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Section Co-Chairs' Corner

We are pleased to present to you the Fall 2011 Edition of the Health Law Section's Health Law Reporter. Once again, the Health Law Reporter offers BBA members information and unique perspectives of expert practitioners, to help keep them informed of important issues and events.

In addition to our usual thanks for the hard work of our editors, authors and our peer reviewers in making this Health Law Reporter possible, we want to take this opportunity to thank two particular members of the Health Law Section. First, we thank our past co-chair, Alan Einhorn, for his two years at the helm of the section. In addition to his work on the BBA's Education Committee, Alan gave innumerable hours on behalf of the Health Law Section over the past two years. We're very glad that Alan continues to be an important contributor to our Steering Committee.

We give equal thanks, and a fond farewell, to the out-going co-editor of the Health Law Reporter, Mark Rogers. After many years of practice, Mark has made a career change and now serves as Founder and CEO at BoardProspects, Inc., where he will try to match individuals with positions on private, public, and nonprofit boards. Our thanks go out to Mark for his time and invaluable contributions.

We also welcome Alan's successor as co-chair, Leslie Joseph, General Counsel at Mt. Auburn Hospital and a long-time contributor to the Health Law Section, and Mark's successor as co-editor, David Sontag, of Beth Israel Deaconess Medical Center.

These are exciting times for health care lawyers, with new developments coming every day, from federal ACO regulations to Massachusetts payment reform initiatives. One of the best ways

to keep abreast of these issues is through the Health Law Section. For anyone who wishes to join our section, or to just contribute your talents and ideas, we invite you to do so. The Health Law Section has several committees to choose from (CLE, Communications, Membership, Legislative Update, Social Action); or you can volunteer as a speaker at one of our CLE programs or Brown Bags. All ideas for new programs, events or approaches to making our Section better are welcome.

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The Self-Evaluative Privilege: Still No More Reliable than a One-Iron

by Christopher J. Hunter, Esq.

In an era of WikiLeaks and over-sharing through social media, the notion of maintaining the confidentiality of anything seems quaint. In law, confidentiality protections have been waived or vitiated, voluntarily or under pressure, so often that for a while, the *refusal* to waive confidentiality protections was an aggravating factor in federal government criminal enforcement actions. As those who work in the health care community know, governmental expectations of self-disclosure have never been greater. Yet the need for confidentiality endures because of the earnest bedrock principle on which privileges and other confidentiality protections are built: to encourage honesty and candor, the free and full exchange of information and opinions.

Health care providers and administrators depend upon numerous privileges and confidentiality protections every day. Some are culturally sacrosanct, such as the physician-patient privilege. Others are decidedly less revered, and often honored only in the breach. Such is the case with the self-evaluative privilege, also known as the self-critical analysis privilege.

Responsible health care providers are in a continual state of self-assessment and self-improvement. Voluntary risk assessments or risk audits are key components to effective compliance programs and are, by their nature, self-evaluative. The self-evaluative privilege would seem like a logical privilege to assert during civil litigation to main-

tain the confidentiality of voluntary risk assessments and audits. Similarly, pulling a one-iron out for a long approach in windy conditions also would seem logical to the golfing cognoscenti. Often, however, neither is wise.

Elements of the Self-Evaluative Privilege

Despite a recent string of rejections of the self-evaluative privilege and continued questioning of its legitimacy, the privilege has accepted elements and at least some jurisprudential heritage.¹ A Ninth Circuit appellate decision, *Dowling v. American Hawaii Cruises, Inc.*, is often cited to identify its elements. Though even there, the Ninth Circuit was equivocal about its viability and rejected its application.

In *Dowling*, the plaintiff sued his employer under the Jones Act alleging his employer's negligence caused his on-the-job injury aboard a cruise ship.² During pretrial litigation, the defendant successfully asserted the self-critical analysis privilege to avoid producing in discovery minutes of the ship's safety committee meetings held prior to the date of the plaintiff's accident.³ The case went to trial, and a jury found that the defendant was not negligent and the cruise ship was seaworthy.⁴

The verdict did not stand. On appeal, the Ninth Circuit held that "no privilege of 'self-critical analysis' protects routine internal corporate reviews of matters related to safety

concerns[.]" vacated the verdict, remanded the case for a new trial, and ordered production of the minutes of the safety committee.⁵ "Even if such a privilege exists," the court wrote, "the justifications for it do not support its application[.]"⁶ The "justifications" or elements the Ninth Circuit identified were as follows:

- (1) "the information must result from a critical self-analysis undertaken by the party seeking protection; []
- (2) the public must have a strong interest in preserving the free flow of the type of information sought; []
- (3) the information must be of the type whose flow would be curtailed if discovery were allowed'[:...]
- (4) [the information or document must have been] prepared with the expectation that it would be kept confidential."⁷

Voluntary risk assessments by health care providers might satisfy some of these elements, but probably not all. The first element might be satisfied because voluntary risk assessments are inherently self-critical. They reveal information that presents opportunities for operational improvements or compliance enhancements, for example. The second element could be satisfied because the public is the ultimate beneficiary of health care services. As a result, the public—potential patients and payors—has a strong interest in preserving the free flow of information to encourage prompt identification of risk ar-

eas and equally prompt mitigation of identified risks.

The third element is a breakdown point, however. Too much is at stake for health care providers to forgo voluntary risk audits. A hospital or a physician network that chooses not to conduct voluntary risk audits for fear of disclosure of the results assures itself legal and reputational liability that it will learn about only *after* a patient or whistleblower sues, or the government serves a grand jury subpoena. As the Ninth Circuit observed in *Dowling*, “Organizations have many incentives to conduct such reviews that outweigh the harm that might result from disclosure. The most prominent of these is surely the desire to avoid lawsuits arising from unsafe conditions. But organizations also have a strong incentive to avoid developing a reputation for having an unsafe premises.”⁸

The fourth element—expectation of confidentiality—is fact-dependent. Finding the facts will likely reveal inconsistent internal expectations, which also could defeat application of the privilege.

Recent Rejections

Earlier this year, the self-evaluative privilege was rejected in three non-health care cases in federal courts in Pennsylvania involving voluntarily prepared documents. The decisions are reminders of the limits of the privilege and why it should not be a first or even second line of defense when trying to maintain confidentiality of voluntarily conducted risk assessments and audits.⁹

In *Craig v. Rite Aid Corporation*, a class action lawsuit in the Middle District of Pennsylvania alleging violations of the Fair Labor Standards Act (“FLSA”), the plaintiffs

sought documents relating to the defendants’ “voluntary internal assessment of their compliance with the [FLSA], labor laws, and existing bargaining agreements [which assessment] the company undertook as part of a store-level restructuring program.”¹⁰ The defendants sought to prevent discovery of documents relating to that assessment by invoking the “self-critical analysis privilege.” The court expressed skepticism as to the viability of the privilege at all, and ruled at the end of December 2010 that there was no compelling interest that would permit the defendants to refuse to produce materials relating to the internal FLSA compliance assessment based on the self-critical analysis privilege. Summarizing how other courts in the Third Circuit have viewed the privilege, the court observed “it has not been widely applied in cases such as the one at bar, where a defendant has voluntarily undertaken an internal review of its own practices and policies[.]”¹¹

In *Sabric v. Lockheed Martin*, also in the Middle District of Pennsylvania, the court reached the same conclusion in February 2011.¹² Lockheed Martin asserted the self-critical analysis privilege to try to avoid producing an internal report of a shooting death, but the court rejected the privilege and found that no compelling public interest outweighed the need of the plaintiff to have access to the internal report.¹³

Finally, in *Slaughter v. Amtrak*, a judge in the Eastern District of Pennsylvania in March 2011 rejected Amtrak’s assertion of the self-critical analysis privilege and ordered Amtrak to produce an unredacted copy of an accident investigation report to the plaintiff.¹⁴

Attorney-Client Privilege

The self-evaluative privilege is not, of course, the only option for trying to maintain confidentiality of voluntary risk audits. In two of the three cases out of the district courts in the Third Circuit, the judges expressly held open the possibility that the attorney-client privilege could preserve confidentiality where the self-evaluative privilege would not.

In *Craig*, the court noted that the defendants still might be able to avoid disclosing documents relating to their voluntary FLSA compliance assessments if the materials “are embraced by other, universally recognized legal privileges. Defendants also assert that in addition to the self-critical analysis privilege, each of the documents it has withheld from production is also protected by the attorney-client privilege, or otherwise constitutes attorney work product.”¹⁵

In *Sabric*, after rejecting the self-evaluative privilege, the court decided to conduct an *in camera* inspection of investigative reports to decide whether any material should nevertheless be redacted because it was covered by the attorney-client privilege or work-product doctrine.¹⁶

The contours of the attorney-client privilege are well-known and well-established.¹⁷ Equally well-established is the need for regulated entities such as health care providers to rely on attorneys every day in order to assess and ensure compliance with the complex regulatory structure in which they operate.¹⁸ Involving lawyers in voluntary risk assessments will, if done properly, improve the odds that the risk assessment or at least components of it will remain confidential. The ensuing robust risk assessment

and mitigation should benefit not only the health care provider, but its stakeholders as well.

Little Faith in the One-Iron

In golf, a one-iron is a very difficult club to hit. Yet some golfers remember the one time they hit a ball purely with a one-iron. As a result, they carry a one-iron in their bag and pull it out from time to time with the hope of replicating that one pure shot. They almost never do.

The same can be said of the self-evaluative privilege. Lawyers might know of the few cases where courts endorsed the assertion of the self-evaluative privilege to keep voluntarily prepared documents confidential. As a result, they raise the privilege to try to prevent disclosure of documents or information that inevitably will be characterized as harmful. It almost never works, as the trio of recent cases from the Third Circuit demonstrates.

A properly used and asserted attorney-client privilege remains the more likely way to preserve the confidentiality of voluntary risk assessments and audits. Use your one-iron only if you have no other club to hit.

(Endnotes)

1 See *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249, 250-51 (D.D.C. 1970), *aff'd*, 479 F.2d 920 (D.C. Cir. 1973) (recognizing the self-evaluative privilege concept).

2 *Dowling v. Am. Hawaii Cruises, Inc.*, 971 F.2d 423, 424-25 (9th Cir. 1992).

3 See *id.*

4 See *id.*

5 *Id.* at 426-27.

6 *Id.* at 426.

7 *Id.* at 425-26 (internal citations omitted).

8 *Id.* at 426.

9 “Voluntary” is a key modifier here. A different analysis is conducted when the self-evaluative privilege is invoked to prevent disclosure of assessments prepared pursuant to government requirements.

10 *Craig v. Rite Aid Corp.*, 2010 WL 5463292,

at *1 (M.D. Pa. Dec. 29, 2010).

11 *Id.* at *5.

12 *Sabric v. Lockheed Martin*, 2011 WL 742568, at *1 (M.D. Pa. Feb. 23, 2011).

13 See *id.*

14 *Slaughter v. Nat’l R.R. Passenger Corp. (Amtrak)*, 2011 WL 780754 (E.D. Pa. Mar. 4, 2011).

15 *Craig*, 2010 WL 5463292, at *5 & n.3. The application of these privileges was not before the court at the time.

16 See *Sabric*, 2011 WL 742568, at *3.

17 See, e.g., *United States v. United Shoe Mach. Corp.*, 89 F. Supp. 357, 358 (D. Mass. 1950) (identifying elements).

18 Cf. *Upjohn Co. v. United States*, 449 U.S. 383, 392 (1981) (“In light of the vast and complicated array of regulatory legislation confronting the modern corporation, corporations, unlike individuals ‘constantly go to lawyers to find out how to obey the law[.]’”) (internal citation omitted).

The Supreme Court Confirms First Amendment Protections for Pharmaceutical and Medical Device Manufacturers

by Ingrid S. Martin, Esq.

