



THE HEALTH LAWYER

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THE CANNABIS CONUNDRUM: MEDICATION V. REGULATION

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Marijuana is highly sought after by both law enforcement officials and medical marijuana advocates. The former seek to control it; the latter desire expanded access to it. The ideological dance between these adversaries is part of a growing national conversation that continues to pose more questions than answers. This article reviews the medical use of marijuana from two perspectives: clinical and regulatory.

Cannabis Sativa – The Call of the Weed

Marijuana, or *cannabis sativa*, is part of the hemp plant family^{1,2} and despite its plain jane Latin name, which translates to “sown hemp,” the debate about its role in medicine remains a high profile issue worthy of continued study. While marijuana is the common name for *Cannabis sativa*, it is also generally used to reference the parts of the plant that are ingested. *Cannabis sativa* has numerous narrow, green, razor-edged leaves and can reach heights of four to ten feet or more depending on the subspecies and growing conditions. Marijuana is a relatively pretty plant during the

leafing, or vegetative state. However, the female plant morphs into sticky, fuzzy-looking, “snowy” masses of trichomes, or hair-like projections, which are located on the small leaves accompanying the flowering tops, a far cry from garden daisies. Interestingly, Illinois, Missouri, Pennsylvania, and West Virginia designate marijuana as a noxious weed,³ with Illinois placing it in the same lowly company as the reviled, allergy-triggering ragweed.⁴ In fact, Illinois law imposes a duty on every person to eradicate marijuana on land owned or controlled by such person.⁵

Recreational marijuana users typically smoke the dried, trichome-covered leafy flower buds of the female plant, which contain the highest concentration of the chemical that produces the much-pursued high. Medical marijuana users may smoke cannabis; they may also vaporize the cannabis or, like some recreational users, ingest food items, such as brownies or sodas, that contain cannabis or active plant extracts.

Cannabinoids

Cannabinoids are a group of chemicals that exert physiological effects when they bind to cannabinoid receptors.⁶ It is believed that there are

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DRUGS

No, I am not referring to the song by Talking Heads, nor am I seeking to conjure the spirits of Jimi, Janis or Hunter S. Rather, recent events have brought into focus the degree to which drugs, and especially the abuse of prescription drugs used to relieve pain, have become part of the array of issues that health lawyers must address when counseling their clients. This realization began, strangely enough, at the Section's Washington Healthcare Summit (more on that event in a future column). According to the attendees' reviews, the most popular event at the Summit was a lunchtime presentation by Joseph Rannazzisi of the Drug Enforcement Administration's ("DEA") Office of Drug Diversion Control. Mr. Rannazzisi began with a harrowing description of the methamphetamine epidemic that plagues America's rural communities in particular. By halfway through his presentation, his listeners had learned how to "cook" meth in the rear of a car traveling the back roads of Appalachia using ingredients largely obtainable at a store like Wal-Mart. The second half of his presentation focused on a different epidemic, that of the abuse of prescription drugs, principally those of the opioid class. Think Michael Jackson or Rush Limbaugh. Think Florida, where recent articles in the national press have described a flourishing industry of "pill mills" dispensing prescriptions for Schedule II narcotics to all comers and whose state government, on "privacy" grounds, had until recently blocked efforts to establish the same data base linking doctors, pharmacies, patients and controlled drug prescriptions that exists in other states. Similar problems with pill mills, of a lesser magnitude perhaps, exist in other states. That is the enforcement view of the world.

Yet, the larger picture is more complex. Prisons and jails are bursting with incarcerated drug users. Treatment programs, underfunded in the best of times, face a dire future as government budgets are slashed. Especially troubling are the disproportionate penalties for "crack" as opposed to "powder" cocaine, which have resulted in African-Americans receiving substantially longer sentences than white Americans, based solely on their preferences for the form of drug. This issue, among other concerns, is detailed in a recent article in the *New York Review of Books* by Justice John Paul Stevens, "Our 'Broken System' of Criminal Justice." Last year Congress passed the Fair Sentencing Act of 2010, which lessened

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more than 100 types of cannabinoids, which are found naturally in humans and other animals as well as plants such as marijuana.⁷ Cannabinoids can also be made synthetically: examples are the Food and Drug Administration (“FDA”)-approved cannabinoids dronabinol and nabilone, which are discussed below.

An important naturally occurring cannabinoid is Δ^9 -tetrahydrocannabinol (“THC”). THC is considered to be “fatty,” which allows it to readily travel from blood into the brain. It is also the most psychoactive cannabinoid in marijuana, producing a variety of effects including euphoria, diminished anxiety, sedation, hallucinations, and depression. Other cannabinoids may have immunosuppressive effects, benefiting autoimmune diseases such as multiple sclerosis, and may even ameliorate the psychoactive effects of THC, including THC’s involvement in marijuana dependency.⁸

Let’s Get Clinical

When considering pharmacological treatment for a patient, how is the right drug identified? The effectiveness of a medication in treating a patient’s medical condition is typically of primary importance; however, selection of a medication may be tempered by the drug’s side effects, particularly given the patient’s medical conditions and existing drug regimen as well as the availability of therapeutically equivalent alternative medications. If efficacy and side effect profiles are substantially the same for two or more drug options, then costs are considered.

Marijuana doesn’t fit nicely into this model. Medical literature lacks a robust array of studies comparing the efficacy of marijuana to other drugs in the treatment of medical conditions. Further, the FDA has not approved marijuana as a drug that is safe and

effective,⁹ and the Drug Enforcement Administration (“DEA”) has statutorily designated marijuana as a Schedule I controlled substance that cannot legally be prescribed under federal law.¹⁰ Nevertheless, it is generally viewed that physicians can discuss and recommend marijuana to patients without running afoul of federal law.¹¹ But when is marijuana the appropriate drug for recommendation to patients?

First, a little history. In 1999, the Institute of Medicine (“IOM”) published a comprehensive report that researched and evaluated the science of marijuana and its use in medicine.¹² The Office of National Drug Control Policy,¹³ under the Clinton administration, commissioned the IOM report. More than ten years later, the report is still cited by researchers, practitioners, and regulators. For example, the DEA references the IOM report on its Web site, stating “[T]he study concluded that smoking marijuana is not recommended for treatment of **any** disease condition.”¹⁴

While the DEA declaration is technically true in that the IOM report did not recommend marijuana for treatment of diseases such as cancer or diabetes, the IOM report acknowledged the existence of therapeutic value in marijuana as treatment for disease *symptoms*. In fact, the IOM report recommended that, under certain conditions, short-term smoked marijuana be used by patients with debilitating symptoms such as intractable pain or vomiting.¹⁵ Indeed, the Arizona, Delaware, Michigan, New Jersey, Rhode Island, and Vermont legislatures cited the IOM Report as a basis for passing their medical marijuana laws.¹⁶

IOM and others have recognized marijuana as having therapeutic activity against chemotherapy-induced nausea and vomiting (“CINV”), but

many drugs treat CINV. For example, legally available synthetic cannabinoids such as Marinol¹⁷ and Cesamet have been shown to be as good, or better, than “old school” anti-CINV medications such as Compazine.¹⁹ A 2001 analysis of various studies comparing smoked marijuana and oral THC, including Marinol, indicated that smoked marijuana was at least as effective as oral THC in treating CINV, if not better in some instances.²⁰ On the other hand, two CINV studies comparing cannabinoids and smoked marijuana have shown that neither had an ameliorative effect on CINV, and one study found that oral THC was superior to smoked marijuana.²¹

In 1991, a groundbreaking new drug was introduced that transformed CINV treatment.²² Zofran and others in its class block the effects of the chemical serotonin, which is associated with nausea and vomiting. Newer medications that work in a different manner, such as Emend, help fortify current CINV drug therapy.²³ In fact, studies show “modern” drugs such as Zofran and Emend, either together or Zofran in combination with the steroid dexamethasone, are very good options for treatment of CINV. In fact, these modern medications are recommended by the American Society of Clinical Oncology (“ASCO”) for treatment of CINV.²⁴

But what about “toe-to-toe” CINV studies comparing marijuana to the modern drugs? Unfortunately, none could be found.^{25,26} The dearth of research on this topic may be due, in large part, to the fact that the modern drugs provide very effective treatment for CINV, and FDA-approved oral THC medications provide relief from CINV that is more or less equivalent to that of smoked marijuana. Given the lack of studies evaluating the efficacy of marijuana versus ASCO-recommended

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modern medications in the treatment of CINV, and the federal legal status of marijuana as a Schedule I controlled substance, a clinician would be hard-pressed to even consider marijuana as first-line therapy for CINV. Moreover, consistency in the potency of marijuana, which varies by plant type and growing conditions, and whether the quantity of marijuana active ingredients is even known, impact whether a physician can reliably recommend marijuana and if so, the “dose.” Such factors pose little concern for physicians when prescribing standardized, FDA-approved oral or injectable CINV drug therapies.²⁷

Compared to the modern medications in the treatment of CINV, marijuana does not meet the efficacy test in the three-part drug selection process that also considers side effects and costs. Nevertheless, if modern medications fail to treat CINV, synthetic cannabinoids, such as Marinol and marijuana could be considered as back-up therapy for CINV based upon their more or less equivalent efficacy, but side effects should be carefully considered.²⁸ For some patients, the “high” caused by cannabinoids may benefit the patient in coping with the dread or anxiety associated with the underlying disease of cancer.²⁹ Nevertheless, there are serious concerns about abuse of cannabinoids, particularly with marijuana. It is well documented that marijuana is the most widely used illicit substance in the United States, and many studies, clinicians, and patients have documented marijuana dependence and abuse.³⁰

If both efficacy and side effects are deemed to be substantially equivalent between synthetic cannabinoids and marijuana, cost is typically the decision-maker in the drug selection process. Cannabinoids, particularly the synthetic ones, can be expensive. Marinol has an average price of \$18.00 per 5 mg capsule, while its

generic counterpart, dronabinol, is less expensive at about \$13.00 per 5 mg capsule.³¹ If a one-day dose of four capsules is used for CINV treatment, the cost is about \$72.00 per day for Marinol and \$52.00 per day for generic dronabinol.

Marijuana, on the other hand, is generally less expensive than its synthetic counterparts. One organization located in Michigan, a state permitting use of marijuana for medical purposes, offers a particular variety of marijuana for \$15 per gram. Depending on potency and variety of the marijuana, the condition being treated, patient age, and the length of time that he or she has been using marijuana, the dosing amount can differ significantly. A low dose is reportedly one cigarette or 0.5 grams per day;³² however, average doses of eight grams per day or more have reportedly been used by long-term marijuana patients with a variety of ailments.³³ Based upon the \$15 per gram cost and dose variations, the broad marijuana cost range is \$7.50 – \$120 per day.

Notwithstanding the Schedule I status of marijuana, if synthetic cannabinoids and marijuana are generally considered therapeutic equivalents for a patient who has failed first-line modern drug therapy for CINV, then the higher cost of the synthetics likely makes marijuana a better option, particularly if the patient does not have insurance or the means to pay for the synthetic cannabinoids.^{34,35}

Cannabinoids and the Future

Research on endogenous, plant, and synthetic cannabinoids, their pharmacology, and physiologic effects on diseases and symptomology should continue. In fact, the IOM report specifically recommended that plant-derived and synthetic

cannabinoids, as well as marijuana, be studied for physiologic and therapeutic effects.³⁶ Therapeutic value for synthetic and natural cannabinoids may lie, ironically, in their ability to produce a high. Because a number of patients appear to benefit from the sense of well being produced by THC, studies of the anxiety-alleviating effects of cannabinoids could be valuable, particularly if cannabinoid efficacy, dependence, abuse, and withdrawal are compared to such data for existing anti-anxiety medications such as Valium, Xanax, and others in this drug family.³⁷

There are a variety of factors impacting cannabinoid research that should not be ignored. Researchers report difficulty in obtaining marijuana through official government channels, including the procurement of a DEA Schedule I controlled substances license to obtain and handle government-produced marijuana, as well as government approval of the clinical study and its purpose.³⁸ Maintaining consistency in the chemical composition of marijuana plants and their growing conditions, as well as the ability to compare research results across U.S. and international studies pose challenges. Moreover, patients may cloud symptom alleviation with euphoria or the high that results from marijuana or synthetic cannabinoid ingestion, making it difficult for researchers to identify actual pharmacological effects. Published studies may only involve small numbers of participants, so general application of the study results to larger populations may not be accurate or appropriate.

Nevertheless, exploration of cannabinoids for treatment of pain, muscle spasticity, tumors and other areas where they have shown promise, both individually and as a synergistic component to traditional medications, would contribute important information to the growing body of cannabinoid scholarship.

Based on the current body of scientific literature, some researchers and physicians may believe that marijuana is a viable drug option for certain medical conditions, if even as second or third line therapy.³⁹ The federal government does not agree.

Dim Federal View

The federal government's stance on marijuana has not been consistent. Marijuana was listed as a medicinal drug in the United States Pharmacopoeia as early as the 1850s, and medical use of marijuana continued to be recognized, and legally permitted, after passage of the Marijuana Tax Act in 1937.⁴⁰ Nevertheless, in an about-face just four years later, marijuana was removed from the U.S. Pharmacopoeia and in the process was stripped of its designation as acceptable for medical use.⁴¹

In 1968, the federal government launched a program to grow marijuana and make it available to researchers.⁴² Yet two years later, in 1970, Congress enacted the Federal Controlled Substances Act, which officially classified marijuana as a Schedule I controlled substance because it was deemed to be of high abuse potential and lacking in accepted medical use in the United States.⁴³

Despite the Controlled Substances Act designation of marijuana, the federal government formalized an investigational new drug ("IND") program permitting "compassionate use" of marijuana to research its treatment of medical conditions.⁴⁴ In 1976, the Department of Health, Education, and Welfare ("HEW") approved a petition filed on behalf of a 28-year-old glaucoma patient. Robert Randall requested access to government marijuana for research and treatment purposes for his intractable glaucoma.^{45,46} To support his original federal request, Randall stated that he was subject to a comprehensive medical examination and trials of every available glaucoma

medication, all of which failed to treat his eye condition. The National Institute on Drug Abuse ("NIDA")⁴⁷ resumed supplying Randall with medical marijuana in settlement of a lawsuit that he filed in 1978, paving the way for a modest number of additional individuals and their physicians to petition the federal government for access to medical marijuana through the IND process. Nevertheless, in 1992, The Department of Health and Human Services, the successor to HEW, halted the marijuana IND program and declined to admit new enrollees.⁴⁸ However, NIDA continues to provide government-grown marijuana to a handful of remaining patients.⁴⁹

Federal drug regulatory resources focused more on cocaine than marijuana in the 1980s and into the 1990s.⁵⁰ In particular, tighter federal drug control policy, the "Just Say No" anti-drug campaign, and implementation of the Office of National Drug Control Policy defined the Reagan administration in the 1980s.⁵¹ The George H.W. Bush administration also embraced strong drug control policies. In 1992, the DEA denied a petition to reschedule marijuana from Schedule I to Schedule II, citing a lack of adequate and well-controlled studies proving the drug's efficacy and no expert recognition of its medicinal value.⁵² The Clinton administration did not resume the compassionate use marijuana IND program, and continued strict drug control policies related to marijuana.⁵³

It was during President Clinton's presidency that the DEA saw a rise in medical marijuana advocacy at the state level.⁵⁴ In 1994, the DEA began efforts to assist state and local law enforcement agencies to oppose marijuana legalization.^{55,56} Despite DEA initiatives, five states implemented medical marijuana programs from 2001 to 2008 under the George W. Bush administration.⁵⁷ Although the administration reallocated law enforcement resources, including the DEA, to combat terrorism after the

September 11, 2001, attacks,⁵⁸ it did not waiver in its views against legalization of marijuana for medical purposes.

In notable contrast to its predecessors, the Department of Justice ("DOJ") under President Obama announced a significant shift in federal marijuana policy. In October 2009, Attorney General Eric Holder issued guidelines instructing DOJ attorneys to exercise enforcement discretion, and to decline prosecution of individuals using marijuana in compliance with state medical marijuana programs.⁵⁹ Arguably, this policy conferred a modicum of legitimacy on state medical marijuana initiatives and seriously ill patients seeking relief through such programs. Medical marijuana advocates hailed the guidelines as a humane step in support of seriously ill patients.⁶⁰

Eighteen months later, medical marijuana proponents complained that the administration was not adhering to its 2009 policy. In the spring of 2011, the DEA raided marijuana dispensaries in several states, including Washington, where the DEA seizure of dispensaries' marijuana ironically occurred on the same day that marijuana advocacy groups were teaching classes on raid preparedness.⁶¹ The DOJ then issued another memorandum to DOJ Attorneys in June 2011, stating commercial cultivation or distribution of marijuana is subject to federal criminal prosecution, regardless of whether the operation complies with state law.⁶²

Some medical marijuana proponents decried the 2011 memorandum because it purportedly contradicted the October 2009 guidance, which stated that individuals and caregivers in clear and unambiguous compliance with state medical marijuana laws should not be prosecuted. But the 2009 guidance also stated that a prosecution priority was commercial enterprises selling marijuana for profit, including those that may claim compliance with state law. Moreover,

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under the controversial 2005 U.S. Supreme Court decision in *Gonzales v. Raich*, the federal government has broad authority to enforce the federal Controlled Substances Act: individuals' non-commercial, intrastate use of personally grown marijuana, in compliance with state medical marijuana laws, is still subject to federal enforcement action pursuant to the government's larger interstate regulatory scheme.⁶³ While the Obama administration initially adopted a policy to refrain from using its enforcement authority under *Raich*, it has clearly signaled that it will not tolerate "non-profit" medical marijuana dispensaries that operate on a large scale or enjoy excessive financial gains.

