HLB
HOOPER, LUNDY & BOOKMAN, PC
HEALTH CARE LAWYERS
Celebrating 25 YEARS of excellence

HEALTH LAW PERSPECTIVES

Newsletter
Volume 14, No. 10
December 2012

HLB Opens Federal Government Relations Practice in Washington, D.C.
Experienced Team Will Provide Congressional and Regulatory Advocacy

Hooper, Lundy & Bookman, PC, is pleased to announce the opening of its new Federal Government Relations and Public Policy Department.

Based in the firm's Washington, D.C. office, the new department is led by Martin A. Corry. Veteran health care lobbyist, Kelly L. Lavin and economic policy specialist, Alex M. Brill round out the team.

"With health care policy moving strongly to the federal level, it is vital that our practice evolve to meet our clients' needs," said HLB Managing Partner, Robert W. Lundy. "Marty, Kelly, and Alex are a strong team with a proven track record. I am confident they will serve our client interests well."

"As health reform implementation continues to unfold, the delivery of care is increasingly affected by decision making in Washington," said Department Chair Martin Corry. "Furthermore, Congress and the Executive Branch will continue to pursue policies to reduce federal health spending, increase transparency and compliance and improve health outcomes. Providers and payers alike will be well served by engaging policymakers to help guide these decisions. We are very excited to join HLB and its nationally recognized team of health care lawyers. We look forward to serving clients in an integrated, outcome-oriented manner."

HLB's Government Relations Team

In addition to almost 30 years as a federal lobbyist, **Martin Corry** is the former Special Assistant to the Administrator of the Centers for Medicare and Medicaid Services (CMS) where he served from 2002-2007. In this capacity, Mr. Corry was involved with a wide range of matters ranging from implementing the Medicare Modernization Act (MMA) to the annual issuance of CMS payment rules, where he interfaced with the Office of Management and Budget. Prior to joining CMS, Mr. Corry spent 15 years as the Director of Federal Affairs for the American Association of Retired Persons (AARP).

Kelly Lavin brings significant policymaking experience to HLB. She is a former legislative assistant to former U. S. Representative Phil English, who served on the powerful House Ways and Means Committee. She served as director of federal government affairs for the American Physical Therapy Association (APTA). Ms. Lavin has expertise in a variety of areas, including Medicare reimbursement, scope of practice and health information technology.

As the department's economic policy advisor, **Alex Brill's** experience includes serving as the senior advisor to former chairman of the House Ways and Means Committee, Bill Thomas and as the chief economist of that Committee. He also served as an economist at the White House Council of Economic Advisors and more recently as a consulting advisor to the Simpson-Bowles Commission. He is currently a research fellow at the American Enterprise Institute.

In This Issue

Scope of Services

HLB's Federal Government and Public Policy Department is immediately available to assist the firm's health care clients with a full complement of services, including:

- Legislative and Regulatory Advocacy
- Proposed Legislation Development and Monitoring
- Strategic Planning and Risk Assessment
- Assistance with Funding and Grant Applications
- Coalition Building

For additional information, please contact Mr. Corry, Ms. Lavin or Mr. Brill at 202.580.7700.

Partner Jon Neustadter Departs HLB for Career In the Arts Sector

HLB Partner Jon Neustadter has announced that he will leave HLB at the end of 2012 to pursue his passion to serve the Los Angeles non-profit arts community. Mr. Neustadter has been a highly valued member of the firm since he joined over 18 years ago.

"I cannot imagine a better firm to have worked at, or a more impressive and sophisticated group of lawyers and clients to have worked with, over these past 18 years," said Mr. Neustadter. "I will miss the everyday collaboration and strategizing on significant, complex regulatory healthcare matters, but I am also excited to have the opportunity to dive deeper into, and further support, various non-profits in Los Angeles."

Mr. Neustadter received a B.A. with distinction from the University of Virginia in 1991. He received a J.D. degree from UCLA Law School in 1994 and was admitted to the California bar that year.

