Contents:

The Impact of Healthcare Reform on Medical Device Companies .................................................. 2
Kristian Werling, Holly Carnell, and Drew McCormick

Mealey’s Corner ......................................................... 7

Health Care Law Monthly welcomes your comments and opinions. Please direct all correspondence and editorial questions to: Caroline Conway, 1252 Riverside Ave., Baltimore, MD 21230 (1-410-685-2169); e-mail: caroline.conway@lexisnexis.com. For all other questions, call 1-800-833-9844. Note: The information herein should not be construed as legal advice, nor utilized to resolve legal problems.

Editors-In-Chief
Elissa Moore
McGuireWoods
Charlotte, North Carolina

Jason Greis
McGuireWoods
Chicago, Illinois

Health Care Law Monthly welcomes your comments and opinions. Please direct all correspondence and editorial questions to: Caroline Conway, 1252 Riverside Ave., Baltimore, MD 21230 (1-410-685-2169); e-mail: caroline.conway@lexisnexis.com. For all other questions, call 1-800-833-9844. Note: The information herein should not be construed as legal advice, nor utilized to resolve legal problems.

(Pub. 349)
The Impact of Healthcare Reform on Medical Device Companies

By

Kristian Werling, Holly Carnell, and Drew McCormick

The Patient Protection and Affordable Care Act1 ("PPACA") as it was amended by the Health Care and Education Affordability Reconciliation Act of 20102 ("HCEARA") passed in the spring of 2010 and was signed into law by President Obama. PPACA and HCEARA combined comprise the "Healthcare Reform Act." The Healthcare Reform Act has a broad range of provisions that will start the process of reshaping health care in the United States. There are also a number of provisions that warrant specific attention from the medical device industry. This article provides a brief summary of the key provisions of the Healthcare Reform Act that will have the greatest effect on medical device manufacturers and other players in the medical device industry.

1. Industry Fees. The Healthcare Reform Act included the much talked about "industry fees" or taxes that are applicable to pharmaceutical and medical device manufacturers, insurance companies, and pharmacy benefit managers. The medical device fee is effective as of 2012, pursuant to which manufacturers of medical devices will be required to pay 2.3% of the sales price for such devices as an industry fee. The definition of a "taxable medical device" includes any device that is defined in Section 201(h) of the Federal Food, Drug and Cosmetic Act and is intended for human use. A limited number of medical devices, including eyeglasses, contact lenses, hearing aids, and any other device that is determined by Centers for Medicare and Medicaid Services ("CMS") to meet the "retail exception," are exempted from this fee. The medical device industry fee is tax deductible by medical device manufacturers. Unlike the pharmaceutical fee, the medical device fee applies to all manufactures, regardless of size and revenue levels.

2. Paying for Expanded Coverage. The primary purpose of the Healthcare Reform Act was to expand coverage to a broader range of patients in the United States. In part, the Act accomplishes this expansion through a significant broadening of the eligibility criteria for enrollment in Medicaid. Specifically, the Medicaid expansion enables most individuals with incomes of less than 133% of the Federal Poverty Level to enroll in the Medicaid program. Additionally, the mandatory insurance requirement and broader availability of health insurance through Health Benefit Exchanges will help to ensure that there are more patients that have access to health care. Increases in access to care may result in a positive near-term impact on device manufacturers, as a result of the increased demand for medical services.

However, the Act does not contain significant changes to reimbursement methodologies or major decreases in reimbursement for healthcare providers. Therefore, Congress will likely be back at the table within the next three to ten years to address the cost issues that are attendant with the expansion of availability of healthcare services. It is unclear how Congress will address these cost issues, but one possibility is that it will decrease reimbursement in the future. Device manufacturers that are in high-tech, high-cost niches should begin to plan for potential reimbursement reductions in their sector. Additionally, it will be important for all device manufacturers to be able to differentiate their products as providing true clinical benefits instead of simply building a "better mousetrap."

3. Comparative Effectiveness. The final version of the Healthcare Reform Act did not include
comparative effectiveness rules that apply to the CMS coverage of healthcare products and services. However, the Act did lay the groundwork for future inclusion of comparative effectiveness measures when CMS makes payment decisions. The Act provides funding for a new independent entity called the Patient Centered Outcomes Research Institute ("PCORI"), which will study the effectiveness of various services, products, and therapies and will issue reports regarding their effectiveness. The reports that are generated by PCORI may be relied on by CMS or other third-party payors making decisions about payment, coverage, and treatment. Notably, the reports will be peer reviewed to assess scientific integrity and adherence to methodological standards. In addition, the reports will include a number of checks and balances to ensure their independence, such as review by experts in the scientific field relevant to the research under review who are screened for conflicts of interest and bias. At this time, CMS will not be directed to rely entirely on these reports for coverage decisions, but it can be anticipated that at some point in the future the content of these reports will likely have a major impact on the decision making of CMS and other payors.

4. Physician Payment Sunshine Act. The Healthcare Reform Act included many provisions that had previously been introduced in the Senate in the form of the Physician Payment Sunshine Act. The Physician Payment Sunshine Act provisions in the Healthcare Reform Act will require covered manufacturers that make a payment or other transfer of value to a physician or teaching hospital to report such payments annually in electronic form. Payments or transfers of value include consulting fees, payments for clinical trial participation, charitable donations, royalties, and a variety of payments that may be made to physicians and teaching hospitals. There are some payments that are exempted from the disclosure obligations. These exempted payments include annual aggregate payments to a recipient of less than $100 and individual payments of less than $10, payments that are made entirely through market research organizations, and the provision of samples to a physician or teaching hospital for the benefit of patients.

Manufacturers will be allowed to delay the publication of certain payment disclosures where the payment is made pursuant to a product development agreement or in connection with research on a potential new medical technology or device. This will help to protect confidentiality of product development initiatives. CMS is charged with providing an online report showing each manufacturer’s payments to the physicians and teaching hospitals.