Most recently, the DEA dealt a blow to medical marijuana advocates hoping for an expansion of federal support beyond the Obama administration's October 2009 policy. In June 2011 the DEA declined to reclassify marijuana from Schedule I to Schedule III, IV, or V, as requested in a 2002 petition.^{64,65} Pursuant to a memorandum of understanding between the FDA and NIDA describing their collaborative procedures for scheduling of drugs of abuse,⁶⁶ the FDA performed a medical evaluation of marijuana and concluded, with the concurrence of NIDA, that eight factors supported general control of marijuana through the federal Controlled Substances Act, and that marijuana additionally met the three factors required to specifically categorize it in Schedule I. The eight factors evaluating drug control, set forth in 21 U.S.C. § 811(c), generally consider pharmacological effects, safety, and data on abuse and dependence.⁶⁷ The three criteria specific to Schedule I classification assess whether marijuana has a high substance abuse potential, has any currently accepted medical use in treatment, and lacks accepted safety criteria for use under medical supervision.⁶⁸

Although the DEA retained marijuana in Schedule I of the Controlled Substances Act, it is not clear whether its June 2011 decision considered data from the decades-old "compassionate use" IND marijuana program in which NIDA provided marijuana to participating patients. The DEA's decision cited only one study related to the program.^{69,70} The petitioner submitted the 2002 Russo study, which evaluated four of the remaining seven compassionate use IND program patients. The study stated that marijuana exerted clinical effectiveness in treating the patients' illnesses, and that only mild adverse physiological effects were observed relating to lung functioning.⁷¹ However, the DEA dismissed the study as inadequate based on the small number of patients involved, and it does not appear that the FDA or NIDA considered the study.⁷²

The DEA's staunch stance against medical marijuana has not stymied federal legislators. While the states have been implementing medical marijuana programs since the mid-1990s, federal legislation has been regularly proposed to reclassify marijuana for medical purposes.⁷³

One of the most prolific supporters of pro-medical marijuana legislation is Massachusetts Congressman Barney Frank. In fact, since 1995, Congressman Frank has continuously introduced legislation to move marijuana from Schedule I to Schedule II under bill names such as the "Medical Use of Marijuana Act" and the "States' Rights to Medical Marijuana Act."⁷⁴ He has not succeeded in this endeavor to date. Nevertheless, Congressman Frank introduced two bills in 2011 aimed at making medical marijuana more accessible.⁷⁵ Unlike his previous bills to reschedule marijuana to Schedule II, the States' Medical Marijuana Patient Protection Act ("Act") directs the Secretary of

Health and Human Services, in cooperation with the IOM, to recommend to the DEA that marijuana be listed in any controlled substances schedule other than Schedules I or II.⁷⁶ The proposed Act further requires the DEA to issue a notice of proposed rulemaking for the scheduling of marijuana as anything other than a Schedule I or Schedule II substance. The proposed Act ignores the established roles of the FDA and the NIDA in evaluating the scientific and medical factors that may make a drug prone to abuse and their roles in recommending whether a substance should be controlled.⁷⁷ Instead, the Act delegates those roles to the IOM, which is a private organization and author of the landmark 1999 report, *Marijuana and Medicine Assessing the Science Base*, that is discussed earlier in this article.⁷⁸ The bill outlining the Act was referred to the House Subcommittee on Health on June 3, 2011, and no further action has been taken as of November 2011.⁷⁹

More recently, Congressman Frank introduced a bill entitled "Ending Federal Marijuana Prohibition Act of 2011."⁸⁰ The June 2011 bill proposes two major amendments to existing law: it removes marijuana from Schedule I and it seeks to limit application of federal marijuana laws to consumption, distribution, and other purposes. Specifically, the bill would make marijuana a non-controlled substance under federal law and would allow an individual to transport or ship marijuana across state lines, without running afoul of federal law, so long as the transported or shipped marijuana is not intended to be received, possessed, or sold in violation of state law.⁸¹ On August 25, 2011, this bill was referred to the Subcommittee on Crime, Terrorism, and Homeland Security, and no further action has been taken.⁸²

While the marijuana battle rages at the federal level, the states are taking matters into their own hands.

State of Medical Marijuana Affairs

Despite the federal designation of marijuana as a Schedule I controlled substance that has no currently accepted medical use,⁸³ states are increasingly turning their backs on the federal government and forging their own regulatory paths. By recognizing therapeutic value in marijuana and believing that the benefits outweigh risks, states are effectively usurping the role of the FDA as the exclusive U.S. arbiter of what is a safe and effective drug.⁸⁴ In fact, 17 U.S. jurisdictions (16 states and the District of Columbia) have passed laws permitting their residents to ingest marijuana for medical purposes: Alaska, Arizona, California, Colorado, Delaware, Hawaii, Maine, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, and Washington.⁸⁵

Although it is beyond the scope of this article to address all state “compassionate” marijuana programs, state laws and regulations commonly address issues such as implementation of patient registries through departments of public health and the designation of medical conditions for which marijuana may be used. For example, most states permit marijuana use to treat cachexia (weight loss and physical wasting due to chronic disease), including Alaska, Nevada, Oregon, Rhode Island, and Vermont.⁸⁶ Delaware and New Mexico permit marijuana use for treatment of post-traumatic stress disorder.⁸⁷ These laws also commonly establish criteria for medical marijuana dispensaries, such as location, business model, restrictions or prohibition of on-site consumption, and quantity limits for individuals who possess or grow marijuana for personal medical use. Unlike most jurisdictions that have enacted medical marijuana laws, Delaware, New Jersey, and the District of Columbia prohibit patients from growing marijuana at home for medical purposes.^{88,89}

State medical marijuana programs also typically set standards for

recommending marijuana for medical use. These standards run the gamut from broad and permissive to narrow and rigid. For instance, the District of Columbia requires a comprehensive assessment before a physician can recommend medical marijuana. After reviewing “other approved medications and treatments that might provide the qualifying patient with relief,” the physician must then determine that medical marijuana “is necessary” in order to recommend it.⁹⁰ On the other hand, Colorado regulations establish a relatively low “patient might benefit” threshold when physicians are evaluating whether to recommend marijuana for an individual diagnosed with a state-defined debilitating medical condition.⁹¹

In contrast, New Mexico promulgated a much more stringent regulation: before recommending medical marijuana, other medical therapies must be utilized for the patient’s qualifying medical condition, these therapies must have failed, and the patient must have current, unrelieved symptoms.⁹² New Mexico medical certification also requires that a practitioner attest that the patient has one of the state-recognized debilitating medical conditions and that the benefits of the medical use of marijuana outweigh its health risks.

Interestingly, New Mexico permits appropriately licensed nurse practitioners and physician’s assistants, as well as physicians, to write a certification for medical cannabis.⁹³ Certain debilitating medical conditions require additional supporting documentation as part of the New Mexico certification process. For example, glaucoma must be diagnosed by an ophthalmologist, and severe chronic pain requires two medical certifications from a primary care provider and a specialist with expertise in pain management or the physiological process that causes the pain.⁹⁴

California Sets the Stage

California was the first jurisdiction to decriminalize use and cultivation of marijuana under its Compassionate Use Act of 1996;⁹⁵ however, marijuana

remains a Schedule I substance under the California Uniform Controlled Substances Act.⁹⁶ Given California’s 15 years of experience in medical marijuana matters, its program requirements will be the focus of this state regulation discussion.

The California Medical Marijuana Program (“Program”), codified in § 11362.7, et. seq. of the Health and Safety Code, establishes requirements for physicians to recommend marijuana to patients and the government qualification process for individuals seeking to obtain marijuana for medical purposes. The Program mandates that a validly licensed California attending physician physically examine a patient and determine whether the patient has a serious medical condition for which marijuana may be appropriate. California broadly defines “serious medical condition” to include arthritis, migraines, cancer, multiple sclerosis, seizures, severe nausea, and any other chronic or persistent medical symptom that substantially limits a major life activity or, if not alleviated, may cause serious harm to a patient’s safety or physical or mental health.⁹⁷

Unlike New Mexico, whose regulations require failure of non-marijuana medical therapies before a practitioner can recommend marijuana, the Medical Board of California published guidelines for physicians to consider when recommending medical marijuana for patients, stating that a patient need not wait until all standard medications have been tried, and failed, before recommending marijuana.⁹⁸ Instead, the physician must determine that the risk/benefit ratio of medical marijuana is as good or better than other medications that could be used for the patient. The California guidelines for physician-recommended marijuana anticipate that a medical history, in-person examination, discussion of side effects, and a treatment plan, with periodic review for efficacy, would occur. Nevertheless, these guidelines do not require or specifically

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recommend that other medications be tried prior to marijuana, particularly medications regarded as first line therapy by clinical practitioners.⁹⁹

In some instances, compliance with the California risk/benefit medical marijuana guidelines may not provide optimal care for patients. Specifically, the guidelines may permit less effective drugs to be used for treatment. For example, medical evidence and specialty physician associations support the preferential use of modern drugs like Zofran and Emend with a steroid for treatment and prevention of CINV.¹⁰⁰ But studies comparing marijuana and older anti-nausea medications show marijuana is as good, or better, than the older medications in ameliorating CINV.¹⁰¹ Accordingly, under California Medical Board guidelines, marijuana could be recommended for CINV if its safety risks are generally equivalent to the older CINV drugs.¹⁰² Because California does not require that “standard medical therapy” be tried and fail prior to a physician recommending marijuana, California patients using medical marijuana for CINV may be receiving substandard care if these patients have never even tried the modern drugs for prevention and treatment of CINV.

On the other hand, strict adherence to California Medical Board guidelines could be viewed as creating unnecessary obstacles to certain patient populations seeking to use marijuana to alleviate suffering. For example, requiring a pre-recommendation physical examination, standard evaluation of marijuana risks and benefits, or discussion of marijuana addiction or dependence side effects are likely irrelevant to some terminally ill patients and could delay access to those whose remaining days on earth are few.^{103,104,105,106,107}

Controlled Access

The sheen on the California medical marijuana program is losing its luster in some communities. In Anaheim, medical marijuana opponents won a significant victory when the Superior Court in Orange County California ruled that the city’s ban on medical marijuana dispensaries was a valid exercise of its constitution-granted powers and was not pre-empted by state medical marijuana laws.¹⁰⁸ Anaheim enacted the prohibition, pursuant to its nuisance ordinance, in an attempt to limit mass distribution of medical marijuana.

More recently, Los Angeles responded to neighborhood activists’ complaints and a significant increase in dispensaries from four in June 2005 to hundreds by the end of 2009. The city passed an ordinance capping at 70 the number of dispensaries that will be permitted to provide medical marijuana.^{109,110} The ordinance also requires that the dispensing organizations be proportionally distributed throughout the city based on population in a designated neighborhood. On October 14, 2011, the Superior Court in Los Angeles County, California denied injunctive relief to a coalition of medical marijuana advocates and dispensaries that sued Los Angeles over its capping ordinance. The Court upheld the ordinance, declaring that it did not establish an arbitrary process to limit dispensaries.¹¹¹

Efforts to better control access are spreading to other states’ communities. A hotly contested proposal to ban medical marijuana dispensaries was put to a vote in Fort Collins, Colorado in November 2011. Residents voted to prohibit medical marijuana dispensaries from doing business in the city and to require those that are currently operating to close in 90 days.¹¹²

However, medical marijuana advocates are concerned that delays in implementing medical marijuana laws

harm patients, particularly those for whom marijuana is the only effective therapy. The District of Columbia and New Jersey enacted their medical marijuana laws in 2010, but marijuana is not yet available through dispensaries (and qualified patients are prohibited from growing their own marijuana plants). After approving a medical marijuana program in 1998, D.C. voters had to wait 12 years for enactment of its law because Congress continued to block the program until 2010.¹¹³ The first of five dispensaries permitted under the D.C. medical marijuana law is not expected to begin offering medical marijuana until 2012. The volume of inquiries about D.C.’s open application and selection processes, as well as required rulemaking procedures, are causing implementation to take longer than anticipated.¹¹⁴

New Jersey’s medical marijuana law was supposed to become effective six months after it was signed into law on January 18, 2010.¹¹⁵ Newly elected governor Chris Christie took office one day later, and implementation of the medical marijuana program has been slowed due to disagreement among the legislature, the state health department, and the governor’s office on a variety of issues. Background checks for proprietors of dispensaries, known as “alternative treatment centers” in New Jersey, the selection process for organizations applying to become treatment centers, and concerns that state employees of the medical marijuana program could be federally prosecuted for facilitating the availability of marijuana continue to hamper program implementation.¹¹⁶

Noxious Weed

Some proprietors of medical marijuana dispensaries bring an entrepreneurial spirit to their activities. Home delivery services are offered and savvy operators use social media, such as Twitter and Facebook, to provide medical marijuana-related

information to subscribers and facilitate communications with patients.¹¹⁷

However, certain aspects of the business of medical marijuana undermine well-intentioned efforts to expand marijuana research and provide seriously ill patients with access to the medicinal plant. For example, some medical marijuana names are absurd, such as AK 47, Cat Piss, Sour Diesel, and Mr. Nice.¹¹⁸ Although experienced users may be able to identify the type of marijuana by such names, the nomenclature likely confuses those new to medical marijuana and does not readily identify the cannabinoid content or potency of the marijuana product. If the physician or healthcare provider recommending medical marijuana does not fully discuss appropriate dosing or cannabinoid content, or does not have such knowledge, then naïve patients may select the product on their own or may seek such advice from dispensary staff, who may not have appropriate training or education.¹¹⁹

Moreover, some of the pageant-like celebrations and contests centered around medical marijuana, such as the Doesha Cup, which includes a cannabis tasting competition, on site “medicating,” and celebrity appearances are of dubious merit.¹²⁰ News articles describing individuals who submit unsigned or suspicious physician recommendations for medical marijuana and undercover reporters who easily obtain medical marijuana registration cards based on questionable medical complaints further fuel regulators’ concerns.¹²¹ The totality of these elements of the medical marijuana industry may unwittingly support the efforts of medical marijuana opponents and hamper seriously ill patients’ access to medical marijuana.

In addition, crimes involving medical marijuana patients and dispensaries are taxing law enforcement authorities that are already facing dwindling resources. In 2009, the California

Police Chiefs Association issued a white paper with sobering details of murders, burglaries, shootings, and theft related to medical marijuana dispensaries, their operators, and patients.¹²² The founder of two California medical marijuana dispensaries was shot and killed in his home in November 2005, and law enforcement authorities believed it was related to his marijuana cultivation and dispensing.¹²³ Medical marijuana dispensaries throughout California have been subject to attack, with perpetrators stealing marijuana and/or cash in a number of burglaries perpetrated over the years. In July 2011, three men attempted to rob a San Diego medical marijuana dispensary using pepper spray, but were thwarted by employees who activated the locks on security doors.¹²⁴ Reports of California marijuana dispensary customers being held-up at gunpoint and assaulted by robbers only add to law enforcement agencies’ concerns about the safety of medical marijuana operations and whether stricter controls are required.¹²⁵

Medical marijuana-related crimes are not limited to California. Arizona, New Mexico and Washington recently reported theft and assault crimes tied to medical marijuana.¹²⁶ Less restrictive oversight of dispensaries, lower standards for physicians to recommend medical marijuana, the proliferation of dispensaries, difficulty controlling patients who may sell or transfer medical marijuana to non-registered individuals, and cash transactions all reportedly contribute to medical marijuana crime and diversion.¹²⁷

Yet not all law enforcement officials are convinced that medical marijuana dispensaries result in increased crime. The Denver Police Department compared crime statistics for December 2008 and December 2009, which were collected for crimes committed within 1,000 feet of dispensary locations.¹²⁸ In December 2008, no dispensaries were operating;

in December 2009 hundreds of dispensaries had newly opened. The Denver Police Department was unable to determine if having a dispensary in the area resulted in an overall increase in crime.¹²⁹ Although the total number of reported crimes within 1,000 feet of dispensaries decreased by 3.7 percent and violent crime declined or remained the same, loitering and criminal mischief increased.¹³⁰

The Los Angeles police chief stated in 2010 that banks were more likely to get robbed than medical marijuana dispensaries.¹³¹ A 2009 police department analysis of citywide robberies did not demonstrate an increase due to medical marijuana dispensaries.¹³² However, the police chief qualified the analysis by stating that some dispensaries may not report robberies and ATM crimes were not included in the data.¹³³ Notwithstanding the robberies analysis, the chief recommended that medical marijuana diversion, including unlawful sales, be considered in any evaluation of medical marijuana dispensary regulation. The chief also supported increased dispensary oversight and a limit on the number of operating dispensaries in Los Angeles.^{134,135}

Conclusion

The ability to satisfy all stakeholders in the medical marijuana juggernaut seems largely illusory. However, when traditional medications fail patients who have serious or debilitating illnesses and no other viable treatment options are available, providing access to marijuana for medical purposes is humane and arguably a form of public health protection. The mechanism for providing access to marijuana needs to be better controlled in many cases. Permitting marijuana to be used in lieu of traditional or peer-recommended medications, or pursuant to an appropriate medical evaluation, disregards the patient’s best interests and promotes diversion of a widely abused controlled

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substance. Moreover, reported difficulties in obtaining and researching marijuana should be identified and resolved. Cannabinoid research should be expanded, particularly studies comparing marijuana and its synthetic counterparts to standard medication regimens. Promoting scholarship in areas such as “designer” cannabinoids that provide maximum therapeutic benefit and minimize undesirable effects may ultimately help bridge the gap between the needs of the medical marijuana community and the obligations of law enforcement agencies.

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Endnotes

- 1 Marijuana is not native to the continental United States. Hemp was introduced to New England in the 1600s by, ironically, the Puritans who brought it to New England for household use in weaving. Hemp cultivation in the states increased throughout the 1700s and 1800s, where it was used for cordage and sails for ships. U.S. Dept. of Agriculture, *Industrial Hemp in the United States*, <http://www.ers.usda.gov/publications/ages001e/ages001ec.pdf> (accessed Oct. 9, 2011).
- 2 U.S. Dept. Agriculture, Natural Resources Conservation Service, *Plants Database*, <http://plants.usda.gov/java/profile?symbol=CASA3> (accessed Apr. 10, 2011).
- 3 *Id.* at http://plants.usda.gov/java/noxious_driver (accessed Apr. 10, 2011).
- 4 505 Ill. Comp. Stat. § 100/1 (2011).