A member of the HLB Regulatory Department, Mr. Neustadter specialized in Medicare and Medicaid reimbursement and fraud and abuse disputes. He represented many types of health care entities, including hospitals, laboratories, home health agencies, DME suppliers, skilled nursing facilities and physicians in reaching negotiated settlements, pursuing administrative remedies, and in litigating federal and state court cases.

"I have known Jon for his entire legal career and can say with some assurance that few people that practice in this area are as talented and even fewer have contributed so greatly to ensure fair payment by government health programs to members of the industry we serve," said John Hellow, chairperson of the HLB Regulatory Department. "Jon's wise counsel will be missed by all, and by me in particular."

Mr. Neustadter was also active in many pro bono cases referred by the HIV & AIDS Legal Services Alliance (HALSA) and won HALSA's Pro Bono Service Award in 2004 and 2010.

U.S. Senate Holds Hearing on Dual-Eligibles Demonstration Projects

By Kelly Lavin

On Thursday, December 13, the U.S. Senate Committee on Finance held a hearing entitled ***Improving Care for Dually-Eligible Beneficiaries: A Progress Update.***

Witnesses before the Senate Finance Committee included: **Melanie Bella**, Director, Medicare-Medicaid Coordination Office, Centers for Medicare & Medicaid Services (CMS); Tom Betlach, Director, Arizona Health Care Cost Containment System; **Mary Anne Lindeblad**, Director, Washington State Health Care Authority and **John McCarthy**, Director, Ohio Department of Job and Family Services, Office of Health Plans.

For several years there has been bi-partisan support for improving the coordination of the Medicare/Medicaid dual population. Such support resulted in the requirement for a five-year demonstration project and care coordination for this patient population in Sections 2601 and 2602 of the Accountable Care Act. However, since CMS started their process on the Financial Alignment Demonstrations (demonstrations), concern from the Hill has risen.

In June, Senator Jay Rockefeller (D-WV), Chairman of the Senate Finance Subcommittee on Health Care, sent a letter to U.S. Health and Human Services (HHS) Secretary Kathleen Sebelius, calling on HHS to revisit the way it is implementing the demonstrations for beneficiaries who are eligible for both Medicare and Medicaid under the Federal Coordinated Health Care Office. In the letter, Rockefeller urged HHS to reject state proposals not designed as careful demonstration programs, assure full protection of beneficiaries' rights and access to high quality medical care, and thoroughly evaluate the effectiveness of new models of care before expanding them on a larger scale.

Other Members of Congress have concerns as well. The December 13 hearing was to make clear the seriousness of the Hill's concern. In addition, as policy makers on Capitol Hill look into broader Dual-Special Needs Plans (D-SNP) reauthorization and possible SNP policy reform next year, this issue will arise again in those debates.

Despite the testimony providing only positive news on the demonstrations, Rockefeller expressed strong concerns about these efforts to coordinate care for people who are dually eligible for Medicare and Medicaid benefits. The first panel included Melanie Bella, the Director of CMS's Medi-

care-Medicaid Coordination Office who testified that "CMS continues to make progress in our efforts to create a more streamlined system that delivers appropriate, quality, cost-effective care." Senator Rockefeller opened with the question "progress for whom?" and went on to blast CMS for not addressing concerns he expressed in his June letter to HHS about the demonstration.

At the hearing he again asked this demonstration be halted so CMS may retool the program, which he says can be harmful to beneficiaries because they are limited in their ability to opt-out and may not have access to the same providers they rely on to care for their unique needs. Managed care plans never have demonstrated success "with even small numbers of dually eligible beneficiaries." Further, the large number of people involved in the demonstration programs indicates that the programs "aren't really demonstrations" and instead are policy changes, he added.

Other Senate Finance Committee members asked questions and voiced their concern on an array of issues including; specific questions about their home state demonstrations, concerns over the high complexity of care for this population and the need for CMS to be more flexible with states that were too advanced in the area of care and low cost to benefit from the duals demo. In addition, there was bi-partisan concern that CMS is focusing too much on cutting cost and not enough on coordination of care.

The second panel included the three state representatives and each gave a brief summary of how their state is preparing for the demonstrations. Tom Betlach, Director of Arizona's Health Care Cost Containment System, stated that a recent study showed that their state's Medicaid managed care has been a success and they are currently planning on increasing their dual-eligible alignment from 40,000 to 100,000.