Manufacturers have already started to make certain disclosures in states such as Vermont and Massachusetts. However, the Act contains some transparency provisions that are different than those in Massachusetts and Vermont. The Act preempts the provisions of state law that require the same types of information to be reported. However, a state law with more stringent requirements, or one that requires additional types of payments to be reported, is not preempted. For example, a state law requiring manufacturers to disclose payments made to nurses or allied health professionals would not be preempted by the Act. Manufacturers should work to ensure that they have a method for collecting the applicable payment data. Further, manufacturers should be prepared to provide justification for these payments and documentation to support the fair market value of such payments.

5. Amendments to Current Fraud and Abuse Laws. The Healthcare Reform Act amends certain federal fraud and abuse laws. Specifically, the Act amended the False Claims Act ("FCA"), the Anti-Kickback Statute ("AKS") and the Federal Sentencing Guidelines. The FCA subjects a person to monetary penalties and/or imprisonment for knowingly and willfully falsifying, concealing or covering up a material fact, making materially false representations, or using a document known to contain

---

any materially false statement. The Act expands the jurisdiction of the FCA to payments made in connection with the new Health Benefits Exchanges. More significant to medical device manufacturers is the elimination of the FCA’s “Public Disclosure Bar.” The Public Disclosure Bar prevented a qui tam plaintiff from using publically available information as the basis for a claim against an entity suspected of violating the FCA. The removal of this bar will increase the potential financial reward for certain qui tam plaintiffs. Therefore, the number of claims brought against medical device manufacturers will likely increase significantly.

The Act also amends the AKS, which prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration to induce or reward the improper referral of items or services reimbursable by a federal healthcare program. The Act reduces the “knowledge” standard, by providing that a person need not have actual knowledge or specific intent to commit a violation of AKS to constitute a violation. This amendment will make it easier to prosecute entities under the AKS in certain jurisdictions. In addition, the Act amends the Federal Sentencing Guidelines to increase sentences for defendants convicted of federal healthcare offenses and adds violations of AKS to the federal healthcare offense category. Finally, the Act also clarifies that a claim originating from a referral in violation of the AKS constitutes a false claim, thus enabling a violation of the AKS to serve as the basis for liability under the FCA. The likely result of these amendments to the fraud and abuse laws will be increases in claims brought and successful prosecutions, as well as more severe penalties for companies prosecuted under these laws.

6. Payment Reductions. The Healthcare Reform Act did not include direct payment reductions that apply to specific types of medical devices; however, there are provider payment reductions that will indirectly affect medical device manufacturers. For example, total payment reductions to hospitals during 2011 are expected to be in the range of .35% less than 2010 payments, according to the American Hospital Association. The Congressional Budget Office estimates that this will amount to $112.9 billion in hospital payment reductions over the next 10 years.

The payment reductions will take the form of direct provider reimbursement reductions. The majority of reimbursement cuts that will affect hospitals are in the Disproportionate Share Hospitals (“DSH”) program, which pays hospitals based on their volume of charity care. These reductions will equal about $36 billion over 10 years, beginning in 2014. Another example of a reimbursement cut is a new Medicare readmissions policy, slated to begin in fiscal year 2012, which will subject hospitals with readmission rates over a certain threshold to payment penalties. The overall expected impact of the readmission policy on the hospital industry is approximately $7 billion.

These reimbursement reductions will directly affect hospital budgets for certain types of capital spending and for spending related to devices that are not reimbursed as part of a Diagnostic Related Group. Device manufacturers should understand their customers’ budgets so they can anticipate whether their hospital and other provider customers may decrease their budget allocations for device purchases.

7. Shared Cost-Savings Reimbursement Programs. The Healthcare Reform Act sets forth certain reimbursement programs focused on rewarding providers for reducing the cost of care, including the formation of so-called accountable care organizations, or “ACOs,” and extending the gainsharing demonstration program. An ACO is essentially an organization of physicians and other healthcare providers that is assigned a population of Medicare beneficiaries and is paid a share of savings achieved through coordinated care efforts, provided certain quality standards are achieved.

The Act also authorizes the extension of the gainsharing demonstration program. CMS has an ongoing demonstration program that was initially enacted as part of the Deficit Reduction Act of 2005 to examine the benefits of gainsharing

---

7 See Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson, 130 S. Ct. 1396, 176 L. Ed. 2d 225 (U.S. 2010) (applying the public disclosure bar where a qui tam suit was brought on the basis of publically available information).
programs. Gainsharing is a program that is structured to allow for the sharing of certain cost savings achieved through the coordinated care efforts of providers within a particular service line, often through the management of supply costs. The demonstration program will have an impact on whether this type of program is implemented in a continued form.

While ACOs and gainsharing programs are not expected to have an immediate impact on medical device manufacturers, if these types of organizations gain traction, the utilization of certain devices and procedures may decrease. Device manufacturers that are preparing future sales projections should be aware of the development of these organizations and the potential impact thereof.

8. **Bundled Payment Pilot Program.** The Healthcare Reform Act also mandates that the Secretary establish a pilot program for bundling payments around an episode of care provided to an applicable beneficiary in order to improve the coordination, quality, and efficiency of healthcare services. Under the program, an episode of care includes the three days prior to admission to a hospital, the hospitalization itself, and post-acute care provided during the 30 days following discharge from the hospital. The Secretary will focus the pilot program on up to eight medical conditions, selected based on pre-defined criteria including the cost of treatment. The Secretary will also develop quality measures for use in the pilot program, which will include the reduction in rates of avoidable hospital readmissions and certain efficiency measures. Entities that participate in the pilot program will be expected to improve the quality of care provided. Though there is no direct impact on device manufacturers, providers will be required to provide all medically necessary services within a fixed budget. Therefore, providers will be incented to reduce the cost of care—while still improving quality. A potential byproduct of this payment model may be a reduction in providers' expenditures on certain medical devices where such reduction will not have an adverse impact on quality.

