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Section Co-Chairs' Corner

Greetings to the Health Law Section. This is a busy time of year for many of us, and the end of what has been a transformative year for health law, both locally and nationally.

This fall, the Health Law Section sponsored, or co-sponsored, a number of events at the cutting edge of law and policy. I particularly enjoyed our stem cell program, at which a leading scientist and the head of the Harvard Stem Cell Institute came to the BBA to talk about this new technology and the legal issues surrounding it. We also sponsored a timely CLE on electronic medical records and the new federal incentives which were created to move physicians to use this technology.

Our second *Health Law Reporter* of the 2010-11 year touches on the new legislation that has recently been enacted at the state and federal level.

New on the federal side is the Stark voluntary self-disclosure protocol; Meghan Cosgrove has provided us with a helpful summary of these provisions and the mechanics of self-disclosure under the new rules.

Another piece of legislation that you may have not heard much about is the Medical-Legal Partnership for Health Care. Justin Fitzgerald has provided us with a summary of this proposed legislation, which was introduced in the U.S. House and Senate this summer. The legislation is modeled after a program that many BBA member firms participate in at Boston Medical Center, under the leadership of Dr. Barry Zuckerman and BBA member Samantha Morton.

We also have an article that outlines the elements of the newest in the series of health reform legislation from our own State House, Chapter 288 of the Acts of 2010. While this law did not get the same attention as the groundbreaking 2006 law,

it has many significant elements that are worth your attention.

Our appreciation goes out to all of our authors in this issue, our Publications Committee, led by Mark Rogers and Julia Hesse, the peer reviewers who ensure the high quality of the items we publish in the *Health Law Journal*, and, of course, our readers.

If you would like to contribute to an upcoming edition of *Health Law Journal*, or have an idea for a CLE program, or just a comment or suggestion on how we can improve this Section, please let Alan or Colin, or a committee chair, know. Our contact information is on the Health Law Section website.

Section Co-Chairs 2010-2011



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Several Steps Later with More to Go: Massachusetts Embarks on Short & Long Term Health Care Reforms

by Merritt Dattel McGowan, Esq. and Georgia Maheras, Esq.¹

Introduction

Policymakers in Massachusetts and the nation are facing an unprecedented challenge as they attempt to contain health care costs. Health care costs are an increasing share of state budgets as well as an increasing burden on employers, including municipalities. Over the past year, the combination of the economic recession and rising health care costs led to efforts by Massachusetts' policymakers to provide relief to small businesses.

This article lays out the history of legislative approaches to curtail small business health care costs during the most recent legislative session, summarizes key provisions in Chapter 288 of the Acts of 2010, and examines the possible outcomes of these important provisions.

History

In February 2010, responding to concerns from small business owners over double-digit health insurance premium increases, Governor Patrick filed legislation aimed at decreasing costs for small businesses in the short term.¹ The legislation proposed freezing unemployment insurance rates and providing a tax credit for new jobs created by

small businesses—provisions that dealt with broader economic issues. However, the Governor's legislation also incorporated sections specifically to deal with rising health insurance rates, including requiring insurers to offer a reduced network product in the small group market; creating open enrollment periods for individuals buying coverage; requiring insurers to file their premium increases in advance with the Division of Insurance (DOI) and for DOI to presumptively disapprove premium increases above a certain threshold; and allowing the Division of Health Care Finance and Policy (DHCFFP) to review provider contracts and presumptively disapprove provider rate increases above a certain threshold.² After a hearing, the health care portions of the Governor's bill were redrafted and reported favorably by the House members of the Joint Committee on Health Care Financing, but the bill did not advance further in the House. Although the Governor's proposed legislation was not ultimately adopted by the Legislature, it along with emergency regulations issued by DOI did start the conversation and many of its ideas served as the precursor to Chapter 288 of the Acts of 2010.³

Acknowledged as the first part of a two-phase plan, the short term small business cost con-

tainment bill handled by Senate President Therese Murray's office contained many of the same concepts as the Governor's bill: open enrollment periods, reduced network products, and the regulation of insurer premiums.⁴ Absent, however, was direct review of provider contracts with insurers. The Senate President's bill contained a new assessment on providers to be used for providing premium relief to purchasers, dependent on the hospital's operating margin and percentage of private payers.⁵ After a quick passage in the Senate in May 2010,⁶ the bill was pared down in the House in July⁷ and then passed by both branches and signed by the Governor on August 10, 2010 as Chapter 288 of the Acts of 2010.⁸

Analysis of Key Provisions

Chapter 288 offers an approach for reducing the rate of increase in health insurance premiums for small businesses and individuals by requiring all health insurers offering a provider network and having 5000 or more enrollees in plans sold to small business or individuals to provide at least one reduced or tiered network product in at least one market, with premiums that are 12 percent lower than their comprehensive network products.⁹ The law also promotes wellness programs for employees, limits insurance

enrollment to specific open enrollment periods per year, prohibits certain anti-competitive provisions in provider/insurer contracts, and allows for several additional studies of the health insurance market.¹⁰ In addition, the law institutes a pilot program for bundled payments for two acute and two chronic conditions to study the transition from fee-for-service to global payments on a small scale.¹¹ Discussed below are more in-depth analyses of some of the most significant provisions of the new law.

Open Enrollment

Chapter 288 replaces Massachusetts' current continuous enrollment practice for individual health insurance with annual open enrollment periods.¹² This is a significant shift in how individuals purchase insurance in the state. In 2011, individuals that do not fall under an exception will be able to purchase insurance only from January 1 to February 15 and from July 1 to August 15.¹³ Beginning in 2012, there will be only one open enrollment period per year.¹⁴

The state adopted open enrollment to stabilize the merged insurance market and lower health care premiums. Several insurance carriers reported anecdotal evidence that individuals were jumping in and out of the merged market for the sole purpose of obtaining expensive services for a short time.¹⁵ According to the DOI's *Analysis of Individual Health Coverage in Massachusetts Before and After the July 1, 2007 Merger of the Small Group and Nongroup Health Insurance Markets*, the establishment of open enrollment periods should

lower health care premiums one to two percent.¹⁶

Chapter 288 thus balances the need to lower health care costs with ensuring that health care consumers have access to health insurance. As any limitation on buying insurance could undermine health reform's goal of universal coverage, the Legislature built on federal HIPAA protections by creating a waiver process.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) defines a class of eligible individuals who can obtain coverage at any point during the year.¹⁷ Individuals who have lost creditable coverage because of "qualifying events," such as divorce, loss of employment, aging out as a dependent child under a parents' plan, and adoption of a child, will be able to enroll in health benefits outside of the open enrollment periods.¹⁸ Individuals who do not meet a HIPAA exception will also be able to apply for a waiver through the Office of Patient Protection (OPP).¹⁹ The OPP recently outlined the waiver process in proposed regulations.²⁰ The final regulation should provide for a waiver process that protects innocent consumers as intended by the Legislature.

