



Boston Bar
ASSOCIATION



SPRING 2011

VOLUME 6, ISSUE 2

The Boston

Health Law Reporter

A PUBLICATION OF THE BOSTON BAR ASSOCIATION HEALTH LAW SECTION

VOLUME 6, ISSUE 2

SPRING 2011

Section Co-Chairs' Corner

We are pleased to present to you the Spring, 2011 Edition of the Health Law Section's Health Law Reporter. As always, the Reporter offers timely and topical articles which will help keep Health Law practitioners abreast of important issues and events.

Front and center in the Spring Edition is Dave Szabo's interview with Christie Hager, HHS Regional Director for Region 1 (Christie is also a former Adjunct Lecturer on Health Policy and former Deputy Director of the Division of Public Health Practice at the Harvard School of Public Health, and former Chief Health Counsel in the Office of the Speaker during the development, enactment and first three years of implementation of the Massachusetts health reform law passed in 2006.)

In addition, Karyn Brudnicki and Erin Talati have written about the Proposed 2011 Federal Budget and its Impact on Pediatricians; Alyssa Yenikomshian has written an article entitled "The Affordable Care Act—Consumer Protections in the Appeals Process", Edward Zacharias has written an OCR Enforcement Update on Cignet and MGH; and Audrey Perlow has written this edition's Health Law Brief, on the case of *Law v. Griffith*.

This edition of the Health Law Reporter follows a busy couple of months for the Health Law Section, which included an extraordinarily broad array of Section-sponsored events. These events included CLE and Brown Bag programs on such topics as "The Massachusetts All-Payer Claims Data-Base", "Accountable Care Organizations", "Issues in the Life Sciences Industry: Tech Transfer, Partnering and Off-Label Promotion", "Recent Developments in Legislation and Law Enforcement", "Emerging Issues for Healthcare Employers in the Age of Social Media", "Patient-Centered Decision-making About Life-Sustaining Treatments", and "Recent HIPAA Actions."

We want to thank our authors and our peer reviewers for their time and efforts in contributing to the Health Law Reporter. We also want to thank all of our committees, committee members, and presenters for making all of our wonderful CLE and Brown Bag programs possible. These have truly been team efforts.

For anyone who wishes to join our team, 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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Policymaker Profile: Christie Hager, J.D., M.P.H.

by Dave Szabo, Esq.

In April, 2010, President Obama appointed Christie Hager as the Regional Director for Region One (New England) of the U.S. Department of Health and Human Services (HHS). There are ten Regional Offices across the United States. The Regional Directors ensure HHS maintains close contact with state, local and tribal governments, and seek to address the needs of communities and individuals served through HHS programs and policies.

Many readers of the Health Law Reporter will remember Christie as a long-time member of the Health Law Section's Steering Committee, and as Chief Health Counsel in the Office of the Speaker of the Massachusetts House of Representatives. However, not content with these superficial facts, the Reporter has conducted an in depth investigation to provide you with unique insights into the past and present of the current HHS Regional Director.

Christie is a graduate of Smith College, and received her master's degree in Public Health from Boston University. Although she had her sights set on law school, she took a "short-term" position with the New England Journal of Medicine, working for Dr. Marcia Angell. This short-term stint lasted for six years, which gave her great exposure to medical science, and health policy, and an opportunity to complete her master's degree part-time. She extricated herself from the medi-

cal society to get her law degree from the University of Connecticut, but admits that her interest in health policy kept her on the U. Conn Medical School campus almost as much as she was present at the law school.

Christie has previously served as Deputy Director of the Division of Public Health Practice at the Harvard School of Public Health and most recently returned to Harvard as an Adjunct Lecturer on Health Policy. At Harvard, her research and teaching focus on state regulation of health care and public health, health care access, and the legislative process.

Her involvement in state government included working on the staff of the Legislature's Health Care Committee, where she worked for John McDonough during his tenure as chairman. When she returned to state government in 2004, she served as Chief Health Counsel in the Office of the Speaker during the development, enactment and first three years of implementation of the Massachusetts health reform law.

When the Reporter caught up with Christie in her office at the JFK Federal Building, she described the scope of her role within HHS, and the specific challenges of serving as Regional Director during the implementation of the Affordable Care Act. As Regional Director, she is charged with building strong relation-

ships with the Governors of all six New England states and their healthcare cabinet officials. Additionally, the Regional Director is responsible for healthcare issues impacting the New England tribal governments, and with private organizations that impact health policy. This responsibility cuts across almost all of the component agencies within HHS, many of which maintain a presence within the Boston Regional Office.

Another key role of the Regional office is to participate in inter-agency cooperation with other federal agencies. For example, Christie has worked with the Small Business Administration to put on educational programs explaining the impact of the Affordable Care Act for small businesses and their employees. Another example would be collaboration with the Department of Housing and Urban Development on initiatives around homelessness. The ability to cooperate and coordinate with other agencies that have overlapping goals and constituencies creates a kind of multiplier effect for the role of the Regional Office in implementing healthcare reform and other initiatives. However, she also noted that "the challenges are commensurate with the opportunities" and that ongoing coordination among federal agencies and state agencies is one of the biggest jobs facing the Regional Office.

What does this mean as a practical matter? For one thing, it means a lot of driving for the Regional Director. Because she is committed to personally meeting with state, tribal, and federal officials, Christie estimates that she has driven more miles since taking on her new role than during her previous three years. More significantly, the Regional Office is a focal point for cooperation between the Federal Government and the individual states for the implementation of the Affordable Care Act. While each New England state has experience with its own health reform efforts, each state has a different experience with prior reforms, and each is at a different starting point when it comes to implementation of the Affordable Care Act.

Massachusetts, for example, has already achieved a high percentage of coverage, and the state Health Connector Authority could easily be seen as a prototype for the insurance exchanges envisioned by the federal reform law. While Massachusetts will experience many changes as a result of the implementation of the Affordable Care Act, other states will experience much more dramatic changes in their health-care systems, but all will face more transition issues. Further, Christie notes, the flexibility that is built into the Affordable Care Act will mean that each state will work closely with HHS on implementation of various provisions of national health reform. She feels that her own experience in living through the negotiation of Chapter 58 and the implementation of the law will serve her well in the implementation of federal reform. Given the similarities

of Massachusetts reform to the Affordable Care Act, she hopes to effectively support the New England states in navigating the many significant changes that she knows are ahead.

Christie closed by noting that implementation of the Affordable Care Act offers enormous potential to improve the quality and accessibility of healthcare, and that the role of HHS is “all about serving the lives that we touch.”

Health Insurance Appeals Post-PPACA: Dealing with a Patchwork of Laws

by Alyssa Yenikomshian, Esq.

More than one year after its enactment, the Patient Protection and Affordable Care Act's (PPACA) goals of expanding coverage, improving the delivery of health care, and making health care affordable to consumers has proven to be an evolving process. For the approximately 64% of consumers in the United States with private health insurance¹, PPACA has built on existing laws governing private insurance to create stronger consumer protections. Enforcement of these protections on the consumer level is achieved through the appeals process. PPACA made several changes to the internal claims and appeals and external review processes which will be reviewed in this article.

Setting for Reform

While we are a nation that is constantly seeking to make things simpler through innovation and technology, the health care industry becomes more complex with each day as new technologies breed new laws and regulations. Terms such as experimental and investigational treatment, medical necessity, and pre-existing condition have emerged making the simple activity of going to a doctor for treatment a complicated endeavor. Often while suffering with serious health conditions or caring for sick loved ones, health insurance consumers must wade their way through the appeals process with blinders on, not understanding their rights under the law and presuming that an insurance company's final determination will be the correct one.