The Supreme Court's recent decision in *Sorrell v. IMS Health, Inc.* will have a lasting impact on the legal landscape surrounding the marketing of pharmaceuticals and medical devices. In *Sorrell*, the Supreme Court struck down a Vermont law that restricted the sale, disclosure, and use of physician prescription data in connection with pharmaceutical detailing. Writing for the 6-3 majority in *Sorrell v. IMS Health, Inc.*, Justice Anthony Kennedy declared that speech in aid of pharmaceutical marketing "is a form of expression protected by the Free Speech Clause of the First Amendment" and found that Vermont's law was an impermissible restriction on speech.¹ While the idea that pharmaceutical marketing is a form of expression may not seem remarkable, the path the Court's opinion took to reach this conclusion may have far-reaching ramifications for the health care field, including the government's ability to regulate and to forbid off-label marketing.

Background to the Supreme Court Decision

The Digital Age: Data Mining to Examine Physician Prescribing Patterns

The *Sorrell* decision grows out of technological advances in data aggregation and data mining. In the course of filling a prescription, pharmacies acquire a host of information, including the prescriber's name and address; the prescribed drug's name, quantity and dosage; and non-patient-identifiable information such as the patient's

age and gender. Third-party companies purchase this information from pharmacies and aggregate it in such a manner that it becomes possible to determine individual physicians' prescribing patterns. These third party data aggregators (or "data miners") re-sell this "prescriber-identifiable information" to pharmaceutical manufacturers. Pharmaceutical manufacturers, in turn, use this information to help with "detailing," the individual meetings between a salesperson and a physician. As the Supreme Court noted, "Salespersons can be more effective when they know the background and purchasing preferences of their clientele, and pharmaceutical salespersons are no exception. Knowledge of a physician's prescribing practices ... enables a detailer better to ascertain which doctors are likely to be interested in a particular drug and how best to present a particular sales message."²

Pharmaceutical companies are not the only parties who use aggregated prescriber data. State and federal agencies use this data to examine prescriber patterns through various Prescription Drug Monitoring Programs ("PDMPs"). For example, the Food and Drug Administration ("FDA") and the Drug Enforcement Agency ("DEA") use prescriber data to help identify prescribers who may be engaged in illegal opiate prescribing practices.³ Here in Massachusetts, the Board of Registration in Medicine examines prescribing data to help ensure that Massachusetts licensed physicians are practicing within the standard of

care.⁴ Notably, however, Vermont law at issue in *Sorrell* targeted only pharmaceutical companies. Vermont's law did not limit the use of prescriber data by government agencies, scientists, or any other entity that was not engaged in pharmaceutical marketing.

Vermont's Prescription Confidentiality Law

In 2007, Vermont sought to stop the sale of prescriber information to pharmaceutical companies through a specific provision in its newly enacted "Prescription Confidentiality Law."⁵ In Section 4631(d) of that law, Vermont prohibited the sale or use of prescriber-identifiable data if the data was to be used for marketing purposes, unless the prescriber consented to have his or her information used in such a manner.⁶ Before the Supreme Court, Vermont asserted that the law was intended to achieve two broad goals: first, to support the privacy of the doctor-patient relationship by protecting physician-patient confidentiality and reducing interference into the relationship by aggressive pharmaceutical sales personnel; and second, to reduce health care costs, which the Legislature believed were being inflated by what it viewed as improper persuasion by sales personnel.⁷

The law was challenged in two federal law suits, one brought by three data miners, the other by the Pharmaceutical Research and Manufacturers of America. Both sets of plaintiffs contended that Section 4631(d) violated their First Amendment rights and

sought injunctive and declaratory relief. The suits were consolidated and on summary judgment, the District Court upheld the law.⁸ The Second Circuit then reversed and found in favor of the plaintiffs' First Amendment claims.⁹ However, the Second Circuit's holding was in conflict with opinions by the First Circuit in *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008) and *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010), in which the First Circuit had upheld similar laws passed by Maine and New Hampshire.

The Circuit Split

Before turning to the Supreme Court's analysis, it is worth examining the difference in the opinions rendered by the First and Second Circuits. The First Circuit viewed the law prohibiting the sale of prescriber data as a restriction on conduct, not as a restriction on First Amendment speech activity.¹⁰ Judge Bruce Selya colorfully wrote that data miners "who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure."¹¹ In part because there were no pharmaceutical manufacturer plaintiffs in the First Circuit appeal, the court refused to allow its analysis to be influenced by the clear intent of these laws to impact the conversation between physicians and pharmaceutical salespeople.

In contrast, the Second Circuit concluded that the Vermont law was a restriction on speech, not merely on conduct. The Second Circuit held that the First Amendment protects "even dry information, devoid of advocacy, political relevance, or artistic expression" and that the First Amendment is in play when such dry data is "sold for profit."¹² The Second Circuit expressly

rejected the First Circuit's "beef jerky" analogy and found that Vermont's law was "clearly aimed at influencing the supply of information, a core First Amendment concern."¹³

Another critical divergence between the two Circuits was the value that the respective courts placed on pharmaceutical detailing. Although the First Circuit acknowledged that no pharmaceutical companies were a party to the litigation before it, it nevertheless expounded at some length on the effectiveness and usefulness of detailing. "In the service of maximizing drug sales," wrote the First Circuit, "detailers use prescribing histories as a means of targeting potential customers precisely and as a tool for tipping the balance of bargaining power in their favor. As such, detailing affects physician behavior and increases the likelihood that physicians will prescribe the detailers' (more expensive) drugs."¹⁴ The First Circuit accepted the view that brand-name drugs and generics were sufficiently equivalent, meaning that efforts to promote brand-name drugs over generic versions were creating unnecessary health care costs that the states could permissibly regulate.¹⁵

The Second Circuit took a more favorable view of detailing. It found that pharmaceutical companies use prescriber information, in part, "to direct scientific and safety messages to physicians most in need of that information, to track disease progression, to aid law enforcement, to implement risk mitigation programs, and to conduct clinical trials and post-marketing surveillance required by the United States Food and Drug Administration."¹⁶ The Second Circuit also was more cautious than the First Circuit about treating generic and brand-name drugs as interchangeable. It stated that "Bioequivalent generic drugs are not necessarily identical to the brand name version, but are re-

quired to demonstrate an absorption rate between 80 and 125 percent of the brand-name drug. Variations in absorption rates among branded or generic drugs may cause different reactions, such as side effects."¹⁷

It is impossible to know whether facts drove the two Circuits' divergent opinions, or whether the Circuits' differing interpretations of the law drove them to focus on different aspects of the record. There is, however, a clear interplay in the two opinions between facts, analysis, and conclusions. The First Circuit accepted the government's view that effective detailing has the negative consequence of unnecessarily inflating health care cost. It also saw the government's response as an effort to regulate economic activity, and any ancillary effect on speech was insufficient to invoke First Amendment protection. In contrast, the Second Circuit saw detailing as playing an important role in communicating medical information to physicians. It therefore was more protective of the detailers' activities and found that while the law's immediate impact was on the data miners, its ultimate impact on the dialogue between physician and salesperson was determinative.

The Supreme Court's Decision

The Majority Opinion

The Supreme Court affirmed the Second Circuit's holding that the Vermont law was an improper restriction on speech. After describing the law's operation, the Court concluded that it was plain that Section 4631(d) disfavored speech with a particular content, and that it disfavored specific speakers – pharmaceutical companies.¹⁸ As a result, the Court found that the law went "beyond mere content discrimination, to actual viewpoint discrimination."¹⁹ Unlike the First Circuit, which had focused on the law's impact on data miners, the Supreme Court's

analysis focused on the class of individuals whose speech was burdened by Section 4631(d), even though this burden was imposed through restriction on another party's activities.

The Supreme Court concluded that "heightened scrutiny" of the law was required, as in any circumstance where the government regulates speech because it disagrees with the message being conveyed.²⁰ It held that this principle applied even for "commercial speech," as a consumer's concern for the free flow of commercial speech can be "far keener than his concern for urgent political dialogue. That reality has great relevance in the fields of medicine and public health where information can save lives."²¹

This holding appears to subject Vermont's law to an even higher level of scrutiny than what had been applied by the Second Circuit. The Second Circuit had struck down the law under the "intermediate scrutiny" test for commercial speech restrictions established in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 561-66 (1980).²² The Supreme Court held that Vermont could not defend its law on the basis that it burdened mere commercial speech.²³ The Court explained that "the outcome is the same whether a special speech inquiry or a stricter form of judicial scrutiny is applied," as both the *Central Hudson* test and a more heightened form of judicial review require the State to show that the challenged statute "directly advances a substantial governmental interest and that the measure is drawn to achieve that interest."²⁴ Through this conclusion, the Supreme Court throws into question its practice of treating commercial speech as a distinct type of First Amendment activity, and seems to be moving towards a more all-purpose free speech test.

The Supreme Court then examined Section 4631(d) and concluded that even if the law were analyzed only as a restriction on commercial speech, the law was not designed to advance or achieve Vermont's stated objectives: protecting physician privacy and controlling health care costs. First, the Court rejected Vermont's claim that the law was intended to protect physician privacy, since Section 4631(d) did not prohibit pharmacies from sharing prescriber data with a host of third parties, including insurers, researchers, journalists, and the State itself.²⁵ The Court also had little sympathy for Vermont's claim that physicians felt harassed by pharmaceutical detailers. "Many are those who must endure speech they do not like, but that is the cost of freedom."²⁶ On the whole, the Court seemed to believe that detailing was not an intrusion into a physician's practice that needed to be cured; it wrote that detailing could be viewed as "beneficial speech" and that to the extent that it "affects treatment decisions, it does so because doctors find it persuasive. ... [T]he fear that speech might persuade provides no lawful basis for quieting it."²⁷

Second, the Supreme Court was not persuaded by the Vermont's argument that pharmaceutical detailing was driving up the prescription of brand-name drugs in lieu of cheaper generic alternatives. It found that silencing a viewpoint was an improper way for the government to try to influence the pharmaceutical industry. Vermont could not seek to remove popular but disfavored brand-name products from the marketplace "by prohibiting truthful, nonmisleading advertisements" for those products.²⁸ "That the State finds expression too persuasive does not permit it to quite the speech or to burden its messengers."²⁹ So long as the information that the pharmaceutical salespeople

provide is not false or misleading, it cannot be burdened simply because the State would prefer that doctors prescribe generics.³⁰

The Dissent

In his dissent, Justice Stephen Breyer disapproved of the majority's apparent dissolution of the Court's historical practice of treating restrictions on commercial speech more leniently than other types of speech restrictions.³¹ He pointed out that regulatory agencies routinely issue rules that impact speech by specific industries.³² For example, the Federal Reserve Board regulates what members of the financial industry are permitted to say in their advertising as well as in loan proposals or interest rate disclosures.³³ Under the majority's approach of applying "strict scrutiny" to any regulation that affects content and is targeted at a specific type of speaker, such regulations arguably would be at risk of violating the First Amendment.³⁴ "If the Court means to create constitutional barriers to regulatory rules that might affect the content of a commercial message, it has embarked upon an unprecedented task – a task that threatens significant judicial interference with widely accepted regulatory activity."³⁵

Turning to Vermont's law, Justice Breyer concluded that Section 4631(d) survived the traditional "intermediate scrutiny" test. He found that it worked "only modest harm" to pharmaceutical companies' ability to detail, and that the First Amendment was not offended where the data withheld from the pharmaceutical companies only existed due to a governmental mandate to collect that information.³⁶ At the same time, he found that the state's interest in the law was substantial, particularly because matters of public health are within the traditional scope of a state's police powers.³⁷ Interestingly, Justice Breyer aligned himself with the view of the

First Circuit that detailing was a questionable practice. He wrote that when armed with prescriber information, detailers succeed by “diverting attention from scientific research about a drug’s safety and effectiveness, as well as its cost. This diversion comes at the expense of public health and the State’s fiscal interests.”³⁸ Accordingly, when balancing the “modest” harm to speech against the “substantial” state interest, Breyer found that Section 4631(d) should have been upheld.

Potential Ramifications for Off-Label Marketing

Sorrell is a powerful affirmation of the right to engage in pharmaceutical marketing, an arena that has historically been subject to significant regulation and oversight by various government agencies. *Sorrell*’s holding — that the First Amendment requires “heightened scrutiny” of any regulation that burdens a specific industry’s efforts to advertise its products — is in direct conflict with the FDA’s traditionally tight control over what pharmaceutical companies and medical device manufacturers can say about their products.