Premium Review (Efficiency Guarantee)

There are two provisions in Chapter 288 which seek to help consumers and small businesses realize the full value of their health insurance payments and make health coverage more affordable by controlling health care premiums: the establishment of minimum Medical Loss Ratios (MLRs)

and the expansion of a premium review process.²¹

A minimum MLR restricts the amount of premium that can be spent on administrative costs by mandating the percentage of premium a carrier must spend on medical costs. Appropriately distinguishing clinical costs from administrative expenses is essential to realizing this goal. This provision applies to all plans in the merged health insurance market.²² Chapter 288 does not provide for an open-ended categorization as medical expenses of plan activities that are of value to their enrollees or that pursues a valid health policy goal, including goals endorsed by Chapter 288. Rather, the law establishes a presumption that insurance enrollees are entitled to have 88 percent of their premiums spent on clinical health care services.²³

Chapter 288 delegates the authority to define the MLR to the Massachusetts DOI.²⁴ The DOI released emergency regulations on October 1, 2010,²⁵ which incorporate the definition developed by the National Association of Insurance Commissioners (NAIC) into the state's definition of MLR. Assuming the US Department of Health and Human Services adopts the NAIC definition, the DOI regulations will align the definitions at the state and federal level in 2011.²⁶

The NAIC definition provides a detailed distinction between the administrative and medical costs incurred by a carrier.²⁷ It also allows items that are considered to improve quality to be considered medical costs pursuant to the Affordable Care Act. The definition ensures that smaller plans

receive special consideration under the definition so that they are not disadvantaged for a random fluctuation in utilization.

Premium review also works to ensure that consumers and employers get value for their health care dollars. This is because premium review looks at all of the financial information for the company in its totality and not just by line of business.²⁸ The new standards for premium review take into account reserves and surpluses held by each of the carriers, as well as investment income on those reserves and surpluses. This information, plus other financials will also be publicly available so that consumers, consumer advocates and businesses will have actionable information. Health insurance buyers will be able to sit in on premium review proceedings and offer evidence that the premium being charged is excessive.²⁹ They will be able to provide public comment on the rates, use media to attract attention to the rates or work with stakeholders to change the health care system to lower costs for all. Chapter 288 extends DOI's premium review authority by giving them presumptive disapproval for rates charged by health insurance carriers.³⁰ The law requires carriers to refund premiums paid to subscribers if they exceed the MLR standards, if a carrier's contribution to surplus exceeds 1.9 percent, or the growth is higher than the New England medical Consumer Price Index for the previous year.³¹ The DOI will promulgate regulations in the coming months identifying the process they will follow regarding the refund. The rebates are intended as an "efficiency guarantee" to drive carriers to

be as frugal with premium dollars as possible.

The intent of the law is clear for both premium review and MLR: lowering costs for consumers and small businesses. As both premium review and MLR are implemented, Massachusetts consumers and small businesses should be confident that the products they are purchasing are priced to give them the best value.

Transparency, Uniform Reporting, and Provider Contract Prohibitions

In response to studies by the Special Commission on the Health Care Payment System, the Attorney General's Office (AGO), DHCFP, and DOI,³² the Massachusetts Legislature incorporated provisions into Chapter 288 to address shortcomings in the state's health care system, including lack of transparency regarding insurer and provider costs, rates and quality information; inconsistent reporting of this information; and anti-competitive behavior of insurers and providers around contract negotiations for rates.³³

In particular, the AGO examined the development of negotiations, contracts and payment practices between insurers and providers. The AGO found a lack of transparency, not only in the price of health care services and in the process of how prices are negotiated, but also in how value relates to price.³⁴ The AGO's report concludes, in part, that prices vary greatly for similar services and within geographic regions; price variations are correlated to market leverage, not to quality, complexity, proportion of public

payers, academic teaching status, research facility status, or hospital costs; and contracting practices between insurers and providers "reinforce and perpetuate disparities in pricing."³⁵ Unlike other consumer marketplaces for goods, such as a grocery store where similar products are lined up next to each other for easy comparison shopping, the health care market is not structured in a way that promotes informed choices. As such, the AGO outlined several recommendations to improve the current Massachusetts health care system including tracking and publishing standardized data on price and quality of health care services and providers, as well as prohibiting "insurer-provider contract provisions that perpetuate market disparities and inhibit product innovation."³⁶

Consequently, in Chapter 288, the Legislature established standardized transparency measures, annual public reporting requirements, and collection of relevant financial information that apply to insurers operating in the fully insured and public insurance markets (MassHealth, Commonwealth Care, or the Group Insurance Commission). In some cases, the law also extends to insurers and third-party administrators operating in the self-insured market. The law makes DOI and DHCFP responsible for determining uniform methodologies for calculating and reporting insurer medical loss ratios,³⁷ health status adjusted total medical expenses, hospital costs and expenses, and relative prices paid by insurers to providers.³⁸ The agencies will also collect and publicly report this information,³⁹ as well as information on premiums, plan designs, medical

and administrative expenses, and reserves and surpluses for insurers operating in the large and small group markets and the public market.⁴⁰ In addition, the law requires insurers to provide all of their members with information related to provider expenses, relative prices and quality measurements as part of their benefit policies.⁴¹ Regarding quality measurements, the Department of Public Health, in consultation with an advisory committee, must establish a “standard quality measure set” for health care providers to track and report at least annually.⁴² To encourage transparency, insurers and third-party administrators are required to submit annual financial statements to DOI on all components of administrative costs. DOI will make this information publicly available and submit a summary report.⁴³

The standardized reporting of the costs, quality, and prices of hospitals and other providers are intended to decrease marketplace ambiguity, lead to greater accountability, and help providers offer better care to patients.⁴⁴ Transparency likewise is intended to promote value-based purchasing of health care services by more informed consumers.⁴⁵ In addition, collecting insurer and provider financial information should allow for ongoing policy discussions about long-term system reform. However, there is a risk that lower-paid providers could use publicly-available pricing information as leverage to demand higher prices.⁴⁶ On the other hand, insurers could use the information about their competitors’ price relativity to try to force provider rates down.

In order to prohibit anti-competitive behavior in provider and insurer contracts, Chapter 288 introduces increased scrutiny of provider contracts by banning contract provisions that contain a guaranteed right of participation, all-or-nothing clauses, third-party parity agreements, supplemental payments without public disclosure, or no opt-out rights.⁴⁷ The law also grants expanded enforcement rights to the Commissioner of DOI for implementing these contract prohibition sections.⁴⁸

Imposing restrictions on contract practices between insurers and providers is one step forward in combating anti-competitive behavior that drives up prices in the health care market. Since insurer contracts with providers have been virtually inscrutable until the recent AGO investigation, the enhanced oversight offered by the new law is intended to increase competition and lessen the effect of market leverage. DOI, which is tasked with promulgating regulations on contracting practices, should employ broad definitions of these practices within the bounds of Chapter 288 in order to include all unwanted behaviors between insurers and providers that the Legislature intended to capture. For instance, the AGO report states that supplemental payments can have a misleading effect, because they may be part of reimbursement for a given treatment but are not part of the “unit price.”⁴⁹ Thus, the definition of “supplemental payment” in the regulation should be broad enough to include all payments made from insurers to providers that may or may not be for medical services provided. Further regulation might be needed to

prevent insurers and providers from finding loopholes to circumvent the intent of this law.

Conclusion

As the responsible state agencies complete their implementation of Chapter 288, more will be known on its effect of controlling health care costs for small businesses. However, with more still to accomplish, it is likely that this will not be the last step that policymakers in Massachusetts will take in the health care debate.

Endnotes

¹ This article represents the opinions and legal conclusions of its authors and not necessarily those of the Office of the Attorney General. Opinions of the Attorney General are formal documents rendered pursuant to specific statutory authority.