To add to the complexity, prior to PPACA, a consumer's right to an internal or external appeals process depended on many factors, including whether the health plan was fully insured or self-insured, whether the insurance was employer-sponsored or purchased by a consumer on the open market. Although the regulation of health insurance was traditionally the responsibility of the states, the enactment of the Employee Retirement Income Security Act (ERISA) in 1974 resulted in the preemption of state laws that relate to an employee benefit plan.² As a result, in some cases, ERISA requirements coexist with state law, and in other cases ERISA requirements preempt state law.³ ERISA's strong preemption provides a uniform regulatory regime designed to ensure that employee benefit plan regulation is "exclusively a federal concern."⁴ Accordingly, state law causes of action concerning an employee benefit plan that duplicate, supplement, or supplant ERISA are preempted because of the conflict with congressional intent to make ERISA's remedy exclusive.^{5,6}

PPACA's Answer

In response to the patchwork of laws governing internal and external appeals, PPACA sought to create uniformity and strengthen consumer protections by adding section 2719 to the Public Health Service Act (PHSA).⁷ Section 2719 not only enhanced consumer protections for the internal claims and appeals process by building on ERISA's requirements⁸, but it created heightened

requirements for external review.⁹ Most importantly, section 2719 applies to both group health plans and health insurance issuers offering group or individual health insurance.

On July 23, 2010, the U.S. Departments of Health and Human Services, Treasury, and Labor ("the Departments") issued final regulations to interpret PHSA section 2719.¹⁰ The regulations contained seven new rules that apply to the claims and appeals processes of group health plans and group or individual health insurance issuers, three new rules that apply to individual health insurance issuers, numerous requirements for state external review processes, and guidelines for a federal external review process. The regulations are effective for health plan years beginning on or after September 23, 2010.¹¹

Grandfathered Plans

Exempt from PHSA §2719 are grandfathered plans.¹² This provision of the new law reflects back to the adage "if you like your health plan, you can keep it" which was heard during the health care reform debate. Grandfathered plans are group health plans or other health insurance coverage that were in effect on March 23, 2010, PPACA's enactment date.¹³

By virtue of their grandfathered status, grandfathered plans may choose to maintain their current scheme of cost-sharing and health benefits or they can comply with the new law's requirements as they take effect. It

is projected by the Departments that approximately 31 percent of small employers and 18 percent of large employers will make changes that will require them to relinquish grandfather status in 2011.¹⁴ Grandfather status can be relinquished in the following ways: significantly cutting or reducing benefits to diagnose or treat a particular condition, raising co-insurance charges, significantly raising deductibles, significantly lowering employer contributions, and adding or tightening an annual limit on what the health plan pays.¹⁵

Internal Claims and Appeals - Seven New Rules

The first change to the internal appeals process was the broadening of the definition of adverse benefit determination.¹⁶ ERISA defines an adverse benefit determination as a denial, reduction, or termination of, or failure to provide or make payment (in whole or in part) for a benefit.¹⁷ An adverse benefit determination is important because it triggers a consumer's right to an internal appeal with his or her health plan or issuer. Under ERISA, an adverse benefit determination also includes a decision that is based on a determination of a participant's or beneficiary's eligibility to participate in a plan.¹⁸ Massachusetts law defines an adverse determination as a determination to deny, reduce, modify, or terminate an admission, continued inpatient stay, or the availability of any other health care services.¹⁹

PPACA maintained ERISA's existing definition of adverse benefit determination, but added the rescission of coverage to the definition.²⁰ Rescission is defined as the cancellation or discontinuance of coverage that has a retroactive effect except to the extent that it is attributable to a failure to timely pay required premiums towards the cost of coverage.²¹ A group

health plan or issuer may, however, rescind coverage if an individual performs an act that constitutes fraud or intentionally misrepresents a material fact.²² The ban on rescission applies to grandfathered as well as non-grandfathered plans.²³

The second change to the internal appeals process is that urgent care benefit determinations must be made as soon as possible but no later than 24 hours.²⁴ This new law will supplant the current 72-hour standard under ERISA and the 48-hour standard under Massachusetts law for the resolution of urgently needed services.²⁵

ERISA mandates that health plans or plan fiduciaries conduct a full and fair review of a claim for benefits and an adverse benefit determination.²⁶ PPACA's third change to the appeals process was the broadening of protections under full and fair review. ERISA affords plan participants and beneficiaries several protections including, but not limited to: 180 days to appeal an adverse benefit determination, prohibition on a health plan's deference to an initial adverse benefit determination during an appellate review of a claim, and consultation with a health care professional with experience and training to make a medical judgment.²⁷

PPACA maintained ERISA's requirements for full and fair review, but added two important protections. First, consumers must be provided with any new or additional evidence considered and generated by the health plan or issuer.²⁸ Second, after a consumer has submitted an appeal, the health plan or issuer must afford the consumer the opportunity to respond to a new rationale before it upholds its adverse determination.²⁹ These two new consumer protections are important because they help foster a meaningful dialogue

between the consumer and the health plan about the claim.³⁰ Moreover, these new rules prevent health plans from changing the rationale for an adverse decision without allowing the consumer to respond before the end of the administrative appeals process, an action that is sometimes referred to as sandbagging.³¹

The fourth change to the internal appeals process is new criteria to avoid conflict of interest. Health plans must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision.³² Decisions such as hiring, compensation, termination, and promotion may not be made based upon the likelihood that the individual who is the subject of these actions will support a denial of benefits.³³ The government's focus on conflict of interest reflects the Supreme Court's position that, in cases brought under ERISA, conflict of interest is a factor that must be weighed in determining whether the plan administrator or fiduciary's decision was unlawful.³⁴ Moreover, discovery in ERISA cases is permitted in certain circumstances; conflict is one of them. The U.S. First Circuit Court of Appeals has allowed targeted discovery to examine whether structural conflict has morphed into actual conflict.³⁵ Accordingly, in the ERISA context, a consumer may be able to use the authority of PPACA to support discovery on whether conflict of interest played a role in the administration of his or her claim.

The fifth change to the internal appeals process is heightened notice requirements. First, health plans and issuers must now provide notice of adverse benefit determinations in a culturally and linguistically appropriate manner.³⁶ This means translated notices, disclosure statements

regarding translation on notices that are in English, and call center services that are provided in languages other than English. This new provision of the law is important to combat racial and ethnic disparities and ensure that culturally and linguistically isolated communities benefit from the full range of consumer protections afforded by PPACA.³⁷ Second, health plans and issuers must include additional information on adverse determination notices such as information sufficient to identify the claim, the reason(s) for the decision, the standard used to render the decision, a discussion of the decision, description of available individual and external review processes, and the availability of consumer assistance programs.³⁸ These added protections will assist consumers to understand the basis of an adverse decision and provide information on where to go to get help with an appeal.

The sixth change to the internal appeals process is a “deemed exhaustion” provision. If a plan or issuer fails to adhere to the requirements of the internal appeals process, the claimant is deemed to have exhausted the internal claims process and may request an external review and/or judicial review of the adverse benefit determination.³⁹ In practice, this new rule should be exercised with cautious optimism. As a primary matter, judicial review of ERISA benefit denials are generally adjudicated on the record compiled before the plan administrator.⁴⁰ This means that a consumer must submit to the health plan all information that supports his or her claim. After the health plan has rendered its final adverse benefit determination and the administrative record is “closed,” it is difficult to introduce additional documentation for judicial review.⁴¹ Therefore, it is important to ensure

that the administrative record is complete prior to judicial review.