- 5 Ill. Admin. Code tit. 8, pt. 220 (2002).
- 6 Kenneth Mackie, Presentation, *The Scientific Side of Medical Marijuana*, (Natl. Assn. Bds. of Pharm. Fall Symposium, Dec. 3, 2009), available at <http://www.nabp.net/events/past-educational-sessions/symposium/>. Examples of human cannabinoid receptors include CB₁ and CB₂ receptors located in the brain and body tissues to which internal, or endogenous, cannabinoids and Δ⁹-tetrahydrocannabinol may bind.
- 7 Sunil K. Aggarwal & Gregory T. Carter, Presentation, *Cannabis in the Treatment of Chronic Pain*, (Natl. Assn. Bds. of Pharm. Fall Symposium, Dec. 3, 2009), available at <http://www.nabp.net/events/past-educational-sessions/symposium/>.
- 8 *Id.*
- 9 21 U.S.C. § 355(b)(1)(A) (2008).
- 10 21 U.S.C. § 812(b)(1) (2010).
- 11 *See Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002).
- 12 *See* Janet E. Joy, Stanley J. Watson, Jr., & John A. Benson, Jr., Editors, *Marijuana and Medicine Assessing the Science Base*, (Inst. of Med. 1999), available at http://medicalmarijuana.procon.org/sourcefiles/IOM_Report.pdf. Since 1970, the independent, nonprofit Institute of Medicine has served as an advisor to the government, public, and private sector on a variety of healthcare issues. *See* <http://www.iom.edu/About-IOM.aspx>.
- 13 The Office of National Drug Control Policy (“ONDCP”) was established in 1988 as a component of the Executive Office of the President and advises the President on drug control issues, among other things. ONDCP also produces the National Drug Control Strategy. *See* <http://www.whitehouse.gov/ondcp/about>.
- 14 U.S. Drug Enforcement Admin., *Exposing the Myth of Medical Marijuana*, <http://www.justice.gov/dea/ongoing/marijuanap.html> (accessed Oct. 9, 2011) [emphasis DEA].
- 15 *See* Joy, *supra* n. 12, at 7.
- 16 *See, e.g.*, N.J. Sen. Health, Human Serv. and Senior Citizens Comm., *New Jersey Compassionate Use Medical Marijuana Act*, 213th Leg., Reg. Sess. 2a (January 18, 2010), available at http://www.njleg.state.nj.us/2008/Bills/S0500/119_R3.HTM. For other states’ regulations and legislation addressing medical use of marijuana, visit ProCon.org at <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881>.
- 17 The generic name for Marinol is dronabinol. *See* RxList, *Marinol*, <http://www.rxlist.com/marinol-drug.htm> (last reviewed May 29, 2008) (accessed Nov. 9, 2011).
- 18 The generic name for Cesamet is nabilone. RxList, *Cesamet*, <http://www.rxlist.com/cesamet-drug.htm> (last reviewed Feb. 26, 2009) (accessed Nov. 9, 2011).
- 19 F.C. Machado Rocha, S.C. Stéfano, R. De Cássia Haiek, L.M.Q. Rosa Oliveira, & D.X. Da Silveira, *Therapeutic Use of Cannabis Sativa on Chemotherapy-Induced Nausea and Vomiting Among Cancer Patients: Systematic Review and Meta-Analysis*, 17 Euro. J. Cancer Care. 431, 440 (2008).
- 20 Richard E. Musty & Rita Rossi, *Effects of Smoked Cannabis and Oral Δ⁹-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials*, 1 J. Cannabis Therapeutics 29, 53 (2001).
- 21 Sunil K. Aggarwal, Gregory T. Carter, Mark D. Sullivan, et.al., *Medicinal Use of Cannabis in the United States: Historical Perspectives, Current Trends, and Future Directions*, 5 J. Opioid Mgt. 153, 156 (May/June 2009).
- 22 *See* Joy, *supra* n. 12, at 110-111. *See also* GlaxoSmithKline, *Prescription Medicines – Zofran*, http://us.gsk.com/products/assets/us_zofran.pdf (accessed Nov. 8, 2011). *See also* Kristi Monson, Arthur Schoenstadt, *Zofran*, <http://cancer.emedtv.com/zofran/zofran.html> (accessed Nov. 8, 2011). The generic name for Zofran is ondansetron, and it is a serotonin receptor antagonist.
- 23 Merck & Co., Inc., *Prescription Products – Emend*, http://www.merck.com/product/usa/pi_circulars/e/emend/emend_pi.pdf, (accessed Nov. 8, 2011). The generic name for Emend is aprepitant, and it is a substance P/ neurokinin 1 receptor antagonist.
- 24 Am. Soc. of Health Sys. Pharmacists, *American Hospital Formulary Service Drug Information*, 2969 (ASHP 2011) (noting that the American Society of Clinical Oncology currently recommends a three drug antiemetic regimen consisting of a serotonin receptor antagonist such as Zofran, dexamethasone, and Emend).
- 25 A study comparing smoked marijuana and the serotonin receptor antagonist ondansetron (Zofran) on nausea induced by ipecac, a non-chemotherapeutic agent, showed ondansetron was superior to marijuana, which exerted only modest anti-nausea/vomiting effects. *See* Anna H. Söderpalm, Alyson B. Schuster & Harriet de Wit, *Antiemetic Efficacy of Smoked Marijuana: Subjective and Behavioral Effects on Nausea Induced by Syrup of Ipecac*, 69 Pharmacology, Biochemistry, and Behavior 343 (March/April 2001).
- 26 *See also* Joy, *supra* n. 12, at 111. The 1999 IOM report states that smoked marijuana, like cannabinoids, was apparently effective in treating chemotherapy-induced vomiting in some studies, but efficacy was no greater than that of available antiemetic agents [the “old school” drugs discussed in this article], and that the most effective regimens are oral serotonin receptor antagonists [one of the “modern” drugs discussed in this article such as Zofran] with dexamethasone.
- 27 *Id.* at 161.
- 28 Subject to inter-patient variability and dosage, the adverse effect profiles for cannabinoids and marijuana are relatively similar and include increased heart rate, low blood pressure and fatigue, as well as euphoria, detachment, and drowsiness, which are common central nervous system side effects of cannabinoids.

- 29 On the other hand, geriatric patients and those who are naïve to cannabinoids may not tolerate these substances due to disorientation, depression, paranoia and even hallucinations.
- 30 See Alan J. Budney, Roger Roffman, Robert S. Stephens & Denise Walker, *Marijuana Dependence and Its Treatment*, 4 *Addiction Sci. & Clinical Prac.* 4, 5 (Dec. 2007). Research also shows that dependent marijuana users can experience withdrawal symptoms, particularly in long-term users.
- 31 Synthetic cannabinoid prices reflect an average of prices provided by two Chicago-area pharmacies, a national chain pharmacy and a hospital outpatient pharmacy in May 2011.
- 32 ProCon.org, *How Does the Cost of Marijuana Compare to the Cost of Marinol?*, available at <http://medicalmarijuana.procon.org/view.answers.php?questionID=91> (accessed Aug. 15, 2011).
- 33 See Sunil K. Aggarwal, Muraco Kyashna-Tocha, & Gregory T. Carter, *Dosing Medical Marijuana: Rational Guidelines on Trial in Washington State*, 9 *Medscape Gen. Med.* 52 (Sept. 2007).
- 34 Affordability of cannabinoids poses interesting public policy issues that no doubt affected the implementation of some state medical marijuana programs, but such issues are beyond the scope of this article.
- 35 A new cannabinoid medication may be on its way. Developed by a company in the United Kingdom, Sativex is a mouth spray that contains two cannabinoids, THC and cannabidiol, both of which are extracted from the *Cannabis sativa* plant. It is in Phase III clinical trials in the United States for treatment of cancer pain that is inadequately responding to conventional medications, but has not yet been approved by the FDA. GW Pharmaceuticals, *Sativex*, <http://www.gwpharm.com/Sativex.aspx> (accessed Nov. 4, 2011). See also GW Pharmaceuticals, *FAQs – Where is Sativex available?*, <http://www.gwpharm.com/faqs.aspx> (accessed Nov. 4, 2011).
- 36 See Joy, *supra* n. 12, at 3, 7.
- 37 For example, marijuana withdrawal symptoms appear to be mild compared to those from benzodiazepines, the family of drugs that includes diazepam (Valium). *Id.* at 42. Further, withdrawal symptoms in marijuana-dependent individuals may generally last one to three weeks, whereas the duration of such symptoms in benzodiazepine-dependent individuals may last for weeks or months. See Alan J. Budney, *Are Specific Dependence Criteria Necessary for Different Substances: How Can Research on Cannabis Inform This Issue?*, 101 *Addiction* (Supp. 1) 126 (2006); Steve R. Onyett, *The Benzodiazepine Withdrawal Syndrome and Its Management*, 39 *J. Royal Coll. Gen. Pract.* 160, 161 (Apr. 1989).
- 38 The federal government is the only legal producer of marijuana for medical research in the United States. See Am. College of Phys., *Supporting Research into the Therapeutic Role of Marijuana*, 1, 7 (ACP 2008).
- 39 Of the few studies that have evaluated smoked cannabis in patients with neuropathic pain, the results have led some researchers to suggest that cannabinoid therapy may be an effective option in patients who fail to achieve pain relief using traditional first line medications such as opiates and nonsteroidal anti-inflammatory medications (e.g. ibuprofen). See, e.g., Barth Wilsey, Thomas Marcotte, Alexander Tsodikov, et. al., *A Randomized, Placebo-Controlled, Crossover Trial of Cannabis Cigarettes in Neuropathic Pain*, 9 *J. Pain* 506 (Jun. 2008); Ronald J. Ellis, Will Toperoff, Florin Vaida, et. al., *Smoked Medicinal Cannabis for Neuropathic Pain in HIV: A Randomized, Crossover Clinical Trial*, 34 *Neuropsychopharm.* 672, (Feb. 2009), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3066045/?tool=pubmed> (accessed Oct. 22, 2011). See also, N. Attal, G. Cruccu, R. Baron, et. al., *EFNS Guidelines on the Pharmacological Treatment of Neuropathic Pain: 2010 Revision*, 17 *Euro. J. Neuro.* 1113, 1115 (Sept. 2010), available at <http://www.efns.org/Guideline-Archive-by-topic.389.0.html> (accessed Oct. 22, 2011).
- 40 Kathleen Ferraiolo, *From Killer Weed to Popular Medicine: The Evolution of American Drug Control Policy 1937: 2000*, 19 *J. Policy History Vol.*, 147, 153-155 (2007). The Marihuana Tax Act of 1937 imposed taxes on the importation, manufacture, prescribing, dispensing, administering, and giving away of marijuana, established registration requirements, and set forth penalties if tax payments were not made.
- 41 During the 1930s, the Federal Bureau of Narcotics (“FBN”), a predecessor of the DEA, took steps to increase control of marijuana by supporting the Marihuana Tax Act and warning the public of serious dangers associated with marijuana. Despite requests from the American Medical Association for evidence of the reported dangers, the Marihuana Tax Act was enacted and FBN continued its efforts. In fact, FBN reportedly was a primary force behind the removal of marijuana from the U.S. Pharmacopoeia. *Id.* at 154-55.
- 42 ProCon.org, *Did You Know? Little Known Facts in the Medical Marijuana Debate*, available at <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000091> (accessed Nov. 9, 2011).
- 43 U.S. Drug Enforcement Admin., *Drug Scheduling*, <http://www.justice.gov/dea/pubs/scheduling.html> (accessed Aug. 6, 2011). Other substances currently designated as Schedule I drugs include PCP, Ecstasy, and heroin.
- 44 Natl. Inst. on Drug Abuse, *Provision of Marijuana and Other Compounds for Scientific Research – Recommendations of the National Institute on Drug Abuse National Advisory Council*, <http://archives.drugabuse.gov/about/organization/nacda/MarijuanaStatement.html> (January 1998) (accessed Aug. 7, 2011).
- 45 Robert Randall, 53; *Sued for Marijuana*, N.Y. Times Archives, <http://www.nytimes.com/2001/06/08/us/robert-randall-53-sued-for-marijuana.html> (June 8, 2001) (accessed Aug. 6, 2011).
- 46 Alice O’Leary, Speech. *A Remembrance of Bob Randall*, (Santa Barbara, Cal., Apr. 7, 2006), http://www.drugscience.org/Archive/bcr1/n1_oleary1.html (accessed August 6, 2011).
- 47 Natl. Inst. On Drug Abuse, *About NIDA*, <http://www.nida.nih.gov/about/welcome/milestones/Milestones.html>, (accessed Oct. 22, 2011). The U.S. government established the National Institute on Drug Abuse (“NIDA”) in 1974; it became a part of the National Institutes of Health in 1992. NIDA seeks to focus on scientific research to answer questions about drug abuse and addiction.
- 48 Natl. Inst. on Drug Abuse, *Drug Facts Chat Day 2009 – The Transcript*, <http://drugfactsweek.drugabuse.gov/chat/2009/index.php> (accessed Aug. 6, 2011).
- 49 *Id.*
- 50 See generally Frontline, *Thirty Years of America’s Drug War – A Chronology*, <http://www.pbs.org/wgbh/pages/frontline/shows/drugs/cron/> (Oct. 2000) (accessed Nov. 9, 2011).
- 51 See generally *Id.*
- 52 *DEA History Book Part 2 3*, <http://www.justice.gov/dea/pubs/history/> (accessed Aug. 7, 2011).
- 53 See Frontline, *supra* n. 50.
- 54 See generally ProCon.org, *16 Legal Medical Marijuana States and DC, Laws, Fees, and Possession Limits Summary Chart*, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881> (accessed Nov. 9, 2011). Alaska, California, Colorado, Hawaii, Maine, Nevada, Oregon, and Washington passed laws permitting use of marijuana for medical purposes during the William J. Clinton administration.
- 55 *Id.* at 27.
- 56 Natl. Crim. Just. Ref. Serv., *Speaking Out Against Drug Legalization*, <http://www.ncjrs.gov/App/Publications/abstract.aspx?ID=158530> (1994) (accessed Oct. 23, 2011). See also U.S. Drug Enforcement Admin., *A Message from the Drug Enforcement Administration*, <http://www.justice.gov/dea/demand/speakout/director.htm> (2010) (accessed Oct. 23, 2011). In August of 1994, the DEA held an “Anti-Legalization Forum” in Quantico, Virginia, in which police chiefs, government representatives, and members of the private sector participated to identify arguments against drug legalization and effective communication methods. Following the forum, the DEA issued a report citing 10 major bases for its opposition to drug legalization, including increased crime, proliferation of drug addiction, and the fact that there are no compelling medical reasons to prescribe marijuana to sick individuals.
- 57 ProCon.org, *supra* n. 54 (accessed Aug. 7, 2011). Michigan, Montana, New Mexico, Rhode Island, and Vermont passed laws permitting use of marijuana for medical purposes during the George W. Bush administration.
- 58 See, e.g., U.S. Drug Enforcement Admin., *Fact Sheet: Justice Department Counter-Terrorism Efforts Since 9/11*, <http://www.justice.gov/opa/pr/2008/September/08-nsd-807.html> (Sept. 2008) (accessed Oct. 23, 2011). The DEA has assisted Afghan authorities in targeting terrorist organizations funded through illicit drug transactions, and has worked with its counterparts to gather intelligence on illicit drug manufacturing and trafficking routes in Afghanistan.
- 59 Memo from David W. Ogden, Deputy Attorney General, to Selected United States Attorneys, *Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana* (Oct. 19, 2009) available at <http://blogs.usdoj.gov/blog/archives/192> (accessed Aug. 7, 2011).

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- ⁶⁰ CBS/AP, *Medical Marijuana Arrest Guidelines Eased*, <http://www.cbsnews.com/stories/2009/10/19/politics/main5395248.shtml> (Nov. 9, 2009) (accessed Nov. 9, 2011).
- ⁶¹ Rob Kauder, *Authorities Raid Spokane Medical Marijuana Dispensaries*, <http://www.kxly.com/news/27708933/detail.html> (April 28, 2011) (accessed Aug. 7, 2011).
- ⁶² C.J. Ciaramella, *Justice Department and Obama Reverse Stance on Medical Marijuana Raids*, <http://dailycaller.com/2011/07/01/justice-department-and-obama-reverse-stance-on-medical-marijuana-raids/> (July 1, 2011) (accessed Aug. 13, 2011).
- ⁶³ See *Gonzales v. Raich*, 545 U.S. 1 (2005).
- ⁶⁴ 76 Fed. Reg. 40551 (July 8, 2011), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-07-08/html/2011-16994.htm>.
- ⁶⁵ In 1972, two years after the federal Controlled Substances Act was passed, the National Organization for the Reform of Marijuana Laws (“NORML”) filed the first petition to remove marijuana from Schedule I. See *NORML, et. al., v. Ingersoll*, 497 F.2d 654, (D.C. Cir. 1974). After 22 years of legal wrangling, the United States Court of Appeals for the District of Columbia denied NORML’s and its fellow petitioners’ petition to review the 1989 DEA order. The DEA refused to reschedule marijuana on the basis that that it had no accepted medical use. *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, (D.C. Cir. 1994), available at <http://law.justia.com/cases/federal/appellate-courts/F3/15/1131/536307/> (accessed Oct. 29, 2011).
- ⁶⁶ U.S. Food and Drug Administration, *MOU 225-85-8251 Memorandum of Understanding Between the National Institute on Drug Abuse and the Food and Drug Administration*, <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116365.htm> (December 1984) (accessed Oct. 23, 2011).
- ⁶⁷ The eight factors that are determinative of control or removal from controlled substance schedules, pursuant to 21 U.S.C. § 811(c), are: 1) actual or relative potential for abuse; 2) scientific evidence of pharmacological effect, if known; 3) state of current scientific knowledge regarding the drug; 4) history and current pattern of abuse; 5) scope, duration and significance of abuse; 6) what, if any, risk there is to public health; 7) its psychotic or physiological dependence liability; and 8) whether the substance is an immediate precursor of a substance that is already controlled under the federal Controlled Substances Act.
- ⁶⁸ 21 U.S.C. § 812(b)(1) (2010).
- ⁶⁹ Ethan Russo, Mary Lynn Mathre, Al Byrne, Robert Velin, et. al., *Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis*, 2 J. Cannabis Therap. 3, 51 (2002), available at <http://medicalmarijuana.procon.org/sourcefiles/RussoChronicCannabisUse.pdf>.
- ⁷⁰ Patients Out of Time, *Presentations for the Second Clinical Conference on Cannabis Therapeutics, Portland, OR May 2-3, 2002*, <http://www.medicalcannabis.com/Video/2002-conference-videos> (accessed Nov. 8, 2011).
- ⁷¹ *Id.* at 4.
- ⁷² Beyond the 2002 Russo study, it is not clear what other data has been collected from the compassionate use IND marijuana program and, if the data is available, why it was not considered in the June 2011 DEA decision. About thirty patients have participated in the compassionate use IND marijuana program since its inception in 1978. This program seemingly represents a solid opportunity to collect and evaluate abuse, efficacy, and safety data for long-term use of standardized, government-approved cannabis, and whether marijuana continues to meet the three criteria requiring its current Schedule I status. See ProCon.org, <http://medicalmarijuana.procon.org/view.answers.php?questionID=257> (accessed Nov. 8, 2011); see also Patients Out of Time, *Presentations for the Second Clinical Conference on Cannabis Therapeutics, Portland, OR May 2-3, 2002*, <http://www.medicalcannabis.com/Video/2002-conference-videos> (accessed Nov. 8, 2011); and Russo, *supra* n. 69, at 5.
- ⁷³ California was the first state to implement a medical marijuana program: the Compassionate Use Act of 1996. Cal. Health & Safety Code, § 11362.5, available at <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11357-11362.9>.
- ⁷⁴ H.R. 2618, 104th Cong. (November 10, 1995); H.R. 1782, 105th Cong. (June 4, 1997); H.R. 912, 106th Cong. (March 2, 1999); H.R. 1344, 107th Cong. (April 3, 2001); H.R. 2233, 108th Cong. (May 22, 2003); H.R. 2087, 109th Cong. (May 4, 2005); H.R. 5842, 110th Cong. (April 17, 2008); H.R. 2835, 111th Cong. (June 11, 2009); and H.R. 1983, 112th Cong. (May 25, 2011) all are available at <http://thomas.loc.gov/home/multicongress/multicongress.html> (accessed Oct. 29, 2011).
- ⁷⁵ H.R. 1983, 112th Cong. (May 25, 2011); H.R.2306, 112th Cong. (June 23, 2011) available at <http://thomas.loc.gov/home/LegislativeData.php?&n=BillText> (accessed Oct. 29, 2011).
- ⁷⁶ H.R. 1983, 112th Cong. (May 25, 2011).
- ⁷⁷ In determining the scheduled status, if any, of a drug, § 811 of the Controlled Substances Act requires the DEA to obtain a scientific and medical evaluation of a drug and a recommendation regarding whether it should be controlled from the Secretary of Health and Human Services. See 21 U.S.C. § 811(b). The Secretary, through the Assistant Secretary for Health, has delegated this evaluation process to the FDA. The FDA and NIDA agreed to collaborate on the evaluation pursuant to a Memorandum of Understanding. See U.S., *supra* n. 66.
- ⁷⁸ IOM is an independent, non-profit organization. In its 1999 report, IOM did not recommend rescheduling marijuana to a class below Schedule I for purposes of medical use or prescribing to patients. IOM did, however, recommend changes in the Controlled Substances Act to eliminate the Act’s barriers to conducting clinical research. See *About the IOM*, available at <http://www.iom.edu/About-IOM.aspx> (accessed Oct. 29, 2011). See also Joy, *supra* n. 12, at 151.
- ⁷⁹ See The Lib. Of Cong. Thomas, *Bill Summary & Status*, H.R. 1983, All Congressional Actions, available at <http://thomas.loc.gov/cgi-bin/bdquery/D?d112:1:./temp/~bdjhKF:@@X|/home/LegislativeData.php> | (accessed Oct. 30, 2011).
- ⁸⁰ H.R. 2306, 112th Cong. (June 23, 2011), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112hr2306ih/pdf/BILLS-112hr2306ih.pdf> (accessed Oct. 30, 2011).
- ⁸¹ *Id.*
- ⁸² See The Lib. Of Cong. Thomas, *Bill Summary & Status*, H.R. 2306, All Congressional Actions, available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d112:HR02306:@@X> (accessed Oct. 30, 2011).
- ⁸³ *Supra* n. 10.
- ⁸⁴ *Supra* n. 9.
- ⁸⁵ Natl. Conf. State Legis., *State Medical Marijuana Laws*, <http://www.ncsl.org/default.aspx?tabid=19587> (updated May 2011) (accessed July 9, 2011).
- ⁸⁶ See, e.g., Alaska Stat. § 17.37.070 (2011) available at <http://medicalmarijuana.procon.org/sourcefiles/ASTitle17Ch37.pdf> (accessed Nov. 5, 2011).
- ⁸⁷ Del. Code tit. 16, § 4902A(3)(a) (2011) available at <http://delcode.delaware.gov/title16/c049a/index.shtml> (accessed Nov. 5, 2011); N.M. Dept. of Health, *Medical Cannabis Program Frequently Asked Questions*, available at http://www.health.state.nm.us/idb/mcp_faq.shtml#qualifying (accessed Nov. 5, 2011).
- ⁸⁸ See, e.g., ProCon.org, *16 Legal Medical Marijuana States and DC – Home Cultivation Note*, <http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881#NewJersey> (accessed Nov. 5, 2011).
- ⁸⁹ Of the five states that have pending bills permitting marijuana to be used for medical purposes, Illinois, Massachusetts, New Hampshire, New York, and Pennsylvania, four of them would permit registered patients to possess marijuana plants. See Ill. H.B. 0030, 97th Gen. Assembly (Jan. 12, 2011); Mass. H. 00625, 187th Leg. (Jan. 14, 2011); Ohio H.B. 214, 129th Gen. Assembly (Apr. 26, 2011); and Pa. S.B. 1003, 2011 Session (Apr. 25, 2011).
- ⁹⁰ D.C. Code § 7-1671.04 (a), (b) (West 2011) available at <http://weblinks.westlaw.com/result/default.aspx?cite=UUID%28N9A355C20A6%2DF911DF91FBC%2DDE97B415A7D%29&db=1000869&findtype=VQ&fn=%5Ftop&pb=DA010192&rlt=CLID%5FFQR LT734211512511&rp=%2FSearch%2Fdefault%2Ew1&rs=WEBL11%2E10&service=Find&spa=DCC%2D1000&sr=TC&vr=2%2E0> (accessed Nov. 5, 2011).
- ⁹¹ 5 Colo. Code Regs. 1006-2, Regulation 2.B.5 (2011).
- ⁹² 7.34.3.8(A)(1) NMAC (2010).