² Scot Lehigh, *Health Care Costs Burden Small Business*, BOSTON GLOBE, Feb. 5, 2010, available at http://www.boston.com/bostonglobe/editorial_opinion/oped/articles/2010/02/05/health_care_costs_burden_small_business/. See also Steven Syre, *Patrick’s Bold Stroke*, BOSTON GLOBE, Feb. 12, 2010, available at http://www.boston.com/business/healthcare/articles/2010/02/12/patricks_bold_stroke/.

³ H.B. 4490, 186th Gen. Ct. (Mass. 2010).

⁴ As a companion piece to the Governor’s proposed legislation, DOI also issued emergency regulations requiring health insurers to file their small group premium increases or changes to small group rating factors with effective dates on or after April 1, 2010, at least 30 days in advance of their effective dates along with an actuarial memorandum containing detailed financial information. See 211 Mass. Code Regs. 43.08 (2010); DOI Bulletin 2010-05. The emergency regulations also described the process the Commissioner of DOI would take to disapprove a filing. See 211 Mass. Code Regs. 43.08 (2010); DOI Bulletin 2010-05.

⁵ S.B. 2447, 186th Gen. Ct. (Mass. 2010).

⁶ *Id.*

⁷ Michael Norton & Kyle Cheney, *Senate Adopts Changes to Spur Small Biz Health Care Rate Relief*, STATE HOUSE NEWS SERVICE, May 18, 2010, http://www.statehousenews.com/cgi/as_web.exe?rev2010+D+7353595; Mass. Senate Approves Health-care Savings Plan, LOWELL SUN, May 19, 2010, available at <http://insurancenewsnet.com/article.aspx?id=191567&type=newswires>.

⁸ H.B. 4915, 186th Gen. Ct. (Mass. 2010). The House version of the bill removed the assessment on hospitals while adding a provision to help equalize the rates that providers are paid by insurers. *Id.*

⁹ 2010 Mass. Acts ch. 288.

¹⁰ *Id.* § 33.

¹¹ *Id.* §§ 5, 26-27, 32-33, 44, 57-61, 65.

¹² *Id.* § 64.

¹³ *Id.* §§ 26-27.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ One example is available at: <http://letstalkhealthcare.org/ma-health-reform/a-costly-wrinkle-in-the-merged-market/>. Accessed on October 29, 2010.

¹⁷ The report is available online at the Office of Consumer Affairs and Business Reg-

ulation website: <http://www.mass.gov/?pageID=ocahomepage&L=1&L0=Home&sid=Eoca>.

¹⁸ 42 U.S.C. § 300gg-41(b).

¹⁹ 2010 Mass. Acts ch. 288, § 26; Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 9801(f), 110 Stat. 1936, 2077 (1996).

²⁰ 2010 Mass. Acts ch. 288, § 26.

²¹ The OPP promulgated proposed regulations on December 15, 2010. These regulations were open for comment until January 10, 2011.

²² 2010 Mass. Acts ch. 288, § 25, 29-31.

²³ 2010 Mass. Acts ch. 288, § 29.

²⁴ Chapter 288 provides for an 88 percent MLR, increasing effective October 1, 2011 to 90 percent. For purposes of these comments, we will use the 88 percent that is going into effect first. 2010 Mass. Acts ch. 288, § 29-30.

²⁵ *Id.* at § 50.

²⁶ 211 CMR 147.00 is available online at the Office of Consumer Affairs and Business Regulation website: <http://www.mass.gov/?pageID=ocahomepage&L=1&L0=Home&sid=Eoca>.

²⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2718; 124 Stat. 119, (2010).

²⁸ PATIENT PROTECTION AND AFFORDABLE CARE ACT MEDICAL LOSS RATIO REGULATION § 2718 (Nat'l Ass'n of Ins. Comm'rs 2010).

²⁹ *Id.* at § 29(b).

³⁰ 2010 Mass. Acts ch. 288, § 29(e).

³¹ 2010 Mass. Acts ch. 288, § 29(c)-(d).

³² *Id.* at § 29(d).

³³ See 2008 Mass. Acts ch. 305. Chapter 305 authorized the payment reform commission to "investigate reforming and restructuring the system to provide incentives for efficient and effective patient-centered care and to reduce variations in the quality and cost of care." 2008 Mass. Acts ch. 305, § 44. Chapter 305 also required cost trend hearings to be held by DHCFP and the Attorney General's Office. 2008 Mass. Acts ch. 305, § 24. See also, M.G.L. ch. 118G, § 6½(b) (2008).

³⁴ See, e.g., RECOMMENDATIONS OF THE SPECIAL COMMISSION ON THE HEALTH CARE PAYMENT SYSTEM (2009), available at http://www.mass.gov/Eoohhs2/docs/dhcfp/pc/Final_Report/Final_Report.pdf; MASSACHUSETTS DIVISION OF HEALTH CARE FINANCE & POLICY, MASSACHUSETTS HEALTH CARE COST TRENDS PART I: THE MASSACHUSETTS HEALTH CARE SYSTEM IN CONTEXT: COSTS, STRUCTURE, AND METHODS USED BY PRIVATE INSURERS TO PAY PROVIDERS (2010), available at http://www.mass.gov/Eoohhs2/docs/dhcfp/tr/cost_trends_files/part1_system_in_context.pdf; OFFICE OF ATTORNEY GENERAL MARTHA COAKLEY, EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS: REPORT FOR ANNUAL PUBLIC HEARING (2010), available at http://www.mass.gov/Cago/docs/healthcare/final_report_w_cover_appendices_glossary.pdf [hereinafter EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS]; MASSACHUSETTS DIVISION OF HEALTH CARE FINANCE & POLICY, MASSACHUSETTS HEALTH CARE COST TRENDS 2010 FINAL REPORT, (2010), available at http://www.mass.gov/Eoohhs2/docs/dhcfp/cost_trend_docs/final_report_docs/health_care_cost_trends_2010_final_report.pdf [hereinafter MASSACHUSETTS HEALTH CARE COST TRENDS 2010 FINAL REPORT].

³⁵ EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS, *supra* note 34, at 2-3.

³⁶ *Id.* at 3-4. It is worth noting, however, that several of the AGO's conclusions are disputed by other reports including one commissioned by Partners Healthcare System, Inc.. See Paul Dreyer, Ph.D., Analysis of the Attorney General's Report Titled "Examination of Health Care Cost Trends and Cost Drivers (June 17, 2010); *but cf.* Letter from Thomas O'Brien, Chief, Health Care Division, Office of the Attorney General, to Brent Henry, Vice President and General Counsel, Partners Healthcare System, Inc. (June 25, 2010) (outlining consistent findings and conclusions of the two reports).

³⁷ EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS, *supra* note 26, at 5. Specific objectionable contracting practices include payment parity agreements, product participation provisions, "tie-in deals," supplemental payments, and growth caps. *Id.* at 40-43; MASSACHUSETTS HEALTH CARE COST TRENDS 2010 FINAL REPORT, *supra* note 26, at 7-8.

³⁸ See *infra* note 32.