Mary Anne Lindeblad, Director of Washington State Health Care Authority, discussed their state's plan and highlighted their ability to meet a diverse population, including the most diverse zip code in the country, which has 72 languages spoken in it. Unlike other states, Washington is planning to cover less than 50 percent of their state's dual population starting in April 2013. John McCarthy, Director of Medicaid and the Office of Medical Assistance in Ohio discussed their state's newly approved demonstration program, wherein they set three primary goals to have: 1) one central contact for beneficiaries; 2) seamless care; and 3) easy navigation of the program for both beneficiaries and providers.

Irrespective of the serious concerns raised by Senators in last week's hearing, CMS is still moving forward with the demonstrations and we will probably see more states approved in the first of 2013.

For more information, please contact Kelly Lavin, Director of Government Relations & Public Policy (a non-lawyer professional) in Washington, D.C. at 202.580.7704; or the following attorneys: John Hellow or Lloyd Bookman in Los Angeles at 310.551.8111; Mark Johnson in San Diego at 619.744.7300; Mark Reagan in San Francisco at 415.875.8500; or Robert Roth in Washington, D.C. at 202.580.7700.

Federal Court Strikes Down Restraints on Promoting Lawful, Off-Label Use of FDA Approved Drugs

By Brad Tully & Brett Leitner

Bucking a trend of increased federal enforcement activity against the promotion of "off-label" use of prescription drugs that has resulted in settlements totaling in the billions of dollars, the United States Court of Appeals for the Second Circuit, on December 3, struck a potentially serious blow to the Federal Food, Drug and Cosmetic Act (the FDCA) by holding that the government cannot prosecute a pharmaceutical manufacturer's representative under the FDCA for speech promoting the lawful, "off-label" use of an FDA-approved drug (United States v. Caronia 2012 WL 5992141 (C.A.2 (N.Y.)). Caronia represents a wider recent trend among federal courts of striking down regulations that restrict the free flow of information in the pharmaceutical sector based upon the First Amendment's guarantee of free speech.

Alfred Caronia had been found guilty by a jury of conspiracy to introduce a misbranded drug (Xyrem, used for the treatment of narcolepsy) into interstate commerce, which is a misdemeanor violation of 21 U.S.C. §§ 331(a) and 331(a)(1). The FDCA prohibits "misbranding," or "the introduction or delivery for introduction into interstate commerce of any … drug … that is … misbranded." 21 U.S.C. § 331(a). A drug is misbranded if, inter alia, its labeling fails to bear "adequate directions for use," 21 U.S.C. § 352(f), which FDA regulations define as "directions under which the lay[person] can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. FDA regulations in turn define "intended use" by reference to "the objective intent of the persons legally responsible for the labeling of drugs." Such intent may be demonstrated by, among other evidence, "oral or written statements by such persons or their representatives" and "the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." 21 C.F.R. § 201.128.

The FDA has concluded that "an approved drug that is marketed for unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include adequate directions for use." See U.S. Food and Drug Administration, *Draft Guidance, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Ap-*

proved of Cleared Medical Devices (2009). Thus, the government has treated promotional speech as more than merely evidence of a drug's intended use – essentially, it has construed the FDCA to prohibit promotional speech as misbranding itself. *Caronia* held this to be impermissible.

In so doing, the court relied heavily on principles set forth in the recent decision of the United States Supreme Court in *Sorrell v. IMS Health*, which was handed down in June 2011. *Sorrell* reviewed the Vermont Prescription Confidentially Law (the VPCL), which prohibited pharmaceutical companies and similar entities from using prescriber-identifying information for marketing purposes. The *Sorrell* Court held that the Vermont statute set forth content and speaker-based restrictions, and that the statute was therefore subject to heightened scrutiny. Because the VPCL disfavored speech with a particular content (marketing) when expressed by certain disfavored speakers (pharmaceutical manufacturers), the Court held that is unconstitutionally restricted speech.