The deemed exhaustion provision does, however, have its benefits. As a general rule, claimants with ERISA-governed plans are required to exhaust their administrative remedies before bringing a lawsuit to recover benefits.⁴² The deemed exhaustion rule provides for the expeditious adjudication of a claim. This new rule may also affect the standard of review utilized by a reviewing court. Traditionally, a deferential standard of review, the “abuse of discretion” standard of review, is utilized when an ERISA plan grants the administrator or fiduciary discretionary authority to determine eligibility for a benefit.⁴³ Several courts have held that when a claim is “deemed exhausted” no discretion has been exercised and the plan administrator or fiduciary is thus stripped of the discretionary authority that it may have held.⁴⁴ The case is then reviewed under the *de novo* standard of review⁴⁵ which is generally more favorable to the claimant.

The final change to the internal appeals process is that health plans must provide continued coverage pending the outcome of an internal appeal.⁴⁶ Under ERISA, health plans are required to notify the claimant of an adverse benefit determination sufficiently in advance of the reduction or termination of benefits in order to allow the claimant to appeal.⁴⁷ The seventh change to the internal appeals process, therefore, now applies to all group health plans and individual insurance issuers.

Individual Health Plans – Three New Rules

As stated previously, PPACA built on existing federal ERISA requirements for internal claims and appeals processes.⁴⁸ These protections are ex-

tended to the individual insurance market. Individual health insurance coverage must also comply with three additional rules. First, any decision to deny coverage to an applicant in an initial eligibility determination is considered an adverse benefit determination which is appealable.⁴⁹ Second, individual policies may have only one level of internal appeals, unlike group health plans which may have a second level.⁵⁰ Finally, third, individual policies must maintain records of all claims and notice associated with their internal claims and appeals process for at least six years (the standard under ERISA).⁵¹

External Review

When consumers exhaust the internal appeals process with their health plan, they may be able to seek an independent medical review of their case through an external review. Massachusetts law provides for the creation and regulation of an external review process.⁵² Consumers with fully-insured health plans may exercise their right to an external review with the Office of Patient Protection within the Department of Public Health after exhausting the internal appeals process with their health plan.⁵³ In 2009, the Office of Patient Protection received 404 requests for external review.⁵⁴ Some states, however, either have no or an inadequate process for external review. Also, since self-insured plans are not subject to state regulation, many consumers who participate in self-insured plans do not have the benefit of an external review process.⁵⁵

PPACA mandated that state external review processes meet, at a minimum, the consumer protections of the NAIC Uniform Model Act.⁵⁶ PPACA also called for a federal external review process for states that do not meet the minimum criteria and for self-insured plans.⁵⁷ For the most

part, Massachusetts complies with the NAIC model; however, several changes will need to be made in order to bring Massachusetts' process into compliance with federal law. For example, under the NAIC model, consumers must have at least four months after receipt of a notice of an adverse benefit determination to request an external review.⁵⁸ In Massachusetts, a consumer must elect external review within 45 days of receiving a final adverse determination.⁵⁹

Conclusion

The ultimate goal of these new appeals rules is to create uniform standards that govern the appeals process and enhance consumer protections. The changes to the internal appeals process will enable consumers to better understand their rights and will encourage insurance companies to administer claims fairly. In addition, the changes to the external review process will not only improve current state systems, allowing consumers to have an impartial review of an insurer's decision, but will also open the process to more consumers, such as those consumers who participate in self-insured plans. The impact and strength of these new provisions will be tested as consumers exercise their appeal rights.

(Endnotes)

1 U.S. Census Bureau, Current Population Survey, 2009 and 2010 Annual Social and Economic Supplements.
 2 29 U.S.C. §1144(a).
 3 See *Rush Prudential HMO v. Moran*, 536 U.S. 355 (2002) (discussing ERISA preemption).
 4 See *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) citing *Alessi v. Raybestos—Manhattan, Inc.*, 451 U.S. 504, 523 (1981).
 5 *Id.*
 6 While PPACA expanded consumer protections with respect to the internal and external appeals processes, it did not amend Section 502(a) of ERISA which authorizes various civil actions that may be brought by a participant or beneficiary of a plan and the remedies available to a plaintiff. In particular, Section 502(a)(1)(B) provides that a successful plaintiff may only receive the benefits that the plaintiff would have been entitled to under the terms of the plan. Punitive and compensatory damages are not

available to a plaintiff in an ERISA action.
 7 See 42 U.S.C. §300gg-19.
 8 See, generally 29 C.F.R. §2560.503-1. One of the core requirements under ERISA is that a Plan's claims procedures must provide a claimant with a full and fair review of a claim. This tenet of ERISA includes such protections such as: 1.) employee benefit plans must allow claimants to submit documents and records relating to their claim for benefits, and 2.) employee plans must provide claimants, upon request, with copies of all documents relevant to the claim for benefits.
 9 42 U.S.C. §300gg-19.
 10 29 C.F.R. §2590.715-2719.
 11 29 C.F.R. §2590.715-2719(g).
 12 42 U.S.C. §18011. One exception is the mandate that rescission was added to the definition of adverse benefit determination for grandfathered and non-grandfathered plans. See 42 U.S.C. §18011(a)(4)(3).
 13 42 U.S.C. §18011(1).
 14 Interim Final Rules for Group Health Plan and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 34552 (June 17, 2010).
 15 29 C.F.R. §2590.715-1251(g).
 16 29 C.F.R. §2590.715-2719(b)(2)(ii)(A).
 17 29 C.F.R. §2560.503-1(m)(4).
 18 *Id.*
 19 105 C.M.R. §128.128.020.
 20 See 29 C.F.R. §2590.715-2719(b)(2)(ii)(A); see also 29 C.F.R. §2590.715-2712.
 21 29 C.F.R. §2590.715-2712(a)(2).
 22 29 C.F.R. §2590.715-2712(a)(1).
 23 42 U.S.C. §18011(4)(A)(iii).
 24 29 C.F.R. §2590.715-2719(b)(2)(ii)(B). This provision of the law is waived until January 1, 2012.
 25 See 29 C.F.R. §2560.503-1(f)(2)(i) and 105 §128.309(2).
 26 See 29 C.F.R. §2560.503-1(h).
 27 See 29 C.F.R. §2560.503-1(h)(3).
 28 29 C.F.R. §2590-715-2719(b)(2)(ii)(C)(1).
 29 29 C.F.R. §2590-715-2719(b)(2)(ii)(C)(2).
 30 See *Glista v. Unum Life Ins. Co. of America*, 378 F.3d 113, 129 (1st Cir. 2004).
 31 See *Bard v. Boston Shipping Ass'n.*, 471 F.3d 229, 244 (1st Cir. 2004) (defining sandbagging as a Plan's shifting of the targets that a plan participant aims for, and then penalizing the participant for aiming at the first round of targets).
 32 29 C.F.R. §2590-715-2719(b)(2)(ii)(D).
 33 *Id.* For example, a health plan cannot give bonuses to a claims adjudicator based on the number of claims that he or she denies.
 34 See *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. 105 (2008) citing *Firestone Tire and Rubber Co. v. Bruch*, 109 S.Ct. 948 (1989).
 35 See *Denmark v. Liberty Life Assurance Co. of Boston*, 566 F.3d 1, 10 (1st Cir. 2009) (structural conflict of interest is a function of a Plan's dual role as both administrator and payer of claims); see also *Liston v. Unum Corp. Officer Sev. Plan*, 330 F.3d 19, 23 (1st Cir. 2003).
 36 See 29 C.F.R. §2590-715-2719(b)(2)(ii)(E). This provision of the law is waived until January 1, 2012.
 37 "Patient Protection and Affordable Care Act of 2010: Advancing Health Equity for Racially and Ethnically Diverse Populations," Joint Center for Political and Economic Studies, July 2010.
 38 See 29 C.F.R. §2590-715-2719(b)(2)(ii)(E).
 39 29 C.F.R. §2590-715-2719(b)(2)(ii)(F). This provision of the law is waived until January 1, 2012.
 40 See *Denmark v. Liberty Life Assurance Co. of*