³⁹ 2010 Mass. Acts ch. 288 §§ 11-12, 51-52. Section 51 requires DHCFP, in consultation with DOI, to establish a uniform methodology for calculation and reporting by carriers of health status adjusted total medical expenses of provider groups by January 1, 2011. 2010 Mass. Acts ch. 288, § 51; 2010 Mass. Acts. ch. 359, § 107. Section 52 requires DHCFP, in consultation with DOI, to establish a uniform methodology for calculation and reporting by carriers of the relative prices paid to hospitals and physician groups by January 1, 2011. 2010 Mass. Acts ch. 288 § 52; 2010 Mass. Acts. ch. 359, § 108. On December 23, 2010, DHCFP issued proposed regulations defining health status adjusted total medical expenses and relative prices as well as establishing the reporting methodology and deadlines for filing. See 114.5 MASS. CODE REGS.23.00 available at http://www.mass.gov/Eoohhs2/docs/dhcfp/g/regs/114_5_23_p.pdf

⁴⁰ 2010 Mass. Acts ch. 288 §§ 50, 53; 2010 Mass. Acts ch. 359, §§ 106, 109.

⁴¹ 2010 Mass. Acts ch. 288, § 13. Section 13 also requires DHCFP to request data from the federal Centers for Medicare and Medicaid Services on health status adjusted total medical expenses from provider groups that serve the Medicare population. *Id.*

⁴² *Id.* § 38.

⁴³ *Id.* §§ 7, 54.

⁴⁴ *Id.* § 40.

⁴⁵ MASSACHUSETTS HEALTH CARE COST TRENDS 2010 FINAL REPORT, *supra* note 33 at 26-27.

⁴⁶ RECOMMENDATIONS OF THE SPECIAL COMMISSION ON THE HEALTH CARE PAYMENT SYSTEM, *supra* note 33, at 12; EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS, *supra* note 33, at 26-27; MASSACHUSETTS HEALTH CARE COST TRENDS 2010 FINAL REPORT, *supra* note 33, at 2-3, 43-44.

⁴⁷ EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS, *supra* note 33, at 26-27; MASSACHUSETTS HEALTH CARE COST TRENDS 2010 FINAL REPORT, *supra* note 33, at 2-3, 43-44.

⁴⁸ 2010 Mass. Acts ch. 288 § 39.

⁴⁹ *Id.* §§ 18-19, 39.

⁵⁰ EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS, *supra* note 33, at 26-27; MASSACHUSETTS HEALTH CARE COST TRENDS 2010 FINAL REPORT, *supra* note 26, at 42.

How to Read Tea Leaves: CMS' Self-Referral Disclosure Protocol

by Meghan Cosgrove, Esq.

It's 5:27p.m. on Friday, September 24, 2010, and your favorite community hospital client calls your office to explain that it has just discovered a box with 22 unsigned medical director agreements from 2007. The client is panicked about the potential penalties for these unsigned agreements under the physician self-referral statute, commonly referred to as the Stark Law. Not to worry you tell the client, just yesterday the Centers for Medicare and Medicaid Services ("CMS") published the voluntary Self-Referral Disclosure Protocol ("SRDP")¹, which sets forth a process for providers and suppliers to disclose actual or potential violations of the Stark Law. The client is relieved, thanks you for your counsel, and you make it out the door in time to see the Sox-Yankees game. Over the weekend, you review the SRDP in detail and begin having mixed feelings about the advice you provided.

Overview of the Stark Law

The federal physician self-referral law was enacted in 1989 and is commonly referred to by the name of one of its sponsors, Congressman Pete Stark. The Stark Law is a strict liability statute, meaning that the government does not need to prove improper intent. The Stark Law prohibits a physician from making a referral for certain designated health services² ("DHS") payable by Medicare³ to an entity with which the physician (or an immediate family member) has a

financial relationship (ownership or compensation arrangement), unless an exception applies⁴. The law further provides that the DHS entity that receives the prohibited referral may not present or cause to be presented a Medicare claim for the item or service, and may not bill another individual, entity, or third party payor for the item or service. There are thirty-seven (37) statutory and regulatory exceptions that, if satisfied, protect certain legitimate business arrangements from scrutiny under the Stark Law.

Non-payment, therefore, is the basic penalty for violations of the Stark Law. However, where there is a knowing violation, the statute authorizes the imposition of civil monetary penalties of \$15,000 per item or service⁵ as well as exclusion from participation in federal and state health care programs. In addition, a knowing violation of the Stark Law may form the basis for liability under the False Claims Act, 31 U.S.C. §3729, *et. seq.*

Background of the SRDP

Congress required CMS, in cooperation with the Department of Health & Human Services' ("HHS") Office of the Inspector General ("OIG"), to establish the SRDP under Section 6409(a) of the Patient Protection and Affordable Care Act ("PPACA") enacted on March 23, 2010. More importantly, however, Section 6409(b) of PPACA gives the Secretary of

HHS broad authority to reduce the amounts owed by providers for Stark Law violations based on certain mitigating factors discussed in more detail below. In addition, the Secretary of HHS is required to present a report to Congress by March 23, 2012 that details the impact of the SRDP, including how many disclosures CMS receives, the types of violations, and the amounts collected.

Prior to the release of the SRDP, most providers self-disclosed actual or potential violations of the Stark Law to the OIG through the OIG's self-disclosure protocol (the "SDP"), which has been in place since 1998⁶. The OIG, however, put an end to its role as the de facto Stark Law self-disclosure channel on March 24, 2009 in its Open Letter to Health Care Providers⁷. In that letter, the OIG stated that it would no longer accept self-disclosures that involve Stark Law violations only, unless the disclosure also contained a colorable Anti-kickback Statute⁸ violation. In addition, the OIG set a minimum settlement amount of \$50,000 under the SDP.

Overview of the SRDP

The SRDP is open to all health care providers and suppliers that wish to resolve any overpayment liability for conduct that, in the reasonable opinion of the health care provider or supplier, is an actual or potential violation of the Stark Law. A provider or supplier is not

automatically prevented from using the SRDP if it is under investigation or inquiry by other governmental agencies, or is subject to a corporate integrity agreement (“CIA”) or certification of compliance agreement (“CCA”) with the OIG. Providers whose conduct raises liability under both the Anti-kickback Statute and the Stark Law should continue to disclose to the OIG through its SDP rather than through CMS’ SRDP. The SRDP, however, gave no indication that CMS will release providers who disclose under the OIG’s SDP from Stark Law liability. The SRDP is separate from the CMS Stark Law advisory opinion process, which providers should continue to use if seeking to obtain a determination from CMS as to whether an actual or potential Stark Law violation occurred.

The SRDP is silent as to whether “knowing” Stark Law violations will be accepted into the SRDP. Instead, the SRDP requires that any disclosure is made in good faith and that the disclosing party fully cooperates with CMS. Failure to work with CMS may result in a provider being removed from the SRDP, or may have a direct effect on the resolution of the provider’s overpayment liability with CMS. Once CMS reviews a provider’s disclosure under the SRDP, it may refer the disclosed conduct to law enforcement, or it may prepare a recommendation to the OIG or the Department of Justice (“DOJ”) for resolution of other liabilities raised by the conduct.

Content of SRDP Disclosure

All disclosures must be made electronically to 1877SRDP@cms.hhs.gov with an original and one copy sent to CMS by mail. Providers will receive immediate e-mail notifica-

tion of the success of the online submission followed by a letter from CMS either accepting or rejecting (e.g., due to incomplete information) the submission. Once a provider or supplier receives electronic confirmation from CMS that their SRDP submission has been accepted, the new sixty (60) day timeline to report and return identified overpayments under Section 6402 of PPACA is suspended until the provider or supplier either (i) enters into a settlement agreement with CMS, (ii) withdraws from the SRDP, or (iii) is removed by CMS from the SRDP. In addition, disclosing parties that are accepted into the SRDP and resolve their overpayment exposure through a settlement with CMS must waive their appeal rights to the claims related to the disclosed conduct.