9. **Funding for Medical Device Innovation.** The Healthcare Reform Act included funding for grant monies to spur medical device innovation. The grant program, called the Cures Acceleration Network, enables the Director of the National Institutes of Health to award grants in order to promote innovation in technology supporting advanced research, development, and production of so-called “high need cures,” including through the development of medical products. To receive grant money, an entity must submit an application containing detailed information about the project for which the entity is seeking the grant, contribute non-federal funds to the project in the amount of $1 for every $3 awarded under the grant, and must also issue a final report at the end of the project describing the project outcomes. The award maximum is $15 million per project for the first fiscal year that the project is funded, with the possibility of receiving additional monies of up to $15 million in the subsequent fiscal year. Currently, Congress has authorized $500 million for the program for fiscal year 2010.

In addition to the grant program, the Healthcare Reform Act authorized the Qualifying Therapeutic Discovery Project, which grants a tax credit for any taxable year in an amount equal to 50% of the investment in any qualifying project. Qualifying projects include projects designed to treat or prevent diseases or conditions through activities including clinical trials and studies, carrying out research protocols, and developing products, processes, or technologies to further the delivery or administration of therapeutics. Alternatively, grants may be provided in lieu of tax credits for investment in a qualifying project in the amount of 50% of the investment, as long as the investment is made during a taxable year beginning in 2009 or 2010.

10. **Pay for Quality.** The Healthcare Reform Act includes numerous new initiatives pursuant to which provider reimbursement will be increased or decreased depending on the quality of care that providers are able to demonstrate. For example, Section 3008 of the Act provides that hospitals in the top quartile with respect to national rates of hospital-acquired conditions will have their Medicare payments for all discharges reduced by one percent. Similarly, Section 3007 of the Act directs the
Secretary to develop and implement a system where physicians are paid additional amounts for providing quality health outcomes for Medicare beneficiaries at a lower cost. These changes to payment systems will occur over an extended time period, but demonstrate that the CMS is moving toward a system focused less on payment for individual services, and more on paying for efficient, high quality, low cost care. Medical device manufacturers should take this into account in their near and long-term marketing and business plans. Even more so than in the past, to successfully market devices, manufacturers will be required to demonstrate that hospitals and healthcare providers can improve efficiency, quality, and value through the use of their medical devices.

***

The above 10 points are just the tip of the iceberg of how medical device manufacturers will need to adjust to the new healthcare landscape following the passage of the Healthcare Reform Act. Device manufacturers are advised to closely follow as the regulations implementing certain provisions of the Act are promulgated over the next three years. Most importantly, successful manufacturers will take into account these changes as they develop their business plans for the short and long term.
EMERGING DRUGS & DEVICES

6-3-2010
Judge Orders Presentence Report in Guidant Heart Device Criminal Case

A Minnesota federal judge on May 18 ordered the U.S. Probation Office to prepare a presentence report to determine whether there are any unintended consequences from placing Guidant LLC and its related entities on probation for charges that it violated the Food, Drug and Cosmetic Act (FDCA) for failing to submit information about changes to its cardiac devices (United States of America v. Guidant LLC; formerly doing business as Guidant Corp. et al., Crim. No. 10-mj-67 (DWF), D. Minn.; 2010 U.S. Dist. LEXIS 40994; See May 6, 2010, Page 6).

(Order available 52-100617-001R)

On February 25, the government charged Guidant with violating the FDCA by submitting a false and misleading report to the Food and Drug Administration on August 19, 2003, that concerned a change made to the Prizm implantable cardioverter defibrillator (ICD) on or about November 13, 2002. Guidant is also accused of failing and refusing to file a report to the FDA in June 2005 concerning a correction made to the Renewal ICD device. Because both products are Class III devices, the manufacturer could not make any modification that affects the safety or effectiveness without first receiving approval from the FDA. As many as 20,146 patients in the United States may have been implanted with the devices between late 2002 and June 2005, and of those patients, 2,657 are claimants in the Guidant products liability multidistrict litigation in the U.S. District Court for the District of Minnesota.

Guidant submitted the plea agreement in which it pleaded guilty to the criminal charges on April 5, 2010, and Judge Donovan Frank heard arguments from Guidant, the government, and the MDL plaintiffs as to whether the agreement should be adopted. Public Interest

On April 27, Judge Frank rejected the government’s and Guidant’s arguments that the court lacked the power to order restitution. In support of his finding, Judge Frank looked to the Sixth Circuit U.S. Court of Appeals’ ruling in In re McNulty (597 F.3d 344 [6th Cir. 2010]). The judge also found, though, that the MDL plaintiffs are not victims of conduct underlying the criminal charges against Guidant.

Judge Frank further found that he could not accept the plea agreement because probation is appropriate in this case based on Guidant’s history and “could be fashioned in order to serve the public’s interest.”

In his May 18 order, Judge Frank said that in his previous order he noted that a presentence report would be useful in determining the appropriate sentence or additional conditions of probation.

Presentence Report

On May 12, Guidant submitted a letter to Judge Frank stating that it consents to the preparation of a presentence report and “looks forward to working with the United States Probation Office to supply information relevant to its preparation. Additionally, Guidant LLC is exploring methods to address the other concerns raised by the Court in the order and is committed to trying to resolve them.”

Judge Frank said in his order that the government has not submitted any response to his April 27 order or to Guidant’s letter.

He therefore ordered the Probation Office to prepare the report and said that upon completion of the report, he would set a sentencing date.

The federal government is represented by U.S. Attorney Robert M. Lewis and Ross S. Goldstein of the U.S. Department of Justice, Office of Consumer Litigation, in Washington, D.C.

EMERGING DRUGS & DEVICES

6-3-2010
Counsel for Mentor Defend Legal Work, Candor in Obtape

Counsel for Mentor Corp. on May 5 defended their work on the issue of disclosure of impeachment material and asked the judge overseeing the ObTape multidistrict litigation to correct his suggestion that they did not act with candor (In re: Mentor Corp. ObTape Transobturator Sling Products Liability Litigation, MDL Docket No. 2004, No. 08-md-2004; Shirley Stafford, et al. v. Mentor Corporation, No. 07-101; Jeannie Tucker, et al. v. Mentor Corporation; No. 07-102, Kellie Looper, et al. v. Mentor Corporation, No. 07-130, M.D. Ga., Columbus Div.). (Letter available 28-100603-025B)

In a May 4 ruling, U.S. Judge Clay D. Land of the Middle District of Georgia chastised Mentor’s counsel for stating that it had no duty to disclose documents that the plaintiffs would use solely for impeachment purposes. He said Mentor’s counsel failed to cite applicable law from the Sixth Circuit U.S. Court of Appeals.