Boston, 566 F.3d 1, 10 (1st Cir. 2009); see also *Liston v. Unum Corp. Officer Severance Plan*, 330 F.3d 19, 23 (1st Cir. 2009); *Lopes v. Met. Life Ins. Co.*, 332 F.3d 1, 5 (1st Cir. 2003); *Ormdorf v. Paul Revere Life Ins. Co.*, 404 F.3d 510, 519 (1st Cir. 2005).
 41 See *Vlass v. Raytheon Employees Disability Trust*, 244 F.3d 27 (1st Cir. 2009) (not foreclosing supplementation of the administrative record with information not available to the administrator at the time of its decision). This same issue is not present if a consumer pursues external review of his or her claim. The Massachusetts external review regulations mandate that carriers make a good faith effort to obtain records relevant to the external review and not in the possession of the carrier from providers. Also, the interim final regulations promulgated by the Departments mandate that claimants are allowed to submit to an independent review organization (IRO), the entity conducting the external review, additional information that the IRO must consider when conducting the external review. See 75 FR 43330; citing the NAIC Uniform Model Act, <http://www.dol.gov/ebsa> and <http://www.hhs.gov/ocio/>.
 42 See *Terry v. Bayer Corp.*, 145 F.3d 28, 40 (1st Cir. 1998) (citing reasons for exhaustion include minimizing the number of frivolous ERISA lawsuits, promoting consistent treatment of benefit claims, providing a nonadversarial dispute resolution process, and decreasing the cost and time of claims settlement).
 43 *Metropolitan Life Ins. Co. v. Glenn*, 544 U.S. 105, 105 (2008), citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 103 (2006).
 44 See, e.g., *Jebian v. Hewlett-Packard Co. Employee Benefits Organization Income Protection Plan*, 349 F.3d 1098, 1105 (9th Cir. 2003) ("deference applies only when the decision is made by the body vested with discretion").
 45 See *Firestone Tire and Rubber v. Bruch*, 489 U.S. 101, 102 (1989) (holding that the *de novo* standard of review applies unless the benefit plan expressly grants discretionary authority).
 46 29 C.F.R. §2590-715-2719(b)(2)(iii).
 47 29 C.F.R. §2560.503-1(f)(2)(ii).
 48 See *supra* text accompanying note 8 and note 27.
 49 45 C.F.R. §147.136(b)(3)(ii)(A).
 50 45 C.F.R. §147.136(b)(3)(ii)(G).
 51 45 C.F.R. §147.136(b)(3)(ii)(H).
 52 See M.G.L. 176 §14 and 105 C.M.R. §128.400.
 53 M.G.L. 176 §14.
 54 Massachusetts Department of Public Health Office of Patient Protection, External Review Requests, January – December 2009. http://www.mass.gov/?pageID=eohhs2terminal&L=5&LO=Home&L1=Researcher&L2=Insurance+%28including+MassHealth%29&L3=Managed+Care+Protections+and+Grievances&L4=External+Review+Statistics+from+the+Office+of+Patient+Protection&sid=Eeohhs2b=terminalcontent&f=dph_patient_protection_r_opp_statistic_09&csid=Eeohhs2
 55 See 29 U.S.C. §1144(b)(2)(B) (ERISA's deemer clause exempts self-funded plans from state laws that regulate insurance within the meaning of the savings clause at §1144(b)(2)(A)).
 56 See 42 U.S.C. §300gg-19(b) and 29 C.F.R. §2590.715-2719. See also Uniform Health Care External Review Model Act, National Association of Insurance Commissioners, April 2010. <http://www.dol.gov/ebsa/pdf/externalreviewmodelact.pdf>.
 57 42 U.S.C. §300gg-19(b).
 58 29 C.F.R. §2590.715-2719(c)(2)(vi).
 59 105 C.M.R. §128.400.

The Obama Administration's 2012 Proposed Budget Raises Concerns About Health Care Access for Children

by Karyn Brudnicki and Erin Talati

In March, the Obama Administration released its proposed budget for 2012. Among many budget changes was the elimination of funding for the Children's Hospitals Graduate Medical Education Program, which has the potential to significantly impact the pediatric workforce, ultimately limiting access to pediatric general and subspecialty care. This article first outlines the current funding scheme for graduate medical education, including the evolution of the Children's Hospitals Graduate Medical Education Program, then describes the proposed budget changes, and lastly argues how these changes may negatively impact access to care for the youngest patients.

Background

Upon graduation from medical school, in order to be eligible to sit for specialty boards and become board certified, physicians must complete residencies ranging from 3 to 5 years. In addition, fellowships of 1 to 3 years following residency training prepare graduates to become subspecialists in certain fields. These residencies and fellowship training are referred to as graduate medical education ("GME").

Most GME is funded by Medicare Part A as part of the expense of caring for Medicare patients.¹ In 2008, Medicare paid approxi-

mately \$8.4 billion to teaching hospitals through direct medical education ("DME") payments and indirect medical education ("IME") adjustment payments.² DME payments are intended to cover resident and faculty salaries, benefits, teaching time of faculty, and overhead, while IME attempts to address additional factors that increase costs in a teaching hospital.³ As Congress has stated, IME is "a proxy to account for a number of factors that may legitimately increase costs in teaching hospitals."⁴ For example, when training residents, staff productivity declines such that fewer hours are available for direct patient care.⁵ In addition, medical trainees—who are still developing their knowledge and clinical skills—may order diagnostic studies that a more experienced clinician may not.⁶ Moreover, while Medicare's prospective payment system reimburses hospitals based on the diagnosis related groups ("DRG") that apply to an individual patient,⁷ teaching hospitals tend to treat more severely ill patients than their DRG suggests because they often operate as safety-net and tertiary care hospitals.⁸ Finally, in teaching hospitals 24-hour care is provided by doctors rather than nurses or other healthcare providers. IME is calculated based on the percent of patient bed-days that are supported by Medicare and fund-

ing for the particular hospital is based on the ratio of residents to beds in a given facility.⁹ In 2008, IME payments were approximately twice DME payments.¹⁰

Pediatric residency positions are funded in two ways: first, many teaching hospitals have pediatrics departments that are part of the larger hospital system, which receives funding for residency positions based on the funding scheme described above. However, a number of the largest children's hospitals in the country are so-called free standing children's hospitals, which are dedicated exclusively to the care of children. Free standing children's hospitals receive less funding from the federal government through DME and IME payments compared to other hospitals because they care for fewer Medicare patients.¹¹

In 1999, however, Congress established the Children's Hospitals Graduate Medical Education (CHGME) Program through the Healthcare Research and Quality Act to provide support for free-standing children's hospitals' GME programs that train resident physicians,¹² providing a second funding source for pediatric residency positions. In 2006, CHGME was reauthorized for an additional five years.¹³ "This program compensates for the disparity in the level of Federal funding for

freestanding children's hospitals and other teaching hospitals supported by Centers for Medicare and Medicaid Services (CMS) GME funds."¹⁴ While GME is an entitlement, CHGME is funded through an annual appropriation.¹⁵ Hospitals are eligible to apply for this funding if they: 1) participate in an approved GME program, 2) have a Medicare Provider Agreement, 3) are excluded from the Medicare Inpatient Prospective Payment System (IPPS) under section 1886(d)(1)(B)(iii) of the Social Security Act, and its accompanying regulations, and 4) operate as a "freestanding" children's teaching hospital.¹⁶ All eligible hospitals receive DME and IME funding under the CHGME, which is structured similarly to funding available to other hospitals under Medicare.