The potential consequences of the *Sorrell* decision are particularly apparent in the context of off-label marketing, an area where numerous pharmaceutical companies have come into conflict with federal agencies, including the United States Department of Justice (“DOJ”). DOJ has brought criminal actions against companies alleged to be promoting drugs or medical devices for non-approved uses, arguing that such promotion is illegal promotion of “misbranded” or “new unapproved drugs” under the Food Drug and Cosmetic Act (“FDCA”).³⁹ Under this theory, such “off-label” promotion violates the FDCA because it is either “misleading” because it is used to promote the drug or device

for medical uses not approved by the FDA, or because the FDA-approved label accompanying the drug or device does not contain “adequate directions” for the off-label use.⁴⁰

The criminal defense bar has long asserted that the criminalization of truthful off-label promotion violates the First Amendment. Some holdings in civil cases offer support for this view. In 1998, the D.C. District Court accepted the argument by the Washington Legal Foundation that the FDA’s restrictions on a drug company’s ability to disseminate clinical reports about off-label uses violated the First Amendment.⁴¹ In 2002, the United States Supreme Court held that pharmacists could not be prohibited from promoting compounded drugs that were legal to sell, even if the compounded drugs had not been tested to the same level as their component drugs.⁴² *Sorrell* now strongly suggests that the Supreme Court might not countenance off-label prosecutions where the defendant had disseminated truthful off-label information. So long as pharmaceutical and medical device manufacturers make clear that their promotions are for an off-label use, and do not attempt to conceal the limits of the testing that has been done to explore the risks and efficacy of their products, *Sorrell* suggests that the First Amendment may shield their communications with physicians from government restriction. Given the extraordinarily high stakes involved in off-label prosecutions — including multi-million dollar penalties and potential exclusion from participation in federal health care programs — companies would be unwise to launch off-label promotion programs solely on the promising decisional language of *Sorrell*. However, given the DOJ’s continuing pursuit of perceived off-label promotion, this issue is likely to be addressed soon in the Circuit Courts, and eventually by the Supreme Court. The Supreme

Court’s generally positive view in *Sorrell* of the legal protections afforded to pharmaceutical detailing suggests that ultimately the FDA and DOJ’s role in overseeing pharmaceutical and medical device promotion could be substantially diminished.

(Endnotes)

1 *Sorrell v. IMS Health*, 564 U.S. ___, Supreme Court Slip Op. 10-779 at 1 (June 23, 2011) (“*Sorrell Slip Op.*”).

2 *Sorrell Slip Op.* at 2.

3 See Office of National Drug Control Policy, Press Release, “Obama Administration Releases Action Plan To Address National Prescription Drug Abuse Epidemic,” (Apr. 19, 2011).

4 See 105 CMR 700.006(J)(4)(a)(1) (granting the Board of Registration in Medicine access to the prescriber data collected as part of the Massachusetts Prescription Drug Monitoring Program).

5 Vt. Acts No. 80 (2007).

6 This provision was Section 17 of the Act; it was codified at Vt. Stat. Ann. tit. 18, § 4631.

7 *Id.*

8 *IMS Health Inc. v. Sorrell*, 631 F. Supp.2d 434 (D.Vt. 2009).

9 See *IMS Health Inc. v. Sorrell*, 630 F.3d 263 (2d Cir. 2010).

10 *Ayotte*, 550 F.3d at 52.

11 *Id.*

12 *IMS Health v. Sorrell*, 630 F.3d at 271-72.

13 *Id.* at 272.

14 *Id.* at 54.

15 See also *Ayotte*, 550 F.3d at 46 (describing generics as “pharmacologically indistinguishable from their brand-name counterparts save for potential differences in rates of absorption”).

16 *IMS Health v. Sorrell*, 630 F.3d at 267.

17 *Id.* at 268.

18 *Sorrell Slip Op.* at 8.

19 *Id.* at 9.

20 *Sorrell Slip Op.* at 8.

21 *Sorrell Slip Op.* at 11.

22 *IMS Health v. Sorrell*, 630 F.3d at 273, 275-82.

23 *Sorrell Slip Op.* at 16.

24 *Id.*

25 *Sorrell Slip Op.* at 17-18.

26 *Id.* at 20.

27 *Id.* at 21.

28 *Sorrell Slip Op.* at 22.

29 *Id.*

30 *Id.* at 24.

31 *Sorrell Slip Op.*, dissent, at 4-5.

32 *Id.*, dissent, at 9-10.

33 *Id.*

34 *Id.*

35 *Id.*

36 *Sorrell Slip Op.*, dissent at 14-16.

37 *Sorrell Slip Op.*, dissent at 17.

38 *Id.*, dissent, at 18.

39 See 21 U.S.C. §§ 331, 333, 352, 355.

40 See 21 U.S.C. § 352.

41 See *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998).

42 *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

Visible Hand-to-Hand Combat: Attorney General and the DHCFP Cost Containment Hearings: Addressing Market Pricing Trends

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Since the topic of cost containment became ubiquitous in discussions of health care reform, Massachusetts has established several initiatives for investigating and recommending cost containment strategies. With its roots in market economics and regulatory policy, cost containment has become a beacon of hope for those concerned about Massachusetts' health care cost inflation.¹ On June 22, 2011, the Attorney General's Office published its *Examination of Health Care Cost Trends and Cost Drivers Pursuant to G.L. c. 118G, § 6½(b)*, which presented its findings after years of collecting data on pricing trends in the health care market.² What the Attorney General's Office has found in its studies may surprise some economists and policy experts: popular cost containment strategies have not produced the desired effects. The Attorney General has recommended increased government regulation and incentives to encourage care management by providers, both of which may present new challenges, opportunities, and legal issues for health care entities.

This article examines the troubling implications of the most recent cost containment findings and summarizes the recent discussions of lawmakers, who plan to address the Attorney General's findings through further regulation. First, this article will provide a background of post-reform cost containment strategies

and reports. The next section will give an overview of the most recent data on pricing, as presented by the Attorney General and recent hearings on cost containment. The third section of this article will consider the proffered regulatory responses to price inflation, especially price caps. This article aims to explain to health care attorneys the current mixed feelings of Massachusetts lawmakers towards payers and providers and to prepare counselors for a new wave of regulatory measures directed at pricing and contracting practices.

The Cost Containment Initiative

As a part of health care reform in 2006, the General Assembly established the Health Care Quality and Cost Council (HCQCC) under the umbrella of the Executive Office of Health and Human Services (EO-HHS) to hold regular hearings and make recommendations on cost and quality strategies.³ In 2007, the General Assembly recognized that rising costs and price inflation would be the greatest barriers to the success of health care reform. With so many theories as to which factors affect prices the most, the General Assembly empowered the Division of Health Care Policy and Finance (DHCFP) to explore cost containment strategies through a series of hearings and reports in concert with the HCQCC.⁴ In 2008, the General Assembly went a step further and gave the Attorney Gen-

eral the responsibility of executing civil investigative demands (CID's) and publishing reports on the cost data collected, to be publicly presented to the HCQCC and DHCFP.⁵

After three years of hearings and data collection, the HCQCC its final "Roadmap" report in 2009 and concluded that implementing certain cost control measures could cut the growth of health care costs by roughly one third, as compared to the projected growth path by 2020 without such measures.⁶ The Roadmap proposed payment reform, quality-based payments, increased preventative measures, and simplified administration, among other items, in order to slow the growth of health care costs.⁷ HCQCC described payment reform as a "long-term strategy" and suggested that the state should encourage the immediate implementation of global payment systems, which pay providers a lump sum for the total health care costs of a beneficiary rather than a single payment per unit of service.⁸

In the report of DHCFP's Special Commission on the Health Care Payment System, the Special Commission endorsed global payments and quality-based payments as tools for slowing the rate of increase of costs of health care and improving quality.⁹ The Special Commission explained the tangible benefits of provider alliances in accountable care organizations

(ACO's) and their potential for coordinating the transition to global and quality-based payments.¹⁰ This report, along with another provided by the RAND Corporation, indicated that there could be financial incentives built in to such a system to encourage quality and access, even though the overall goal would be cost reduction.¹¹ When compared to the current fee-for-service (FFS) scheme, alternate payment systems could reward doctors and reduce costs at the same time.

With such a bright outlook on future cost reductions, "global payments" and "accountable care" became buzz words in the cost containment forum, and the economic models suggested that these modified payment structures would directly result in a flatter growth curve.¹² However, in January 2010, the Attorney General reported that the current payment reform systems had not yet reflected any tangible cost savings and instead presented some "serious system-wide failings" as indicated by the data.¹³ The Attorney General was blunt in its preliminary report: pricing in health care markets was directly correlated to market leverage of the contracting providers and payers, while price was not correlated to quality of care, population sickness, or even hospital costs.¹⁴

In March 2010, DHCFC presented similar testimony on its data analysis of health care markets dating back to 2004.¹⁵ Massachusetts's adjusted health care spending per capita was 27% higher than average spending in the United States.¹⁶ Both the Attorney General and DHCFC concluded that there were still many incentives for payers and providers to increase prices while there was "limited pressure" to decrease prices.¹⁷ The

result was, according to the Attorney General's report, a "distorted" market essentially controlled by the five major health insurance companies, which make up 70% of the market in Massachusetts.¹⁸

In May 2011, DHCFC published a report on cost trends among insurers in Massachusetts, and on June 22, 2011, the Attorney General's office published its final report on market cost trends.¹⁹ The Attorney General's final report presented a more comprehensive snapshot of pricing in the health care market and renewed its criticisms of current contracting practices that created a "dysfunctional" market.²⁰ DHCFC's publication also confirmed that premiums in Massachusetts are increasing at a greater rate than the national average because of market distortions.²¹ Even without necessarily assigning blame for the market's inherent "dysfunctions" lawmakers have noted that change must begin with certain market participants—the large hospital systems and the five major health insurers—who control a vast majority of the market and therefore the pricing trends.²²

In the last week of June, DHCFC held its annual meetings in which these recent reports and possible solutions were the main focus. Knowing that popular strategies have not been successful in reducing costs, the Attorney General's reports and the recent DHCFC hearings have presented explanations of the market dysfunction, and painting a less than flattering picture of payers and providers in Massachusetts. While the words "antitrust" and "oligopoly" do not feature in these reports, they appear to be on tips of some tongues.

Report Findings: A Visible Hand

The Attorney General's and DHCFC's reports present the same basic findings: health care costs in Massachusetts are rising at a rate higher than inflation and higher than the rate of national health care costs. For the period between 2007 and 2009, premiums increased by roughly 5 to 10% per year, according to DHCFC, and individuals in smaller group markets paid more per month than their counterparts in larger markets, as measured by adjusted premiums.²³ Among the seven major findings of the report, the overarching theme is that large market participants are setting prices, resulting in a market that is unresponsive to quality, actual cost, actual risk, patient needs, and payment systems.²⁴

The Attorney General's report confirmed that much of what the HCQCC, health policy experts, and economists suggested about payment reform was wrong. And, according to the Attorney General's Office, there is a simple explanation: the market power of a few key players has created price inelasticity through private contracting arrangements.²⁵ Instead of bringing prices down through competition and incentivized payment systems in a "free" market, contract negotiations between large payers and large providers have distorted the effects that those free market motivators would have on price.²⁶

Global Payment Contracts

Among the providers receiving the most scrutiny in the Attorney General's report are those that have implemented global payment systems without affecting a positive change in cost control. In fact, there were a handful of large provider systems that implemented

global payment compensation over four years ago, and the Attorney General's data reflected surprising increases in total medical expenses (TME), measured per member per month (PMPM) and adjusted for certain population differences.²⁷ Though there may be some rationale to the increased pricing due to factors like the "agency costs" associated with provider risk-sharing, the Attorney General's report suggests that the price increases are the result of deliberate contracting practices.²⁸

The Attorney General's data indicate that some of the most expensive providers in the state have been operating under global payment systems with the major insurance companies Blue Cross Blue Shield of Massachusetts (BCBSMA), Tufts Health Plan (THP), and Harvard Pilgrim Health Care (HPHC).²⁹ For some of these providers with global contracts, the TME as measured on a PMPM basis have increased by more than 30% between 2008 and 2009. Further, the pricing for services of these providers is often 140% to 160% of the average reimbursement rate.³⁰ These alarming numbers speak for themselves and need no further analysis to convey their intended message.