Beyond providing the basic identifying and contact information for the health care provider or supplier, each submission must include (i) a description of the actual or potential violation(s), (ii) a financial analysis (as further described below), and (iii) a certification regarding the good faith nature of the submission. Providers are required not only to identify the nature of the matter being disclosed, but also to provide a full legal analysis of the application of the Stark Law and any applicable exceptions to the disclosed conduct. Furthermore, CMS requires providers to identify how the disclosed conduct was discovered, the provider’s history of conduct similar to that being disclosed, the existence of any compliance program the provider had in place, and a description of the corrective actions and compliance measures the provider has put into place to guard against a recurrence of the disclosed conduct in the future. In addition, the

disclosing party must describe any notices required to be provided to other government agencies as well as whether the disclosing party has any knowledge that the matter is already under investigation by another government agency.

The financial analysis requires a disclosing party to set forth the actual or potential overpayment amount based on the time during which the disclosing party may not have been in compliance with the Stark Law (the “look back period”). Importantly, CMS did not limit this retrospective review to the time frames set out in the claim reopening rules at 42 C.F.R. §405.980, *et. seq.*, (e.g. 4 years). Parties must indicate to CMS the methodology used to calculate the potential overpayment as well as whether any estimates were used in the provider’s calculation. At the recent American Health Lawyers Association (“AHLA”)/Health Care Compliance Association’s Fraud and Compliance Forum⁹, a representative of CMS indicated that the appropriate calculation under the SRDP would be the dollar amount of claims that were paid based upon prohibited referrals rather than a general calculation of the improper benefit to the DHS entity. Finally, the disclosing party must include a summary of any audit activity undertaken.

Until CMS verifies that the disclosed conduct is, in fact, a violation of the Stark Law, CMS will not accept presumed overpayments from a provider. Notably, unlike the OIG’s SDP, the CMS SRDP does not set a minimum settlement amount. However, CMS encourages providers to place repayment funds aside in an interest-bearing escrow account during the time the disclosure is pending. In addition, the SRDP is clear that providers must refund any amounts paid by beneficiaries

affected by the disclosed conduct. CMS may (but is not required to) reduce a provider's overpayment amount. Instead, CMS has indicated that it will make a case-by-case determination of whether such mitigation is appropriate based on the facts and circumstances. Factors CMS may consider in making this decision include (i) the nature and extent of the improper or illegal practice; (ii) the timeliness of the self-disclosure; (iii) the provider's cooperation in providing additional information related to the disclosure; (iv) the litigation risk associated with the matter disclosed; and (v) the financial position of the disclosing party.

Following the submission of a complete disclosure, CMS will engage in a verification and validation exercise. The nature and extent of this process depends solely on the quality and thoroughness of a disclosing party's submission; presumably a disorganized and incomplete submission will cause CMS to ask a provider more questions during the verification process. During this time, CMS may request additional financial statements, notes, disclosures and other supporting documents in order to resolve the disclosure, and providers will have at least thirty (30) days to provide the additional information. In general, CMS will not request that attorney-client privileged documents be produced, although CMS may work with a disclosing party's counsel to gain access to certain documents that may be covered by the work product doctrine should CMS deem them critical to resolving the disclosure.

Considerations for Health Care Providers and their Legal Counsel

There are many challenges posed by the SRDP that health care pro-

viders and their legal counsel should consider. Providers will have to make the decision to disclose and prepare the SRDP submission, including a complete financial and legal analysis, under a very tight 60-day timeline under Section 6402 of PPACA.

As a preliminary matter, however, prior to making a decision to enter the SRDP, an analysis should be conducted to determine whether the Stark Law does, in fact, apply to the conduct in question and, if so, whether an argument may be made that the potentially disclosed conduct fits into one of the lesser known Stark Law exceptions. For example, perhaps there is no "remuneration" as defined at 42 C.F.R. §411.351 if the benefit in question flows primarily to the DHS entity (e.g. the hospital) rather than to the physician. Alternatively, a provider could rely on the temporary noncompliance exception at 42 C.F.R. §411.353(f) if the non-compliance has not exceeded ninety (90) days, the compensation unrelated to DHS exception at 42 C.F.R. §411.357(g), the payments by a physician exception at 42 C.F.R. §411.353(h), or the isolated transaction exception at 42 C.F.R. §411.357(f). Furthermore, the six (6) month holdover protection offered by the space and equipment lease exceptions, 42 C.F.R. §§411.357(a) and (b) respectively, may also offer protection. If there is no viable argument that would protect the arrangement, disclosing providers should make sure that any legal analysis applies the Stark Law rules as in effect during the time the conduct occurred, as the analysis may differ during certain points in time. In addition, while preamble language may be helpful, ultimately the statutory and regulatory Stark Law text will

govern the liability created by the disclosed arrangement.

It is critical that the initial SRDP submission to CMS be as complete as possible, as new matters discovered by CMS during the verification process are considered outside the scope of the SRDP. Therefore, a thorough initial submission will minimize the amount of "verification" CMS has to perform. The initial submission should also be narrowly tailored, since CMS may share the information it obtains through the SRDP with the OIG and/or the DOJ. The SRDP provided no comfort to the industry as to whether the government is precluded from using statements made in a disclosure submission to CMS against a health care provider or supplier in a civil or criminal action. Therefore, disclosing providers should tread carefully to avoid outright admissions and should present clear legal arguments. This balance may be difficult to strike, as a narrow submission may cause CMS to allege that the disclosing provider is not acting in good faith.

Unfortunately, and to the dismay of the American Hospital Association ("AHA"), AHHA, and others in the industry, the SRDP does not promise or imply that CMS will reduce the amount owed for technical violations of the statute. The AHA had suggested that CMS provide a two-track process to separately dispose of technical (e.g. missing signature) and substantive violations of the statute. Instead, the SRDP does not distinguish between technical and substantive violations of the Stark Law. Nor did CMS incorporate the additional mitigating factors proposed by AHHA into the SRDP including the lack of harm to the Medicare program, or to the quality or necessity

of care provided by the disclosing party. Some in the industry hope that these considerations, while not found in the SRDP, may be taken into account by CMS during the SRDP evaluation process.

While the decision to disclose should be weighed carefully, the SRDP does provide some good news. CMS has finally been given the authority to reduce Stark Law liability, and the 60-day overpayment clock is suspended while the parties seek to resolve potential overpayment liability. In addition, use of the SRDP by providers may be viewed favorably by the OIG and/or the DOJ. The biggest benefit of the SRDP, however, is its potential to protect a health care provider from a whistleblower action, since qui tam relators are barred from bringing a case using information that has been publicly disclosed¹⁰.

It is likely that health care providers facing False Claims Act or Civil Monetary Penalty exposure, as well as those who may be subject to a whistleblower action, will be among the first to enter the SRDP in the hopes of minimizing their liability. Less certain is whether health care providers and suppliers with arguably technical violations of the Stark Law, such as the community hospital described above, will disclose or make the calculated risk to avoid self-disclosure. For providers with a potential substantive Stark Law issue, perhaps seeking a formal determination as to whether a violation exists through an advisory opinion is the best course of action, as there is no indication that an unfavorable advisory opinion precludes using the SRDP at a later date. A provider's decision whether to disclose and to whom – CMS or a Medicare Administrative Contract-

tor, the OIG under its SDP, or the DOJ – should be made carefully in order to balance the considerations discussed above.