Current Challenges

In FY 2010, the CHGME payment program was funded at \$317.5 million¹⁷ (with an authorization of \$330 million¹⁸), providing support for 56 freestanding children's teaching hospitals.¹⁹ Although they represent 1 percent of all hospitals, freestanding children's hospitals train about 40 percent of general pediatricians (almost 60 percent of whom are in general pediatrics), 43 percent of all pediatric specialists and the majority of pediatric researchers, and provide required pediatric rotations for residents in general internal medicine and family medicine.²⁰ Furthermore, almost 50 percent of the patient care that children's teaching hospitals provide is for low-income children and over 75 percent of inpatient care is for children with one or more chronic conditions.²¹ As referral centers for those with severe illnesses, children's

teaching hospitals provide critical pediatric services, and are the only source of care for many children. Thus, changes to GME funding have great potential to significantly impact pediatric care and the education of future pediatric generalists and subspecialists.

"Prior to the creation of CHGME, the number of medical residents in children's hospitals had declined more than 13 percent in the 1990s," increasing by 35% after CHGME provided funding for physician training.²² Over 80% of the growth in pediatric residency training is due to free standing children's hospitals.²³ However, there remains a workforce shortage in pediatric generalists and subspecialists. A national survey revealed that a substantial minority of children with special health care needs have unmet needs for routine and specialty care.²⁴ While the total number of physicians in the United States has increased from 153 medical doctors per 100,000 people in 1975 to 253 in 1997, the increase in physicians practicing in a pediatric subspecialty has been very limited.²⁵ This may in part be due to the fact that pediatric sub-specialization practice is generally not financially lucrative for physicians, with average salaries half that of adult specialty medicine physicians.²⁶

A survey of members of the National Association of Children's Hospitals and Related Institutions revealed that these "shortages of doctors across a multitude of pediatric sub-specialties are forcing 90% of hospitals to delay appointments, lose patients or refer them elsewhere," some positions remain unfilled for over a year, and almost half

of hospitals reported vacancies in pediatric-rehabilitation medicine, hematology and oncology, and cardiology.²⁷ These shortages and increased wait times are particularly acute in rural areas.²⁸ In 2010, sixteen states lacked at least one physician in one of thirteen sub-specialties.²⁹

Proposed Decrease in Funding and Impact on Access to Pediatric Care

Section 5503 of The Patient Protection and Affordable Care Act will reduce the direct GME and IME full-time equivalent caps for certain hospitals and permit a redistribution of full-time equivalent ("FTE") resident slots on July 1, 2011.³⁰ The Obama administration's proposed budget for 2012 would also eliminate the \$300 million annual appropriation that funds GME programs that train resident pediatricians at children's hospitals. The budget would replace the program with "targeted investments to increase the primary care workforce."³¹

U.S. Representative Frank Pallone, a New Jersey Democrat and a member of the Energy and Commerce Health Subcommittee, expressed concern over the impact on access to primary care and specialty care for children and announced on March 3, 2011 his intention to introduce a bill to reauthorize and fund the program.³² A letter dated March 22, 2011, signed by 40 senators urges the Obama Administration to provide full-authorized funding at \$330 million in Fiscal Year 2012.³³ At this time, no formal legislation has been introduced, leaving an expected shortfall in funding that will acutely affect free standing children's hospi-

tals with the potential for long term consequences on access to general and subspecialist pediatric providers.

It is unclear what the “targeted investments to increase the primary care workforce” would involve, but it is clear it would be a substantial reduction from prior funding levels.³⁴ The Patient Protection and Affordable Care Act addresses one aspect of the access to care issue by mandating health care coverage for all Americans through the imposition of a fine. Requiring everyone to have insurance, however, does not resolve the access to care issue if there are insufficient providers available to provide the care.

Hospitals are already coping with pediatric shortages by using telemedicine and asking adult specialists to treat children,³⁵ and shortfalls in funding for pediatric training can only be expected to exacerbate these shortages.

Hospitals receiving CHGME funding would feel the effects of the proposed funding cut the most and will either need to secure alternative funding for individual positions and/or find alternative care providers, further adding to the costs at individual hospitals. The net effect may be to significantly decrease access to pediatric providers both in the short and long term. In the short term, as the American Academy of Pediatrics Committee on Pediatric Workforce has concluded, “[c]hildren in underserved communities served by pediatric residents may be affected by reductions in the number of residents and residency programs.”³⁶ In the long term, if free standing children’s hospitals cannot obtain funding for pediatric train-

ing positions, the existing access shortages discussed above will be heightened.

Beyond access concerns, the proposed decrease in funding is problematic because it may lead to increases in the cost of pediatric care, as it can be costly to have physicians who are not pediatric subspecialists provide care for children. A Pediatric Subspecialist of the Future Workgroup of the Second Task Force on Pediatric Education examined several studies comparing the costs of services provided by pediatric subspecialists with other providers and found that hospital stays were shorter when pediatric subspecialists provided care and costs for a child with a heart murmur were 33% less when provided by a pediatric cardiologist compared to a pediatric generalist.³⁷

Every state with a free standing children’s hospital will likely feel the impact of the proposed CHGME cuts if they are enacted without a new federal funding alternative to preserve the current level of support. The consequences of the funding cuts are likely to be particularly significant in Massachusetts, where a significant amount of pediatric GME training takes place.³⁸ With the budget challenges most hospitals face,³⁹ if federal funding for GME is decreased, hospitals may naturally turn to their state legislatures for alternative funding. When Massachusetts enacted its health care coverage mandate in 2006,⁴⁰ it purported to replace uncompensated, safety-net emergency level access to care with insurance based access by requiring nearly every state resident to obtain insurance coverage. The Massachu-

setts approach has become a national model for health care reform. As a state with a large number of GME programs in pediatrics, and a state already facing pediatric care access issues, the state’s response to the proposed federal funding decrease will also undoubtedly be closely observed.

(Endnotes)

1 Patient care revenues of the teaching hospital funded GME before Medicare was enacted.

2 Elissa Fuchs, Association of American Medical Colleges, *Overview: Medicare Direct Graduate and Indirect Medical Education Payments*, at https://www.aamc.org/newsroom/reporter/feb09/87798/feb09_payments.html (February 2009).

3 42 C.F.R. §§ 413.75-83 (2010); 42 C.F.R. § 412.105 (2010). See also, American Academy of Pediatrics Committee on Pediatric Workforce, *Financing Graduate Medical Education to Meet Pediatric Workforce Needs*, 107 PEDIATRICS 785, 785 (2001) (describing the distinction between DME and IME payments).

4 American Academy of Pediatrics Committee on Pediatric Workforce, *supra* note 3, at 785 (quoting H.R. WAYS AND MEANS COMM. REP. NO. 98-25 (1983) and S. FINANCE COMM. REP. NO. 98-23 (1983)).

5 U.S. Department of Health and Human Services, *Children’s Hospitals Graduate Medical Education Payment Program*, at <http://bhpr.hrsa.gov/childrenshospitalgme/> (last visited Apr. 29, 2011).

6 *Id.*

7 Office of the Inspector General, *Medical Hospitals Prospective Payment System: How DRG Rates are Calculated and Updated*, 1, 5 (August 2001) (explaining the DRG payment rates are determined by calculating the average cost of treating a patient with a particular disease, such as providing “routine nursing services, room and board, and diagnostic and ancillary services,” but explicitly exclude direct medical education costs).

8 See Fuchs, *supra* note 2; American Academy of Pediatrics Committee on Pediatric Workforce, *supra* note 3, at 786.

9 42 C.F.R. § 412.105 (2010).

10 Fuchs, *supra* note 2.

11 American Academy of Pediatrics Committee on Pediatric Workforce, *supra* note 3, at 785.

12 Healthcare Research and Quality Act of 1999, Pub. L. No. 106-129, § 340e.

13 Children’s Hospital GME Support Reauthorization Act of 2006, Pub. L. No. 109-

307, § 2.