Alternative Quality Contracts

The Attorney General presented similar data indicating that BCBSMA's alternative quality contracts (AQC's) have also resulted in a short-term increase in TME, rather than encouraging a decrease in spending through care coordination and rewarded quality payments.³¹ Though the Attorney General's office only has data for AQC's operating in 2008 and 2009, the report includes a projected TME for the next three to four years to predict whether the AQC can achieve cost savings over five years, as suggest-

ed.³² In the short term, AQC's have resulted in an increase in TME by 5.4% to 17.6% for providers who have implemented such contracts, as compared to non-AQC providers, whose average TME increase was 1.7% for the same period.³³ Given that the average growth for non-AQC's was 1.7% in 2008-2009, the Attorney General has suggested that the rate of TME growth will actually be significantly higher for AQC's over the next three years, though there is some dispute over this projection.³⁴ The Attorney General concludes that the use of AQC payment systems without any further regulation will not likely result in reduced TME growth over a five-year period.³⁵

Medical Spending Variations by Beneficiary Income

The Attorney General organized its data by geographic location to determine if location had an effect on pricing.³⁶ Using information from the Internal Revenue Service (IRS), the Attorney General was able to calculate the average income of each zip code, and when comparing that average income to the average TME for that zip code, the Attorney General found a direct relationship between level of average income and the amount spent PMPM.³⁷ Across the board, the TME spent PMPM for the wealthiest populations was roughly \$120 higher than the average TME spent PMPM on the poorest populations of the state.³⁸ Thus, even when controlling for many factors, a health plan spends far more on the health care of the wealthy than it spends on the health care of the poor.

The conclusion—that health plans spend more on the wealthy—does not address the lingering question of what factors actually cause the increased TME for the wealthy.

The Attorney General notes that increased spending on the wealthy may be a result of conscious choices made by the wealthy beneficiaries reflecting their more expensive tastes.³⁹ Considering the unexplained aspects of the data, the Attorney General recommends focusing on incentives or regulation that could discourage the resulting discrepancy, such as a relative price variation caps.⁴⁰

Lasting Lessons, Lingering Questions

To round out its findings, the Attorney General offers three key "lessons" gleaned from its interviews with sixteen different providers that vary greatly in size, location, and structure. First, the Attorney General concludes that there is no single structure that spells cost-efficiency: a small independent practice can achieve efficient care management and patient satisfaction without a corporate management team.⁴¹ This conclusion suggests that a big push for ACO's and other structural reforms to increase care coordination may be misguided. If a provider of any size can effectively manage its patients and reduce administrative costs, this is evidence that lawmakers should not be focusing on the structure of providers and networks.⁴² Rather, lawmakers should be looking for ways to encourage providers of all sizes and kinds to continue innovating.

Second, global payment systems require substantial start-up costs that may not be affordable for smaller providers, and providers may overestimate the risks associated with their particular patient base, resulting in higher TME.⁴³ This conclusion comes close to admitting that when weighing the real costs and hypothetical benefits of

global payments, lawmakers may be setting up the system for, at the very least, short price increases. Not surprisingly, in larger providers who did have the capital to implement global and quality-based payments, prices did increase across the board, as discussed above. This second “lesson” suggests that policy-makers made their own bed when it comes to price inflation.

The third lesson is that providers and insurance companies themselves could better address their cost problems if they had more information about the market in areas like system-wide overutilization or practice patterns.⁴⁴ Lawmakers expect providers to understand system-wide problems, yet many providers who are expected to act as coordinators and gate-keepers are isolated and self-reliant. The Attorney General makes a sound point that increasing access to aggregate system information could inform more decisions. However, because most providers are focused on their individual practice’s needs and the aggregate data may not be relevant to complex cases in real settings, more information about the market at large will not alleviate those physicians’ day-to-day problems.⁴⁵

Implications: Hand-to-Hand Combat

The Attorney General uses the term “dysfunction” to highlight one of the major issues in cost containment: the strategies proposed by experts have not been successful. And, in some instances, those strategic mechanisms have backfired, resulting in price spikes. Because the Attorney General has framed current discussions of market conditions in terms of correctable market “dysfunctions” caused by deliberate contracting practices,

lawmakers will respond by identifying the variables that created the dysfunction and eliminating their influence. As a preliminary measure, the state will likely engage in regulation of contracting practices and premium or payment pricing.⁴⁶

Attorney Regulatory

The Attorney General provides six recommendations for addressing the market dysfunction evidenced by its report. Those recommendations can be divided into two basic categories of carrots and sticks: behaviors that the Attorney General wishes to encourage and those that it wishes to discourage through regulation.⁴⁷ Having found that tiered and limited network plans produce actual savings to their beneficiaries, the Attorney General suggests that the government should encourage these kinds of plans in some way.⁴⁸ Further, because PCP coordination appears to be the most cost-effective management style regardless of provider structure, the Attorney General would similarly recommend encouragement of PCP use and increased government funding for care management.⁴⁹

On the other hand, there should be more statutory restrictions on the market, and the Attorney General suggests beginning with a temporary restriction on price variations to “moderate price distortions without price setting.”⁵⁰ Using the existing all-payer claims database (APCD), the Attorney General believes that the government should be more aggressive in collecting data, publishing reports, and standardizing information to make pricing and utilization information available and presumably to increase accountability.⁵¹ Finally, to address the major report findings on global payments and AQC’s,

the Attorney General suggests increased regulation of these contracts in a manner similar to the regulation of insurance contractors.⁵² The DHCFP hearings and other recent development indicate that price regulation is the likely response.

General’s Recipe

DHCFP Annual Meeting Give Some Hints

1) Price Regulations from the DOI

At the DHCFP hearings in late June, the Division of Insurance (DOI) Commissioner, Joseph G. Murphy, introduced his proposals for further regulation of health insurance companies to address price inflation.⁵³ Commissioner Murphy noted the previous successes of the DOI in saving consumers \$100 million by disapproving rate increases, and he suggested that the DOI could do more to stabilize costs if the General Assembly granted even more authority to the DOI.⁵⁴ Commissioner Murphy did not discuss the push-back from health plans during the previous period of aggressive DOI rate disapproval and the DOI’s difficulty in accomplishing its price regulation goals.⁵⁵

The DOI has disapproved rate increases for many health plans, but the DOI’s disapprovals did not have their intended effect because insurers like HPHC won their appeals on the grounds that the insurers had some “valid reasons” for increasing their premiums.⁵⁶ Under the current law, the DOI is limited in its ability to unilaterally cap insurance premiums.⁵⁷ Commissioner Murphy seeks the greater authority to disapprove rate increases based on factors like “inefficient systems of care” and “excessive levels of provider reimbursement,” both of which are addressed in the Governor’s bill, filed in February 2011.⁵⁸

Thus, one of the most immediate effects of these reports could be new restrictions on pricing of insurance products and provider reimbursement rates because the General Assembly may be more likely to agree with the Governor and the DOI that a price ceiling is a valid mechanism by which to weaken insurers' pricing practices.⁵⁹

2) Price Regulation to Weaken Insurers' Hand in the Market

Testimony at the annual hearings confirmed that price restrictions are not merely a possibility but are rather one of the key strategies for curbing the price inflation caused in part by deliberate contracting practices.⁶⁰ From the perspective of insurers, the providers' "increased costs" account for up to 75% of the health plans' hike in premiums, indicating that insurers are merely increasing their premiums to reflect the providers' demands.⁶¹ According to the Assistant Attorney General's presentations at the annual hearings, more than half of aggregate TME inflation for the health care market was the result of nominal pricing increases by insurers.⁶² There is apparently little trust between large insurers and providers that premium and price inflation are the result of legitimate cost increases.

Echoing the Attorney General's reports, the Assistant Attorney General encouraged the use of systems that will discourage expensive taste, but price regulation was the most specific regulatory suggestion.⁶³ Because there is evidence that price variation does not correlate strongly to quality of service or location factors, lawmakers are more likely to see the price problem as an artificial parity that can be addressed with a similarly artificial downward pricing pressure: price caps.

To further support this end, DHCFCP presented further data on price variations among Massachusetts hospitals and concluded that hospitals were not setting their rates at higher levels for the purpose of off-setting lower Medicare or Medicaid rates, as many hospitals have previously claimed.⁶⁴ Other recent studies predict that powerful providers could shift their increased costs onto private payers, without demonstrating that the cost increases were either necessary or correlated to increases in cost.⁶⁵ These reports paint a picture of untrustworthy large providers who have little incentive to cut their costs when they can simply push those costs onto payers who have relatively less bargaining power.⁶⁶ And, policy-makers rely on these reports as they formulate new laws.⁶⁷

A series of graphs from DHCFCP suggested that there is no correlation between quality of services versus the wide variety of charged rates for these services.⁶⁸ This presentation emphasized the annual hearings' focus on pricing and the stakeholders' ability to set "artificial" prices that do not reflect value. As one of the Attorney General's most concrete recommendations from the final report was price regulation, providers and payers should expect to see either relative price restrictions, premium caps, or increased medical loss ratios. Providers will need to reexamine their rationale for charging such variable rates among payers and should expect further scrutiny from the Attorney General and DHCFCP if variable rates continue.

3) DHCFCP's Own Case Against Price Caps

Despite the benefit of nearly \$5 billion in savings for freezing insurance premiums and provider

reimbursements, DHCFCP has previously found that the downside of such aggressive price regulation would far outweigh the \$5 billion savings.⁶⁹ The result could be highly unstable insurance companies that cannot adequately cover their risk or maintain the surpluses required by law.⁷⁰ Both the Massachusetts Hospitals Association (MHA) and Massachusetts Medical Society (MMS) have strongly opposed the suggestion of price regulations, stating that price fixing has not worked in the past and the market needs more time to experiment with payment reform.⁷¹

When the DOI disapproved rate increases in 2010, the Massachusetts Association of Health Plans (MAHP) sought an injunction to prevent Commissioner Murphy from enforcing those disapproval, illustrating MAHP's willingness to challenge the DOI.⁷² The judges in those appeals found that the DOI did not have concrete or adequate grounds for disapproving the rate, which a future court might find even with expanded DOI discretion.⁷³ Nevertheless, the discussions of rate-setting at the annual hearings and the possibility of increased DOI power via the Governor's bill illustrate that rate regulation is no longer out of the question, despite DHCFCP's own arguments against price ceilings in the past.⁷⁴

4) Further Payment System Reforms

Other speakers at the hearings supported further payment reforms that could better address rising costs, though there were no new or detailed proposals for payment reform.⁷⁵ The Attorney General's office explained how global payment contracting should work and how current global payments have not achieved intended results (yet),

while DHCFF recommended that more providers entertain the use of bundled payments.⁷⁶ In DHCFF's model, bundled payments achieve cost savings that global payments cannot, because the provider is not saddled with as much risk.⁷⁷ These presentations did not explain how bundled payments could avoid the price inflation that global contracts experienced.

Other experts suggested that global payment systems are an adequate model for cost containment, but without an ACO to manage the delivery of care, the integrated provider will not actually be able to reduce administrative costs and encourage cost savings. Nancy Kane of Harvard's School of Public Health and Cathy Schoen of the Commonwealth Fund suggested that regardless of the payment system, the daily transaction costs associated with any current non-ACO are so high that payment method may have little effect on cost inflation.⁷⁸ Testimony from the Attorney General's office reiterated that coordination through the PCP relationship is the best mechanism by which to reduce costs in any payment system for any provider, and the simple model of PCP-centered care is one of the only ones that has demonstrated TME reduction in the real world.⁷⁹

Beyond the somewhat vague and general policy suggestions of these strategies, the most concrete proposals focused on price regulation. The Attorney General and DHCFF's reports have depicted a Massachusetts health care market guided by the hand of the powerful insurers and providers. The imminent answer to that market force is the analogous guiding hand of government regulation in the form of nominal or relative price regulations.

Conclusion

Attorneys working with health care providers, physician networks, and insurance companies should expect to see new statutory restriction on pricing and contracting practices. More specifically, if the Governor's bill passes following the most recent cost containment discussions, the DOI will have greater authority to disapprove premium increases, set price ceilings, and restrict variation in reimbursement rates. Attorneys should further expect increased CID requests for information on their clients' financial data as the Attorney General and DHCFF continue to investigate cost trends.