In reaching this conclusion, *Sorrell* employed a two-step analysis. First, the Court considered whether the government regulation restricting speech was content and speaker based. The Court held that it was, and was therefore subject to heightened scrutiny and "presumptively invalid." Second, the Court considered whether the government had shown that the restriction on speech was consistent with the First Amendment under the applicable level of heightened scrutiny. The Court concluded that the government did not meet its burden.

Using this same analysis, the *Caronia* Court first concluded that the government's interpretation of the FDCA's misbranding provisions to prohibit off-label promotion was content based, because it distinguished between favored speech and disfavored speech on the basis of the ideas or view expressed. The FDCA's misbranding provisions were also speaker-based because they targeted only one kind of speaker – pharmaceutical manufacturers – while allowing others, such as physicians, to speak without restriction.

Following the framework of *Sorrell*, the *Caronia* Court then considered whether the government had shown that the restriction on speech was consistent with the First Amendment. In doing so, the Court borrowed the 4-part test from *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980). First, to warrant First Amendment protection, the speech in question must not be misleading and must concern lawful activity. The Court noted that promoting off-label drug use concerns lawful activity, and the promotion of off-label drug use is not in and of itself false or misleading. Second, to justify regulations restricting speech, the asserted government interest must be substantial. The Court accepted that the government's interests in drug safety and public health are substantial. The third and fourth prongs of *Central Hudson* require that the regulation must directly advance the government interest asserted and must be "narrowly drawn" as not to be more extensive than necessary to serve the interest. It is here, according to *Caronia*, where the FDCA fell short.

As the off-label drug use by physicians itself is not prohibited,

HLB Briefs

- HLB is pleased to announce its new **Health IT Blog**, covering current developments in health care technology. To visit the blog, please go to hlbhitblog.com. For additional information on HLB's Health IT practice, please contact attorneys, Paul Smith or Stephen Phillips in San Francisco at 415.875.8500; Hope Levy-Biehl, Karl Schmitz or Amy Joseph in Los Angeles at 310.551.8111; or Jennifer Hansen in San Diego at 619.744.7300; or Kelly Lavin, *director of government relations & public policy* (a non-attorney professional) in Washington, D.C. at 202.580.7700.

- HLB Los Angeles attorneys, Charles Oppenheim and David Hatch, recently updated the Professional Corporations Chapter of the 2012 update of CEB book, *Selecting and Forming Business Entities*.

- HLB San Diego attorney, Gregory Daniels, has been elected 2013-2014 Co-Chair of the San Diego Bar Association's Law and Medicine Section.

the Court found that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would not directly further the government's goal of preserving the efficacy and integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs. Further, the government's construction of the FDCA to impose a complete and criminal ban on off-label promotion by pharmaceutical manufacturers was found to be more extensive than necessary to achieve the government's substantial interest. Instead, a ban on only inaccurate or misleading speech could have served the government's interests without at the same time ensnaring wholly legitimate speech.

Despite *Caronia*, the government will likely remain free to prosecute false or misleading claims regarding pharmaceutical promotion, and can prove misbranding through evidence other than speech. Moreover, the opinion of a dissenting judge suggests a path by which the government will likely try to limit the impact of the decision. Intriguingly, even the majority opinion did not question the ability of the FDCA to penalize the misbranding of drugs by introducing them into commerce without adequate labeling relating to their intended use. Using the speech of marketers in promoting the off-label use of drugs as evidence of the intended use of the drug in a misbranding case appears to continue to be permitted. The problem that the government had in *Caronia* was that it had taken the overly broad position that the promotion of off-label use, essentially, resulted in illegal misbranding in itself. Future court decisions will no doubt have to sort out more carefully the question of how off-label promotion is to be used to prove the intended use of the drugs. The government therefore may be able to regain much of the ground it lost in *Caronia* by focusing its prosecutions more narrowly.

The combined weight of *Sorrell* and *Caronia* indicate that federal courts are more willing to view much of the marketing done in the health care industry as protected First Amendment speech. Going forward, *Sorrell* and *Caronia* will effectuate an increase in free flow of information among consumers, sales representatives, manufacturers and physicians. However, whether there will be any increase in the marketing of prescription drugs for off-label uses remains to be seen.