- ⁹³ Washington State permits physician assistants, advanced registered nurse practitioners, and naturopaths to recommend marijuana for medical purposes. See Wash. Rev. Code § 69.51A.010 (2) (2011) available at <http://apps.leg.wa.gov/RCW/default.aspx?cite=69.51A&full=true#69.51A.030> (accessed Nov. 5, 2011).
- ⁹⁴ N.M. Dept. of Health, *New Mexico Medical Cannabis Program Patient Application Set*, <http://www.nmhealth.org/IDB/medicalcannabis/Patient%20Packet%201-24-11.pdf> (Jan. 20, 2011) (accessed Nov. 9, 2011).
- ⁹⁵ Cal. Health & Safety Code, § 11362.5, available at <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11357-11362.9>.
- ⁹⁶ Cal. Health & Safety Code, § 11054(d)(13), available at <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11053-11058>. Unlike California, New Mexico took a bold step and listed marijuana as a Schedule II controlled substance if it is medically used by certified patients in conformance with the state's "Lynn and Erin Compassionate Use Act."
- ⁹⁷ The California Medical Marijuana Program has various administrative components. Physician marijuana recommendations must be documented in the patient's medical record, which is then used by the patient to obtain an identification card through the health department in the county where the patient resides. Upon the patient's submission of an application and payment of fees imposed by the state and county, the health department reviews the application for approval or denial. As part of the review, the department obtains a patient photo, verifies that the attending physician holds a valid California physician license in good standing, and contacts the physician to confirm that the patient-submitted medical record recommending marijuana is authentic and accurate. Those with an identification card can purchase or grow marijuana for medical purposes. Fifty-six of California's 58 counties have implemented the Program and, as of May 2011, have collectively issued over 50,000 identification cards since implementation of the Program. Cal. Dept. Pub. Health, *California Department of Public Health Medical Marijuana Program (MMP) Facts and Figures (MMP Fact Sheet)*, <http://www.cdph.ca.gov/programs/mmp/Pages/Medical%20Marijuana%20Program.aspx> (July 8, 2011) (accessed July 9, 2011).
- ⁹⁸ Med. Bd. of Cal., *Medical Marijuana Statement*, http://www.mbc.ca.gov/medical_marijuana.html (May 7, 2004) (accessed Nov. 8, 2011).
- ⁹⁹ Am. Soc., *supra* n. 24, at 2969.
- ¹⁰⁰ See *Id.* See also Joy, *supra* n. 12, at 111. The IOM report states that smoked marijuana, like cannabinoids, was apparently effective in treating chemotherapy-induced vomiting in some studies, but efficacy was no greater than that of available antiemetic agents [the "old school" drugs discussed in this article], and that the most effective regimens are oral serotonin receptor antagonists [one of the "modern" drugs discussed in this article such as Zofran] with dexamethasone.
- ¹⁰¹ See the following three studies: F.C. Machado Rocha, S.C. Stéfano, R. De Cássia Haiek, L.M.Q. Rosa Oliveira, & D.X. Da Silveira, *Therapeutic Use of Cannabis Sativa on Chemotherapy-Induced Nausea and Vomiting Among Cancer Patients: Systematic Review and Meta-Analysis*, 17 Euro. J. Cancer Care. 431, 440 (2008); Richard E. Musty & Rita Rossi, *Effects of Smoked Cannabis and Oral Δ⁹-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials*, 1 J. Cannabis Therapeutics 29, 53 (2001); Sunil K. Aggarwal, Gregory T. Carter, Mark D. Sullivan, et. al., *Medicinal Use of Cannabis in the United States: Historical Perspectives, Current Trends, and Future Directions*, 5 J. Opioid Mgt. 153, 156 (May/June 2009).
- ¹⁰² *Id.*
- ¹⁰³ See generally Karl E. Miller, Martha M. Miller & Monica R. Jolley, *Challenges in Pain Management at the End of Life*, 64 Am. Fam. Physician 1227-1235 (Oct. 1, 2001) available at <http://www.aafp.org/afp/2001/1001/p1227.html> (accessed Oct. 30, 2011); Leah Shafer, *Too Little, Too Late: Treating the Pain of the Terminally Ill*, Rx.magazine (March 28, 2011) available at http://rx.magazine.tripod.com/eol_20010328.htm (accessed Oct. 30, 2011).
- ¹⁰⁴ The California Program establishes few requirements for marijuana providers, authorizing the state Attorney General to promulgate requirements to prevent diversion and counties or municipalities to implement their own requirements consistent with California law. In 2008, the California Attorney General issued guidelines to help prevent diversion of medical marijuana. Those guidelines recommend that patients submit applications to the organization distributing medical marijuana, and that the organization verify that the patient is qualified to receive marijuana for medical purposes by checking the validity of the patient's state medical marijuana identification card or personally contacting the recommending physician. Additionally, the Attorney General recommended that accepted business practices be followed, such as tracking and documenting the source of marijuana, making regular cash drops at a bank and maintaining accurate financial records. See Edmund G. Brown, Jr, Attorney General, *Guidelines for the Security and Non-Diversion of Marijuana Grown for Medical Use* (Aug. 2008) available at http://medicalmarijuana.procon.org/view_additional-resource.php?resourceID=001735 (accessed Oct. 30, 2011).
- ¹⁰⁵ California cities and counties typically require dispensaries to apply for a permit; their proprietors must submit to a criminal background check; dispensary business hours are limited; they cannot be located near schools or parks; patients must be verified; and patient records and a security system must be maintained. Interestingly, Los Angeles County requires dispensaries to post a readable sign identifying the facility as a medical marijuana dispensary; however, marijuana cannot be grown on site. On the other hand, San Mateo County permits signage only for the dispensary address, but marijuana can be grown and processed on site so long as it is not visible from outside the dispensary. The city of Santa Barbara requires dispensaries to provide the Chief of Police with contact information for its on-site "community relations" staff person in the event that the city needs to report operational problems. See generally Cal. State Assn. of Counties, CSAC *Advocacy – Medical Marijuana*, <http://www.counties.org/default.asp?id=2848> (accessed Nov. 4, 2011). See also Los Angeles Co. Code (Cal.) § 7.55 (2011) available at http://search.municode.com/html/16274/_DATA/TITLE07/Chapter_7_55_MEDICAL_MARIJUANA.html (accessed Nov. 4, 2011); San Mateo Co. Code (Cal.) § 5.148 (2009) available at http://library.municode.com/HTML/16029/level2/TIT5BURE_CH5.148RECOCUDIMEMA.html (accessed Nov. 4, 2011); and Santa Barbara Mun. Code (Cal.) Ch. 28.20 (2011) available at http://www.santabarbaraca.gov/Government/City_Hall/Municode/ (accessed Nov. 4, 2011).
- ¹⁰⁶ State law establishes quantities of medical marijuana that a patient may possess. Under § 11362.77 of the California Health & Safety Code, qualified patients are permitted to possess up to eight ounces (240 grams) of dried marijuana and no more than six mature or 12 immature marijuana plants, unless a doctor recommends a larger amount to meet the patient's needs. However, in 2010, the California Supreme Court affirmed a lower court decision deeming these limits unconstitutional. Instead, the Court deferred to the language of Proposition 215, the Compassionate Use Act, which states that the marijuana possessed or grown must be for the patient's personal medical purposes. In essence, the amount a California patient needs to treat her medical malady is the quantity the patient can possess. *People v Kelly* 47 Cal.4th 1008 (2010).
- ¹⁰⁷ Additionally, California created exemptions for certain third parties that are likely to encounter issues related to medical marijuana. For example, employers are not required to accommodate or allow use of medical marijuana on their properties. Similarly, hospitals and clinics are not required to permit patients to smoke medical marijuana, and health insurers do not have to pay for the costs incurred in the medical use of marijuana. Nevertheless, employers and healthcare organizations may wish to draft or update their policies to designate the status of medical marijuana and its use by employees or patients on premises. Hospital pharmacy and therapeutics committees may wish to identify alternative medications or equivalent therapeutic doses of synthetic cannabinoids that pharmacists may recommend, and physicians may prescribe, if patients are not allowed to use their personal supply of marijuana for medical purposes. See Cal. Health & Safety Code, § 11362.785, 11362.79, available at <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11362.7-11362.83>. See also Gregory T. Carter, Patrick Weydt, Muraco Kyashna-Tocha, & Donald I. Abrams, *Listening to Marinol: Rational Guidelines for Dosing*, J. Cal. Cannabis Research Med. Group, available at <http://www.ccrmg.org/journal/05aut/marinol.html> (Autumn 2005) (accessed July 25, 2011).
- ¹⁰⁸ *Qualified Patients Association v. City of Anaheim*, No. 07CC09524, Minute Order at 2 (Cal. Sup. Ct. August 15, 2011) available at http://www.safeaccessnow.org/downloads/Anaheim_Superior_Court_Trial_Ruling.pdf (accessed Nov. 5, 2011). See also John Hoeffel, *Superior Court Sides with Anaheim in Lawsuit Over Medical Pot Ban*, <http://articles.latimes.com/2011/aug/20/local/la-me-dispensaries-20110820> (accessed Nov. 5, 2011). The *Los Angeles Times* article quotes estimates from the Americans for Safe

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- Access organization, which states that 161 California cities and 17 counties ban medical marijuana dispensaries; the Coalition for a Drug Free California, a group that opposes medical marijuana, states that 224 cities and 15 California counties prohibit dispensaries.
- ¹⁰⁹ John Hoefel, *L.A. Acts to Cap Medical Marijuana Dispensaries*, <http://articles.latimes.com/2009/dec/09/local/la-me-medical-marijuana9-2009dec09> (accessed Nov. 5, 2011).
- ¹¹⁰ Los Angeles Mun. Code (Cal.) § 45.19.6.2 (2011) available at http://www.amlegal.com/nxt/gateway.dll?f=templates&fn=default.htm&vid=amlegal:lamc_ca (accessed Nov. 5, 2011).
- ¹¹¹ *Americans for Safe Access, et. al. v. City of Los Angeles*, et. al., No. BC433942, (Cal. Sup. Ct., Oct. 14, 2011) (Plaintiffs filed a second amended complaint in this case) available at <https://www.lasuperiorcourt.org/OnlineServices/CivilImages/> (accessed Nov. 5, 2011). See also John Hoefel, *L.A.'s Much-Contested Medical Pot Ordinance is Upheld*, <http://articles.latimes.com/2011/oct/15/local/la-me-pot-decision-20111015> (Oct. 15, 2011) (accessed Nov. 5, 2011).
- ¹¹² Fox31 Denver, *Fort Collins Medical Marijuana Ban Passes*, <http://www.kdvr.com/news/kdvr-fort-collins-medical-marijuana-ban-passes-20111102,0,1371662.story> (Nov. 2, 2011) (accessed Nov. 5, 2011). Opponents of medical marijuana believe that Fort Collins dispensaries lead to an increase in crime; advocates are concerned that legitimate dispensaries will be closed, resulting in patients having to travel farther to obtain marijuana. Fort Collins is one of more than 75 Colorado communities prohibiting medical marijuana dispensaries. Moreover, Livonia, Michigan successfully dismissed a lawsuit in July 2011. The American Civil Liberties Union unsuccessfully sued to overturn Livonia's zoning ordinance, which banned marijuana production because such land use violated federal law. The City of Livonia, *Judge Upholds Livonia Ordinance Banning Marijuana Growing Operations*, <http://www.ci.livonia.mi.us/tabid/1155/Government/Press%20Releases/Press%20Releases.aspx> (July 28, 2011) (accessed Nov. 5, 2011).
- ¹¹³ Martin Austerhuhle, *Yet Another Delay for D.C. Medical Marijuana Program* http://dcist.com/2011/10/25/another_delay_in_dc_medical_mar.php (Oct. 25, 2011) (accessed Nov. 5, 2011). See also Tim Craig, *Council Approves Medical Marijuana Bill*, http://voices.washingtonpost.com/dc/2010/05/council_approves_medical_marij.html?hpid=moreheadlines (May 4, 2010) (accessed Nov. 5, 2011); Tim Craig *Medical Marijuana Now Legal*, http://voices.washingtonpost.com/dc/2010/07/medical_marijuana_now_legal.html (July 27, 2010) (accessed Nov. 5, 2011). In 2010, Congress did not intervene and block the medical District of Columbia marijuana law, as it had done since about 1998, so the law became effective 30 days after the Mayor signed it.
- ¹¹⁴ D.C. Code § 7-1671.01, § 7-1671.06 (West 2011) available at <http://weblinks.westlaw.com/toc/default.aspx?Abbr=dc%2D%2Dweb&Action=ExpandTree&AP=N174E4570A6F811DF91FBCDE97B415A7D&ItemKey=N174E4570A6F811DF91FBCDE97B415A7D&RP=%2Ftoc%2Fdefault%2Ewl&ServiceTOC&RS=WEBL11.10&VR=2.0&SPa=DCC-1000&pbcc=DA010192&fragment=N174E4570A6F811DF91FBCDE97B415A7D> (accessed Nov. 5, 2011).
- ¹¹⁵ N.J. Stat. § 24:GI-1 (2011) available at http://lis.njleg.state.nj.us/cgi-bin/om_isapi.dll?clientID=672203&Depth=2&depth=2&expandheadings=on&headingswithhits=on&hitsperheading=on&infobase=statutes.nfo&record={9DEE}&softpage=Doc_Frame_PG42 (accessed Nov. 6, 2011).
- ¹¹⁶ Phil Gregory, *More Delays for New Jersey's Medical Marijuana Program*, <http://www.wbgo.org/newsarticle/more-delays-for-new-jerseys-medical-marijuana-program> (Oct. 24, 2011) (accessed Nov. 6, 2011); NJ.com, *Gov. Christie to Delay Implementing N.J.'s Medical Marijuana Law*, http://www.nj.com/news/index.ssf/2011/06/christie_to_delay_implementing.html (June 16, 2011) (accessed Nov. 6, 2011). A New Jersey alternative treatment center was the first to be denied a permit by a local zoning board, which would prefer that the center be located close to a hospital. Geoff Mulvihill, *Zoning Board Turns Down 1st NJ Medical Pot Site*, <http://www.businessweek.com/ap/financialnews/D9QBEMM00.htm> (Oct. 13, 2011) (accessed Nov. 6, 2011).
- ¹¹⁷ See, e.g., The Green Cross, <http://thegreencross.org/index.php> (accessed Nov. 5, 2011) (based in California); Local Product of Colorado, www.localproductco.com (accessed Nov. 5, 2011) (based in Colorado).
- ¹¹⁸ See, e.g., Medical Marijuana Strains, www.medicalmarijuanastrains.com (accessed Nov. 6, 2011).
- ¹¹⁹ Few states' medical marijuana regulations require education or training for dispensary owners or staff. The District of Columbia has comprehensive training mandates for dispensary staff that address compliance with law, medical marijuana use, security, and theft prevention. See D.C. Code § 7-1671.06(h)(3) available at <http://government.westlaw.com/linkedslice/default.asp?RS=GVT1.0&VR=2.0&SP=dcc-1000&Action=Welcome> (accessed Nov. 6, 2011). Maine established rules requiring dispensaries to provide medical marijuana educational materials and information to patients. See Code Me. R. 10 144 122 (Weil 2010) available at <http://www.maine.gov/dhhs/dlrs/mmm/index.shtml> (accessed Nov. 6, 2011).
- ¹²⁰ Doesha Cup, <http://doeshacup.weebly.com/index.html> (accessed Nov. 6, 2011) (www.doeshacup.com Web site was not operational on access date).
- ¹²¹ Lisa Leff & Marcus Wohlsen, *Medical Marijuana Doctors Help Make Pot Available in California*, <http://www.usatoday.com/yourlife/>
- health/healthcare/doctorsnurses/2010-11-01-marijuana-california_N.htm (Nov. 1, 2010) (accessed Nov. 6, 2011); Jonathan Martin, *No Medical Records? No Problem. Got My Pot Card at Hempfest*, http://seattletimes.nsource.com/html/localnews/2015969811_marijuana21m.html (Aug. 20, 2011) (accessed Nov. 6, 2011).
- ¹²² Cal. Police Chiefs Assn., *White Paper on Marijuana Dispensaries*, http://california-policechiefs.org/files/marijuana_files/TaskForce.html (2009) (accessed July 31, 2011).
- ¹²³ *Id.* at 8.
- ¹²⁴ 10News.com, *Man Trapped in Pot Dispensary Arrested After Failed Robbery*, <http://www.10news.com/news/28543884/detail.html> (July 14, 2011) (accessed July 19, 2011).
- ¹²⁵ See generally Report Presented to the California Chiefs of Police Association, *Medical Marijuana Dispensaries and Associated Issues*, page 4, http://www.californiapolicechiefs.org/files/marijuana_files/files/CCOP_Presentation_01.pdf (accessed Nov. 9, 2011).
- ¹²⁶ In June and July 2011, robberies were allegedly committed in Vancouver, Washington and Phoenix, Arizona related to medical marijuana. In the Arizona incident, a medical marijuana grower shot and killed a person who reportedly attempted to rob him at gunpoint. In October 2011, New Mexico law enforcement officials arrested a man who allegedly stabbed a home-grower of medical marijuana and stole the owner's plants. KATU, *Two in Custody After Allegedly Robbing Medical Marijuana Grow*, <http://vancouver.katu.com/news/crime/two-custody-after-allegedly-robbing-medical-marijuana-grow/441947> (July 19, 2011) (accessed Nov. 6, 2011); Deborah Stocks, *Medical Marijuana Buy Ends in Shooting*, http://www.abc15.com/dpp/news/region_phoenix_metro/central_phoenix/medical-marijuana-buy-ends-in-shooting (June 3, 2011) (accessed Nov. 6, 2011); David Romero, *Medical Marijuana Stolen at Knifepoint*, <http://www.krqe.com/dpp/news/crime/Medical-marijuana-stolen-at-knifepoint-dr> (Oct. 5, 2011) (accessed Nov. 6, 2011). Additionally, pursuant to SB0423, Montana tightened its medical marijuana program requirements, effective July 1, 2011, to address concerns about the diversion of medical marijuana for recreational and other uses. A basis for the legislation was the number of registered users in Montana's medical marijuana program, which exploded from 7,300 to 30,000 in approximately an 18-month period from 2009 to 2011. Although the First Judicial District Court of Montana issued a preliminary injunction prohibiting implementation of certain portions of the new law, such as a prohibition on dispensaries receiving compensation from patients, other aspects of the law, including patient fingerprinting, have been implemented. See generally Laura Wilson, *Dispensaries Adjust to New MT Medical Marijuana Law*, <http://www.kpax.com/news/dispensaries-adjust-to-new-mt-medical-marijuana-law/#!prettyPhoto/0/> (Oct. 10, 2011) (accessed Nov. 6, 2011); Montana