(Endnotes)

- 1 DIVISION OF HEALTH CARE FINANCE AND POLICY, RECOMMENDATIONS OF THE SPECIAL COMMISSION ON HEALTH CARE PAYMENT SYSTEMS 5-6 (2009) available at http://www.mass.gov/eohhs2/docs/dhcfp/pc/Final_Report/Final_Report.pdf [hereinafter the "SPECIAL COMMISSION 2011 REPORT"]
- 2 OFFICE OF THE ATTORNEY GENERAL, EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS PURSUANT TO G.L. c. 118G, § 6½(b) (2011) [hereinafter the "2011 COST TREND REPORT"].
- 3 M.G.L. c. 6a, §16k (2006).
- 4 See M.G.L. c. 118G, §2 (2006).
- 5 *Id.* § 6½(b).
- 6 HCQCC, ROADMAP TO COST CONTAINMENT 1 (2009) available at http://www.mass.gov/lhqcc/docs/roadmap_to_cost_containment_nov-2009.pdf.
- 7 *Id.* at 2.
- 8 2011 COST TREND REPORT, *supra* note 2, at 7-8.
- 9 SPECIAL COMMISSION 2011 REPORT, *supra* note 1, at 10-11
- 10 SPECIAL COMMISSION 2011 REPORT, *supra* note 1, at 12-14. See 42 U.S.C. § 1395jjj(b)(2010); Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119-1025 (2010). The House version of the Act defines and ACO's as "organizations that link various providers that together take responsibility for improving the health status and efficiency of care for a specific patient population." See H.R. 3590, 111th Cong. (2010).
- 11 SPECIAL COMMISSION 2011 REPORT, *supra* note 1, at 17; RAND Corporation, *Controlling Health Care Spending in Massachusetts: An Analysis of Options 2* (2009).
- 12 See, e.g., James J. Mongan, et al., *Options for Slowing the Growth of Health*

Care Costs, 358 NEW ENG. J. MED. 1509 (2008); Christine Borger et al., *Projecting Long Term Medical Spending Growth*, 27 J. HEALTH ECON. 69 (2007); James C. Robinson, *Theory and Practice in the Design of Physician Payments*, 79 MILLBANKS Q. 149 (1996).

13 OFFICE OF THE ATTORNEY GENERAL, PRELIMINARY REPORT, INVESTIGATION OF HEALTH CARE COST TRENDS AND COST DRIVERS 2 (Jan. 29, 2010) [hereinafter "PRELIMINARY COST REPORT"].

14 *Id.* at 9, 13.

15 DIVISION OF HEALTH CARE FINANCE AND POLICY, MASSACHUSETTS HEALTH CARE SYSTEM IN CONTEXT (2010) available at http://www.mass.gov/pageID=eohhs2terminal&L=6&L0=Home&L1=Researcher&L2=Physical+Health+and+Treatment&L3=Health+Care+Delivery+System&L4=Health+Care+Cost+Trends&L5=2010+Health+Care+Cost+Trends&sid=Eohhs2&b=terminalcontent&f=dhcfp_government_cost_trends_hearing_march_16th&csid=Eohhs2.

16 *Id.*

17 PRELIMINARY COST REPORT, *supra* note 13, at 1. See also DIVISION OF HEALTH CARE FINANCE AND POLICY, MASSACHUSETTS HEALTH CARE COST TRENDS: PRICE VARIATION IN HEALTH CARE SERVICES (2011) [hereinafter the "PRICE VARIATION 2011 REPORT"].

18 PRELIMINARY COST REPORT, *supra* note 13, at 1, 13, 17-18. The Attorney General and DHCFF never use the term "oligopoly", but in describing the current health care market in this context, they certainly suggest that the current market is in fact in such a state because there is a direct correlation between high prices and market leverage of a handful of firms.

19 See PRICE VARIATION 2011 REPORT, *supra* note 17; 2011 COST TREND REPORT, *supra* note 2.

20 2011 COST TREND REPORT *supra* note 2, at 6, 8.

21 PRICE VARIATION 2011 REPORT, *supra* note 17, at 2-3.

22 2011 COST TREND REPORT *supra* note 2, at 3.

23 2011 COST TREND REPORT *supra* note 2, at 17-18.

24 See PRELIMINARY COST REPORT, *supra* note 13, at 2.

25 *Supra* 2011 COST TREND REPORT *supra* note 2, at 1-3.

26 See PRELIMINARY COST REPORT, *supra* note 13, at 1, 13.

27 *Supra* 2011 COST TREND REPORT *supra* note 2, at 19-22.

28 Robinson, *supra* note 12, at 153; PRELIMINARY COST REPORT, *supra* note 13, at 40.

29 2011 COST TREND REPORT, *supra* note 2, at 20-21.

30 2011 COST TREND REPORT, *supra* note 2, at 20-21.

31 2011 COST TREND REPORT, *supra* note 2, at 24.

- 32 See 2001 COST TREND REPORT, *supra* note 2, at 25-26.
- 33 2011 COST TREND REPORT, *supra* note 2, at 24-25.
- 34 2011 COST TREND REPORT, *supra* note 2, at 26. See Zirui Song, et. al, *Health Care Spending in Year 1 of the Alternative Quality Contract*, N. ENG. J. MED. (Jul. 13, 2011) available at <http://www.nejm.org/doi/pdf/10.1056/NEJMsa.1101416>. This study challenges the basic assumption that AQC's resulted in marked increases in spending but acknowledges that the long-term success of AQC's as a cost-saving measure will depend on changes in utilization and elimination of inefficient care.
- 35 2011 COST TREND REPORT, *supra* note 2, at 26.
- 36 2011 COST TREND REPORT, *supra* note 2, at 27-28.
- 37 2011 COST TREND REPORT, *supra* note 2, at 28.
- 38 2011 COST TREND REPORT, *supra* note 2, at 29-31. In generating these graphs to represent income correlations, the Attorney General controlled for "differences in health status" between the zip codes, indicating that the variation in TME among income groups is not a product of the population being "sicker or older."
- 39 2011 COST TREND REPORT, *supra* note 2, at 31, n 41.
- 40 2011 COST TREND REPORT, *supra* note 2, at 31.
- 41 2011 COST TREND REPORT, *supra* note 2, at 40-41.
- 42 ROADMAP TO COST CONTAINMENT, *supra* note 6, at 8. See also SPECIAL COMMISSION 2011 REPORT, *supra* note 1, at 11.
- 43 2011 COST TREND REPORT, *supra* note 2, at 45-46.
- 44 2011 COST TREND REPORT, *supra* note 2, at 49-51.
- 45 See Thomas Bodenheimer, *Coordinating Care—A Perilous Journey Through the Health Care System*, 358 New Eng. J. Med. 1064, 1066, 1069 (2008).
- 46 An Act Improving the Quality of Health Care and Controlling Costs by Reforming Health Systems and Payments, H. Res. 1849, 187th Sess. (2011).
- 47 2011 COST TREND REPORT, *supra* note 2, at 53.
- 48 2011 COST TREND REPORT, *supra* note 2, at 53.
- 49 2011 COST TREND REPORT, *supra* note 2, at 53.
- 50 2011 COST TREND REPORT, *supra* note 2, at 52.
- 51 2011 COST TREND REPORT, *supra* note 2, at 53.
- 52 2011 COST TREND REPORT, *supra* note 2, at 53.
- 53 See Health Care Cost Trends Public Hearings, Testimony of Commissioner Joseph G. Murphy, DHCFC Annual Public Hearing: health Care Cost Trends, Jun. 27, 2011.
- 54 Commissioner Joseph G. Murphy, DHCFC Annual Public Hearing: health Care Cost Trends, Jun. 27, 2011.
- 55 Jenn Abelson & Todd Wallack, *Rate Cap for Insurer Overturned*, BOSTON GLOBE (Jun. 25, 2010) available at http://www.boston.com/business/healthcare/articles/2010/06/25/rate_cap_for_insurer_overturned/.
- 56 Harvard Pilgrim Health Care, Inc. v. Division of Insurance, Docket No. R2010-02, at 6, 10 (Jun. 24, 2010).
- 57 M.G.L. c. 176G, §16; 211 C.M.R. 43.08.
- 58 An Act Improving the Quality of Health Care and Controlling Costs by Reforming Health Systems and Payments, H. Res. 1849, 187th Sess. (2011); Health Care Cost Trends Public Hearings, Testimony of Commissioner Joseph G. Murphy, DHCFC Annual Public Hearing: Health Care Cost Trends, Jun. 27, 2011.
- 59 See An Act Improving the Quality of Health Care and Controlling Costs by Reforming Health Systems and Payments, H. Res. 1849, 187th Sess. (2011). See also REXFORD E. SANTERRE & STEPHEN P. NEUN, *HEALTH ECONOMICS 261-67*(2009), for an interesting discussion of the consequences of government price fixing.
- 60 Health Care Cost Trends Public Hearings, Testimony of DHCFC, Massachusetts Health Care Cost Trends: Price Variation in Health Services, Jun. 28, 2011.
- 61 PRELIMINARY COST REPORT, *supra* note 13, at 36-38, referencing Massachusetts Association of Health Plan's data on insurer cost increases.
- 62 See Health Care Cost Trends Public Hearings, Testimony of Office of the Attorney General, Price Variation in Massachusetts Health Services, Jun. 28, 2011.
- 63 See *id.*
- 64 Health Care Cost Trends Public Hearings, Testimony of DHCFC, Massachusetts Health Care Cost Trends: Price Variation in Health Services, Jun. 28, 2011.
- 65 CONGRESSIONAL BUDGET OFFICE, *KEY ISSUES IN ANALYZING MAJOR HEALTH INSURANCE PROPOSALS 115-16* (2008) available at <http://www.cbo.gov/ftpdocs/99xx/doc9924/12-18-KeyIssues.pdf>.
- 66 *Id.*
- 67 Press Release, Office of the Governor, Patrick-Murrey Administration Propose Comprehensive Health Care Cost-Containment Legislation (Feb. 17, 2011) available at http://www.mass.gov/?pageID=gov3pressrelease&L=1&L0=Home&sid=Agov3&b=pressrelease&f=110217_healthcare_cost_containment&csid=Agov3.
- 68 Health Care Cost Trends Public Hearings, Testimony of DHCFC, Massachusetts Health Care Cost Trends: Price Variation in Health Services, Jun. 28, 2011.
- 69 See DHCFC, *Impact of Freezing Provider Rates*, prepared at the request of HCQCC, (2009). In the 2009 Report, the DHCFC concluded that setting a cap on prices could bankrupt many providers and lead insurance companies to dig into up to 83% of their reserves in a single year.
- 70 See *id.*
- 71 Press Release, Massachusetts Hospital Association, (Jun. 22, 2011) available at http://www.mhalink.org/AM/Template.cfm?Section=Payment_Reform&template=/CM/ContentDisplay.cfm&ContentID=16019; Lynda Young, *Does Payment Reform Save Money? Comments on the Attorney General's Report* (Jun. 24, 2011).
- 72 Mass. Assoc. of Health Plans v. Murphy, 2010 WL 2102723, *1 (Mass. Super. Apr. 23, 2010).
- 73 *Id.*
- 74 Testimony of National Institute for Health Care Reform, Paul B. Ginsburg, *Containing Health Care Costs: Market Forces and Regulation*, 2011.
- 75 Health Care Cost Trends Public Hearings, Testimony of DHCFC, *Bundled Payments: Demonstration of Potential Savings Associated with the Prometheus Model*, Jun. 29, 2011; Health Care Cost Trends Public Hearings, Testimony of Harold D. Miller, *From Volume to Value, How Better Payment Systems Can Help Improve Quality and Control Costs*, 2011.
- 76 See *Bundled Payments, supra* note 75.
- 77 *Bundled Payments, supra* note 75.
- 78 Health Care Cost Trends Public Hearings, Testimony of the Commonwealth Fund, *Thinking Creatively about the Health Care System We need for the 21st Century*, 2011; Health Care Cost Trends Public Hearings, Testimony of Nancy M. Kane *Implementing Alternative Payment Methodologies: Challenges for Providers and Payer and Potential Solutions*, Jun. 29, 2011.
- 79 Health Care Cost Trends Public Hearings, Testimony of Attorney General's Office, Lois Johnson, *Challenges in Care Coordination*, Jun. 30, 2011.