Judge Land cautioned that all counsel must practice candor with the court.

Case Law Cited

In their May 5 letter, counsel for Mentor submitted supplemental case law cites in support of their position. “We apologize to the Court for not having these citations to the Eleventh Circuit [U.S. Court of Appeals] precedent at our fingertips during the pretrial conference,” counsel said.

“We take quite seriously all of our professional and ethical obligations, including the duty of candor to the tribunal,” they said. “We also value our professional reputations. In light of the discussion in this letter, we respectfully request that the Court correct the suggestion in yesterday’s Order that we had not dealt in candor with the Court.”

Mentor is represented by John Q. Lewis of Jones Day in Cleveland and Edward J. Sebold of Jones Day in Houston.

The plaintiffs are represented at trial by Henry G. Garrard III, Gary B. Blasingame, and Andrew J. Hill III of Blasingame, Burch, Garrard & Ashley in Athens, Georgia, and Norwood S. Wilner of Wilner, Hartley & Metcalf in Jacksonville, Florida.

EMERGING DRUGS & DEVICES

6-3-2010
Nine Hospitals to Pay $9.4M for False Claims Allegations Involving Kyphoplasty


The settlements resolve government allegations that the hospitals overcharged Medicare between 2000 and 2008 when performing kyphoplasty, a minimally invasive procedure used to treat certain spinal fractures that often are due to osteoporosis. The government said that in many cases, the procedure can be performed safely as a less costly outpatient procedure, but the hospitals performed the procedure on an inpatient basis in order to increase their Medicare billings.

The settling facilities and the amounts being paid by each are: Ball Memorial Hospital, Muncie, Indiana, $1,995,431; Bethesda Memorial Hospital, Boynton Beach, Florida, $356,079; Bloomington Hospital, Bloomington, Indiana, $1,443,848; Genesis Regional Medical Center, Grand Blanc, Michigan, $931,742; Huntsville Hospital, doing business as The Health Care Authority of the City of Huntsville in Huntsville, Alabama, $1,992,756; Palmetto Health, doing business as Palmetto Health Baptist Hospital in Columbia, South Carolina, $1,861,083.14; St. Elizabeth Medical Center, Utica, New York, $195,976; St. Mary’s of Michigan Hospital, Saginaw, Michigan, $260,065.21; and United Hospital, St. Paul, Minnesota, $428,656.
Medronic Settlement
In May and September 2009, nine other hospitals settled similar allegations. In May 2008, Medronic Spine LLC paid $75 million to settle allegations that it defrauded Medicare by counseling hospital providers to perform kyphoplasty procedures as an inpatient procedure. Medronic Spine was successor of Kyphon, Inc.

All but two of the settling facilities—St. Elizabeth Medical Center and United Hospital—were defendants in a 2008 False Claims Act lawsuit filed in the U.S. District Court for the Western District of New York by Craig Patrick and Charles Bates. Patrick is a former reimbursement manager for Kyphon, and Bates is a former regional sales manager for Kyphon in Birmingham, Alabama.

The relators will receive a total of approximately $1.5 million as their share of the settlement proceeds.

Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.

EMERGING DRUGS & DEVICES

6-3-2010
Angio-Seal Case out on Judgment as a Matter of Law When No Expert Represented

A Louisiana federal judge on May 26 granted judgment as a matter of law in an Angio-Seal defect case, saying the plaintiff’s opposition to summary judgment was untimely and that her reliance on res ipsa loquitur absent an expert witness cannot defeat the defense motion (Linda Rollins v. St. Jude Medical, et al., No. 08-387, W.D. La., Monroe Div.; See September 3, 2009, Page 26).

(Opinion available 28-100603-013Z)

In February 2007, Linda Rollins underwent an angiogram, after which an Angio-Seal femoral arterial plug made by St. Jude Medical was used to seal the puncture wound in her femoral artery. Rollins developed a large hematoma in her groin and experienced pain.

She underwent emergency surgery, during which blood clots were removed. The surgeon noted that the Angio-Seal was “in the middle of the artery” and caused “a lot of damage to the common femoral artery.”

In 2008, Rollins sued St. Jude in the Ouachita Parish District Court. St. Jude removed the case to the U.S. District Court for the Western District of Louisiana. 

Expert Named Late

Rollins initially failed to name an expert witness, and St. Jude moved for summary judgment. Rollins’ counsel said the deadline was missed because of personnel problems in his law firm and moved to reopen discovery, naming a biomechanical engineer as an expert.

In August, Rollins was allowed time to name an expert. She did so, and the court conducted a hearing on May 18, 2010, on St. Jude’s motion to exclude the plaintiff expert.

Rollins stipulated during the hearing that her expert would not testify. She also filed a motion for leave to file an untimely opposition to summary judgment.

'Untimely and Unconvincing'

Judge Donald E. Walter said Rollins’ motion is “untimely and unconvincing” and said that since St. Jude’s material facts are uncontroverted, “there is no genuine issue of material fact for trial.”

Reviewing Rollins’ opposition out of an abundance of caution, Judge Walter said: “Even if were not deemed untimely, the result would not be different.” He said that by withdrawing her expert, Rollins is left with only circumstantial evidence that the Angio-Seal was defective based on the testimony of the treating physician.

Judge Walter said Rollins appears to rely on the doctrine of res ipsa loquitur to oppose summary judgment, but said, “[g]iven the evidence presented to this Court, the principle of res ipsa loquitur is defeated because an inference can reasonably be drawn that something other than a defect in the Angio-Seal caused Plaintiff’s injuries.”


Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.
EMERGING DRUGS & DEVICES

5-20-2010
Federal Circuit Affirms Vaccine Court’s Rejection of Vaccine-Autism Theory

In the first appeal to be considered of the Vaccine Court’s rejection of a connection between childhood vaccines and autism, the Federal Circuit U.S. Court of Appeals on May 13 affirmed that the petitioners’ evidence was unreliable and insufficient (Rolf Hazlehurst, et al. v. Secretary, No. 2009-5128, Fed. Cir.; 2010 U.S. App. LEXIS 9759).

(Opinion available 56-100519-015Z)

The petition on behalf of Yates Hazlehurst, 10, was the second in a group of three brought to test the claim that neuroinflammation created by entry of measles virus from the measles-mumps-rubella (MMR) vaccine into the brain caused the children’s autism.

The panel said the petition was undermined by reliance on the work of Dr. Andrew Wakefield and Unigenetics, a for-profit laboratory established in Dublin, Ireland, to develop evidence supporting a vaccine-autism causation theory, and that of Dr. Stephen Walker and colleagues at the Wake Forest University School of Medicine.

“The special master found that Dr. Wakefield’s work had been largely discredited within the scientific community and that none of the studies indicating the presence of measles virus in autistic children had been successfully replicated by an accredited laboratory independent of Dr. Wakefield or Unigenetics,” the panel said. “In particular, the special master found that Dr. Wakefield’s early 1990s research on persistent measles infections was reviewed by the Medical Research Council of the United Kingdom and found to lack important controls and sufficiently specific reagents for detecting measles virus.”

“She also found that Dr. Wakefield’s subsequent research was dismissed by the scientific community as methodologically unsound. In that regard, she noted that 10 of 12 co-authors on Dr. Wakefield’s controversial 1998 article in the medical journal The Lancet subsequently retracted their support for the article’s conclusion that there is a potential causal link between the MMR vaccine and autism.”

Key Witness
The Hazelhursts’ key witness was Yates’s pediatric neurologist, Dr. Jean-Ronel Corbier, who according to the panel relied heavily on the results of the Unigenetics and Walker studies as support for his opinion that Yates’s February 8, 2001 MMR vaccination played a substantial role in causing Yates’s autism.

The petitioners complained that the government obtained an unfair advantage by introducing Dr. Stephen Bustin to undercut the petitioners’ reliance on the Unigenetics findings because the materials on which Bustin relied in the British litigation no longer exist or are under seal. The complaint, the panel said, was self-inflicted.

“The special master’s decision to admit and consider Dr. Bustin’s testimony and reports was in full accord with the principle of fundamental fairness,” the panel said. “Although not obligated to do so, the petitioners chose to introduce the Unigenetics data and thus placed its validity squarely in issue. Fairness dictated that the government be given an opportunity to refute that critical evidence.”

Same Conclusion
“In any event, we agree with the Court of Federal Claims that the special master would have reached the same conclusion regarding the reliability of the Unigenetics data even in the absence of Dr. Bustin’s evidence,” the panel said.

The case was considered by the Office of Special Masters along with Cedillo v. Secretary (No. 98-916V) and Snyder v. Secretary (No. 01-162V), presenting a theory that the combined effect of the MMR vaccine and vaccines containing thimerosal caused the children’s autism, the panel said. The Hazelhursts abandoned that theory in post-hearing briefing, the panel said, and relied on the theory that Yates’s autism was caused by the MMR vaccine alone.

According to the panel, Yates developed normally during his first year of life. On February 8, 2001, three days before his first birthday, he received an MMR vaccination. Within a month after his MMR vaccination, according to his family, Yates became “wild,” “very hyperactive,” and “out of control.” By the summer of 2001, Yates had lost all meaningful speech, although he had previously used words such as “mama,” “please,” and “thank you.” At about the

(Peb. 349)
same time, he developed chronic diarrhea and abdominal pain, the panel said.

Circuit Judge William C. Bryson wrote for the court. Circuit Judge Pauline Newman concurred, as did U.S. Judge Andrew J. Guilford of the Central District of California, sitting by designation.

The petitioners are represented by Curtis R. Webb of Twin Falls, Idaho. The government is represented by Lynn E. Ricciardella of the Department of Justice in Washington.

Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.

EMERGING DRUGS & DEVICES

5-20-2010
Gadolinium MDL Judge Approves Settlement Fund, Administrator

The Ohio federal judge overseeing the gadolinium multidistrict litigation on May 13 approved creation of a qualified settlement fund and appointed a fund administrator (In re: Gadolinium Contrast Agents Products Liability Litigation, MDL Docket No. 1909, No. 08-gd-50000, N.D. Ohio).

However, the order by U.S. Judge Dan Aaron Polster of the Northern District of Ohio was sealed, as was the plaintiffs’ motion, and it is unknown what claims are being settled, what the terms are, or which defendant is settling.

On May 3, the first of four MDL bellwether trials was reported settled: Kimberly Bullock v. General Electric Co., et al. (No. 08-50216, N.D. Ohio, Cleveland Div.). The case was set for trial on May 24. Terms were not disclosed.

Gadolinium is a contrast agent used during magnetic resonance imaging studies of patients. The plaintiffs allege that the metal causes nephrogenic systemic fibrosis, an incurable disease that stiffens tissues and organs. Defendants include General Electric Healthcare, Bayer Corp., Mallinckrodt Inc., and Bracco Diagnostics.

Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.
not opt out of the settlement from pursuing any released claims against Aetna and its subsidiaries.

Injunction Issued

In April 2005, the Bankruptcy Court issued a ruling in the adversary action, disallowing NYLCare’s proof of claim and awarding Doctors Health damages of $21.2 million.

As NYLCare, the company appealed the order to the U.S. District Court for the District of Maryland, and as Aetna, the company filed a motion in the District of Florida seeking an order enforcing the release of the agreement as a bar to the Bankruptcy Court’s judgment.

Doctors Health filed a motion in the Bankruptcy Court, seeking an injunction requiring Aetna to withdraw its motion in the District of Florida, which the Bankruptcy Court granted.