Dept. of Pub. Health & Human Serv., *Montana Marijuana Program Changes to Marijuana Law*, <http://www.dphhs.mt.gov/marijuanaprogram/> (accessed Nov. 6, 2011) (court decision and information about modified law is available at the Web site); *Montana Cannabis Industry Association v. State of Montana*, No. DDV-2011-518 (Mont. 1st Jud. Dist. Ct. June 30, 2011).

¹²⁷ Susan K. Livio, *Colorado Residents Say Legal Pot has Economic, Medical Benefits; Officials Criticize Unregulated Industry*, http://www.nj.com/news/index.ssf/2010/06/medical_marijuana_pot_nj_color.html (June 6, 2010, updated Jan. 11, 2011) (accessed Nov. 6, 2011); Jacob Applesmith, Presentation, *California and Medical Marijuana* (Nat. Assn. Bds. of Pharm. Fall Symposium. Dec. 3, 2009) available at <http://www.nabp.net/events/assets/Applesmith.pdf>; Cal. Police Chiefs Assn., *Summit on the Impact of California's*

Medical Marijuana Laws – Dispensary Related Crime, http://californiapolicechiefs.org/files/marijuana_files/files/DispensarySummitPresentation.ppt (Apr. 23, 2009) (accessed Nov. 6, 2011).

¹²⁸ See Livio, *supra* n.127.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ Tony Castro, *LAPD Chief: Pot Clinics Not Plagued by Crime*, http://www.dailynews.com/news/ci_14206441 (Jan. 17, 2010) (accessed Nov. 6, 2011).

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.* The article quoted the following Los Angeles police department 2009 robbery statistics: 71 robberies per 350 banks and 47

robberies per at least 800 medical marijuana dispensaries.

¹³⁵ Interestingly, in September 2011, the RAND Corporation issued a study evaluating Los Angeles crime data near dispensaries, concluding that closure of medical marijuana dispensaries caused increases in local crime rates. In October, however, the Corporation retracted its study when it discovered that the crime data from a site only considered Los Angeles County sheriff department data and had omitted Los Angeles police department crime statistics. See RAND Corporation, *RAND Retracts Report About Medical Marijuana Dispensaries and Crime*, <http://www.rand.org/news/press/2011/10/24.html> (Oct. 24, 2011); see also Tim Cavanaugh, *RAND Pot Dispensary Crime Study Retracted*, <http://reason.com/blog/2011/10/25/rand-pot-dispensary-crime-stud> (Oct. 25, 2011) (accessed Nov. 6, 2011).

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CAN THEY DO THAT? GOVERNMENT THREATS TO ‘COME DOWN AND LOOK AROUND’ TO FORCE SETTLEMENT IN QUI TAM CASES

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In *HealthCare Business News*, the vice president of Greenville Memorial Hospital in Greenville, South Carolina recently related his hospital's experience in settling a civil False Claims Act (“FCA”) *qui tam* suit brought against it by the U.S. Department of Justice (“DOJ”) and the U.S. Attorney from Buffalo.¹ As the *qui tam* suit remained under seal, the DOJ told the hospital that it was implicated in a pending “nationwide investigation” for alleged “kypoplasty” billing fraud. In response, the hospital conducted a “thorough internal review” and “turned up no evidence of wrongdoing.” Yet, the hospital still settled and paid \$1.1 million. The hospital's key reason for settling: “investigators told them they had the power to widen their fraud probe far beyond just the spinal-compression surgery if the hospital refused to settle the litigation.” As the hospital's vice president explained, “Basically, they were saying that they would come in and look at every one day stay that we had for a number of years.”²

The threat to “widen the investigation” if a hospital or other provider will not settle with the government is not an isolated incident. Though wishing to remain anonymous, other hospitals in this investigation have reported similar threats to the effect that the U.S. Attorney's Office “would come down and look around” if they did not settle. Even if such threats are not made explicitly, healthcare providers facing FCA investigations often believe that if they resist settlement with the U.S. Attorney's Office their institutions will face an even broader investigation, far beyond

the scope of any underlying False Claim allegations.

Are such threats to induce settlement lawful? Does a civil assistant U.S. Attorney or an attorney with the DOJ's civil division³ (“civil government attorneys”) have the authority to investigate a hospital in matters unrelated to a pending *qui tam* action and for which they do not have a reasonable suspicion that the hospital has engaged in wrongdoing or other violations? Moreover, can they threaten to use their power to engage in a fishing expedition in the event the defendant does not settle either quickly enough or at the amount demanded by the U.S. Attorney?⁴

Civil government attorneys have broad investigative powers, but their power and authority to conduct investigations, compel the production of documents and data from respondents, and threaten litigants is not unlimited. In the context of a *qui tam* action or FCA case, civil government attorneys do not have the legal authority and tools to investigate areas for which they do not have reason or suspicion to believe an alleged violation of the FCA has occurred. Having limited powers and authority to investigate matters, civil government attorneys do not have the legal right to threaten such fishing expeditions to strong arm a settlement.

In addition to legal limits, practical considerations, ranging from obtaining necessary internal approvals to not having enough resources or personnel to examine records obtained from a civil target limit civil government attorneys. While civil government attorneys have broad authority, they cannot simply “come down and look around” if a hospital does not give in to government settlement demands in a civil *qui tam* action.

Government Cannot Use Criminal Tools to Conduct Civil Discovery

Executives with healthcare companies often believe that civil government attorneys wear both criminal and civil hats and have the benefit of a grand jury available along with other unlimited powers at their disposal. That is incorrect.

Generally, in most U.S. Attorney's Offices, assistant U.S. Attorneys (“AUSAs”) usually serve in separate divisions, civil or criminal (maybe even appellate), and except for smaller U.S. Attorney Offices, they do not practice both civil and criminal law. Civil Division AUSAs or attorneys with the Civil Division of the DOJ have the authority and wield investigative powers provided to them by statute and regulation.⁵ Such attorneys defend actions brought against the federal government, and they can bring affirmative civil actions on behalf of the federal government, such as FCA cases. But, they are not criminal prosecutors. For example, civil AUSAs may not use a grand jury to investigate the government's civil disputes, including FCA cases.⁶ Criminal AUSAs cannot share information gathered by a grand jury with civil government attorneys except under very limited circumstances.⁷ In fact, the U.S. Supreme Court refused to permit civil government attorneys “automatic” access to grand jury material for their use in a FCA case.⁸ As a result, civil government attorneys do not have the authority to threaten the use of the grand jury to induce a civil settlement.

Of course, the civil and criminal divisions of a U.S. Attorney's Office or the DOJ may maintain parallel proceedings. In those cases, each division handles its own investigation and coordinates, where permitted, with each

other and the relevant investigative and regulatory agencies.⁹ Such parallel proceedings, however, bear little in common with *qui tam* actions such as those faced by Greenville Memorial Hospital where there was no parallel criminal investigation and the *qui tam* action was based not on direct evidence of fraud, but on a statistical abnormality, allegedly reflecting too many in-patient admissions for kyphoplasty.¹⁰

Civil Government Attorneys Wield Powerful But Limited Tools to Obtain Documents and Testimony from Prospective Civil Defendants

Federal law affords civil government attorneys powerful tools to broadly investigate *qui tam* actions and false claims, but those tools are not unlimited. First, when a *qui tam* complaint remains under seal and before the government elects to proceed or decline the matter, the FCA and regulations interpreting it provide that DOJ's Civil Division and U.S. Attorneys have the authority to issue Civil Investigative Demands ("CIDs") to any person that may possess documents or information "relevant to a false claims law investigation."¹¹ A CID can compel a person to provide documents, respond to interrogatories, and give oral testimony.¹²

Practical and legal limitations hamper the ability of civil government attorneys who might try to use CIDs to obtain information beyond the scope of an identified investigation or to use it punitively in the event a prospective defendant refuses to settle. Though broad in scope, federal law requires that a CID must "state the nature of the conduct constituting the alleged violation of a false claims law which is under investigation." In turn, a respondent to a CID may challenge it by filing a petition to modify or set aside the CID "based upon any failure of the demand

to comply with the provisions of this section or upon any constitutional or other legal right or privilege of such person."¹³

For example, an AUSA must justify to the U.S. Attorney who approves the issuance of the CID why the CID should be issued and what it seeks, and in so doing, will be required to describe the nature of the investigation. If the investigation concerned kyphoplasty procedures and the proposed CID sought documents and information unrelated to that subject, it likely will not be approved. Going one step further, if an AUSA revealed that the real purpose of the CID was to intimidate the respondent into settling an unrelated matter, such an attempt would likely be a basis for disciplining the AUSA. Of course, the AUSA could try to get around this by drafting a CID that was broad in scope. Yet, if such a request to issue a CID were made to investigate a *qui tam* action, then the AUSA would still have to justify how the use and scope of such an investigative tool related to the claims and allegations at issue.

Second, once the government intervenes in a *qui tam* action, then it becomes a civil litigant much like any other, and its ability to obtain discovery is subject to the Federal Rules of Civil Procedure. Rule 26(b) limits discovery by the parties to any "non-privileged matter that is relevant to any party's claim or defense."

Civil Government Attorneys Likely Violate State Rules of Professional Conduct by Threatening to Use Process Which They Do Not Have Authority to Employ

Civil government attorneys must comply with the governing rules of professional conduct applicable in the district courts and states where they practice.¹⁴ The Model Rules of Professional Conduct have been adopted in all but one state,¹⁵ and they appear to

forbid civil government attorneys from threatening the use of compulsory process to induce a settlement when, as in this instance, government counsel does not have the authority or cause to employ such process. For example, Rule 4.4 provides that ". . . a lawyer shall not use means that have no substantial purpose other than to embarrass, delay, or burden a third person, or use methods of obtaining evidence that violate the legal rights of such a person." In turn, the Comment to Rule 3.1 explains that unless there is a basis in law and fact for doing so that is not frivolous, "[t]he Advocate has . . . a duty not to abuse legal procedure."¹⁶

Although not binding, the clearest applicable statement of a civil government attorney's professional responsibility in the situation described herein may be found in the "ethical considerations" to the Model Code of Professional Responsibility:

A government lawyer in a civil action . . . has the responsibility to seek justice . . . and he should not use his position or the economic power of the government to harass parties or to bring about unjust settlements or results.¹⁷

Hence, a civil government attorney may be subject to discipline by the DOJ for violating a state's rules of professional conduct if he or she threatens to employ government process to "look around" in areas which are outside the scope of the investigation and for which the attorney does not have cause to investigate.

HHS Has Power to Obtain Records, But Will It? and Other Practical Considerations

The U.S. Department of Health and Human Services ("HHS") is the government agency that most often investigates allegations of healthcare fraud, and its Office of Inspector General ("OIG") frequently works with civil government attorneys in investigating FCA

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cases. HHS possesses very broad authority to examine as well as to compel the production of the billing records of Medicare and Medicaid providers. For example, the Patient Protection and Affordable Care Act (“PPACA”) provides that the OIG may obtain “any supporting documentation necessary to validate claims for payment” under any federal healthcare program as well as “any records necessary for the evaluation, economy, efficiency, and effectiveness” of a federal healthcare program.¹⁸ In addition, PPACA further permits the OIG as well as the DOJ to access an “Integrated Data Repository” maintained by HHS that contains claims and payment data for all major healthcare programs for the purpose of “conducting law enforcement and oversight activities.”¹⁹

Acknowledging that the OIG has broad authority and power to access Medicare and Medicaid provider records or the records of a *qui tam* defendant does not resolve the question of whether civil government attorneys can or will “come down and look around” if a party refuses to settle, as in the example of Greenville Memorial Hospital referenced above. First, civil government attorneys do not control the OIG. Contrary to the fears of many in the healthcare industry, the government is not monolithic, and agencies such as HHS and DOJ do not walk in lock step nor always act in concert with U.S. Attorneys. In fact, unless a civil government attorney is acting on the behalf of an agency as its lawyer, the attorney will frequently state that he/she does not and cannot speak for agencies such as HHS. In turn, the civil government attorneys would still have to justify a request to the OIG wherein the agency was requested to obtain billing records regarding a provider. The justification of “let’s go poking around so we can put the fear in this defendant and get it to settle”

may be tempting, but it is hardly a compelling or lawful justification to get an agency to act.

Second, practical considerations have an impact on whether such a threat to “come down and look around” is credible. Who will review and analyze the records? Contrary to the impression that civil government attorneys might like to give, the government and the agencies with whom they work do not have unlimited resources. If a civil government attorney wants to “come down and look around,” who is going to do that? Neither the government nor its agencies has legions of agents at their fingertips, ready to spend several weeks examining records that they have no probable cause contain false claims or overbillings. Certainly, the civil government attorneys are not going to do it: they often carry large case loads, have no expertise in Medicare/Medicaid billing, and do not have the time to look around voluminous billing records from a provider.

Conclusion

While civil government attorneys possess broad powers, they cannot simply compel the production of records without probable cause, nor can they threaten what they do not have the authority to carry out. When faced with government threats such as those made to Greenville Memorial Hospital, healthcare executives should consider challenging the threat. There may be a number of reasons for hospital executives to settle such an investigation, ranging from litigation risk to bad facts concerning the subject of the investigation. Giving in to threats to which the government counsel attorneys do not have the authority to make or carry out, however, should not be one of them.



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Endnotes

¹ Settlement Necessity: Questions over Kyphoplasty Narrow Legal Options, Joe Carlson, *ModernHealthcare.com*, 1/10/11, www.modernhealthcare.com/article/20110110/magazine/110109977. U.S. Attorneys frequently work together with the DOJ on *qui tam* suits filed in a district. This collaboration stems in large part from the fact that U.S. Attorneys have limited settlement authority for FCA claims of up to \$1 million. Claims exceeding that amount are referred to and worked with the Commercial Litigation Branch in DOJ’s Civil Division. See *U.S. Attorney’s Manual* 9-42.010(a) (“Claims of fraud against the

government involving more than \$1,000,000 in single damages plus civil penalties also should be referred to the Civil Division's Commercial Litigation Branch.") Greenville Memorial Hospital was one of several hospitals named by the relators in their *qui tam* action that was filed in the Western District of New York. See DOJ Press Release on 1/4/11, "Seven Hospitals in Six States to Pay U.S. More Than \$6.3 Million to Resolve False Claims Act Allegations Related to Kyphoplasty." www.justice.gov/opa/pr/2011/January/11-civ-006.html.

- 2 *Id.* Dr. Thomas Diller, Vice President of Quality and Patient Safety, Greenville Memorial Hospital, Healthcare Business News, Settlement Necessity.
- 3 Civil assistant U.S. Attorneys are those attorneys who work within a particular U.S. Attorney's Office. The Civil Division is a separate division of the DOJ and is headed by the Assistant Attorney General for the Civil Division. See U.S. DOJ Civil Division web site: www.justice.gov/civil/common/about.html. Civil Division attorneys work out of the DOJ in Washington, D.C.
- 4 The ability and authority of the government to make threats to induce pleas or settlements in criminal cases is outside the scope of this article, which is limited in its analysis to the authority of civil government attorneys to make such threats in *qui tam* cases.
- 5 The U.S. Attorneys Manual ("USAM") describes the scope and roles of the Civil Division and the U.S. Attorney's Office in representing the United States in civil matters. See USAM 4.100 *et seq.* Many statutes enforced by the Civil Division and the U.S. Attorneys provide civil investigative authority and tools outside the scope of civil litigation and the Federal Rules of Civil Procedure. For example, a provision of the Financial Institutions Reform, Recovery and Enforcement Act of 1989 ("FIRREA"), 12 U.S.C. § 1833a(g), provides that in conducting civil investigations of financial institution fraud the Attorney General may issue administrative subpoenas compelling testimony and the production of documents. In turn, the Attorney General has delegated his authority to use these investigative tools to the Assistant Attorney General for the Civil Division, the United States Attorneys, and others. See Civil Remedies for Mortgage Fraud, Leon Weidman, Chief Civil Division, Central District of California, *United States*

Attorneys' Bulletin, May 2010, www.justice.gov/usao/eousa/foia_reading_room/usab5803.pdf. As explained below, the FCA also provides investigative authority to the Civil Division.