Endnotes

¹ While the SRDP was published on the CMS website on September 23, 2010 at http://www.cms.gov/PhysicianSelfReferral/65_Self_Referral_Disclosure_Protocol.asp#TopOfPage, the agency has yet to publish the SRDP in the Federal Register. Many suspect that CMS will give the industry an opportunity to comment on the SRDP at that time.

² Originally the law applied only to clinical laboratory services but was later expanded to include eleven other categories of designated health services, including inpatient and outpatient hospital services.

³ CMS has reserved the issue of how to extend the application of the Stark Law to the Medicaid program for a future rulemaking, as most recently stated in the Stark Law Phase II preamble. 69 Fed. Reg. 16054, 16055 (March 26, 2004).

⁴ 42 U.S.C. §1395nn.

⁵ Civil monetary penalties of up to \$100,000 may be imposed for "circumvention schemes."

⁶ 63 Fed. Reg. 58399 (October 30, 1998).

⁷ <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>

⁸ 42 U.S.C. §1320a-7b(b).

⁹ Stark in the Dark and Out of the Closet: the Discovery of Unintentional Violations and the New Potential for Voluntary Disclosure, J. Kass, S. Clifton, and T. Barsky (September 27, 2010).

¹⁰ 31 USC 3730(e)(4). Under Section 1303(j)(2) of PPACA, the public disclosure bar is no longer a jurisdictional defense to a False Claims action. As such, the court will grant a defendant's motion to dismiss on public disclosure grounds unless the government objects.

The Future of Health Care: Medical-Legal Partnership for Health Act

By Justin Fitzgerald, Esq.

The connection between poverty and health is typically understood in terms of access to proper health care.¹ Poor people may have difficulty improving their health because they don't have health insurance or they can't access quality health services.² But the connection between poor health and economic, social and environmental factors is far more complex than that and has often been overlooked by our health care and legal systems.³

In an effort to better understand this complex connection, Congress has taken a closer look at the problem. In so doing, Congress has found that numerous studies and reports document extensive health disparities across the country.⁴ These studies have found that racial and ethnic minorities and low-income populations are disproportionately afflicted with chronic and acute conditions such as asthma, cancer, diabetes, and hypertension and suffer worse health outcomes, worse health status, and higher mortality rates.⁵

Congress also noted that several recent studies show that health and healthcare quality are a function of not only access to healthcare, but also the social determinants of health, including the environment, the physical structure of communities, socio-economic status, nutrition, educational attainment, employment, race, ethnicity, geography, and language preference, that directly and indirectly affect the health, healthcare, and well-

ness of individuals and communities.⁶

Further, many of these social determinants are directly intertwined with unmet legal needs. Unfortunately, individuals and families on low incomes cannot on their own successfully challenge these situations and therefore many unlawful, and unhealthy, situations persist.⁷ Consequently, these social determinants adversely affect patients by undercutting the effectiveness of drugs and other treatments prescribed to improve their health.⁸ An illness, caused by an individual or family being forced to choose between food and heat in the winter months, will not be prevented or treated with a prescription or a vaccination.⁹ Similarly, someone with asthma will never breathe symptom free, no matter how much medication is administered, if he or she returns from the doctor's office to mold-infested housing.¹⁰

Therefore, it is becoming apparent that there is more involved in maintaining a patient's health than what a doctor alone is able to provide. The seemingly once unrelated policies of medicine and law may be the perfect combination in maintaining a patient's well-being. Formally integrating medical and legal professionals in the health setting may more effectively address the health needs of vulnerable populations and ultimately reduce health disparities¹¹ by implementing preventive law and avoiding legal crises that have health effects.¹²

THE SOLUTION

The concept of integrating the medical and legal professionals in the health care setting is not a new idea. Arguably, the transformation resulting from such integration is well under way and medical-legal partnerships may soon become a staple in future health care. Nearly two decades after being founded at Boston Medical Center by Dr. Barry Zuckerman, medical-legal partnerships have developed from local functions to a nationally recognized program. All over the United States, healthcare providers who take care of low-income individuals and families are partnering with legal professionals to assist them in providing better quality of healthcare.¹³ Currently, there are 85 medical-legal partnerships in operation in 38 states.¹⁴ With over \$8 million in public and private funding¹⁵, these medical-legal partnerships support more than 200 hospitals, clinics, and health centers.¹⁶ They help vulnerable patients with situations that involve substandard housing, discrimination, elder abuse, or problems accessing disability, Social Security, health, or veteran's benefits.¹⁷

In a medical-legal partnership, health care staff at hospitals, clinics, and other sites are trained to screen for health-related legal issues, refer the patient to an affiliated lawyer or legal services team as necessary, and to work with the attorney to resolve problems that impact patient health.¹⁸ Medical-legal partnerships assist patients with securing health care and other

public benefits, addressing housing issues and family problems, and other concerns that can affect one's health and are often more successfully remedied through legal, rather than medical, channels by helping patients navigate complex government, legal, and service systems in addressing social determinants.¹⁹

The value of medical-legal partnerships is threefold. They may generate increased revenues for health centers by assisting eligible patients with obtaining public insurance coverage or helping to reinstate coverage for those patients who lost Medicaid for varying reasons.²⁰ They may also generate increased revenues by mitigating claim denials on behalf of health centers by helping to navigate the varying payment rules for Medicaid, Medicare, and CHIP.²¹

In addition, medical-legal partnerships can benefit patients directly by providing legal services that address the complex social issues they face.²² Such benefits can translate into reduced medical debt, less stress, increased access to preventative medicine, and improved general well-being, all factors associated with better health outcomes.²³

Further, medical-legal partnerships can reduce overall costs by reducing the number of emergency room visits and hospitalizations.²⁴ The average emergency room visit costs \$1,038, and the average cost per day of a hospital stay is \$5,217.²⁵ Preliminary data from an ongoing pilot study in Boston shows a 50% decrease in Emergency Room visits following an intervention by a Medical-Legal Partnership.²⁶ This pilot study illustrates the potential to bring significant cost savings to patients, health systems, and tax payers by preventing poor health and

illness resulting from the unmet basic needs, which in turn keeps patients from costly emergency room and hospital visits.²⁷

THE BILL

A bipartisan coalition of lawmakers is looking to build on the movement of linking medical providers with attorneys as a way to help patients through the health care process, avoid preventable medical conditions and reduce health care costs.²⁸ Legislation introduced in both the U.S. House of Representatives and the U.S. Senate on July 29, 2010, the Medical-Legal Partnership for Health Act, calls for \$10 million to be set aside each year for five years (2011-2015) to fund medical-legal partnership demonstration projects around the country and to study whether they improve health and reduce health care costs for hospitals and clinics.²⁹ The bill is the first federal legislation to address the issue of medical-legal partnerships.