The Maryland District Court vacated the Bankruptcy Court’s injunction and stayed the appeal of the Bankruptcy Court’s rulings on NYLCare’s proof of claim and Doctors Health’s breach of contract judgment pending an order by the District of Florida as to whether the settlement operated to release Doctors Health’s claim against NYLCare in the adversary action.

In January 2009, the District of Florida concluded that Doctors Health was a member of the settlement class and that as such, its claim against NYLCare in the adversary action was released. The court enjoined Doctors Health from pursuing the claim.

Injunction Vacated

On appeal, the Eleventh Circuit vacated the injunction, saying that the settlement did not release Doctors Health’s claim against NYLCare in the adversary action because only claims “based on or arising from the factual allegations of the [Shane] Complaint” were released by the settlement.

The claims pursued by Doctors Health in the adversary action share no factual basis with the Shane complaint; because the claim pursued by Doctors Health in the adversary action is beyond the scope of the release in the settlement, the District of Florida erred in enjoining Doctors Health from pursuing the claim, the Eleventh Circuit said.


(Additional documents available: Appellant brief 31-100519-021B
Appellee brief 31-100519-022B
Reply brief 31-100519-023B)
Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.

MANAGED CARE LIABILITY REPORT

5-19-2010
Illinois Federal Judge Declines to Dismiss Claims for Failure to Provide Documents

An Illinois federal judge on May 6 declined to dismiss claims in a wrongful denial of benefits case, saying that the plaintiffs properly pleaded claims for failure to provide plan documents (Annie O. Lewis, et al. v. Aetna Insurance Agency Inc., et al., No. 09-641, S.D. Ill.; 2010 U.S. Dist. LEXIS 44529).

(Opinion available 31-100519-007Z)
Claims Denied

Herbert and Annie Lewis have health insurance under a plan sponsored by Herbert’s employer, Sherwin Williams Co.

Aetna Insurance Agency Inc. is the plan’s fiduciary in charge of reviewing claims.

In December 2006, Annie was thrown from a horse, causing her fractures of her clavicle and ribs and severe swelling in her upper extremities. She received treatment from numerous health care providers, with her medical bills totaling $38,165.92.

Aetna denied the claim for benefits, citing a preexisting condition and Annie’s failure to verify that she had no other insurance.

The Lewises had their attorney contact Aetna to explain the reason for its denial, but neither Aetna nor Sherwin Williams responded. The Lewises contend that neither Aetna nor Sherwin Williams

(Pub. 349)
responded to additional correspondence from their attorney. Medical providers sued the Lewises, and judgments were entered against them, forcing them to begin making payments.

In July 2009, the Lewises sued Aetna in the Clay County Circuit Court, asserting a claim for breach of contract.

Aetna removed the case to the U.S. District Court for the Southern District of Illinois, saying that the Employee Retirement Income Security Act preempted the claim.

The Lewises amended their complaint to add Sherwin Williams as a defendant and to assert six claims for relief for ERISA violations.

Aetna and Sherwin Williams moved to dismiss four claims brought pursuant to ERISA § 502(c)(1) for failure to provide plan documents as required.

The defendants argued that the Lewises improperly relied on a Department of Labor regulation as the basis for their Section 502(c)(1) claims and that the claims were not well-pleaded because they failed to identify the ERISA provision obligating them to provide the Section 502(c)(1) information.

Sufficient Notice

Judge J. Phil Gilbert said he did not read the Section 502(c)(1) claims to be premised upon 29 Code of Federal Regulation Section 2560.5030-1 because only the general allegations of the complaint contain a reference to the regulation, and that reference does not relate to the demand for a written explanation of the denial of benefits.

The finding leaves open the question of which ERISA provision mandated Aetna and Sherwin Williams to properly respond to the request for information because the amended complaint does not specify the provision, Judge Gilbert said.

Still, the defendants cited no binding authority for their argument that such a lack of specificity means the plaintiffs have failed to state a claim and therefore, dismissal is warranted, and they cannot because federal notice pleading standards do not require such specificity at this stage of litigation, Judge Gilbert said.

Further, Aetna and Sherwin Williams appear to be put on notice of the specific claims asserted against them, and the amended complaint sufficiently alleges the requirements of a Section 502(c)(1) claim by detailing the requests for information, including dates and other specific facts, Judge Gilbert said.


(Additional documents available: Amended complaint 31-100519-008C
Dismissal brief 31-100519-009B
Opposition brief 31-100519-010B)

Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.

MANAGED CARE LIABILITY REPORT

6-2-2010
Pennsylvania Federal Judge Grants Defense Summary Judgment in Medicaid Dispute

A Pennsylvania federal judge on May 19 granted summary judgment in favor of the defendants in a case in which the Commonwealth of Pennsylvania challenged the disallowance of more than $15 million of federal funding for family planning services provided through the state’s mandatory Medicaid managed care program (Commonwealth of Pennsylvania Department of Public Welfare v. United States of America, et al., No. 09-811, W.D. Pa.; 2010 U.S. Dist. LEXIS 49644).

(Opinion available 31-100602-003Z)

Claim Disallowance

The Commonwealth of Pennsylvania receives around 54% of its Medicaid expenditures from federal funding. Congress, however, provided 90% enhanced funding for family planning services. The Commonwealth of Pennsylvania’s Department of Public Welfare (DPW) claimed a total of $114.4 million for the costs of family planning services that managed care organizations under contract to the state’s Medicaid program provided to Medicaid recipients from October 2000 through February 2004.
During this period, Pennsylvania operated its mandatory Medicaid managed care program in 25 of its 67 counties.

The $114.4 million was calculated for family planning services provided through the state’s mandatory Medicaid managed care program, not for family planning services provided on either a fee-for-service or voluntary managed care basis in the remaining 42 counties.

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) conducted audit reviews of family planning services costs for several states, including Pennsylvania. In January 2006, the OIG issued a report concluding that Pennsylvania had overstated its claim by $44.4 million. Based on the OIG’s report, the Centers for Medicare and Medicaid Services (CMS) issued a notice of disallowance to Pennsylvania in November 2006, disallowing $15,070,548 in federal financial participation.