- 6 *United States v. Proctor & Gamble Co.*, 175 F. Supp. 198, 199 (DNJ 1959) (government's use of grand jury for a matter of a purely civil character was a misuse and abuse of the law).
- 7 Federal Rule of Criminal Procedure 6(e) limits the ability of federal prosecutors to share information they obtain through grand jury proceedings with other government agencies. For the most part, Rule 6(e)(3) restricts the disclosure of grand jury information to prosecutors assisting in a criminal investigation and other government personnel necessary to assist the prosecutor in his or her duty in enforcing federal criminal law. See also 18 U.S.C. 3322 (permitting disclosure relating to banking law violations). Rule 6(e)(3) does permit a court to authorize the disclosure of grand jury material "preliminarily to or in connection with a judicial proceeding."
- 8 *United States v. Sells Eng'g, Inc.*, 463 U.S. 418 (1983).
- 9 See July 28, 1997 Attorney General Memorandum, Coordination of Parallel Criminal, Civil, and Administrative Proceedings. www.justice.gov/ag/readingroom/970728.htm. For example, see discussion of parallel proceedings in tax cases and prosecutions. USAM Title 6, Tax Resource Manual, Section 22.
- 10 See *e.g.*, Federal False Claim Act/Qui Tam Strategic blog, February 6, 2009, New National Kyphoplasty Enforcement Initiative, <http://fcaexpert.blogspot.com/2009/02/new-national-kyphoplasty-enforcement.html>.

The methodology of the investigation is quite straight forward and easy for the DOJ to perform. A computer check is run on billings for Kyphon-related services under the appropriate procedure code. If more than a scattering of such claims include requests for inpatient service reimbursement, rather than exclusively outpatient procedures, then the hospital is targeted for further investigation.

The author of this blog entry, attorney Ronald H. Clark, negotiated one of the first kyphoplasty *qui tam* settlements in 2009 on behalf of the HealthEast Care System in St. Paul, Minnesota. See Kyphoplasty cacophony; six more hospitals settle False Claims allegations, by Gregg Blesh, www.allbusiness.com/legal/legal-services-litigation/13378368-1.html.

- 11 See 31 U.S.C. § 3733(a) provides that the Attorney General or a designee may issue the CID, and 28 CFR Part 0, Appendix to Subpart Y, Section 5 provides that "[a]uthority relating to Civil Investigative Demands issued under the False Claims Act is hereby delegated to the United States Attorneys in cases that are delegated or assigned."

12 18 U.S.C. § 3733(a)(1).

13 18 U.S.C. § 3733(j)(2) (emphasis added).

14 28 U.S.C. § 503B provides:

(a) An attorney for the Government shall be subject to State laws and rules, and local Federal court rules, governing attorneys in each State where such attorney engages in that attorney's duties, to the same extent and in the same manner as other attorneys in that State.

15 Every state but California has adopted some form of the Model Rules of Professional Conduct. See ABA Center of Professional Responsibility webpage discussing Rules and their adoption by states: www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct.html.

16 The Model Rules of Professional Conduct and the comments thereto can be found at: www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/model_rules_of_professional_conduct_table_of_contents.html.

17 Model Code of Professional Responsibility EC 7-14 (1981). A copy of the Code can be found at: www.americanbar.org/content/dam/aba/migrated/cpr/mrpsc/mcpr.authcheckdam.pdf.

18 Section 6402(a) of PPACA. Of course, HHS may access records through other avenues than just the OIG. Provider and subcontractor agreements provide CMS with access to records related to Medicare billings. See 42 CFR 489.53 (termination of provider who refuses to provide records to CMS); 42 CFR 413.20 (Medicare intermediary may request records from the provider); and 42 CFR 420.300 *et. seq.* (HHS may access subcontractor records). Medicare providers are required to provide relevant billing records as well in response to a RAC audit by the Medicare Recovery Audit Contractor ("RAC") program. Cf. 42 U.S.C. § 1395ddd.

19 Section 6402(a) of the Patient Protection and Affordable Care Act, amending 42 U.S.C. § 1320a-7k.

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ANOTHER ROUND OF CONTRACTORS: THE MEDICAID RAC FINAL RULE

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Introduction

Healthcare providers continue to notice an increase in auditing efforts from Medicare and Medicaid contractors. They are already inundated with acronyms of contractors tasked to help implement the Centers for Medicare & Medicaid Services' ("CMS") most recent benefit integrity policy to "prevent and detect" improper Medicare and Medicaid payments.¹ ZPICs, MICs, MACs, and Medicare RACs have become key participants in CMS' policy of prevention and detection of improper payments.² CMS' implementation of these audit efforts, while well-intentioned, creates the concern that the existing infrastructure in which the contractors operate is insufficient to protect providers and offer adequate accountability for contractors. Providers are faced with various audit and appeals processes and often are inundated with audits from different contractors. Although audits serve an important purpose, many providers experience insurmountable challenges due to an audit that could severely damage a provider's business. Protecting the Medicaid and Medicare trust funds is an important goal; however, it should be balanced with protecting providers' due process rights.

It is within this framework that the Medicaid RACs will begin to audit providers, joining the audit fray next month.

Background

On September 16, 2011, CMS published in the Federal Register the final rule ("Final Rule") establishing

guidance to states for the funding, start-up, operation, payment and maintenance of Medicaid RACs.³ The Final Rule implements Section 6411(a) of the Patient Protection and Affordable Care Act ("PPACA") which amended Section 1902(a)(42) of the Social Security Act to include a requirement that all states must have contracted with at least one RAC entity by no later than December 31, 2010.⁴ On October 1, 2010, CMS issued a letter to State Medicaid Directors which required states to submit a State Plan Amendment ("SPA") to CMS by December 31, 2010 attesting that the state would establish a Medicaid RAC program or indicate that it would seek an exception from the requirement.⁵ On November 10, 2010, CMS published a Notice of Proposed Rulemaking for the states' Medicaid RAC programs, saying that the states' RAC programs were expected to be fully implemented by April 1, 2011; however, another letter from CMS issued on February 1, 2011 stated that the full implementation date would be announced in the Final Rule.⁶ The Final Rule requires that states implement a RAC program by January 1, 2012.

Medicaid Recovery Audit Contractors

The Medicaid program is a collaborative effort between the federal government and state governments. It is designed to allow states to receive federal matching funds to help provide medical assistance to eligible low income beneficiaries. In order to participate in Medicaid, states must present a State Plan for medical assistance to the Secretary of the U.S. Department of Health and Human Services for approval.

The federal government expends billions of dollars annually to

administer the Medicaid program. Medicaid is the third-largest domestic program in the federal budget after Social Security and Medicare.⁷ During the 2011 Fiscal Year, the federal share in Medicaid programs, also known as the Federal Medical Assistance Percentages ("FMAP") ranged from 50.00 percent to 74.73 percent.⁸ Medicaid is the second largest program in most states' budgets, after elementary and secondary education.⁹ These amounts will likely only increase, as it is projected that by 2019 there will be about 20 million Medicaid enrollees.¹⁰

Viewed in light of the immense funding the Medicaid program requires from both state and federal governments, it is not surprising that the RAC program was expanded to Medicaid. However, since the RAC program was expanded to Medicaid pursuant to PPACA, it is important to recognize that PPACA has been challenged and is on the United States Supreme Court's docket for the current term. If the challenge succeeds, the entire healthcare reform legislation could be overturned, including the provision authorizing the Medicaid RACs. In the event that does not happen, however, it is essential to understand the Final Rule to fully comprehend the impact of the Medicaid RAC program on healthcare providers.

Comparing Medicare RACs and Medicaid RACs

Section 6411(a) of PPACA amended Section 1902(a)(42) of the Social Security Act to state that "...the State shall (i) establish a program under which the State contracts (consistent with State law and *in the same manner as the Secretary enters into contracts with recovery audit contractors...*) with 1 or more recovery audit contractors for the purpose of identifying

underpayments and overpayments and recouping overpayments under the State plan... .”¹¹ This language demonstrates that although the Medicaid RAC program will be administered differently from the Medicare RAC program, the programs will operate in alignment with one another in several areas, including staffing requirements; the claim look-back period; development of an education and outreach program; and minimum customer services measures.¹²

There are three fundamental differences between the Medicare RACs and the Medicaid RACs: funding, authorization, and purpose of the RAC programs. Medicaid RACs are state funded, designed, procured, operated and administered programs.¹³ Medicare RACs, on the other hand, are regionally operated contractors that are funded, procured, operated and administered by the federal government.¹⁴ While the Medicaid RACs are authorized under PPACA, the permanent Medicare RAC program is authorized by section 302 of the Tax Relief and Health Care Act of 2006. The purpose of Medicare RACs is to identify underpayments and overpayments and to recoup overpayments under Parts A and B of the Medicare program, while the Medicaid RAC program identifies improper payments under state Medicaid plans.¹⁵

There are also a number of other differences between the programs, most importantly the amount of control states have over their individual Medicaid RAC programs. A recurring theme throughout the Final Rule was CMS’ position that it would not hold states to a concrete standard or criteria, but would allow the states to make their own decisions on critical elements of the audit program, including the scope of audits, coordination with other audit reviews, and appeals. CMS stated very clearly that it decided to allow states flexibility because it wanted to “...account for differences in the size of the State, Medicaid population, amount of

expenditures, and other State-specific characteristics, for example, allowing smaller States the flexibility to vary the requirements that would otherwise overburden them financially.”¹⁶

Therefore, although the goals of the RAC programs are similar and CMS has instituted some outer boundaries for the Medicaid RAC program that are extensions of the Medicare RAC program, healthcare providers will have the burden of educating themselves on the details of the individual Medicaid RAC programs they may be dealing with, which will vary.

Comparing the Medicaid Integrity Program and Medicaid RACs

Although the Medicaid Integrity Program (“MIP”) and the Medicaid RACs both audit Medicaid claims, the goals of and oversight over the programs differ. MIP was introduced through the Deficit Reduction Act of 2005 and its goal is to eliminate fraud, waste, and abuse in Medicaid.¹⁷ There are three types of Medicaid integrity contractors (“MIC”)s in the MIP program: Review MICs, Audit MICs and Education MICs. The Review MICs review Medicaid claims for potential vulnerabilities and refer potential aberrant billing practices to Audit MICs.¹⁸ Education MICs, however, employ findings from Audit MICs and Review MICs to target specific areas for education and training.¹⁹ Audit MICs conduct post-payment audits of Medicaid providers and advise states of overpayments made to a Medicaid provider.²⁰ Unlike the Medicaid RACs, the MICs are organized regionally and are federal contractors. In addition, the MICs are not paid on a contingency fee basis and are not responsible for collecting overpayments from providers.

Although comments published in the Final Rule expressed concern over the similarities between the Medicaid RACs and the MICs, the Final Rule explains that the MIP is not duplicative of the Medicaid RAC

Program.²¹ In the Final Rule, CMS asserted that RACs are efficient entities to identify payment errors, but they are not necessarily as effective to identify and prevent fraudulent practices, presumably because contingency fee contractors do not receive a contingency fee for referred cases that are determined to be fraudulent.²² Therefore, MICs may focus on issues, including fraud cases, that may not be advantageous for a contingency-fee contractor to pursue.²³ Further, MICs focus on regional and national issues, while Medicaid RACs are positioned to address state-specific issues.²⁴ As will be discussed in more detail, states are required to establish systems to ensure the efforts between the Medicaid RACs and the MICs are coordinated and there is not overlap between the two programs.

Structure of Medicaid RAC Programs

The Final Rule enumerates certain objective criteria that each individual state Medicaid RAC program must incorporate. In many cases, the logistics of implementing these requirements is left up to the individual states. One element that is clear from the Final Rule is the eligibility requirements for Medicaid RACs. The Final Rule establishes 42 C.F.R. § 455.508, which sets forth the requirements an entity must meet before it enters into a Medicaid RAC contract with a state. First, the entity must display to the state that it has the technical capability to carry out the Medicaid RAC tasks.²⁵ This includes an examination of the entity’s employment of trained medical professionals who are in good standing with the relevant state licensing authorities to review Medicaid claims.²⁶ Second, the entity must hire or maintain a minimum of 1.0 full-time equivalent (“FTE”) Contractor Medical Director who is either a Doctor of Medicine or Doctor of Osteopathy in good standing with the relevant state licensing authorities and has relevant work and educational

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experience.²⁷ Third, the entity will be required to hire certified coders unless the state determines that certified coders are not required for the effective review of Medicaid claims.²⁸

Entities contracted as Medicaid RACs must also work with the state to develop an education and outreach program which includes notification to providers of audit policies and protocols.²⁹ While transparency in the state program is encouraged, the nature of the specific education and outreach efforts are left up to the states. The Final Rule, however, does not require states to provide coding/billing guidelines in any way other than how they are currently issued outside of the Medicaid RAC program.³⁰ Further, the right of the RAC contractor to develop or apply its own coverage, payment or billing policies is left to be addressed by contract between the state and the contracted audit entity. In comparison, Medicare offers publicly available manuals, articles, and the Medicare Coverage Database of National Coverage Determinations (“NCD”s) and Local Coverage Determinations (“LCD”s) to inform providers on coverage policies. The lack of an affirmative requirement on the states to provide the applicable coding and billing rules may be cause for provider concern in the face of Medicaid RAC audits and could hinder proactive compliance efforts; however it could also supply defenses to providers during the audit appeals process.

The Final Rule expressly requires that an audit entity must also provide minimum customer service measures and not audit claims that have already been audited or are currently being audited by another entity.³¹ The Medicaid RACs must operate a toll-free customer services telephone number.³² The toll-free number must be included in all correspondence

with providers, and it must be staffed during normal business hours.³³

The Final Rule also directs that Medicaid RACs cannot audit claims that have already been subject to an audit or are in an audit. The Final Rule does not provide a specific mechanism for states to use to coordinate audit efforts; however, the Final Rule does mandate that the coordination occur.³⁴ CMS declined to establish a system by which states would keep track of the claims being audited. Specifically it stated in the Final Rule that it refused “...to require States to create or use a data warehouse at this time.”³⁵ To satisfy a similar requirement in the Medicare RAC program, the RAC Statement of Work expressly provides for the use of the RAC Data Warehouse to determine if another entity has the provider or claim(s) under review.³⁶ The RAC Data Warehouse includes a master list of “excluded” claims – claims that have already been reviewed by another entity.³⁷ A similar coordination tool could be employed by states, but the exact coordination efforts will not be known until states begin to implement their Medicaid RAC programs.

Medicaid RACs will also have the responsibility to refer suspected cases of fraud and/or abuse to the state in a timely manner. The standard proposed by CMS for reporting fraud is if the Medicaid RAC “has reasonable grounds” to believe such activity has occurred.³⁸ A similar requirement was placed on the Medicare RACs, but the requirement did not yield significant referrals. A report released by the Office of Inspector General (“OIG”) for the Department of Health and Human Services announced that during the RAC demonstration program, between 2008 and 2010 the Medicare RACs referred only two cases of potential fraudulent activity.³⁹ Although CMS provides training to

Medicare RACs to identify fraudulent activity during the permanent RAC program, Medicare RACs have still played a limited role in referring fraudulent claims. One likely explanation for this limited role is the effect of the contingency fee payment. As noted above, as contingency fee contractors, Medicare RACs simply do not have the incentive to identify fraudulent claims since if the referred case is determined to be fraud, the contractor does not receive its contingency fee.⁴⁰ An interesting question in the Medicaid RAC program will be whether Medicaid RACs will follow the Final Rule’s requirement that they refer cases of potential fraud to law enforcement in the absence of an incentive to do so.

The Final Rule also requires that Medicaid RACs meet all other obligations that a state might identify.⁴¹

In addition, CMS touched upon the structure of the Medicaid RAC program with regard to the relationship between the federal and state governments. In the proposed rule published on November 10, 2010, CMS planned that states would report to CMS certain elements describing the effectiveness of their Medicaid RAC programs.⁴² These elements included general program descriptors, such as the length of the contracts and the contractors’ names, and specific program metrics, including number of audits, amount recovered and the amount of cases referred for potential fraud.⁴³ In the Final Rule, CMS announced that states must report overpayments to CMS based on the net amount remaining after all fees are paid to the Medicaid RACs.⁴⁴ However, CMS did not identify specific reporting requirements in the Final Rule and noted that sub-regulatory guidance will be specified by CMS in the future.⁴⁵

In the Final Rule, CMS elaborated on its interpretation of section 1902(a)(42)(B)(ii)(IV)(aa) of the Social Security Act which outlines the reimbursement to the states of the expenditures made by the states to carry out the Medicaid RAC program.⁴⁶ CMS interpreted this section of the Act to mean that the amounts paid by a state to establish and operate the Medicaid RAC program will be shared by the federal government at the 50 percent administrative rate applied to all Medicaid expenditures, as provided for in section 1903(a)(7) of the Social Security Act.⁴⁷ This will include the states' appeal costs for appeals by providers of a Medicaid RAC's findings.⁴⁸ States will be required to determine the contingency fee rate paid to the contracted Medicaid RAC based on the percentage of the recovered overpayment amount.⁴⁹ The contingency fee rate set between the state and Medicaid RAC must not exceed the highest contingency fee rate paid to a Medicare RAC in order for CMS to provide federal financial participation.⁵⁰

Presently, the highest Medicare RAC contingency fee is set at 12.50 percent. Absent an approved exception from CMS, any additional contingency fee payments from the state to the Medicaid RAC beyond the highest Medicare RAC contingency fee rate would need to be made using state-only funds.⁵¹ Further, contingency fees must be returned to the state within a reasonable timeframe, defined by the state, if a Medicaid RAC's determination is reversed at any level of appeal.⁵²

Medicaid RAC Audits

Scope of Medicaid RAC Audits

The scope of the audits conducted by the Medicaid RACs will be similar to the scope of those conducted by Medicare RACs. In the Final Rule, CMS published a public comment that suggested the Medicaid RAC should exclude Evaluation and Management ("E/M") Services from RAC review.⁵³

CMS responded that states will contract with a RAC for the RAC to review claims submitted by providers for payment under the Medicaid program and that these claims will likely include E/M services.⁵⁴

CMS also addressed the requirements for medical necessity reviews. It stated that it will not issue oversight provisions regarding medical necessity reviews in the Medicaid RAC program.⁵⁵ CMS expressed that all healthcare providers are required to furnish medically necessary services in accordance with state Medicaid plans.⁵⁶ Therefore, Medicaid RAC medical necessity reviews must be performed within the scope of the state laws and regulations.⁵⁷

In line with this position, CMS responded in the Final Rule to a comment regarding review boards for issues subject to medical necessity reviews.⁵⁸ The comment suggested that Medicaid RACs be required to submit a rationale for each medical necessity review for review and approval.⁵⁹ The response stated that CMS will encourage states to form review teams for Medicaid RACs similar to the Medicare RAC program's "New Issue Review Board."⁶⁰ CMS will provide "technical assistance" to states who decide to include medical necessity reviews in their Medicaid RAC programs.⁶¹ However, notably absent from this language in the Final Rule is the requirement that states require advanced approval of medical necessity reviews. Presumably, the absence of this requirement follows the underlying theme of the Final Rule that CMS will not render mandates on all aspects of the Medicaid RAC program to allow the states considerable flexibility.