The deadline for the government to request full court review by the 2nd Circuit passed on December 17th with no request for review or extension of the date to file such a request.

For additional information, please contact Brad Tully or Brett Leitner in Los Angeles at 310.551.8111; or Mark Johnson or Greg Daniels in San Diego at 619.744.7300.

HLB Assists MemorialCare with Acquisition, Knox-Keene Licensure

HLB is pleased to announce its role in helping Fountain Valley-based MemorialCare Health System to achieve its goal of launching a new health plan in Southern California.

"MemorialCare, like many health systems, is pursuing a multi-dimensional strategy in response to marketplace changes and health care reform initiatives, and views owning a health plan as a key component of that strategy," said Charles Oppenheim, lead HLB attorney handling the transaction.

MemorialCare created a new, fully-owned subsidiary, Seaside Health Plan, and is filing an application with the California Department of Managed Care to become a California (Knox-Keene) licensed health plan. Seaside was formed to support Medi-Cal managed care members and to prepare for the California Children's Services demonstration project, which targets children with certain diseases and ongoing medical conditions. The MemorialCare system currently includes six hospitals, three medical groups, several clinics and outpatient health centers in Los Angeles and Orange County.

In order to facilitate development of the health plan, MemorialCare will be purchasing certain assets from Signal Hill, California-based Universal Care. Universal Care owns the Brand New Day Health Plan, a Medicare Advantage prescription drug special needs plan serving people with severe or persistent mental illness.

Under the purchase agreement, MemorialCare will acquire experienced staff and health plan members via plan-to-plan contracts serviced through agreements with Universal's contracted providers and MemorialCare's primary care physician network.

HLB's role in the transaction includes providing strategic advice, negotiating and drafting the transactional documents, and assisting in all aspects of the Knox-Keene license application.

"Providers now realize that owning their own health plans has benefits independent of the global risks that a plan license allows them to assume," noted HLB attorney Kitty Juniper, a member of the legal team assisting MemorialCare.

The transaction is expected to close on April 1, 2013.

For more information, please contact Charles Oppenheim or Karl Schmitz in Los Angeles at 310.551.8111, or Kitty Juniper in San Diego at 619.744.7300.

HHS Releases De-Identification Guidance

By Hope Levy-Biehl

On November 26, 2012, the Department of Health and Human Services (HHS) issued its long-awaited guidance on methods for de-identifying protected health information or "PHI". The concept of "de-identification" is important under the HIPAA privacy rule because once health information is "de-identified," it is no longer "protected" under HIPAA.

If you have been waiting for new or creative ways to de-identify health information or relief from the limited de-identification construct outlined in the HIPAA privacy regulations, this guidance probably does not get you there. Instead, the guidance focuses on the two methods for de-identification contemplated in the privacy regulations, (i) the so-called "safe harbor" method for de-identifying PHI, accomplished by removing 18 specifically enumerated data elements spelled out in Title 45 of the Code of Federal Regulation, Section 164.514 or (ii) the "expert determination" method in which a statistical expert determines that the risk is very small that the information could be used to identify an individual.

When addressing the expert determination method, HHS clarified that there is no specific professional degree or certification program for designating who is an expert at rendering health information de-identified nor is there a particular process that an expert must use to reach the conclusion that the risk of identification is very small.

As part of its guidance, HHS provided a general workflow for expert determinations, suggesting that the expert determination is part of a multi-step risk assessment process that considers a number of principles, including replicability, data source availability and distinguishability. HHS suggested that although the privacy rule does not explicitly require that an expert determination about de-identification have a set expiration date, technology, social conditions, and the availability of information change over time and as a result, it may be necessary to reconsider and reevaluate health information that has previously been certified as de-identified by an expert to ensure that it continues to be de-identified prospectively in light of these changes.

In the context of the safe harbor exception, HHS clarified that in addition to removing all of the 18 specific data elements in order for health information to be de-identified, using parts or derivatives of any of the listed identifiers will result in the underlying information not being sufficiently de-identified. For example, two identifiers that must be removed for information to be de-identified are a patient's name and social security number.

