Specialty Hospitals Survive Congressional Attack

By Charles G. Vogel

The latest Congressional effort to restrict physician ownership in specialty hospitals was defeated in February. Currently, the "Stark Law" permits physicians to make referrals to a hospital in which they have an ownership interest, as long as the ownership is in the entire hospital and not just a department or other limited part of the hospital.

Opponents of physician ownership succeeded in adding restrictive language to the version of the State Children's Health Insurance Program legislation initially approved by the House of Representatives in January. The restrictions would have prohibited a physician's referral to any hospital in which she or he had an ownership interest if, as of the effective date of the legislation, the physician did not already have an ownership interest in the hospital and the hospital was not already Medicare certified.

The Senate's version of the legislation did not include the restrictive requirements, and the House of Representatives eventually accepted and adopted the Senate version, which President Obama then signed on February 4.

Both proponents and opponents of physician ownership in hospitals have stated that, in effect, the unsuccessful effort to use the State Children's Health Insurance Program bill as a vehicle for

addressing the issue amounted to a battle in what they predict will be a continuing war.

If you have any questions regarding physician-owned specialty hospitals or the regulations that apply to them, please contact Charles G. Vogel (cvoegel@gklaw.com or 414-287-9502) or another member of the Godfrey & Kahn Health Care Team.

October 1, 2009 Stark Deadlines for "Under Arrangements" and "Per Click" Transactions

By Claire K. Finando

In the final 2009 inpatient Prospective Payment System rule (the "Final Rule"), the Centers for Medicare and Medicaid Services ("CMS") released a number of important revisions to Stark regulations. Most of these revisions have taken effect, with two notable exceptions affecting certain "under arrangements" transactions and "per click" and percentage-of-revenue leasing transactions. This is our reminder to you of the remaining deadline.

Under Arrangements

Certain "under arrangements" agreements will no longer escape scrutiny under the Stark Law. The Final Rule expands the definition of "entity" under Stark regulations to include entities that perform services that are billed as Designated Health Services ("DHS") by another entity. Previously, "entity" only included an entity that billed Medicare for DHS. Accordingly, under the previous definition, a number of physicians were able to invest in entities that performed DHS for hospitals' "under arrangements," and the hospitals billed for the DHS. With the expansion to the definition of "entity," these "under arrangements" transactions are now subject to the Stark Law, and will have to be unwound unless they fit within an exception. To compensate for the dramatic change in regulations, CMS has provided these physicians and entities with an October 1, 2009 deadline before the regulations become effective.

CMS declined to define what it means to "perform" DHS, but has noted in its commentary that an entity does not "perform" DHS merely by (i) leasing or selling space or equipment used for the performance of DHS, (ii) furnishing supplies not separately billable but used in the performance of DHS, or (iii) providing management, billing services or staffing services to the entity performing DHS.

Per-Click and Percentage-Based Leasing

CMS has also restricted certain leasing arrangements. The space, equipment, fair market value and indirect compensation exceptions in the Stark regulations will no longer allow leases that charge based upon: (1) a percentage of the revenue attributable to the services performed or business generated in the office space or with the equipment; or (2) per-unit of service, to the extent the charges reflect services provided to patients referred between the parties. Once again, these changes will force many

leasing arrangements to be restructured or unwound.

If you have any questions regarding the Stark Law or its application to hospital-physician relationships, or need assistance with unwinding any noncompliant relationships, please contact Claire Finando (cfinando@gklaw.com or 608-284-2605), Michael Skindrud (mkindrud@gklaw.com or 608-284-2619) or another member of the Godfrey & Kahn Health Care Team.

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