The Final Rule also clarified that states will not be required to include managed care claims within the scope of the Medicaid RAC's review. The proposed rule had not addressed whether managed care claims would be included, but after several commenters requested CMS to clarify its position on this issue, CMS stated in

the Final Rule that Medicaid RACs will not be required to review managed care claims until either a permanent Medicare managed care RAC program is in full effect or a viable state Medicaid model is identified.⁶² At that time, CMS may engage in further rule-making to outline the attributes of those reviews.⁶³

The scope of Medicaid RACs is also affected by CMS' emphasis on certain requirements to help ease the burden of the new audits on healthcare professionals. One aspect of Medicaid RAC audits that will have a direct impact on providers is the requirement that Medicaid RACs accept electronic submissions of medical records, as a part of CMS' requirement that states ensure certain customer service measures are fulfilled. Section 455.508(e)(3) of the Final Rule requires Medicaid RACs to accept electronic submissions of medical records to facilitate provider response to RAC audit record requests, unless the state requests and receives an exception from CMS.⁶⁴ The acceptance of medical records electronically, however, must be accomplished without compromising security and privacy of that data.⁶⁵

Another feature of the Medicaid RAC program that was designed to limit the burden on audited healthcare providers is that states must establish limits on the number and frequency of medical records to be reviewed by the RACs.⁶⁶ The limits set by states may be subject to exceptions requested by the RAC.⁶⁷ In addition, CMS set the look-back period for Medicaid RACs to be the same as the Medicare RAC permanent program, three years from the date of the claim.⁶⁸ However, this requirement is subject to an exception requested by a state through the SPA process if a state's Medicaid Management Information System ("MMIS") only retains adjustable claims data for two years.⁶⁹ Again, this allowance for states in the Final Rule demonstrates CMS' declared commitment to provide states flexibility in forming their Medicaid RAC programs.

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Medicaid RAC Audits – After the RAC’s Review

The steps after an audit contractor has completed the review of claims and issued claim determinations are extremely important, especially for healthcare providers that receive an adverse determination. The Medicaid RAC Final Rule provided some guidance on the series of events that may occur after a healthcare provider’s claims have been reviewed. However, for many of the key issues CMS retained its position that the details must remain within the states’ discretion. For instance, CMS will not mandate a single appeals process for all states to use for Medicaid RAC appeals.⁷⁰ Although § 1902(a)(42)(B)(ii)(III) of the Social Security Act requires that states implement an appeals process for providers to appeal adverse RAC determinations, the appeals process will be developed by the state, subject to CMS approval.⁷¹

During the SPA process, each state provided CMS with assurances that it would comply with the requirement that the state would provide an adequate appeals process for providers faced with adverse RAC determinations.⁷² States have the flexibility to determine whether it will implement a new appeals process strictly for Medicaid RAC determinations or if it will simply use an existing appeals process.⁷³ Notably, CMS recognized in the Final Rule that it will be difficult for healthcare providers to potentially interact with more than one appeals process, but concluded that the burden will not be too challenging because the provider will have already been involved with the state’s overpayment determination process and therefore should have notice of appeals timeframes.⁷⁴

Another post-audit event that CMS determined to leave to states’ discretion is the issue of whether a provider is permitted to re-bill a

corrected claim after a Medicaid RAC identifies an improper payment as a result of a medical necessity review. In the Final Rule, CMS stated that the decision whether the provider in this position can re-bill the claim and the requirements for re-filing the claim will be governed by state law, regulation and policy which set time limits on the submission of providers’ claims.⁷⁵ Similarly, if a RAC identified an underpayment and the time for re-filing a claim has passed, CMS found that the state has the discretion to determine whether the provider may re-file the claims with the correct information.⁷⁶ In response to a comment regarding reimbursement for identified underpayments, CMS took the position that states should compensate all providers for any identified underpayments, consistent with state law.⁷⁷

With regard to the reopening of claims, Medicare RACs are permitted to reopen a provider’s claim within one year for any reason. In order to reopen the claim after one year, a Medicare RAC must have good cause, but the provider cannot challenge good cause. However, after four years, a Medicare RAC can only reopen the claim if there is suspected fraud. CMS addressed the issue of reopening claims for Medicaid RACs by leaving it to the state’s discretion. CMS noted that since states have different administrative appeal processes from the Medicare program, it will not require states to comply with the reopening regulations as set forth in the Medicare RAC program.⁷⁸

Finally, the Final Rule addressed how Medicaid RACs will be paid and the process for collecting overpayments. First, CMS addressed that the Medicaid RACs will be paid through a contingency fee method, in the same fashion as the Medicare RACs. In addition, the Medicaid RAC contingency fees will be based on the overpayments recovered, rather than overpayment simply

identified.⁷⁹ States are given discretion as to when the applicable contingency fee payment is made to the Medicaid RAC. The state may choose to pay the contractor once the overpayment is identified and recovered, regardless of any subsequent provider appeal. In this situation, if the provider successfully appealed the claim denials at any stage of the appeals process, the contractor would be required to return the applicable portion of the contingency fee.⁸⁰ Conversely, the states may choose to pay the RAC its contingency fee after any and all provider appeals are fully adjudicated.⁸¹ Regardless of the payment structure chosen, if the claim determination is subsequently overturned in the provider’s favor on appeal, the RAC is required to return that portion of its contingency fee within a reasonable timeframe, as prescribed by the state.⁸²

Another issue involving payments that was addressed by the Final Rule was the length of time the state has to repay the federal share of the overpayments. Under § 1903(d)(2) of the Social Security Act, states have up to one year to recover overpayments before an adjustment is made in the federal payment to the state to account for the overpayment.⁸³ After this one year period, the states must return the federal share regardless of whether the overpayment is actually recovered.⁸⁴ If there is a change in the overpayment amount following the appeals process that ended after the one-year period for collection, the state may submit a form to the federal government to adjust the overpayment amount.⁸⁵

Impact of the Medicaid RACs

In the Final Rule, CMS outlined the overall and detailed impacts the Medicaid RAC program will have on the healthcare industry and the Medicaid program. Using the Medicare RAC Demonstration program as a guideline, CMS estimates that the Medicaid program will have a limited

financial impact on most providers because significant improper payments are relatively rare.⁸⁶ Despite this statement, CMS estimates that in 2012 the Medicaid RAC program will save the federal government \$60 million and state governments \$50 million.⁸⁷ These amounts will increase to reflect an aggregate net savings of \$2.13 billion for fiscal years 2012 through 2016.⁸⁸ The Final Rule did not project any expected impact of the Medicaid RAC program on Medicaid healthcare providers. However, it is likely that the impact will be similar to that from the Medicare RAC programs.

Unanswered Questions about the Medicaid RAC Program

The Medicaid RAC Final Rule leaves many unanswered questions about the development of the Medicaid RAC program and whether key elements in other audit programs will play a role in the program. For instance, there are no requirements in the Final Rule related to recoupment of identified overpayments or recoupment timeframes. In the Medicare RAC program, the RACs may not initiate the overpayment collection process if it receives a request for redetermination or reconsideration within the timeframes for the limitation on recoupment and must stop recoupment efforts that have already started once the provider requests a redetermination or reconsideration. If an Administrative Law Judge reverses the Medicare overpayment determination, Medicare will refund the principal and interest already collected. This limitation on recoupment is a crucial element to the Medicare RAC appeals process. There may be serious adverse consequences for providers if states do not implement a similar limitation on Medicaid RACs.

Another potential issue is whether Medicaid providers will be able to engage in settlement discussions with a Medicaid RAC that identified an overpayment. Although settlement is

usually an option in state-initiated Medicaid audits, it is unclear whether states will have the authority to unilaterally compromise the federal portion of the claim. Another unanswered question is the Medicaid RACs' use of statistics to extrapolate overpayment determinations. Although Medicare RACs are authorized to utilize statistical sampling, they have not exercised this authority. This is another issue that may vary state-to-state, since states may have different rules for statistical analysis in Medicaid audits. As Medicaid RACs are encouraged to statistically project, this is an issue that will have a serious impact on Medicaid providers, since statistical extrapolation greatly increases overpayment amounts.

The issue of the role of legal counsel in the Medicaid RAC appeals process is also developing. Since the appeals processes will vary among the states, legal counsel may be required to apply for *Pro Hac Vice* admission. Some states may not require legal counsel to apply for *Pro Hac Vice* admission for administrative proceedings, while others may. Therefore, legal counsel must evaluate the provider's state's legal practice requirements in order to represent a healthcare provider in a Medicaid RAC appeals process.

Finally, one of the most significant unanswered questions surrounding the Medicaid RACs and other audit contractors is whether there is sufficient infrastructure in the audit programs to protect providers' and suppliers' due process rights. Audits initiated by any of the various program contractors can lead to significant recoupment, prepayment review and substantial legal and administrative expenses. Further, if withholds are implemented prior to reaching a final adjudication of the merits of the provider's appeal, the provider may suffer irreparable consequences. The question remains, therefore, whether the multitude of well-intentioned audit initiatives implemented at the same time through both state and federal jurisdictions

provide sufficient safeguards for providers to ensure that they may pursue the appeals process without going out of business.

These questions are only examples of the many key elements of the Medicaid RAC program that were not fully explained in the Final Rule. Since many of the program's details will be determined by the states, it is essential that Medicaid providers and their legal counsel carefully follow the developments of the Medicaid RAC program in the states where the providers bill Medicaid for services.

Conclusion

The Medicaid RAC program adds another dimension to the federal government's efforts to tackle improper reimbursements from government healthcare programs. However, since the program is administered by the states, many questions remain unanswered in the Final Rule. Providers and suppliers in the healthcare industry affected by the Medicaid RAC program must pay close attention to the states in which they practice for further guidance, rules and procedures that will be developed for the implementation of the program's requirements. Multi-state providers and suppliers have the additional burdens to not only know the state-specific billing rules, but also the states' RAC programs and administrative appeals processes. These added burdens on Medicaid providers give rise to the question of whether in the zeal to protect the Medicare and Medicaid trust funds, there has been a failure to establish sufficient infrastructure and accountability to protect providers' and suppliers' due process rights.



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- ¹⁰ 2010 Actuarial Report on the Financial Outlook for Medicaid from the Department of Health and Human Services, Dec. 21, 2010 at iii. Available at: <http://www.cms.gov/ActuarialStudies/downloads/MedicaidReport2010.pdf> (Last visited: Nov. 1, 2011).
- ¹¹ 42 U.S.C. 1396a(a)(42) as amended by Section 6411 of the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-152 (Mar. 23, 2010) (emphasis added).
- ¹² 76 Fed. Reg. 57808, 57813. *See also* 42 C.F.R. §§ 455.508(a), (b), (c), (d), (e) and (f).
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- ¹⁴ *Id.*
- ¹⁵ *Id.*
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- ¹⁷ Deficit Reduction Act of 2005, Section 6031.
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- ¹⁹ *Id.*
- ²⁰ *Id.*
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- ³⁸ *Id.*
- ³⁹ 42 C.F.R. §455.508 (i).
- ⁴⁰ 76 Fed. Reg. 57808, 57811.
- ⁴¹ *Id.*
- ⁴² *Id.* at 57841.
- ⁴³ *Id.* at 57811.
- ⁴⁴ *Id.*
- ⁴⁵ *Id.*
- ⁴⁶ *Id.* at 57841.
- ⁴⁷ *Id.* at 57838.
- ⁴⁸ *Id.* at 57817.
- ⁴⁹ *Id.* at 57810.
- ⁵⁰ *Id.* at 57817.
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- ⁵² *Id.*
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- ⁵⁴ *Id.*
- ⁵⁵ *Id.*
- ⁵⁶ *Id.*
- ⁵⁷ *Id.*
- ⁵⁸ *Id.*
- ⁵⁹ *Id.*
- ⁶⁰ *Id.* at 57836.
- ⁶¹ *Id.*
- ⁶² *Id.* at 57821.
- ⁶³ *Id.*
- ⁶⁴ *Id.*
- ⁶⁵ *Id.*
- ⁶⁶ *Id.* at 57836. *See also* 42 C.F.R. § 455.508(f).

67 *Id.* The State Plan Amendment (“SPA”) process is required in order for a state to modify its Medicaid program. CMS will review and approve SPAs for consistency with Section 1902(a) of the Social Security Act. During its review of the modifications, CMS will also review the state’s entire SPA and may identify portions that are contrary to a federal statute, regulation or established guidelines. Medicaid Management Information Systems (“MMIS”) is the claims processing and information retrieval system which states are required to implement, unless the requirement is waived by the Secretary.

68 *Id.* at 57830.

69 *Id.*

70 *Id.*

71 *Id.*

72 *Id.*

73 *Id.* at 57818.

74 *Id.* at 57824.

75 *Id.* at 57825.

76 *Id.* at 57817.

77 *Id.* at 57838.

78 *Id.* at 57822.

79 *Id.*

80 *Id.*

81 *Id.* at 57834.

82 *Id.*

83 *Id.*

84 *Id.* at 57841.

85 *Id.*

86 *Id.*

87 *Id.*

88 *Id.*

Chair’s Corner

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but did not eliminate the disparities in sentencing for cocaine-related crimes.

A decade ago, medical providers were confronted with an increased emphasis on addressing the problem of the undertreatment of pain. Pain became the fifth vital sign. Physicians were prosecuted both administratively and civilly for not being sufficiently aggressive in treating their patients’ pain. As a new, potent generation of opioids (Oxycontin, Fentanyl patches) came on the market, physicians responded by prescribing these medications, sometimes without fully understanding their potential for abuse. Enter the “pill mill” problem. Doctors and other providers were caught in the middle – fearful of underprescribing, fearful of medical board or DEA prosecution for overprescribing. Casting their net even wider, federal and state prosecutors began filing claims against manufacturers of the new generation of opioids, arguing that they had misrepresented the risks of addiction and encouraged physicians to develop “pain practices” using their products.

The risk of developing dependence on controlled drugs has long been considered an occupational

hazard of the practice of medicine (e.g. Freud’s cocaine habit). To address this problem, many states developed physician health programs (“PHP”s).¹ These programs focus on clinical assessment, providing (or overseeing) therapy and drug monitoring for impaired physicians (and often other healthcare professionals) usually in coordination with state licensing boards. Outcome studies of PHPs demonstrate that they are surprisingly successful in their mission of rehabilitating impaired professionals. Relapse, which is the bane of drug treatment programs, is relatively infrequent and usually occurs after the physician leaves the program. For those who relapse and then reenter a PHP the prognosis is still good. Law enforcement, however, is often unsupportive or ignorant of PHPs and their work, with the unfortunate result of the incarceration of healthcare professionals who could be rehabilitated through participation in a PHP and whose essential crime relates to their ability to supply their habit through writing prescriptions and/or obtaining drugs from their patients (“If this Percocet doesn’t work bring it back to me and I’ll prescribe something stronger.”).

Finally, I am particularly pleased to report that there are efforts underway to bring the ABA Standing Committee on Substance Abuse within the Health Law Section. The Standing Committee has long been involved in both public and professional education and legislative and regulatory advocacy related to issues involving substance abuse policy. As I hope the above discussion demonstrates, this union should be a natural fit. We believe that the addition of the Standing Committee would significantly augment the Section’s resources in this important area. I hope to have further news of this development soon. The Standing Committee’s participation in Section activities and our support for its ongoing advocacy and educational efforts will be a strong partnership to address these important issues. Let us know your thoughts as to how the Section can play a role in these issues and whether you would like to participate.

Endnotes

¹ My knowledge of physician impairment and PHPs comes from having represented hospitals and physicians in matters related to impairment in both medical staff and medical board proceedings and having served as a board member of the New Mexico PHP since 2003.

FEDERAL COURTS GRAPPLE WITH THE CONSTITUTIONALITY OF RETROACTIVE AMENDMENTS TO THE FALSE CLAIMS ACT

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The Fraud Enforcement and Recovery Act of 2009 (“FERA”)¹ established an array of substantial changes to the False Claims Act (“FCA”), including retroactive amendments that were designed to legislatively overrule the U.S. Supreme Court’s decision in *Allison Engine Co., Inc. v. U.S. ex rel. Sanders*.² Since the passage of FERA, federal courts have split over the constitutionality of the retroactive amendments. To date, three federal district courts have concluded that the retroactive amendments violate the *Ex Post Facto* Clause of the United States Constitution, with the latest opinion being issued by the Northern District of Iowa on August 1, 2011. On the other hand, the D.C. Circuit Court of Appeals and the District of Connecticut have held that the *Ex Post Facto* Clause does not apply to the FCA because it is a civil statute.

The issue has taken on added significance in the current healthcare enforcement environment. The Department of Justice recently announced record recoveries under the FCA for healthcare fraud, driven in part by the formation of the Health Care Fraud Prevention and Enforcement Action Team (“HEAT”), an interagency task force designed to enhance the prosecution of fraud in the healthcare industry.³ Congress has facilitated the efforts to prosecute healthcare fraud by repeatedly strengthening the FCA since the passage of FERA, expanding its scope through the Dodd-Frank Act⁴ and the Patient Protection and Affordable Care Act.⁵ As a result, it has become increasingly important to determine the limits of the legislature’s authority to amend the FCA.