According to the guidance, a data set that contained a patient's initials or the last four digits of the patient's social security number would not be de-identified. HHS further clarified the elements of dates that must be removed in order for health information to be de-identified and provided some examples of the catch all category of "any other unique identifying number, characteristic, or code" that must be removed in order for health information to be de-identified, including, for example, clinical trial record numbers, patient record or medication barcodes or any other characteristic that distinguishes an individual and allows for identification (such as a unique occupation).

This guidance from OCR should be reviewed carefully before using the safe harbor method to render PHI de-identified. In addition to providing further clarification, the guidance may push covered entities wanting to use de-identified health information into the expert determination exception because of seemingly strict interpretation of the safe harbor exception requirements.

You can access the guidance directly at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html.

For additional information, please contact attorneys Hope Levy-Biehl, Karl Schmitz or Amy Joseph in Los Angeles at 310.551.8111; Paul Smith, Stephen Phillips, or Clark Stanton in San Francisco at 415.875.8500; Jennifer Hansen in San Diego at 619.744.7300; or Kelly Lavin, director of government relations & public policy (a non-lawyer professional) or attorney Robert Roth in Washington, D.C. at 202.580.7700. Additional posts about Health IT may also be viewed on our blog at hlbhitblog.com.

CALENDAR

December 3
CHA Center for Behavioral Health, Huntington Beach
Mark Johnson presents on *California's Coordinated Care Initiative.*

January 2 - 5
National CLE Conference, Snowmass, CO
Robert Roth presents *Report from Inside the Beltway.*

10
CAHF New Laws, Ontario
Mark Johnson presents on the *New Laws and Programs Impacting Long Term Care Providers in California.*

10
ABA Webinar: Challenges in the World of Hospital Mergers: Key State and Federal Regulatory Issues
Stacie Neroni is a co-presenter of this webinar.

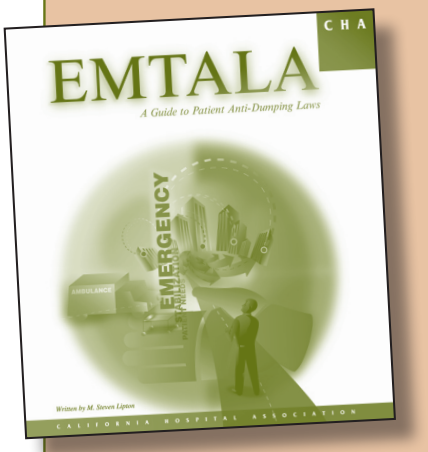
18
CAHF New Laws, Orange County
Mark Johnson presents on the *New Laws and Programs Impacting Long Term Care Providers in California.*

22
CAHF New Laws, San Francisco
Mark Reagan presents on the New Laws and Programs Impacting Long Term Care Providers in California.

23
CAHF New Laws, Sacramento
Mark Reagan presents on the *New Laws and Programs Impacting Long Term Care Providers in California.*

29
California Hospice and Palliative Care Association, Sacramento
Mark Johnson and Jodi Berlin present on *Strategies for ZPIC Audits/Investigations.*

The California Hospital Association has released a newly revised edition of *EMTALA — A Guide to Patient Anti-Dumping Laws.*



Authored by Hooper, Lundy & Bookman Attorney, Steven Lipton, the 8th edition includes the following changes:

- A new chapter describing the complexities of applying EMTALA and California's mental health laws (LPS) to treating emergency psychiatric patients
- Updating the position of CMS on asking emergency patients for financial/insurance information and aggressive debt collection activities
- Changes to California law allowing emergency services to be provided by non-physician practitioners in specified situations
- Guidance on how to respond and prepare for QIO/HSAG reviews and hearings on EMTALA cases
- Update regarding EMTALA obligation waivers during disasters and public health emergencies
- And more…

To order, or for additional information, please visit www.calhospital.org/emtala-manual.

HLB
HOOPER, LUNDY & BOOKMAN, PC
HEALTH CARE LAWYERS
1875 Century Park East, Suite 1600
Los Angeles, California 90067-2799