The bill seeks to support and advance opportunity for medical-legal partnerships to be more fully integrated in healthcare settings nationwide; to improve the quality of care for vulnerable populations by reducing health disparities among health disparities populations and addressing the social determinants of health; and to identify and develop cost-effective strategies that will improve patient outcomes and realize savings for healthcare systems.³⁰

To be eligible to receive funds under the bill, an entity must be an organization experienced in bridging the medical and legal professions on behalf of vulnerable populations nationally, and submit an application demonstrating that the applicant has experience in bridging

the medical and legal professions or a strategy or plan for cultivating and building medical-legal partnerships.³¹

The bill also contains directives on permissible uses of funds. Any amounts received under the bill must be used to assist patients and their families to navigate health-related programs and activities for purposes of achieving one or more of the following goals:

- Enhancing access to healthcare services;
- Improving health outcomes for low-income individuals;
- Reducing health disparities among health disparities populations;
- Enhancing wellness and prevention of chronic conditions and other health problems;
- Reducing cost of care to the healthcare system;
- Addressing the social determinants of health; and
- Addressing situational contributing factors.³²

In addition to the permissible uses listed, the bill places certain restrictions on the use of funds. No funds received may be used for the following purposes:

- Any medical malpractice action or proceeding;
- To provide any support to an alien who is not a qualified alien or a nonimmigrant under the Immigration and Nationality Act or an alien who is paroled into the United States under such Act for less than one year
- To provide legal assistance with respect to any proceeding or litigation which seeks to procure an abortion or to compel any individual or institution to perform or assist in the performance of an abortion

- To initiate or participate in a class action lawsuit.³³

Overall, the bill will help support an additional 60 medical-legal partnership demonstration sites in community health centers, the Veterans Administration, hospitals, and other health care settings.³⁴ These additional medical-legal partnership sites will seek to save health care costs, support a healthier workforce,³⁵ and support hospitals and attorneys partnering to solve local problems.³⁶

Upon completion of the demonstration projects, data will be collected on the effectiveness of the programs and a report will be submitted to Congress. The report will include an evaluation of the program outcomes and recommendations on whether the programs funded achieved the purposes described above.³⁷

CONCLUSION

Medical-legal partnerships have emerged as a key strategy to combat health disparities by recognizing and addressing the non-biological factors that profoundly influence health.³⁸ They can be a highly valuable service to both health centers and their patients.³⁹ The current bill is another step in the continued development of medical-legal partnerships. The demonstration projects funded by the bill will allow Congress to study the benefits of medical-legal partnerships and determine whether they are wise investments for the future. If the demonstration projects prove to be promising, medical-legal partnerships could see broad expansion throughout the country and someday become the standard practice for effective healthcare. The full text of the bill and up-to-date details on its progress can be found at the

National Center for Medical-Legal Partnership website (<http://www.medical-legalpartnership.org/>).

Endnotes

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- 3 *Id.*
- 4 Medical-Legal Partnership for Health Act, H.R. 5961, 111th Cong. § 2(a)(1) (2010).
- 5 *Id.* at § (2)(a)(2).
- 6 *Id.* at § (2)(a)(3).
- 7 See Barry Zuckerman et al., *Medical-Legal Partnerships: Transforming Health Care*, *The Lancet* (November 8, 2008) available at <http://www.medical-legalpartnership.org/sites/default/files/page/Medical-Legal%20Partnerships%20-%20Transforming%20Healthcare.pdf>.
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- 11 H.R. 5961 at § (2)(a)(4)
- 12 Zuckerman, *Medical-Legal Partnerships: Transforming Health Care*
- 13 H.R. 5961 at § (2)(a)(5)
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- 17 *Id.*
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35 Absenteeism and presenteeism (lost productivity due to illness-related underperformance) cost America's businesses over \$1 trillion a year. See Bayh, *Bayh, Harkin, Bond Introduce Medical-Legal Partnership*.

36 Bayh, *Bayh, Harkin, Bond Introduce Medical-Legal Partnership*.

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Health Law Briefs

by Audrey Perlow, Esq.

U.S., Ex Rel. Peter Rost v. Pfizer, Inc. and Pharmacia Corp., Civ. 03-11084-PBS (D. Mass. Sept. 14, 2010)

In June 2003, Peter Rost filed a qui tam complaint in Massachusetts District Court charging Pfizer, Inc., and Pharmacia Corporation with violating the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, through the illegal, off-label marketing of a human growth hormone that led to the submission of false claims to government health insurance programs. In September 2010, the court dismissed the claim, finding that using only one test rather than two to confirm a diagnosis prior to prescribing the drug in question did not constitute off-label use, and that pharmacies innocently submitting claims for reimbursement for drugs allegedly prescribed due to kickbacks was not a violation of the FCA under an implied certification theory.

Pharmacia Corporation, acquired by Pfizer in April 2003, manufactures and markets Genotropin, a recombinant human growth hormone.¹ Genotropin has been approved by the Federal Food and Drug Administration (FDA) for, among other uses, pediatric treatment of growth hormone deficiency (GHD) and idiopathic short stature.

Rost alleged that eight patients of one physician were prescribed the drug after the physician conducted one diagnostic test per patient rather than two before making a GHD diagnosis. The court found no evidence that two tests were required before prescribing Genotropin. Further, the court noted that even if two tests were required, there was no evidence that the defen-

dants encouraged or influenced physicians to perform only one test.

Rost secondly alleged that the defendants provided illegal kickbacks to physicians to encourage them to prescribe Genotropin, leading pharmacies to submit false claims for reimbursement to government agencies in violation of the FCA. The alleged kickbacks took the following three forms: 1) remuneration and personal benefits for physician attendance and participation at Pharmacia-sponsored events; 2) paid participation in an ongoing data surveillance study that surveys pediatric patients who take Genotropin for GHD; and 3) participation in a Pharmacia program that worked with patients, physicians, and insurers to assist in obtaining health insurance coverage for Genotropin.

Defendants are liable under the FCA if they “knowingly...cause[d] to be presented, a false or fraudulent claim for payment or approval.”² Claims may be found to be false or fraudulent either factually (i.e. involving an incorrect description of goods or services provided), or legally. False claims are legally false claims if they are found to falsely certify compliance with applicable statutes and regulations when the government conditions payment on compliance with such statutes. False certifications can be express, where the claim is accompanied by an explicit statement of compliance, or implied, where the act of submitting the claim implies compliance. Implied false certification under the FCA is a still-developing doctrine.

The court here identified the specific legal question as “whether or not the claims submitted by the innocent

third parties, the pharmacies, can be ‘false or fraudulent’ under a theory of implied certification when the drug manufacturer allegedly violated the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b, by paying kickbacks to doctors to induce them to prescribe their drugs in violation of the AKS.”³ Rost argued that the pharmacies’ implied certifications were false because the claims resulted from AKS violations by defendants and the prescribing physicians. The defendants responded that the pharmacies’ implied certification related only to the pharmacies’ own compliance and did not reach back to the defendants’ or prescribing physicians’ actions.

The court discusses how the U.S. Supreme Court has held that a person may be liable under the FCA for causing an innocent third party to submit a false claim to the government. That said, a claim is not false merely because an activity underlying the claim is false— “[i]t is the false certification of compliance which creates liability” (emphasis in opinion).⁴

The court noted that no cases were cited by the parties that “stretched an implied certification theory to reach back to impose FCA liability on a payer of kickbacks where the person who submitted the claim was innocent of wrongdoing and where a) the claim itself was not factually false; b) the claim was not legally false due to express certification of compliance with the AKS; or c) compliance with the federal statute was not an expressly stated precondition of payment.”⁵ Following other courts’ leads that the implied certification theory should be applied narrowly and with caution, the

court held that Rost's implied certification theory failed as a matter of law.