14 Letter from Associate Administrator, Department of Health and Human Services Health Resources and Services Administration, to Children's Hospital (Dec. 1, 2010).

15 For further information on the federal budgeting process and specifically the distinction between entitlement program funding and programs subject to regular reauthorization by Congress with annual review of funding levels, see United States Senate Committee on Authorization, *About the Budget Process*, at <http://appropriations.senate.gov/about-budget-process.cfm> (last visited Apr. 28, 2011) (clarifying the distinction between authorizations and appropriations).

16 U.S. Department of Health and Human Services, *supra* note 5.

17 Letter from Associate Administrator, Department of Health and Human Services Health Resources and Services Administration, to Children's Hospital (Dec. 1, 2010).

18 National Association of Children's Hospitals, *Children's Hospitals Ask Congress: Please Support Continued Stable Funding for Children's Hospitals GME, 2011*.

19 Letter from Associate Administrator, Department of Health and Human Services Health Resources and Services Administration, to Children's Hospital (Dec. 1, 2010); U.S. Department of Health and Human Services, *supra* note 5.

20 Letter from American Hospital Association et al., to Kathleen Sebelius, Secretary, Department of Health and Human Services (Mar. 3, 2011).

21 Letter from Associate Administrator, Department of Health and Human Services Health Resources and Services Administration, to Children's Hospital (Dec. 1, 2010).

22 American Academy of Pediatrics, *Children's Hospitals Graduate Medical Education Program: Support Reauthorization, Maintain Funding to Improve Access to Pediatric Subspecialists*, at <http://www.aap.org/sections/ypn/CHGME.pdf> (last visited April 28, 2011).

23 Letter from American Hospital Association et al., to Kathleen Sebelius, Secretary, Department of Health and Human Services (Mar. 3, 2011).

24 Michelle L. Mayer et al., *Unmet Need for Routine and Specialty Care: Data From the National Survey of Children with Special Health Care Needs*, 113 *PEDIATRICS*, e109, e111-15 (2004).

25 Alan Gruskin et al., *Final Report of the FOPE II Pediatric Subspecialists of the Future Workgroup*, 106 *PEDIATRICS*, 1224, 1224 (2000).

26 Laura Landro, *For Severely Ill Kids, A Dearth of Doctors*, *WALL STREET JOURNAL*, Jan. 20, 2010, available at <http://online.wsj.com/article/SB1000142405274870365210457465231>

1818328216.html. See also E. Ray Dorsey et al., *Influence of Controllable Lifestyle on Recent Trends in Specialty Choice by US Medical Students*, 290 *J. AM. MED. ASS'N* 1173, 1174 tbl. 1 (2003) (noting pediatrics is one of the lowest paid specialties with an "uncontrollable" schedule).

27 Landro, *supra* note 26.

28 *Id.*

29 *Id.*

30 The Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 5503. See also, Center for Medicare & Medicaid Services, Direct Graduate Medical Education (GME), at https://www.cms.gov/AcuteInpatientPPS/06_dgme.asp (last visited Apr. 29, 2011).

31 Julian Pecquet, Healthwatch, <http://thehill.com/blogs/healthwatch/other/147241-pallone-to-introduce-bill-funding-medical-education-at-childrens-hospitals> (Mar. 3, 2011 11:16 EST).

32 *Id.*

33 Letter from Sherrod Brown & Christopher S. Bond, Senators, United States Senate to Tom Harkin, Chairman, and Thad Cochran, Ranking Member, Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Senate Committee on Appropriations, United States Senate (March 22, 2011) available at <http://brown.senate.gov/imo/media/doc/CHGME%20Letter.pdf>.

34 Pecquet, *supra* note 31. Department of Health and Human Services Secretary Kathleen Sebelius acknowledges the cuts were prompted by the deficit.

35 Landro, *supra* note 26.

36 American Academy of Pediatrics Committee on Pediatric Workforce, *supra* note 3, at 788.

37 Gruskin et al., *supra* note 25, at 1236.

38 For example, Children's Hospital Boston has the largest graduate training program in the country. See Benjamin M. Scuderi, *Children's Hospital Faces Budget Cuts*, *THE HARVARD CRIMSON*, Feb. 24, 2011 available at <http://www.thecrimson.com/article/2011/2/24/program-childrens-training-hospital/>.

39 Under pressure from the government, insurers, employers, and patients to cut costs, as one the state's most expensive hospitals, Children's Hospital Boston has recently reduced fees by \$90 million and intends to trim the budget yet further. Liz Kowalczyk & Robert Weisman, *Children's Zeroes in on its Costs*, *BOSTON GLOBE*, Mar. 6, 2011. This will be challenging if the proposed CHGME cuts are implemented.

40 An Act Providing Access to Affordable, High Quality, Accountable Health Care, *MASS. GEN. LAWS ANN. ch. 111M § 2* (2006).

Recent HIPAA Enforcement Actions by the U.S. Department of Health and Human Services Office for Civil Rights

By Edward G. Zacharias, Esq.

On February 4, 2011, the U.S. Department of Health and Human Services Office for Civil Rights (OCR) imposed a civil money penalty (CMP) of \$4,351,600 against Cignet Health of Maryland (Cignet) for violating the privacy standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This was the first time that OCR used its CMP enforcement authority under HIPAA.

Less than two weeks later, OCR entered into a Resolution Agreement and a Corrective Action Plan with Massachusetts General Hospital and its physician organization (MGH) under which MGH agreed to pay \$1 million and comply with the terms of the Corrective Action Plan to settle potential violations of the HIPAA privacy and security standards (the Privacy and Security Rules). Together, the Cignet CMP action and MGH settlement suggest OCR is serious about enforcing HIPAA.

Civil Money Penalty Against Cignet

Cignet's website states that it is a "medical facility" that also offers a health plan.¹ The CMP imposed by OCR against Cignet stemmed from Cignet's failure to provide 41 patients with copies of their medical records after receiving the patients' requests for

them.² Cignet did not respond to any of the 41 individuals' requests. OCR received a number of complaints from patients about Cignet's unresponsiveness. OCR subsequently notified Cignet that it had opened investigations into Cignet's failure to respond to the individuals' requests. Despite OCR's request for a response to its investigation notices, Cignet failed to respond. As a result, OCR issued a subpoena directing Cignet to produce medical records related to certain of the patient complaints. Cignet did not produce the medical records and failed to respond to the subpoena.

After an additional, unsuccessful attempt by OCR to contact Cignet and obtain the requested medical records, the Department of Justice filed a petition to enforce the subpoena in the U.S. District Court for the District of Maryland. The court scheduled a hearing and ordered Cignet to appear, however, Cignet failed to appear and did not defend the action. The court subsequently ordered Cignet to produce the requested medical records. In response to the court's order, Cignet delivered 59 boxes of original medical records to OCR, which included the requested medical records as well as the medical records for approximately 4,500 other individuals for whom OCR had not requested records.

OCR ultimately imposed a CMP of \$3 million for Cignet's failure to cooperate throughout OCR's investigation and \$1,351,600 for Cignet's failure to provide the patients access to their medical records.

Release Agreement and Corrective Action Plan between MGH and OCR

On February 14, 2011, MGH signed a Resolution Agreement (the Agreement) and a Corrective Action Plan (the CAP) with OCR pursuant to which MGH paid the U.S. Department of Health and Human Services \$1 million and agreed to the terms of the CAP in order to resolve potential violations of the HIPAA Privacy and Security Rules. The Agreement and CAP were the result of OCR's investigation of an incident that occurred in March of 2009 when an MGH employee removed paper documents from the MGH premises in order to work from home and inadvertently left certain of the documents on the subway when commuting to work a few days later. The documents included the date of birth, medical record number, health insurer and policy number, diagnosis and provider name for 66 patients, as well as a medical practice's office schedule that listed the names and medical record numbers of patients. The document left on the subway were never

recovered and included the protected health information (PHI) of 192 individuals.