Disallowance Upheld

DPW appealed the disallowance decision to the Departmental Appeals Board of the HHS. DPW also requested an evidentiary hearing before the appeals board to cross-examine CMS staff members who had submitted declarations stating that they had not understood that DPW intended to use statewide data in the numerator of its family planning calculation and to elicit testimony from the OIG regarding the information it used to recalculate the numerator.

In April 2009, the appeals board issued a decision upholding the disallowance in full and denying DPW’s request for an evidentiary hearing. The appeals board issued its decision solely on written submissions but did not consider the declarations from the CMS staff members that DPW sought to cross-examine.

In June 2009, DPW sued the United States and HHS in the U.S. District Court for the Western District of Pennsylvania under the Administrative Procedures Act, seeking judicial review of the appeals board’s decision, including the decision denying the request for an evidentiary hearing.

The parties cross-moved for summary judgment.

Hearing Not Required

The issue on appeal is whether the appeals board erred in denying DPW an evidentiary hearing, Judge Donetta W. Ambrose said.

DPW argued that the appeals board should have conducted an evidentiary hearing, saying that regulations requiring that the parties be given “ample opportunity” to develop the record entitled it to the hearing.

The defendants correctly note, however, that DPW took the regulations out of context and that the regulations at issue provide that “ample opportunity” for developing the record refers only to the written record and that the regulations discourage evidentiary hearings, Judge Ambrose said.

Further, regulations require the appeals board to grant evidentiary hearings only if such a hearing would significantly aid the resolution of the issues, and the written record in the instant matter is more than ample, Judge Ambrose said.

Also, contrary to DPW’s argument, a portion of the appeals board’s practice manual providing when and why evidentiary hearings should be held does not override regulations and only reinforces the point that a hearing is appropriate where the material facts are in dispute and the record requires further factual development through testimony, Judge Ambrose said.

Decision Affirmed

The only question DPW addressed in its summary judgment motion was whether the appeals board erred in denying the request for evidentiary hearing, so the defendants argued that DPW abandoned any challenge to the merits and therefore the appeals board’s decision should be affirmed in its entirety.

DPW countered that it had not abandoned its challenge to the merits, arguing instead that such a challenge was not yet ripe.

The record on which the appeals board based its decision, however, was more than adequate, so DPW was not entitled to an evidentiary hearing and will have no occasion to challenge the merits using a further developed record, Judge Ambrose said in affirming the appeals board’s decision.


(Additional documents available: Pennsylvania’s summary judgment brief 31-100602-004B)
United States' summary judgment brief 31-100602-005B)

Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.

MANAGED CARE LIABILITY REPORT

6-2-2010
Surgical CenterOpposes Dismissal of Reimbursement Dispute in New Jersey Federal Court

A surgical center on May 5 filed a brief in a New Jersey federal court opposing dismissal of its class action complaint alleging that insurance companies manipulate the rates for which they reimburse out-of-network medical providers for services, saying it does have standing to sue and its claims are not preempted (Darlery Franco v. Connecticut General Life Insurance Co., et al., No. 07-6039, D. N.J.; See November 4, 2009, Page 5).

(Dismissal brief available 31-100602-014B
Opposition brief available 31-100602-015B)

Conspiracy Alleged


The case was consolidated with Darlery Franco v. Connecticut General Life Insurance Co., which is pending in the court.

North Peninsula alleges that the defendants conspired to fix reimbursement rates for out-of-network services, resulting in the insureds paying inflated out-of-pocket expenses. North Peninsula asserts that the defendants knew that the usual and customary rate (UCR) that they would be representing to patients was inherently flawed and false and that the UCR would grossly underestimate members' actual medical costs.

The data used to determine the UCRs came from Ingenix Inc. databases, which North Peninsula says are inherently flawed and invalid and, thus, are an inadequate and improper basis for UCR determinations. Ingenix is owned by UnitedHealth Group Inc.

Claims Barred

On March 29, CIGNA moved to dismiss, saying that North Peninsula lacks standing to bring ERISA claims because it has not alleged that the assigning patients were injured or that the patients provided North Peninsula with full assignments of benefits as required under ERISA.

CIGNA also said that North Peninsula's claims for unfair competition are preempted by ERISA, that North Peninsula failed to properly plead its unfair competition claims under the laws of many states, and that many of the claims are barred by applicable statutes of limitations.

North Peninsula has not alleged facts sufficient to state a claim for unfair competition under the pleading requirements of 26 of the 28 state unfair competition laws at issue, CIGNA says.

Some of the states explicitly limit the application of its unfair competition law to acts occurring within that state, some of the states bar unfair competition claims against insurance companies, such as CIGNA, that are subject to state regulation, some of the states provide that individuals cannot bring unfair competition claims without first going through specific dispute procedures, and some of the states prohibit class actions for unfair competition claims, CIGNA says.

Further, some of the states only allow purchasers of goods to bring unfair competition claims, and Northern Peninsula is not a buyer of goods but rather is a provider of medical services, CIGNA says.

Of the 28 unfair competition claims, only two of the states—California and Texas—do not suffer from one of those defects, and therefore, claims under the remaining states should be dismissed, CIGNA says.

Claims Supported

In its May 3 opposition brief, North Peninsula says that it does have standing to sue under ERISA because it has alleged injuries in fact that are traceable to CIGNA. North Peninsula says that it was reimbursed at below-market rates pursuant to assignments from its patients and that balances remain due.
from these patients, and therefore, it has sufficiently alleged the “injury in fact” necessary for standing under ERISA.

Also, courts have rejected the contention that providers alleging ERISA violations are required to prove assignments at the pleading stage, North Peninsula says.

As for its unfair competition claims, North Peninsula says ERISA does not preempt the claims. CIGNA paid the claims, so there is no dispute that the claim is covered under any applicable ERISA plan, and the methodology used to calculate the UCR and set payments to a provider is far removed from plan administration and therefore outside the reach of ERISA, North Peninsula says.

Also, some of the health plans at issue are not ERISA-regulated plans; therefore, ERISA has no application, North Peninsula says.