The HIPAA Accounting for Disclosures NPRM: Proposed New Rules Underscore Trends Toward Information “Rights” and Enhanced Auditing

By Scott Edmiston, Esq.

In a notice of proposed rulemaking (NPRM) published on May 31, 2011 (76 Fed. Reg. 31426), the Office for Civil Rights of the U.S. Department of Health and Human Services (OCR) proposed modifications to the HIPAA Privacy Rule’s¹ accounting for disclosure provisions.² The proposed changes would give effect to statutory mandates required under the HITECH Act.³ Although the comment period closed on August 1, 2011 and scheduled effective dates are more than a year away, the NPRM merits close attention as its provisions elucidate important privacy and security trends as well as the critical role of auditing in compliance and enforcement. In addition to private entities, the NPRM is also relevant to government agencies and parties to government contracts dealing with health information, groups often overlooked as members of the HIPAA covered entity and business associate community.

This article highlights the NPRM’s most significant modifications. Section 1 examines the proposed new individual “right” to an “accounting of disclosures” applicable to HIPAA “covered entities” and “business associates.” Section 2 explains the proposed new individual “right” to an “access report” within the context of existing HIPAA Security Rule obligations and comments on the technical and administrative challenges for covered entities in complex information environments. Section 3 notes miscellaneous provisions. Finally, Section 4 comments on the NPRM’s

context within larger privacy and security enforcement trends, especially OCR’s new compliance review audit approach to HIPAA Security Rule and Privacy Rule enforcement. The article wraps up with comments on how the general landscape in this area is likely to change.

Section 1: “Right” to an “Accounting of Disclosures”

The proposed new individual right to an accounting of disclosures maintains the old rule’s general standard (See 45 CFR 164.528). Under the current rule, an accounting must include the date of the disclosure, the name of the recipient, a brief description of the information disclosed, and a brief description of the purpose of the disclosure. The standard applies to disclosures of Protected Health Information (PHI) in electronic and non-electronic forms.

The proposed new rule would explicitly include business associates in the language of the standard, change the scope of information subject to the accounting to the information about an individual in a “designated record set” and change the accounting period from six years to three years. The new rule would also change the accounting provision’s format, requiring an affirmative list of the types of disclosures subject to an accounting rather than a list of the types of disclosures that are exempt from an accounting.⁴

The standard’s key definition is “Designated record sets,” which include the medical and health care payment records maintained by or for a covered entity, and other records used by or for the covered entity to make decisions about individuals (See the definition of “designated record set” at § 164.501.)⁵ This definition presents particular challenges for covered entities and business associates where information is stored in decentralized environments and such information is used to make decisions about individuals. If not already existing, systems must be designed and implemented to track and report access for such purposes.

OCR notes examples of information sets falling outside the definition of “designated record sets,” such as: patient information used for peer review; files used only to improve patient care at a hospital (not to make decisions about an individual); and transcripts of customer calls used only for customer service review.⁶ Covered entities may want to examine other classes of information that might fall outside of the “designated record sets” definition for purposes of the accounting standard. Another consequence of this definition is that business associates would not be subject to the accounting provision if they do not handle PHI as part of designated record sets for covered entities.

Under the proposed revision, the following disclosures would have to be included in an accounting: (1) dis-

closures not permitted by the HIPAA Privacy Rule, unless the individual has received notification of the impermissible disclosure pursuant to the Breach Notification Rule; (2) disclosures for public health activities, as provided in § 164.512(b), except disclosures to report child abuse, neglect or domestic violence; (3) disclosures for judicial and administrative proceedings, as provided in § 512(e); (4) disclosures for law enforcement purposes, as provided in § 164.512(f); (5) disclosures to avert a serious threat to health or safety, as provided in § 512(j); (6) disclosures for military and veterans activities; (7) the Department of State’s medical suitability determinations, and government programs providing public benefits, as provided in § 164.512(k); and (8) disclosures for workers’ compensation under § 164.512(l).⁷

The proposed rule would exempt the following disclosures, which currently must be included in the accounting: impermissible disclosures for which the individual has already been notified pursuant to the Breach Notification Rule; disclosures about victims of abuse, neglect, or domestic violence under § 164.512(c); disclosures for health oversight activities under § 164.512(d); disclosures for research purposes under § 164.512(i); disclosures about decedents to coroners and medical examiners, funeral directors, and for cadaveric organ, eye, or tissue donation purposes under § 164.512(g) and (h); disclosures for protective services for the President and others under § 164.512(k)(3); and most disclosures that are required by law (including disclosures to the Secretary to enforce the HIPAA Rules). The foregoing disclosures, however, would still have to be included in the proposed new “access report” if made through an electronic designated record set.” (See “access report” discussion below.)

The proposed exemption for research disclosures is particularly noteworthy because, if adopted, it would represent OCR’s response to broad consensus within the research community that this kind of required disclosure, along with other HIPAA provisions, has not only proven to be burdensome and difficult to manage but has also not been demonstrated to have corresponding privacy benefits to patients/research participants.⁸ (Examining the full implications to the research community merits a separate article, including a discussion of the proposed changes to the Common Rule contained in a recent ANPRM announced by the FDA).

Other modifications generally relax existing requirements: currently, the Privacy Rule requires an accounting to include the date of disclosure, name and (if known) address of the recipient, a brief description of the type of PHI disclosed, and a brief statement of the purpose of the disclosure. The proposed rule requires only an approximate date or period of time for each disclosure, if the actual date is not known, instead of the precise date required under the current rule. For multiple disclosures to the same person or entity for the same purpose, the proposed rule permits the covered entity to list the approximate dates of the first disclosure and last disclosure in the accounting period, rather than the more detailed information currently required. The proposed rule also permits a covered entity to omit the name of a recipient where providing the name would itself represent a disclosure of PHI.⁹

Finally, OCR proposes to reduce the permissible response time covered entities have to produce an accounting from 60 days to 30 days and to require the covered entity to produce the accounting in a format requested by the individual “if readily producible,” such as, for example, a PDF or

another word-processor compatible format.¹⁰

Section 2: Right to an “access report”

In addition to the right to an accounting of disclosures, OCR proposes a new section 528(b) to provide individuals with a right to receive an “access report” that indicates who has accessed their electronic designated record set information.¹¹ The access report only applies to access of the electronic health record (EHR), not to paper records.

The “access report” provision places a premium on translating technical audit log data into a reasonably understandable format. The NPRM defines an access report as “a document that a system administrator or other appropriate person generates from the access log in a format that is understandable to the individual.”¹² Importantly, OCR goes on to reference the Security Rule, such that for purposes of the NPRM discussion, the access log is the “raw data that an electronic system containing PHI collects each time a user (as the term is defined in the Security Rule at § 164.304) accesses information.”¹³ Indeed, OCR pre-supposes that entities already have auditing and accounting capabilities electronic and administrative systems due to existing HIPAA Security Rule requirements.¹⁴ At the present time, however, many covered entities and their business associates do not have such capabilities.

OCR notes that an access log also may commonly be referred to as an “audit trail” or “audit log” and an access report is similar to an “audit report.”¹⁵ OCR does not use the terms audit trail or audit log in order to distinguish the access report from documents that are generated by organizations for their internal auditing purposes.¹⁶

The proposed access report provision would abolish the current rule’s distinction between “uses” (access by internal users not subject to accounting) and “disclosures” (access by external users subject to accounting) in favor of requiring that all access of PHI in an EHR be accounted for in the access report regardless of whether it originated internally (as a use) or externally (as a disclosure).¹⁷

Section 3: Other notable provisions

OCR further notes that a covered entity will usually have electronic designated record set information in multiple systems each of which maintain separate access logs. OCR’s expectation is that data from each access log will be gathered and aggregated to generate a single access report (including data from business associates’ systems).¹⁸ Such aggregation presents substantial administrative and technical burdens in distributed and decentralized information environments. These information environments are often held in multiple silos where hybrid manual and electronic systems prevail in any given instance under variable access and control systems. Where covered entities may have robust patient protection procedures, simply obtaining the necessary permissions to aggregate data poses substantial logistical and administrative challenges.

As to the content of the access report, OCR proposes that the access report set forth: (a) the date of access; (b) the time of access; (c) the name of the natural person, if available, otherwise the name of the entity accessing the electronic designated record set information; (d) a description of what information was accessed, if available; and (e) a description of the action by the user, if available (e.g., “create,” “modify,” “access,” or “delete”).¹⁹ OCR goes on to state that it expects that any access report will

readily be capable of providing the date and time of access and the user name, and in many cases can also provide information about what information was accessed and the user’s action (such as create, modify, print, etc.). Other implementation specifications are proposed, but in sum, OCR’s approach seems to require more of a minimalist approach to the access report’s contents, that is, it does not appear to require lengthy descriptions of the purposes for which access is obtained.

Section 4: Notes on enforcement trends

The NPRM’s frequent reference to existing obligations under the HIPAA Security Rule is a signal that audit features will be increasingly important features in demonstrating Privacy Rule and Security Rule compliance. Although OCR has always been the designated federal enforcement agency of the HIPAA Privacy Rule, OCR has only recently been delegated the duty to enforce the Security Rule (July 27, 2009).²⁰

Over the past year, top OCR officials have announced intentions to begin proactive HIPAA compliance audits, as opposed to only conducting compliance investigations in response to individual complaints submitted to the agency.²¹ A contract was recently awarded to KPMG under the title: “OCR HIPAA Audit Protocol and Program Performance” with the anticipation that some 150 audits of entities varying in size and scope would be conducted.²² If past OCR practice is any guide, these audits will last in duration for weeks and months, not days. The prominent investigation resulting in OCR’s Resolution Agreement settlement with Partners HealthCare, for example, lasted more than a year.

It is this author’s opinion based on limited public information available that there will likely be some 12-20 audits initiated in OCR’s Region 1 (the New England States) over the course of 2012. Plans, of course, can change, as past plans had called for the audit program to begin in 2011, which did not occur. The first audits may be completed as early as 2012. The background of the new OCR director, Leon Rodriguez (announced September 13, 2011), as a litigator and prosecutor may portend a more aggressive enforcement approach.

While the nature of these audits remains to be seen, the contract noted that “site visits as part of every audit would include interviews with leadership (e.g., CIO, Privacy Officer, legal counsel, health information management/medical records director); examination of physical features and operations; consistency of process to policy, observation of compliance with regulatory requirements.”²³ The contract award underscores the notion that compliance requires enterprise-wide planning covering administrative, technical and physical safeguards of individual’s protected health information.

The NPRM notes other federal agencies with which OCR collaborates, such as the Office of the National Coordinator for Health IT (ONCHIT). The health law bar continues to watch developments in “meaningful use” definitions. OCR’s interpretations are also substantially informed by NIST publications and FTC privacy enforcement approaches.

Thus the NPRM seems to be in accord with enforcement trends that are increasingly viewing individuals as maintaining some form of “right” in information disclosed to organizations and third parties, with audit trails and accountings being just a few of the many mechanisms intend-

ed to enable such a “right”. This area of the law likely will remain in flux for some time.²⁴

Looking toward the horizon

Is it possible to speculate on what the future holds? If the approximately 435 public responses to the NPRM are any indication, look for substantial revision to the proposed “access report” and “accounting” standards in the direction of accommodating administrative burden concerns. The overwhelming majority of public comments submitted by the provider and research community expressed serious concerns about the practicability of implementing audit, accounting and aggregating systems as envisioned.²⁵ Major Boston area teaching hospitals including Harvard-affiliated academic health centers (i.e. Partners Health-Care) pointed to the profound difficulty and lack of utility of monitoring, tracking and reporting EHR access across heterogeneous information systems, many with their own privacy and confidentiality imperatives. One of the more thoughtful public comments from Stanford University included a sample patient’s EHR activity over a 6 month period to include over 49,632 activity lines.²⁶ Added to the difficulty of accounting for so many points of access, many academic health centers pointed to needless misunderstandings and confusion patients are likely to experience and time and effort spent alleviating the same if such activity lines were assembled into the proposed “access report”. Other providers expressed similar sentiments.