Under the terms of the Agreement and the CAP, MGH paid \$1 million to the Federal Government and agreed to take certain additional steps to safeguard PHI. The CAP requires MGH to:

- (1) develop and/or update certain of its policies and procedures related to the privacy and security of PHI;
- (2) train its workforce members on the policies and procedures;
- (3) designate an individual to monitor MGH's compliance with the CAP (the Monitor); and
- (4) submit an implementation report and annual reports thereafter to OCR. In return, OCR released any claims and causes of action under the Privacy and Security Rules that it may have had against MGH arising out of the incident.³

Under the terms of the CAP, MGH agreed to “develop, maintain, and revise, as necessary, written policies and procedures governing (i) physical removal and transport of [PHI], (ii) laptop encryption, and (iii) USB drive encryption.”⁴ The CAP makes clear that the policies and procedures are in addition to those required under the Privacy and Security Rules. The CAP, however, states that they may be incorporated into such existing policies. The CAP requires MGH to submit the policies and procedures to OCR for review and approval and implement them within 90 days

of such approval. The CAP further states that the policies and procedures will not be deemed to have been implemented until MGH's workforce is trained on them in accordance the CAP. MGH must submit an Implementation Report to OCR and the Monitor summarizing the status of its implementation of the CAP within 120 days of OCR's approval of the policies and procedures, and annual reports thereafter to the Monitor describing its continued compliance with the CAP. MGH is also required to annually review and update, as necessary, the policies and procedures and to submit such revised policies and procedures to OCR for approval. Any violations of the policies and procedures must be reported to the Monitor. Importantly, the CAP requires MGH to “prohibit any member of its workforce from physically removing PHI from MGH premises for use off-site and/or transporting PHI off-site if that workforce member has not” been trained on the policies and procedures and such training is certified in writing.⁵

The Monitor designated by MGH is responsible for assessing MGH's implementation of, and compliance with, the CAP. The Monitor must attempt to validate that MGH's workforce has received training on the policies and procedures and is acting in accordance with them. The CAP explicitly requires the Monitor to conduct unannounced MGH site inspections, interview workforce members and inspect laptops and USB flash drives containing PHI to ensure such devices are encrypted and meet any other requirements of the policies and procedures. The Monitor must submit semi-annual reports to

OCR and MGH and is required to report, any “significant violations” of the CAP. Any actions or omissions of the Monitor are deemed to be actions or omissions of MGH.

OCR's Enforcement Approach

Much has been made in the press of the fact that OCR's enforcement against Cignet was the first time the agency used its CMP enforcement authority under HIPAA. However, given the facts of the case and Cignet's unresponsiveness and lack of cooperation with OCR's investigations, it arguably would have been more surprising had OCR not instituted a penalty in some form. Unlike the Cignet case, the failure of a covered entity to timely respond to an individual's request is often simply due to a breakdown in an organization's HIPAA procedures. It is important for an organization to keep a record of, and train its workforce on how to handle, an individual's or enforcement agency's HIPAA request. OCR routinely asks about an organization's policies and procedures in its complaint investigations and has stated that an organization's failure to implement policies and procedures may cause OCR to conclude that it has a higher culpability level and, therefore, is a candidate for a larger penalty.

The MGH settlement is more instructive than the Cignet case with respect to OCR's approach to enforcing HIPAA compliance, as similar circumstances are likely to occur at other covered entities in the future. In connection with its announcement of the Agreement and the CAP, OCR's director, Georgina Verdugo, stated, “[w]e hope the health care industry will take a close look at

this agreement and recognize that OCR is serious about HIPAA enforcement. It is a covered entity's responsibility to protect its patients' health information."⁶

Covered entities and business associates⁷ should reassess the adequacy and effectiveness of their HIPAA compliance programs. Such a reassessment should include at least the following basic steps required by the Privacy and Security Rules and the Interim Final Rule governing security breaches of PHI⁸:

- Conduct a security risk assessment that identifies the risks and vulnerabilities to its electronic protected health information;
- Implement written security policies that reflect the results of the risk assessment;
- Adopt written privacy policies implementing each provision of the HIPAA privacy standards;
- Train each employee who handles protected health information regarding its privacy and security policies and document the employee names and the dates of the training sessions; and
- Notify employees that if they receive a written request from an individual or a government agency, to forward that request to the HIPAA Privacy/Security Officer for processing.

² See Notice of Proposed Determination, available at <http://www.hhs.gov/ocr/privacy/hipaa/news/cignetnews.html>.

³ The release does not extend to any actions resulting from a HIPAA violation where the offending individual(s) knows he or she is wrongfully using or disclosing individually identifiable health information.

⁴ See CAP, p. 3.

⁵ The CAP includes an exception to this requirement to cover the period between the execution of the CAP and the date by which the policies and procedures are required to have been implemented so long as MGH has provided such workforce members with a communication including, in part, a requirement that they take reasonable steps to protect and secure the PHI.

⁶ See Massachusetts General Hospital Settles Potential HIPAA Violations (February 24, 2011), available at <http://www.hhs.gov/news/press/2011pres/02/20110224b.html>.

⁷ Effective February 18, 2010, the Health Information Technology for Economic and Clinical Health Act made business associates civilly and criminally liable to the government for violations of: (1) the Security Rule's administrative, physical, and technical safeguards requirements as well as its written compliance policy and documentation requirements; and (2) the Privacy Rule's business associate agreement requirements.

⁸ See Breach Notification for Unsecured Protected Health Information; Interim Final Rule, 74 Fed. Reg. 42,740 (August 24, 2009).

(Endnotes)

¹ See Cignet website at <http://www.transatlantictimes.info/plan/index.html> and <http://www.transatlantictimes.info/center/aboutus.html>.

Health Law Brief

by Audrey Perlow, Esq.

Law v. Griffith, 457 Mass. 349 (2010)

This case grapples with the important issue of how to accurately and fairly estimate medical costs in today's complex healthcare environment. Here, the Massachusetts Supreme Judicial Court (SJC) examines "the admissibility of medical bills 'as evidence of the fair and reasonable charge' for medical services provided" in a negligence case.¹ A Massachusetts Superior Court judge excluded the bills in the case at hand because the bills did not reflect the actual amounts paid by the patient's insurer. On appeal, the SJC held that M.G.L. ch. 233, § 79G (§ 79G) does not authorize a court to exclude such evidence. However, the court further concluded that information on the range of actual payments accepted by a provider as payment in full for a particular service - incorporating rates from multiple payers - is admissible under the same statute.

The plaintiff was injured when the defendant's vehicle struck the plaintiff's vehicle. As a result of the accident the plaintiff required surgery and physical therapy, with her medical bills totaling \$112,269.94. Prior to trial the plaintiff filed a notice of her intention to introduce copies of her medical bills into evidence. The defendant filed a motion *in limine* to exclude the bills because the plaintiff had not paid the amounts billed. MassHealth, the patient's insurer, had paid the providers a markedly smaller

sum-\$16,387.14 - based on the negotiated terms of the providers' agreements with the state program. The Superior Court judge "allowed the defendant's motion on the ground that the bills were not relevant to establish the value of the medical services the plaintiff had received because those amounts had not been paid, nor were expected to be paid, by either the plaintiff or her insurer."² The plaintiff challenged the trial judge's exclusion of her bills and the Appeals Court found the Superior Court judge erred in not allowing the bills into evidence. The defendant filed an application with the SJC for further review.