James E. Cecchi and Lindsey H. Taylor of Carella, Byrne, Cecchi, Olstein, Brody & Agnello in Rose- land, New Jersey; Stephen A. Weiss and Christopher A. Seeger of Seeger Weiss in New York; Maury A. Herman and Stephen J. Herman of Herman Gerel in Atlanta and Christopher P. Ridout and Devon M. Lyon of Ridout & Lyon in Long Beach, California, represent North Peninsula. Brian J. McMahon, E. Evans Wohlforth, and William P. Deni Jr. of Gibbons PC in Newark and William H. Pratt, Zachary S. Brez, Joshua B. Simon, and Andrew R. Dunlap of Kirkland & Ellis in New York represent CIGNA.

(Additional document available
First amended complaint 31-100602-016C)
Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.

MANAGED CARE LIABILITY REPORT

6-2-2010
Ohio Federal Judge Grants Transfer of Breach of Contract Dispute


(Opinion available 31-100602-001Z)

Compensation Dispute

In early 2004, National Benefit Programs Inc. and Express Scripts entered into an oral contract under which National Benefit agreed to assist Express Scripts in identifying, retaining, maintaining, and securing large corporate clients for Express Scripts’ prescription drug benefit programs. In return, Express Scripts agreed to compensate National Benefit, in part, based on the number of prescription claims generated from the clients National Benefit found for Express Scripts.

A dispute arose, and National Benefit sued Express Scripts in the U.S. District Court for the Southern District of Ohio, contending that Express Scripts breached the oral contract by failing to compensate National Benefit. National Benefit sought recovery from Express Scripts under alternate theories of unjust enrichment and promissory estoppel.

Express Scripts moved to transfer the case to the U.S. District Court for the Eastern District of Missouri based on a forum selection clause and choice of law provision contained in a letter agreement dated November 4, 2003. The agreement, which was not signed until April 4, 2006, provides that any dispute concerning the agreement or services was to be heard in the St. Louis County Circuit Court or the Eastern District of Missouri.

National Benefit opposed the transfer, saying the forum selection clause as executed in 2006 was irrelevant to the 2003 oral contract under which it brought the action.

Clause Controls

Judge George C. Smith granted Express Scripts’ motion, saying that the action could have as easily been brought in the Eastern District of Missouri and that the forum selection clause in the contract is mandatory, covers the claims at issue, and is presumptively enforceable.

Further, the 2003 oral agreement, according to the letter agreement, “is of no force or effect except to the extent that its terms are embodied in the Letter Agreement,” and under Missouri law, in the absence

(Pub. 348)
of fraud, a valid written agreement merges all prior negotiations, Judge Smith said.

National Benefit did not allege that the clause was the product of fraud or overreaching or that enforcement of the clause would be unreasonable or unjust, Judge Smith said.

Also, a balancing of factors such as the convenience of the parties and public interest in the case do not weigh strongly in either party’s favor, and under such circumstances, a forum selection clause controls, Judge Smith said.


Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.

MANAGED CARE LIABILITY REPORT

6-2-2010
Man Sues in California Federal Court, Says Health Plan Not Entitled to Subrogation

A California man on May 24 sued his health plan, claims administrator, and a collection agency in federal court, seeking declaratory relief that the plan is not entitled to subrogation to recover monies paid on his behalf for medical expenses he incurred after an automobile accident (Andres A. Arauz v. Aegon Companies Medical Plan, et al., No. 10-3900, C.D. Calif.).

(Complaint available 31-100602-010C)

Automobile Accident

Andres A. Arauz was injured in an automobile accident on November 8, 2008. He suffered severe injuries, including disabling brain damage that left him impaired in all areas of higher cognitive function.

Arauz has health insurance through his wife’s employment with Aegon Inc. under the Aegon Companies Medical Plan. United HealthCare Insurance Co. is the claims administrator for the plan, and Ingenix Inc. serves as a collection agent for the plan.

The plan paid approximately $191,000 in medical expenses for the injuries incurred by Arauz.

Arauz sued the driver and owner of the vehicle that struck him and settled for $100,000, the policy limits of the driver and owner’s insurance policy. Arauz also brought a claim against his automobile insurance policy under the uninsured/underinsured (UIM) provisions of the policy. He received $200,000 from his insurance policy, which represented the maximum amount available under the UIM provision.

Subrogation Sought

The plan, through United and Ingenix, sought payment from Arauz through a plan provision titled “Reimbursement to Plan.”

The plan’s provision violates federal regulations because it is not clearly worded, fails to effectively inform participants of the subrogation provision by “hiding” it and by failing to place it in close conjunction with the summary of benefits or cross-referencing it prominently, Arauz says.

The provision also purports to waive all equitable defenses to enforcement, including the make-whole doctrine, the common fund doctrine, and equitable apportionment; as such, the provision is not the type of “appropriate equitable relief” that an Employee Retirement Income Security Act plan can seek under law, Arauz says.

The plan provision, if enforced, would allow legal damages for breach of contract that are not authorized under ERISA and provide for the recovery of attorney fees that is inconsistent with ERISA laws governing the awards of attorney fees, Arauz says.

Additionally, the provision fails to properly limit the plan’s right of recovery to medical expenses the plan paid and to which Arauz says he recovered in his personal injury action.

Relief Sought

Arauz sued Aegon, the plan, United, and Ingenix in the U.S. District Court for the Central District of California, seeking declaratory relief, injunctive relief, and attorney fees and costs.

An actual controversy exists because the plan is in violation of federal law and unenforceable and
because the plan seeks to recover more than the medical expenses it paid, Arauz says.

Further, there is an actual controversy as to whether the plan is entitled to subrogation and/or reimbursement from monies Arauz says he received under his UIM provision.

David L. Margulies of the Law Offices of David L. Margulies in Woodland Hills, California, and Stanley C. Morris of Corrigan & Morris in Santa Monica, California, represent Arauz.

Copyright © 2010, LexisNexis, Division of Reed Elsevier Inc. All rights reserved.