Concurrent with HITECH’s emphasis on individual rights is the law’s arguably greater emphasis on increasing health care efficiency and economic productivity both in clinical and research settings. Many of the accounting provisions would work against this goal. OCR should therefore have

ample ground to provide regulatory relief.

What then is a covered entity to do? While it may be premature to implement access reports in the near term (see proposed compliance dates),²⁷ covered entities would do well to reacquaint themselves with HIPAA’s original Security Rule standards. Theoretically, these standards should have already been implemented, but in reality that is often not the case. Advisors to covered entities should emphasize that compliance is an enterprise-wide activity and not just a problem for the IT department. And eyes should focus not just on OCR, but also on news coming out of the Office of the National Coordinator for Health IT, especially new phases of “meaningful use” addressing audit and accounting system standards.

Conclusion

This NPRM has potentially far reaching application for covered entities and their business associates. Entities in the process of drafting RFA’s/RFP’s or organizations actively engaged in capital planning should look closely at the proposed changes. Though the changes may not take effect for some time, organizations that make strategic adjustments in their audit and accounting capacity now stand to reap immediate fruits – enhanced safeguarding of vital information assets and management of enterprise risk. HITECH did not resolve the tension between enhanced individual rights and efficiency in clinical care and biomedical research. It will be OCR’s challenge to adjust HIPAA’s accounting provisions to ensure that we as a society can have both.

(Endnotes)

1. The “HIPAA Privacy Rule” (Standards for Privacy of Individually Identifiable Health Information. 45 CFR Parts 160 and 164 et seq) under statutory authority of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Title II, Subtitle F - Administrative

Simplification, Public Law 104-191, 110 Stat. 2021.

2 See 45 CFR 164.528. See also special provisions for research related disclosures at § 164.528(a) cross-referencing sections § 164.514(e), § 164.512(i), and § 528(b)(4).

3 Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA)(Pub. L. 111-5) See especially HITECH enabling language at §§ 13405(c), 13101.

4 See 76 Fed. Reg. 31429, 31430

5 *Id.*

6 *Id.*

7 To be listed in new § 164(a)(1)(i).

8 See NPRM references at p. 31433 (*op cit*) to the Sept. 27, 2004 SACHRP letter to the Secretary of HHS at <http://www.hhs.gov/ohrp/sachrp/appendixa.html> and the Institute of Medicine report *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research*, Institute of Medicine of the National Academies (available at <http://www.iom.edu>).

9 See 76 Fed. Reg. 31435

10 *Id.*

11 76 Fed. Reg. 31436

12 *Id.*

13 *Id.*

14 *Id.*

15 *Id.*

16 *Id.*

17 *Id.*

18 *Id.*

19 *Id.*

20 See 74 Fed. Reg. 38630 (Secretary of Health and Human Services delegates HIPAA Security Rule authority to OCR, July 27, 2009)

21 See comments by Sue McAndrew, then Deputy Director of OCR, May 21, 2010 interview http://www.healthcareinfosecurity.com/articles.php?part_id=2557

22 See the federal contract award announcement: <https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=9e045aa4f7e6f8499c5b6f74d5b211e9>

23 *Id.*

24 See e.g. the recent ANPRM proposing major revisions to the Common Rule and making HIPAA the default standard for research. See also the new Texas state privacy law featuring audit requirements.

25 See www.regulations.gov

26 *Id.*

27 OCR has proposed separate compliance dates for the accounting requirement and the access report requirement. Covered entities and business associates will have 180 days after the effective date of the final regulations to comply with the new rules regarding accounting of disclosures (or 240 days after the final regulations are published). With respect to the new regulations on access reports, OCR will enforce those regulations on January 1, 2013 for any electronic designated record set systems acquired after January 1, 2009, and on January 1, 2014 for any electronic designated record set systems acquired on or before January 1, 2009.

Health Law Brief: Shea v. Caritas Carney Hospital Inc.

by Ari Gottlieb, Esq.

In May 2011, the Massachusetts Court of Appeals affirmed a ruling of the Trial Court that the current “Duty to Warn” statute (G.L. c. 123 § 36B(1)(b)) was to be narrowly construed and supplant Massachusetts common law negligence. This case was the first challenge to the mental health professionals’ “Duty to Warn” statute since its enactment in 1989.

Jason Potter was a young man with a long history of mental illness including several hospitalizations. In July of 2002 a former girlfriend obtained an abuse prevention order against him after he threatened to stab her. A subsequent violation of that order the following month resulted in his incarceration. While incarcerated he suffered a head wound during an altercation with another inmate. He was released from prison on September 18, 2002 and taken to the emergency room at Caritas Carney Hospital on September 22, 2002 after a family friend with whom he was staying expressed concern for his mental well being.

Potter was voluntarily admitted to the hospital and evaluated by several mental health professionals (i.e. the defendants) over the course of four days. He was, according to the defendants, “irritable, disorganized, paranoid, and experiencing racing thoughts, but in good control overall.”¹ He denied homicidal or suicidal thoughts and claimed he would “never hurt a fly” or “hit a woman.”² At the time of his release,

the defendants, described him as “more organized, stable, and baseline” as well as “cooperative” and “oriented...had fair judgment and impulse control”.³ All of the treating physicians knew that he had been in jail for violating an abuse prevention order, that he suffered a head injury while incarcerated, and that he lived with his mother and stepfather. Potter killed his mother and stepfather on September 25, 2002, the same day he was discharged from the hospital.

Jason Potter was found not guilty by reason of insanity at his criminal trial. The estate of Potter’s stepfather Richard Sheehan subsequently brought forth a wrongful death action against Caritas Carney Hospitals and the mental health workers that treated Potter under a theory of common law negligence. The civil action alleged that the defendants were negligent in failing to hospitalize Potter or warn Sheehan that he could be a victim of Potter’s violence.⁴ The defendants moved for summary judgment, arguing that no duty to warn existed between the defendants and Sheehan pursuant to G.L. c.123, § 36B, the so-called “Duty to Warn” statute.⁵ The trial court ruled in favor of the defendants motion for summary judgment and Sheehan’s estate appealed.

The appellate court relied on the test laid out in G.L. c.123, § 36B, which states that a licensed mental health professional has a duty to warn a potential victim

if it can be established that “(1) the patient’s history of physical violence is known to the professional; (2) the professional has a reasonable basis to believe there is a clear and present danger the patient will attempt to kill or inflict serious bodily injury; and (3) the potential victim is reasonably identified.”⁶ Failure to meet all three requirements absolves the mental health professional of any duty to warn.

The court found that for the first part of the test, there was no disputing the defendants’ knowledge of Potter’s history of violence. All treating physicians knew of both Potter’s abuse prevention order and his altercation in jail. The defense argued that the violence in question needed to be directly connected to the plaintiff. The court disagreed, holding that the statute would have been worded as such if the legislature intended it.

As to the second part of the test, the court held that there was insufficient evidence to show that the defendants had a reasonable basis to believe that there was a clear and present danger that Potter would harm Sheehan. The court found that despite the defendants’ knowledge of Potter’s at times tenuous mental state, his statements to the defendants that he had no homicidal or suicidal inclinations and “would not hurt a fly” or “hit a woman” were to be taken on their face.⁷ This, in combination with his improved mental state upon discharge, led

the court to conclude that there was no indication to the defendants that Potter intended to physically harm anyone.

Finally, the court held that even with the most liberal interpretation of a “reasonably identified victim,” which would have required the defendants to conduct a thorough investigation of Potter’s history and personal interactions with Sheehan, there was no evidence to suggest that Potter intended any violence toward him.⁸

The plaintiffs made one final argument that, in the alternative, the defendants owed a common law duty of care to Potter’s mother and Sheehan based upon their therapist/patient relationship with Potter. The court disagreed with this argument, holding that the strong wording of G.L. c.123, § 36B was intended to effect an abrogation of the common law duty of care for mental health professionals.⁹

The impact of this case on mental health workers could be significant. The Appellate Court’s narrow interpretation of G.L. c.123, § 36B and the imposition of a complicated, three part “test” to see if a duty of care is owed to potential victims of violence, may make it much more difficult for plaintiffs to meet their burden in malpractice suits. By ruling that the clear legislative intent of G.L. c.123, § 36B was the abrogate the common law duty of care, they have afforded greater legal protection to mental health professionals. While many states have enacted such “Duty to Warn” statutes, largely as a result of the *Tarasoff* case, the court felt the legislature intended a strict standard that balanced the public’s need

for safety with maintaining the integrity of the psychiatric profession.¹⁰

This interpretation of the “Duty to Warn” statute gives mental health care providers freedom to treat their patients without constant fear of frivolous lawsuits. Furthermore, this ruling could have a substantial effect on the economics of American healthcare. Should other states adopt the Massachusetts courts’ approach, it would mean fewer actionable malpractice lawsuits which could ultimately result in lower costs for mental health care.

(Endnotes)

1 See *Shea v. Caritas Carney Hospital, Inc.*, 79 Mass. App. Ct. 530, 532 (2011).

2 *Id.* at 534.

3 *Id.* at 533.

4 *Id.* at 531.

5 *Id.* at 532.

6 *Id.* at 536.

7 *Id.* at 538.

8 *Id.* at 540.

9 *Id.* at 540. (the statute states that “[t]here shall be no duty owed by a licensed mental health professional to take reasonable precautions to warn or in any other way protect a potential victim or victims of said professional’s patient, and no cause of action imposed against a licensed mental health professional for failure to warn or in any other way protect a potential victim or victims of such professional’s patient unless” the statutory conditions in § 36B(1)(a) or § 36B(1)(b) are met.)

10 See *Tarasoff v. Regents of the University of California* [17 Cal. 3D 425](#) (1976). (“once a therapist does in fact determine, or under applicable professional standards reasonably should have determined, that a patient poses a serious danger of violence to others, he bears a duty to exercise reasonable care to protect the foreseeable victim of that danger.”)

Health Law Brief: PLIVA, Inc. v. Mensing

by Matt Beuhler, Esq.

In order to market new products, manufacturers of brand name drugs must first provide clinical data to the Food and Drug Administration (“FDA”) regarding the drugs’ safety and effectiveness. The brand name manufacturers must further submit safety labels for these drugs to the FDA for approval.¹ 21 U.S.C. § 355 (a) & (b). Generic drug manufacturers, however, only have to show that their products are the bioequivalent of, and have the same labels as, their brand name counterparts. 21 U.S.C. § 355(j). After receiving regulatory approval, both brand name and generic manufacturers must submit post-marketing safety information to the FDA. 21 C.F.R. §§ 314.80 & 314.98. Based on this information, brand and generic manufacturers can also submit for FDA approval proposed improvements to their safety labels. Unlike generic manufacturers though, brand name manufacturers can implement these improvements at the time of submission, prior to approval. 21 C.F.R. § 314.70(c)(iii).

The federal statutory scheme does not provide a private right of action to drug consumers for claims based on inadequate labeling. Massachusetts law, however, had previously allowed consumers to bring claims against both brand name and generic drug manufacturers for negligent labeling. See *Kelly v. Wyeth*, 22 Mass. L. Rptr. 384, 387 (2007). Federal law does not preempt such state law claims against brand name manufacturers. *Wyeth v. Levine*, 129 S.

Ct. 1187, 1196-99 (2009). In *PLIVA, Inc. v. Mensing*, the Supreme Court addressed whether such claims were preempted against generic drug manufacturers. 131 S. Ct. 2567 (2011.)

The *PLIVA* case involved the drug metoclopramide. The FDA approved this drug in 1980 under the brand name Reglan®. The label for this drug was subsequently strengthened several times to reflect growing evidence that long term usage could result in tardive dyskinesia, a severe neurological/movement disorder.

In *PLIVA*, two separate individuals developed this disorder after taking generic forms of metoclopramide. They then brought state law claims in Louisiana and Minnesota respectively against the generic manufacturers. The plaintiffs essentially alleged in both cases that, despite mounting evidence of safety risks associated with their products, the generic manufacturers did not change their labels to reflect these risks. These claims were initially dismissed as preempted by federal law but these dismissals were reversed by the Circuit Courts. *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). The manufacturers then appealed these reversals to the Supreme Court and the two cases were consolidated.