Importantly, the court recognized that in March of this year Congress amended the AKS to include language stating "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the FCA.]"⁶ While not relevant to the decision in the case at hand, this may change the analysis of similar FCA violations moving forward.

Bd. of Registration in Med. v. John Doe, 457 Mass. 738 (2010)

The Massachusetts Supreme Judicial Court (SJC) recently issued a ruling that pain management, performed by a licensed psychiatrist, is a subspecialty of psychiatry and, therefore, the patient records of psychiatrists acting in this capacity are protected under the psychotherapist-privilege set out in M.G.L. ch. 233, § 20B. Further, this "statute does not allow for a weighing of the public interest against the interests protected by the privilege," and the psychotherapist's patient records could not be subpoenaed in the case at hand.⁷

John Doe is a physician licensed to practice medicine in Massachusetts. He is board certified in psychiatry and lists psychiatry and pain management as his specialty areas. By his own admission his practice consists of just over 50% of his time spent on pain management and just under 50% of his time dedicated to psychiatry. The psychotherapist-patient privilege statute states that to qualify as a psychotherapist under the statute a physician must devote a "substantial portion of his time to the practice of psychiatry."⁸

In 2007, the Board of Registration in Medicine (Board) received information from a physician expressing con-

cern about Dr. Doe's competence. One of Dr. Doe's patients (patient A) had approached this second physician to obtain narcotics detoxification treatment. When the second physician contacted Dr. Doe to discuss the case, Dr. Doe could not verify the diagnosis of patient A, explain the prescribed medication, or comprehend the second physician's questions.

In 2008, after launching an investigation, the Board requested an interview with Dr. Doe and the medical records of patient A and 23 other patients. Dr. Doe appeared for the interview with only the records of patient A. Dr. Doe stated he believed he could disclose patient A's records because "patient A had violated a pain management agreement with Dr. Doe."⁹ Dr. Doe claimed patient confidentiality prevented him from disclosing additional patients' records.

The Board served Dr. Doe with a subpoena demanding the production of the records of all 24 patients. When Dr. Doe failed to comply the Board filed an action in Superior Court to enforce the subpoena. The Superior Court judge found Dr. Doe was not a psychotherapist within the meaning of the psychotherapist-privilege statute and that privilege, therefore, could not be claimed in this case. Dr. Doe was ordered to produce the records. The SJC then heard the case's appeal on its own motion.

The Board argued that because Dr. Doe spends most of time practicing pain management he does not devote a substantial portion of his time to the practice of psychiatry and the psychotherapist-patient privilege statute does not apply to him. However, the Board "conceded that pain management is a subspecialty of psychiatry."¹⁰ The court found the Board's stated fact that pain management is also a subspecialty of neurology and internal medicine irrelevant and

held that since pain management is a subspecialty of psychiatry Dr. Doe's entire practice consists of psychiatry. Therefore, Dr. Doe qualifies as a psychiatrist under the psychotherapist-patient statute.

In the alternative, the Board argued that it is charged with protecting the public and that even if Dr. Doe is a psychiatrist, "the psychotherapist-patient privilege must give way to the [B]oard's need to review the records."¹¹ However, the court cited numerous statutes in which the legislature has carved out exceptions to the psychotherapist-patient privilege under certain circumstances (e.g. child custody and adoption proceedings; reports of suspected child abuse and neglect) and noted the legislature "has considered the public interest to the extent it deems necessary."¹² With these explicit carve-outs as a backdrop, the court found that by the legislature declining to enact an exception to privilege in the current situation, the legislature "has resolved the conflict in favor of confidentiality."¹³

Endnotes

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- ² U.S., *Ex Rel. Peter Rost v. Pfizer, Inc. and Pharmacia Corp.*, Civ. 03-11084-PBS, slip op. at 16 (D. Mass. Sept. 14, 2010) (citing 31 U.S.C. § 3729(a)(1)(A)).
- ³ *Id.* at 19.
- ⁴ *Id.* at 20.
- ⁵ *Id.* at 24.
- ⁶ *Id.* (citing Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 199 § 6402(f)(1) (2010)).
- ⁷ *Bd. of Registration in Med. v. John Doe*, 457 Mass. 738, 739-40 (2010).
- ⁸ M.G.L. ch. 233, § 20B.
- ⁹ *John Doe*, 457 Mass. at 741.
- ¹⁰ *Id.* at 744.
- ¹¹ *Id.* at 745.
- ¹² *Id.*
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Prior to law school, Ms. Cosgrove was the Director of Project Development at the Federated Ambulatory Surgery Association in Alexandria, VA. Ms. Cosgrove received a Juris Doctorate with a concentration in Health and Biomedical Law with Distinction from Suffolk University Law School, where she was one of the Founding Editors of the *Suffolk Journal of Health & Biomedical Law*. She received her undergraduate degree in English from the College of the Holy Cross, and is licensed to practice law in the Commonwealth of Massachusetts.

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Justin Fitzgerald is a 2010 graduate of the Detroit Mercy School of Law. During law school, he was a law clerk at Berry Moorman where he evaluated business associate agreements for conformance with HIPAA privacy standards. He also clerked for the Michigan Circuit Court and Legal Aid of Western Michigan. While at Detroit Mercy, Mr. Fitzgerald was a member of the Moot Court Board of Advocates and a recipient of the CALI Excellence for the Future Award and the Sr. Emily George Public Interest Fellowship. Mr. Fitzgerald received his undergraduate degree cum laude in Political Science from Hope College in 2006.

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Georgia Maheras is the Private Market Policy Manager at Health Care For All, the state's leading consumer advocacy organization focused on quality, affordable health care for all. Ms. Maheras concentrates in the areas of Private Health Insurance, Prescription Drug Reform and Health Care Cost Containment. Ms. Maheras is a funded consumer representative to the National Association of Insurance Commissioners working in the area of exchanges, rate regulation, and medical loss ratios. Prior to joining HCFA, Ms. Maheras worked for Health Law Advocates representing low-income clients who were denied access to medically necessary health care services. Ms. Maheras was also lead counsel on the successful HCFA v. Romney case, which seeks to increase access to dental services for children on Medicaid. Ms. Maheras earned her JD from Suffolk University Law School and also holds a Master's in Theological Studies from Boston University.

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Most recently, Ms. McGowan served as a senior researcher on the House staff of the Joint Committee on Health Care Financing at the Massachusetts Legislature working on health care policy and legislation. She has also interned for several local non-profits and government agencies including Greater Boston Legal Services, Community Catalyst, and the United States Attorney's Office. She began her career in health care law representing low-income disabled clients in trials and hearings before government agencies to obtain benefits such as Social Security disability benefits, MassHealth, and special education services. Prior to working for the Massachusetts Legislature, Ms. McGowan researched and analyzed public policy related to indigent defense for The Spangenberg Group, which joined George Mason University's Center for Justice, Law and Society.

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Ms. Perlow is a graduate of Georgetown University, the Harvard School of Public Health, and Northeastern University School of Law. As a student she spent time at Partners Healthcare, Office of General Counsel; the Appeals Court of Massachusetts; Prince, Lobel, Glovsky & Tye; and the United States Senate Judiciary Committee. Prior to graduate school she was an emergency management consultant.

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