An important element to the Court's discussion is recognition of - and reaffirmance of - Massachusetts' common-law "collateral source rule." Under the rule "the value of reasonable medical expenses that an injured plaintiff would be entitled to recover from the tortfeasor as a component of her compensatory damages...is not to be reduced by any insurance payments or other compensation received from third parties by or on behalf of the injured person."³ The stated purpose of the collateral source rule is deterrence so that a tortfeasor does not benefit from either contractual arrangements of the injured party (such as with a health insurer) or gifts to the injured party. Ergo, it is preferable for a plaintiff to receive an excessive recovery than for a tortfeasor to be given partial or total immunity

from the consequences of their actions.

The second element to the Court's analysis is an examination of § 79G. The first paragraph of the statute contains two sentences.

"In any proceeding in any court... an itemized bill and reports, including hospital medical records, relating to medical, dental, hospital services, prescriptions, or orthopedic appliances rendered or prescribed for a person injured...shall be admissible as evidence of the fair and reasonable charge for such services or the necessity of such services or treatments..."

"Nothing contained in this section shall be construed to limit the right of any party to the action to summon...such physician, dentist, pharmacist, retailer of orthopedic appliances or agent of such hospital or health maintenance organization for the purpose of cross examination with respect to such bill, record and report or to rebut the contents thereof, or for any other purpose, nor to limit the right of any party...to summon any other person to testify in respect to such bill, record or report or for any other purpose."⁴

When interpreting the first sentence, the Court cites numerous precedents that speak to the fact that statutes should be interpreted according to the intent of the Legislature. Further, when "the language of the statute is clear,

it must be interpreted according to the ordinary meaning of the language used.”⁵ Here, the author(s) of the statute unambiguously state that medical bills are admissible for the plaintiff’s purpose. The SJC, therefore, held that medical bills are admissible and the trial court judge was in error on this point.

The more challenging analysis comes as the Court tries to reconcile the collateral source rule with the second sentence of § 79G in the context of today’s healthcare environment. Under the collateral source rule, Massachusetts courts (and other jurisdictions) have not allowed evidence of “‘outside source’ compensation”⁶ because jurors might be led to reduce or deny recovery. The Court here acknowledges, however, that due to the complexity of contracting arrangements today, medical bills may not bear a “fair and reasonable”⁷ relationship to the value of services rendered. Further, the second sentence of § 79G clearly speaks to the defendant’s right to present evidence to assist a fact-finder in coming to an appropriate fair and reasonable medical expenses determination. One additional twist the court grapples with is that, like the amounts billed, the amounts paid may also not be representative of the fair and reasonable value of services rendered.

The Court takes this information and creates guidance for interpreting § 79G - written in 1958 - today. The SJC instructs that a defendant should be permitted “to call a representative of the particular medical provider whose bill the defendant wishes to challenge, and to elicit evidence concerning the provider’s

stated charges and the range of payments that that provider accepts for the particular type or types of services the plaintiff received.”⁸ Such a witness could acknowledge that the range of payments reflect amounts paid by self-paying patients and third-party payers. The witness would not, however, be permitted to identify a plaintiff’s third-party payer - if there is one - or to testify to an amount actually paid on a plaintiff’s behalf.

Three SJC judges concur with the opinion. They agree on the point that the Legislature, through the enactment of § 79G, intended for medical bills to be admissible into evidence for the purpose of determining fair and reasonable medical charges. They disagree, however, with the court’s creation of a “nervous compromise that will be difficult to implement.”⁹ These three justices share a sentiment that jurors are not given enough credit for their ability to conduct analysis. The trio would give jurors as much information as possible - including the amount actually paid by a third-party payer - to assist in determining the reasonable value of medical services. To this point, the justices note that the collateral source rule is a common law creation, and the judicial branch has the power to revise or eliminate the rule.

(Endnotes)

1 Law v. Griffith, 457 Mass. 349, 349-50 (2010) (citing M.G.L. ch. M.G.L. ch. 233, § 79G).

2 *Id.* at 351.

3 *Id.* at 355.

4 *Id.* at 354 (citing M.G.L. ch. 233, § 79G).

5 Law, 457 Mass. at 353.

6 *Id.* at 355.

7 M.G.L. ch. 233, § 79G.

8 Law, 457 Mass. at 360.

9 *Id.* at 364.

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Karyn Brudnicki teaches Business Law and Ethics at Mount Ida College. She formerly practiced as an associate in the Health Care practice group of Ropes & Gray LLP. Ms. Brudnicki's practice includes transactional, regulatory, and policy work for a range of health care industry clients. Her legal experience includes representing hospitals in connection with mergers and acquisitions and in numerous capital financings.

Ms. Brudnicki earned her undergraduate degree from Dartmouth College (cum laude) and her law degree and Masters in Bioethics from the University of Pennsylvania. While at law school, she served as an editor on the University of Pennsylvania Law Review and advised clients through the Custody and Support Assistance Clinic.

Audrey Perlow, Esq.

Audrey Perlow currently advises members of the life sciences industry on a range of compliance matters. Previously, Ms. Perlow was a fellow at Health Law Advocates (HLA) where she provided direct client advocacy for low- and middle-income Massachusetts residents. In addition to handling formal and informal healthcare appeals she acted as a mental health guardian ad litem for court-involved youth, and through her work she appeared at administrative hearings and in juvenile courts throughout the state. Ms. Perlow worked on a variety of health law policy initiatives while at HLA, including extensive work representing consumer interests during the recent purchase of the Caritas Christi Healthcare System.

Ms. Perlow is a graduate of Georgetown University, the Harvard School of Public Health, and Northeastern University School of Law. Prior to graduate school she was an emergency management consultant.

Erin Talati

Erin Talati, JD, MD, M.Be graduated from the University of Pennsylvania Law School with a juris doctor degree and from the University of Pennsylvania School of Medicine with a Doctor of Medicine and Masters in Bioethics. At Penn, she worked as a child advocate for dependent children through the Penn Legal Assistance Office. She also worked on children's health care issues with the ABA Center on Children and the Law and the Child Welfare League of America. Following completion of her training at UPenn, Dr. Talati completed residency training in Pediatrics at the University of Chicago Hospitals and is currently a fellow in pediatric critical care medicine at Children's Hospital Boston.

Alyssa Yenikomshian, Esq.

Alyssa Yenikomshian is the Project Director for the Consumer Assistance Program at Health Law Advocates. Health Law Advocates is a public interest law firm whose mission is to provide pro bono legal representation to low-income Massachusetts residents experiencing difficulty accessing or paying for needed medical services. The Consumer Assistance Program is committed to handling legal disputes arising out of individuals' access to private health insurance benefits. Ms. Yenikomshian assists individuals with all facets of private insurance appeals and grievances. She also advises individuals on the changes to the private insurance market since the enactment of the Patient Protection and Affordable Care Act.

Prior to joining Health Law Advocates, Ms. Yenikomshian worked as a litigation associate at Rosenfeld Rafik & Sullivan, a law firm specializing in disability and health insurance coverage matters. She represented individuals with chronic illnesses and disabilities in employee-benefit related matters including short-and long-term disability benefits. She also represented individuals in health insurance and long-term care insurance disputes. Ms. Yenikomshian has advocated to secure insurance benefits for her clients through the administrative process and litigation.

Ms. Yenikomshian graduated cum laude from Suffolk University Law School and completed the health and biomedical law concentration with distinction honors. She also graduated cum laude from Tufts University where she earned a Bachelor of Arts degree.

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Edward G. Zacharias is a senior associate at McDermott Will & Emery LLP. Ed represents a variety of health care clients in connection with HIPAA compliance, data privacy and security, fraud and abuse and Stark compliance, reimbursement issues, acquisitions, joint ventures, strategic affiliations, and conversion transactions. He is an active member of the Boston Bar Association and served as a member of the BBA's 2008-2009 Public Interest Leadership Program.

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