Under the Supremacy Clause, federal law preempts state law where it is impossible for a private party to comply with both. Federal law

required the generic manufacturers to have the same warning label as the brand name manufacturer. The state law claims, however, were based on the theory that this label had been inadequate. Put another way, state law implicitly required the generic manufacturers to have stronger labels than the one approved by the FDA with the understanding that the generic manufacturers could have proposed stronger labels to the FDA but did not.

Given this regulatory background, the Court split 5-4 as to what showing the generic manufacturers had to make in order to establish ‘impossibility’ preemption. The majority held that the manufacturers only had to show that it was impossible for them to independently comply with both state and federal law. The generic manufacturers could not change their label without FDA approval. The plaintiffs’ claims were thus preempted as state law required the manufacturers to change the label without such approval. 131 S. Ct. at 2577-2578.

The Court acknowledged that the generic manufacturers could have proposed stronger labels which complied with state law. If the FDA then approved these changes, no conflict would have existed between federal and state law. The Court reasoned, however, that almost every such conflict could be resolved by the possible actions of a government agency or a third party. This would render the Supremacy Clause largely meaning-

less. For that reason, the Court focused only on what generic manufacturers could do independently, i.e., without FDA approval. 131 S. Ct. at 2578-79.

This analysis, however, led to a seemingly unfair result. Under *Wyeth*, an individual who developed tardive dyskinesia after taking Reglan could seek compensation from the brand name manufacturer for negligent labeling. An individual who developed the same condition after taking the generic form of the same drug could not seek compensation from the generic manufacturer.

The Court described this as an “unfortunate” result but emphasized that it was nonetheless consistent with *Wyeth*. 131 S. Ct. at 2581. A brand name manufacturer such as the one in *Wyeth* could change its label without FDA approval. The generic manufacturers in *PLIVA* could not. As a result, federal law preempted state law claims based on negligent labeling against generic manufacturers but not brand name manufacturers. The dissent, however, argued that this analysis misread *Wyeth*. 131 S. Ct. at 2588-89 (SOTOMAYOR, J., dissenting).

The dissent emphasized that the FDA can still reject any changes to a brand name safety label, even if the manufacturer implemented these changes at the time of submission. 21 C.F.R. § 314.70(d). In the long run, a brand name manufacturer can not independently change its safety label, i.e., any changes that it makes are still ultimately contingent on FDA approval. The dissent thus read *Wyeth* as standing for the proposition that, in order to establish impossibility preemption, a brand name manufacturer must produce “clear

evidence that the FDA would not have approved a change to [the] label.” 131 S. Ct. at 2588. (SOTOMAYOR, J., dissenting) (quoting *Wyeth*, 129 S. Ct. at 1198 (alteration in original)).

Based on that reading, the dissent argued that a negligent labeling claim against a generic manufacturer should be preempted only if the manufacturer could establish that the FDA would not have approved a proposed label change. For example, a manufacturer could establish impossibility preemption by showing that it proposed a stronger safety label but the FDA rejected, or failed to act on, the proposed change. 131 S. Ct. at 2588-89 (SOTOMAYOR, J., dissenting).

Of these two positions, the dissent seems preferable. The majority’s opinion is based on a supposed regulatory difference between brand name and generic manufacturers. This difference does not, as a practical matter, exist. The dissent is more logically based on what a manufacturer does to safely label its products. A manufacturer that proposes safer labels can raise the preemption defense; A manufacturer that does nothing cannot raise this defense.

Moreover, over 70% of all prescriptions are currently filled with generic drugs. Pharmacies are, in fact, required in many states to substitute generic drugs for their brand name counterparts. As a result of the majority’s holding, these generic drug consumers can not seek compensation for inadequate labeling. It seems arbitrary to prohibit consumers from seeking relief simply because their prescriptions were filled with generic, rather than brand name, drugs. The dissent’s position would allow

these consumers to seek compensation while also providing an incentive for generic manufacturers to strengthen their safety labels.

On a practical level, Massachusetts consumers can still bring negligent labeling claims under state law against generic manufacturers. Against brand name manufactures, however, such claims are now preempted by federal law. More broadly, a plurality of the Court endorsed expanding the scope of federal preemption. 131 S. Ct. at 2579-81. (THOMAS, J., for plurality).²

Traditionally, the Court had presumed that, in areas typically regulated by states such as healthcare, federal law did not supersede state law absent a clear expression of Congressional intent. The plurality advanced the theory that the Supremacy Clause contains a *non obstante* provision that impliedly repeals conflicting state law. As a result, courts “should not distort federal law to accommodate conflicting state law.” 131 S. Ct. at 2580. (THOMAS, J., for plurality). Put another way, the plurality would no longer apply (and perhaps even reverse) the presumption that federal law does not preempt state law. It remains to be seen whether a majority of the Court adopts this position and, if so, what effect this has on state healthcare law.

(Endnotes)

1 A drug’s label must contain “adequate” safety warnings. 21 U.S.C. § 352(f).

2 Justice Kennedy joined Justices Thomas, Roberts, Alito and Scalia for all of the Court’s opinion except for Section III-B-2. This section contained the plurality’s position on the scope of federal preemption.

Health Law Brief: Finch v. Commonwealth Health Ins. Connector Authority

by Sarah F. Anderson, Esq.

The Supreme Judicial Court (SJC) recently reviewed the state law¹ which ended the eligibility of over 29,000 lawful resident aliens for participation in the Health Reform program known as Commonwealth Care. The key question under review was whether the rational basis test should apply to state laws that discriminate based upon immigration or alienage status. The Court found that the statute in question is subject to strict scrutiny under Article 106, the equal protection provision of the Massachusetts Constitution. Having decided that lawful resident aliens are a discrete and insular minority particularly deserving of heightened vigilance to ensure that they receive the full panoply of constitutional protections,² the Court will decide this term how it applies this standard to the facts of this case.

Commonwealth Care has been an important part of the Commonwealth's initiative to provide access to health insurance coverage for all Massachusetts residents³ since it was enacted in 2006. This health insurance plan provides premium assistance for Massachusetts residents, over age 18, whose income is below 300% of the Federal Poverty Level (FPL) and who have no access to other public or private health insurance. Under the Health Reform law, Chapter 58, lawful resident aliens were able to enroll in and benefit from Commonwealth Care. Both state and federal

funds support this premium assistance program. The federal funds are provided through a Medicaid demonstration project.⁴ If a Commonwealth Care enrollee is a "federally eligible individual",⁵ then expenditures made on their behalf can receive partial federal reimbursement under the state's Medicaid plan. If the individual is not "federally eligible", then only state funds can be used to pay for the expenditures. This means that federally ineligible members are more expensive to the Commonwealth. In spite of this financial impact, the state enrolled such residents in the program until 2009.

The Massachusetts legislature (the General Court) eliminated the eligibility of some legal resident aliens (those for whom it received no federal funds) in a FY2010 supplemental appropriation bill, enacted in the summer of 2009.⁶ At that time the legislature was grappling with a substantial state budget shortfall. Section 31(a) limited Commonwealth Care to those individuals who were "federally qualified" immigrants (eligible for partial federal reimbursement) under PRWORA.⁷ At the same time, the legislature established a new program, Commonwealth Care Bridge (Bridge), for those lawful resident aliens who were no longer eligible for Commonwealth Care due to passage of §31(a). The Bridge provides a lesser amount of health care benefits and requires higher

contributions by the individual. Eligibility was limited to those legal resident aliens who had been enrolled in Commonwealth Care as of August 31, 2009, and lost eligibility as a result of § 31(a). Both the termination of benefits under § 31(a), and the Bridge program under § 31(b), operate under a fixed appropriation, and terminate if not renewed by the legislature each fiscal year. As of June 2010, there were an additional 14,000 legal resident aliens who would have qualified for participation in Commonwealth Care but for the enactment of § 31(a).

In February 2010, Massachusetts residents who lost eligibility for Commonwealth Care solely because they did not meet the PRWORA definition of federally qualified sued the Massachusetts Health Insurance Connector Authority (Connector). They filed a class action in the Supreme Judicial Court for Suffolk County alleging that § 31(a) violated their federal and state constitutional rights, discriminating against them based on alienage. The Connector removed the action to Federal District Court because it raised federal questions.⁸ The plaintiffs filed an amended complaint, raising only a facial challenge to the statute under the Massachusetts Constitution. Remand to the county court was granted by the Federal District Court. The Commonwealth intervened as a defendant. Justice Cordy reserved and reported four

questions to the full court. These were answered in its May 6, 2011 opinion.

The key question⁹ in the opinion was whether the rational basis standard should apply to state laws that discriminate based upon alienage or immigration status. The majority of the court (JJ. Spina, Ireland, and Duffy) concluded that in this case it should not, while the minority (JJ. Gants and Cordy) came to the opposite conclusion. The whole court recognized that Commonwealth Care coverage is an economic benefit, and that since § 31 may discriminate against aliens, strict scrutiny is presumptively applicable unless some exception applies. It also recognized that Congress, and not the General Court, has the authority to discriminate based upon alienage.

The majority, having concluded that the plaintiffs were a “discrete and insular minority”,¹⁰ evaluated § 31(a) under strict scrutiny. The Court discussed the PRWORA eligibility classifications, and concluded that it classified aliens, in part, on the basis of national origin, and that since § 31(a) imported these eligibility criteria, which were based in part upon national origin, § 31(a) must be subject to strict scrutiny under Art. 106. Justice Duffy reached the same result by different means. She separately concluded that under Art.106 alienage was included in the definition of national origin.¹¹ Since § 31(a) was a state law, it was to be interpreted in light of the Massachusetts Constitution. The full Court concluded that PRWORA did not require states to exclude legal immigrants from Commonwealth Care. The majority concluded that in times of economic hardship, the Common-

wealth could reduce funding for social welfare programs, but not by singling out a minority such as the plaintiffs.¹²

In dissent, Justices Gants and Cordy found that an exception to strict scrutiny applied in this case. They viewed Commonwealth Care as a state supplemental program governed by federal law, thus strict scrutiny did not apply. Congress, in PRWORA, was exercising its plenary power over immigration matters by excluding most legal aliens from eligibility for federal public benefit programs, and those decisions are reviewed under the rational basis standard. They recognized that if Commonwealth Care were a “state only” program then strict scrutiny would apply. In their view, Congress exercised its plenary power over immigration by cutting off federal funds that states could have “otherwise used to help pay for the medical benefits of federally ineligible qualified aliens.”¹³ Because the unequal treatment of the plaintiffs was due to the fact that the federal government was not paying an equal amount for these immigrants, the rational basis standard of review should be used in this case.

The Court remanded the case to Justice Cordy, sitting as the county court. Once again he reserved and reported the case to the full Court for resolution in the first instance. The case is pending, and a decision is expected this term.

(Endnotes)

1 St.2009, c.65 § 31 (a)

2 946 N.E. 2d at 1277

3 St. 2006, c.58; see G.L. 118H

4 §1115 of the Social Security Act, 42 U.S.C. § 1315 (2006)

5 Individuals who meet the eligibility standards applicable to federally funded public benefit programs as found in the Personal Responsibility and Work

Opportunity Reconciliation Act of 1996 (PRWORA), Pub.L. No. 104-193, as amended, codified at 8 U.S.C. §§ 1601-1646 (2006)

6 St.2009, c.65 § 31 (a) and (b)

7 Among federally qualified individuals are legal permanent residents who attained that status more than 5 years ago, certain refugees, asylees, certain veterans; see PRWORA §§ 401,402, 403 for the full list

8 28 U.S.C. § 1441 (b)

9 Question 3: If the answers to Question 1 and to Question 2 are negative, should a State classification based upon alienage be subjected to a “rational basis” standard of review under the Massachusetts Constitution to determine whether there is a rational relationship between the disparity of treatment between citizens and aliens and some legitimate governmental purpose? 946 N.E. 2d 1273

10 946 N.E.2d 1277

11 946 N.E. 2d at 1292-93

12 Id.

13 946 N.E. 2d at 1287

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