The *Allison Engine* Amendment

The Supreme Court’s decision in *Allison Engine* focused on § 3729(a)(2) (now designated as § 3729(a)(1)(B)) of the FCA, which, prior to the enactment of FERA, prohibited individuals from making “a false record or statement to get a false or fraudulent claim paid...”⁶ In *Allison Engine*, the Supreme Court adopted a restrictive interpretation of that provision, holding that liability under § 3729(a)(2) could only be established if an individual made a false statement specifically for the purpose of defrauding the government:

We hold that it is insufficient for a plaintiff asserting a § 3729(a)(2) claim to show merely that “[t]he false statement’s use...result[ed] in obtaining or getting payment or approval of the claim,” or that “government money was used to pay the false or fraudulent claim.” Instead, a plaintiff asserting a § 3729(a)(2) claim must prove that the defendant intended that the false record or statement be material to the Government’s decision to pay or approve the false claim.⁷

In 2009, Congress attempted to nullify the Supreme Court’s ruling in *Allison Engine* by eliminating the phrase “to get a false or fraudulent claim paid,” and modifying § 3729(a)(1)(B) to encompass any “false record or statement material to a false or fraudulent claim.”⁸ Section 3729(a)(1)(B) now reads:

- (a) Liability for certain acts.—
 - (1) In general.—Subject to paragraph (2), any person who—
 - ...
 - (B) knowingly makes, uses, or causes to be made or used, a false

record or statement material to a false or fraudulent claim;

...
is liable to the United States Government...⁹

In other words, Congress broadened the provision to apply to all false statements “material” to a false claim, regardless of the reason why they were made. Congress also included a retroactivity clause clarifying that the amendments described above “shall take effect as if enacted on June 7, 2008” – the day the Supreme Court issued its decision in *Allison Engine*.¹⁰ However, after *Allison Engine* was remanded to the Southern District of Ohio, District Judge Rose held that Congress had overstepped its authority.

U.S. ex rel. Sanders v. Allison Engine Co., Inc. (“*Allison Engine II*”)

Following remand, the defendants argued that FERA’s retroactive amendments violates the *Ex Post Facto* Clause of the United States Constitution, which prohibits Congress from passing a law “which renders an act punishable in a manner in which it was not punishable when it was committed.”¹¹ On November 3, 2009, the Southern District of Ohio held that the retroactive amendments were unconstitutional. The Court explained that while the *Ex Post Facto* Clause is generally only applicable to criminal statutes, civil statutes may also fall within its scope in certain circumstances.¹² Citing the Supreme Court’s decision in *Smith v. Doe*,¹³ the Court outlined the contours of the constitutional analysis:

The threshold question in an ex-post-facto analysis is whether the legislature intended to impose punishment when it enacted the law. If the legislature intended to

impose punishment, the inquiry ends and the law violates the *Ex Post Facto* Clause. However, if the legislature's intention was to enact a civil and nonpunitive regulatory scheme, a court must further examine whether the statutory scheme is "so punitive either in purpose or effect as to negate [the State's] intention to deem it 'civil.'"¹⁴

After analyzing the legislative history of both the FCA and FERA, as well as Supreme Court decisions indicating that the FCA's damages multiplier has a punitive function, the Court held that the "retroactive application of the amendments to the FCA violates the *Ex Post Facto* Clause because retroactive application of the amendments to the FCA would impose punishment for acts that were not punishable prior to the enactment of the amendments...."¹⁵

The *Allison Engine II* Court also analyzed whether the FERA amendments would satisfy the second part of the analysis even if the Court had reached an opposite conclusion about the threshold question of whether Congress intended to impose punishment through the FCA.¹⁶ The Court noted that, pursuant to the Supreme Court's decision in *Kennedy v. Mendoza-Martinez*,¹⁷ there are seven factors that courts consider in examining whether a civil statute is "so punitive either in purpose or effect as to negate [the State's] intention to deem it 'civil'": (1) whether the sanction involves an affirmative disability or restraint; (2) whether the sanction has historically been regarded as punishment; (3) whether the sanction comes into play only on a finding of scienter; (4) whether operation of the sanction will promote the traditional aims of punishment-retribution and deterrence; (5) whether the behavior to which the sanction applies is already a crime; (6) whether an alternative purpose to which it may rationally be connected is assigned to the sanction; and (7) whether the sanction appears

excessive in relation to the alternative purpose assigned.¹⁸

The Court concluded that only three of the seven *Kennedy* factors weigh in favor of finding that the *Ex Post Facto* Clause does not apply to the FCA. With respect to the first factor, the Court reasoned that the FCA does not impose a disability or restraint akin to incarceration, and thus the factor supported a finding that the FCA is inherently "civil" in nature. Similarly, the Court found that the fifth factor and the sixth factor also support the civil purpose of the FCA because the submission of false claims is already a criminal offense, and the FCA damages provision serves a compensatory function as well as a punitive one.

However, the Court held that the remaining factors indicate that the FCA is sufficiently punitive to fall within the scope of the *Ex Post Facto* Clause. The Court emphasized that the FCA's statutory penalties have frequently been regarded a punishment, there is a *scienter* requirement for FCA liability, the statutory penalties serve as a deterrent, and "the sanctions recoverable under the FCA can far exceed those necessary to compensate the Government for its loss."¹⁹ As a result, the Court held that FERA's retroactive amendments to the FCA violates the *Ex Post Facto* Clause and is unenforceable.

Four months after the Southern District of Ohio issued its ruling on the constitutionality of FERA's retroactive amendments, the District of New Mexico addressed the issue and reached the same conclusion.

U.S. ex rel Baker v. Community Health Systems, Inc.

On March 19, 2010, in *U.S. ex rel Baker v. Community Health Systems, Inc.*,²⁰ the District of New Mexico adopted the analysis in *Allison Engine II* and held that FERA's retroactive amendments are

unconstitutional.²¹ The Court also reasoned that one additional *Kennedy* factor weighs in favor of the applicability of the *Ex Post Facto* Clause to the FCA:

The Court agrees with, and herein adopts, the analysis conducted by the court in *Allison Engine II*. I would add that the 2009 FERA amendment suggests that another *Kennedy* factor weighs in favor of finding the FCA punitive in nature. The behavior proscribed by the civil version of the FCA is also sanctioned as a crime under the criminal version of the FCA, which the *Allison Engine II* court found to weigh in favor of finding of civil purpose or effect for the civil version of the FCA. However, I propose that the post-FERA version of § 3729(a)(1)(B) effectively broadens the liability base for § 3729(a)(1)(B). I therefore find that the behavior to which the FERA now attaches liability was not previously considered sufficient to find liability under the same provision.²²

Thus, the Court held that the retroactive application of the FERA amendments would violate the *Ex Post Facto* Clause because "the FCA's statutory scheme is punitive in purpose and effect."²³

Following the District of New Mexico's decision in *Baker*, federal courts have disagreed about whether the *Ex Post Facto* Clause applies to the FCA. Three months after *Baker*, the District of Columbia Circuit Court of Appeals became the first appellate court to address the issue.

U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.

On June 22, 2010, the District of Columbia Circuit Court of Appeals held that FERA's retroactive amendments are not unconstitutional because

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the *Ex Post Facto* Clause does not apply to the FCA. The issue came before the Court in *U.S. ex rel. Miller v. Bill Harbert International Construction, Inc.*,²⁴ where the defendants argued that the government was advancing claims under the FCA that were predicated on conduct that occurred outside of the applicable limitations period.²⁵ The government asserted that FERA specifically amended the FCA to clarify that, for the purposes of the statute of limitations, any government pleading relates back to the filing date of the whistleblower's complaint, and the whistleblower's complaint in that case was filed within the limitations period.²⁶ The defendants argued that FERA's "relation back" amendment could not be retroactively applied under the *Ex Post Facto* Clause.

The Miller Court rejected the defendants' position in a brief paragraph, stating:

The *Ex Post Facto* Clause of the Constitution applies only to penal legislation. See *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 390-91, 1 L.Ed. 648 (1798) (opinion of Chase, J.); see also *Landgraf v. USI Film Prods.*, 511 U.S. 244, 266 n. 19, 114 S.Ct. 1483, 128 L.Ed.2d 229 (1994) (citing *Calder*). The FCA is not penal. See *Hudson v. United States*, 522 U.S. 93, 100-03, 118 S.Ct. 488, 139 L.Ed.2d 450 (overruling Court's prior decision that a civil FCA proceeding could be criminal under the Double Jeopardy Clause).

The Court did not conduct an independent analysis regarding the threshold question of whether the legislature intended to impose punishment with the FCA, and the Court did not analyze the *Kennedy* factors. Instead, the Court simply cited to the Supreme Court's decision in *Hudson v. United States*.²⁷ However, the Miller Court's suggestion that *Hudson* addresses this issue is misleading. In fact, a basic review of the *Hudson* decision reveals

that it focused on the applicability of the Double Jeopardy Clause to a civil banking statute, not the FCA.²⁸

The defendants in *Hudson* had been issued civil fines under 12 U.S.C. § 93, a statute that authorizes civil sanctions for banking-related offenses, and they were subsequently prosecuted under a criminal statute for making false bank entries.²⁹ The defendants argued that the criminal prosecution violated the Double Jeopardy Clause of the Constitution, citing the Supreme Court's decision in *United States v. Halper*,³⁰ where the Court held that civil FCA claims could not be brought against an individual following a conviction under the criminal false claims statute because the FCA penalties at issue were so disproportionate to the government's damages that they constituted a second punishment.³¹

The *Hudson* Court applied the seven-part *Kennedy* framework to the banking statute and ultimately concluded that, after weighing those factors, the civil banking statute was not "so punitive either in purpose or effect" to transform the civil sanction into a criminal sanction for the purposes of the Double Jeopardy Clause.³² In doing so, the *Hudson* Court rejected the standard applied by the Supreme Court in *Halper*, which focused exclusively on whether a civil sanction serves "either a retributive or deterrent purposes."³³ The *Hudson* Court criticized the Court's opinion in *Halper* for "elevat[ing] a single *Kennedy* factor – whether the sanction appeared excessive in relation to its nonpunitive purposes – to dispositive status," and emphasized that "all civil penalties have some deterrent effect."³⁴ The *Hudson* Court concluded that the *Halper* test had "proved unworkable" and clarified that no single *Kennedy* factor was controlling.³⁵

Thus, the *Hudson* Court did not reject its previous conclusion that the

FCA could trigger the protections of the Double Jeopardy Clause. The *Hudson* Court simply rejected an amorphous standard that was causing confusion in the courts and weakening the application of an array of civil penalties.³⁶

Given the limited analysis provided in the *Miller* opinion, federal courts may be reluctant to rely on it moving forward. In fact, two months after *Miller* was decided, the District of Connecticut rejected the Southern District of Ohio's position on the constitutionality of FERA's retroactive provisions after an extensive analysis of the issue, but failed to cite *Miller* in support of its decision.

U.S. ex rel Drake v. NSI, Inc.

On August 26, 2010, in *U.S. ex rel Drake v. NSI, Inc.*,³⁷ the District of Connecticut concluded that FERA's retroactive amendments to the FCA do not violate the *Ex Post Facto* Clause because the FCA "is not sufficiently punitive in nature and effect so as to warrant application of the *Ex Post Facto* Clause."³⁸

The *Drake* Court also followed the analytical framework set forth in the Supreme Court's decision in *Smith v. Doe*, first analyzing whether "the intention of the legislature was to impose punishment," and then addressing the application of the *Kennedy* factors to the FCA.³⁹ However, the Court reached a different conclusion about the threshold question, concluding that "historically, courts examining the FCA have not found it to be punitive."⁴⁰ The Court cited several district court cases holding that the FCA does not implicate other constitutional protections that apply in criminal proceedings, but acknowledged that other courts, including the Supreme Court, have also recognized the "punitive nature"

of the FCA.⁴¹ Ultimately, the Court concluded that, on balance, the FCA is a civil statute that does not meet the threshold test for the application of the *Ex Post Facto* Clause.⁴²

The *Drake* Court proceeded to analyze the seven *Kennedy* factors, reaching the same conclusions as the *Allison Engine II* Court about each of them, with the exception of one: whether the FCA has been historically regarded as punishment.⁴³ The Court repeated its analysis on the threshold question, reasoning that, despite the “punitive elements of the FCA,” courts have also recognized “the remedial and compensatory nature of the statutory framework.”⁴⁴ The Court explained that “although there are punitive aspects to the FCA, in light of the fact that it has been viewed as civil, this factor weighs in favor of finding FCA to be civil and remedial in nature and effect.”⁴⁵ With that difference, the *Drake* Court found that four of the seven *Kennedy* factors weigh against applying the *Ex Post Facto* Clause to the FCA, and held that the retroactive amendments are constitutional.⁴⁶

The Court acknowledged that the *Allison Engine II* Court reached a different conclusion about whether the FCA has been historically viewed as punitive, but concluded that the civil aspects of the FCA were more prevalent than the punitive aspects.⁴⁷

Interestingly, the Court did not cite the D.C. Circuit’s opinion in *Miller* in support of its finding. The *Miller* decision was, however, analyzed in *United States v. Hawley*,⁴⁸ the most recent decision addressing the constitutionality of the FERA amendments.

United States v. Hawley

On August 1, 2011, the Northern District of Iowa joined the Southern District of Ohio and the District of New Mexico in holding that FERA’s retroactive amendments are unconstitutional. In *Hawley*, the Court actually concurred with the *Drake* Court on

the threshold question under the *Ex Post Facto* analysis, holding that “it is readily apparent from the text of the statute, amendments, and Senate reports, that Congress intended FCA proceedings to create a civil mechanism to address fraudulent claims.”⁴⁹ The Court emphasized that “[a]ll of this evidence points to the FCA as being civil in intent.”⁵⁰

The Court, however, also made it clear that it was not persuaded by the government’s citation to the D.C. Circuit’s opinion in *Miller* and the Supreme Court’s opinion in *Hudson*. The Court explained that the government was misinterpreting *Hudson*:

Contrary to the government’s assertions, *Hudson* overruled *United States v. Halper*, 490 U.S. 435, 448 (1989), because it disavowed the method of analysis utilized, specifically, “elevat[ing] a single *Kennedy* factor [in the double jeopardy analysis]—whether the sanction appeared excessive in relation to its nonpunitive purposes—to dispositive status... The Court ultimately held that the analysis applied by the *Halper* Court was “ill considered” and “proved unworkable,” because it deviated from longstanding double jeopardy principles.⁵¹

After citing to decisions emphasizing the punitive nature of the FCA, the Court agreed with the central ruling in *Allison Engine II*.⁵² The Court held that “the FCA’s statutory scheme is so punitive either in purpose or effect as to negate Congressional intent to deem it civil...” and thus “retroactive application of the [FERA] amendments to the FCA violates the *Ex Post Facto* Clause...”⁵³

Unfortunately, the *Hawley* Court added uncertainty to the issue by failing to address the *Drake* decision. In fact, after observing that “in relation to the FCA, the *Kennedy* factors have already been analyzed in detail,” the Court cited to *Baker* and *Allison Engine II*, but omitted any reference to *Drake*.⁵⁴ Thus, *Hawley* could be open

to criticism from federal courts that are persuaded by the analysis in *Drake*.

Conclusion

Since the passage of FERA, federal courts have not been able to reach a consensus on whether the retroactive amendments violate the *Ex Post Facto* Clause. The issue hinges on a vague factor of the *Kennedy* analysis – whether the FCA has been “historically regarded” as punishment – and courts have utilized the legislative history of the FCA and jurisprudence interpreting the statute to support opposite conclusions. At this point, the Sixth Circuit Court of Appeals is poised to weigh in on the issue, as the Southern District of Ohio’s decision in *Allison Engine II* is currently before that court on appeal.⁵⁵ However, regardless of the outcome of the *Allison Engine II* appeal, the enforcement of FERA’s retroactive amendments seems likely to vary between the federal circuits, and possibly within them, as courts debate whether to extend the basic constitutional protections of the *Ex Post Facto* Clause to the FCA.



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Endnotes

- ¹ Pub. L. No. 111-21.
- ² 552 U.S. 639 (2008).
- ³ See Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, Department of Justice Recovers \$3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010), available at <http://www.justice.gov/opa/pr/2010/November/10-civ-1335.html>.
- ⁴ Pub. L. No. 111-203. Dodd-Frank expanded the FCA whistleblower provision to encompass conduct engaged in by individuals “associated” with an employee. See Section 1079B(c) of the Dodd-Frank Act.

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- ⁵ Pub. L. 111-148. The Patient Protection and Affordable Care Act contained several substantial changes to the FCA, broadening the circumstances in which FCA lawsuits can be based on publicly disclosed information under 31 U.S.C. § 3730(e)(4), expanding FCA liability for violations of the Anti-Kickback Statute under 42 U.S.C. § 1320a-7b(g), and strengthening FCA liability for the failure to refund overpayments from the government under 42 U.S.C. § 1320a-7k(d)(3).
- ⁶ Compare 31 U.S.C. § 3729(a)(2) (2008) with 31 U.S.C. § 3729(a)(1)(B) (2009).
- ⁷ *Allison Engine*, 552 U.S. at 750.
- ⁸ See 31 U.S.C. § 3729(a)(2) (2008); 31 U.S.C. § 3729(a)(1)(B) (2009).
- ⁹ 31 U.S.C. 3729(a)(1)(B) (emphasis added).
- ¹⁰ Pub. L. No. 111-21, § 4(f)(1).
- ¹¹ *U.S. ex rel. Sanders v. Allison Engine Co., Inc.*, 667 F. Supp. 2d 747, 753 (S.D. Ohio 2009) (“Allison Engine IP”).
- ¹² *Id.* at 753.
- ¹³ 538 U.S. 84, 92 (2003)
- ¹⁴ *Allison Engine II*, 667 F. Supp. 2d at 753 (internal citations omitted) (quoting *Kansas v. Hendricks*, 521 U.S. 346, 361 (1997)).
- ¹⁵ *Id.* at 756.
- ¹⁶ *Id.*
- ¹⁷ 372 U.S. 144 (1963).
- ¹⁸ *Allison Engine II*, 667 F. Supp. 2d at 756.
- ¹⁹ *Id.* at 757-8.
- ²⁰ 709 F. Supp. 2d 1084 (D.N.M. 2010).
- ²¹ *Id.* at 1112.
- ²² *Id.*
- ²³ *Id.*
- ²⁴ 608 F.3d 871 (D.C. Cir. 2010).
- ²⁵ *Id.* at 877.
- ²⁶ *Id.* at 878.
- ²⁷ 522 U.S. 93 (1997).
- ²⁸ *Id.* at 98.
- ²⁹ *Id.*
- ³⁰ 490 U.S. 435 (1989).
- ³¹ *Id.* at 452.
- ³² *Hudson*, 522 U.S. at 105.
- ³³ *Id.* at 100-101.
- ³⁴ *Id.* at 101.
- ³⁵ *Id.* at 102.
- ³⁶ *Id.*
- ³⁷ 736 F. Supp. 2d 489 (D. Conn. 2010).
- ³⁸ *Id.* at 502.
- ³⁹ *Id.* at 499.
- ⁴⁰ *Id.*
- ⁴¹ *Id.*
- ⁴² *Id.*
- ⁴³ *Id.* at 500.
- ⁴⁴ *Id.*
- ⁴⁵ *Id.*
- ⁴⁶ *Id.* at 502.
- ⁴⁷ *Id.* at 500.
- ⁴⁸ 2011 WL 3295419 (N.D. Iowa Aug. 1, 2011).
- ⁴⁹ *Id.* at 10.
- ⁵⁰ *Id.*
- ⁵¹ *Id.* at 11.
- ⁵² *Id.*
- ⁵³ *Id.*
- ⁵⁴ *Id.*
- ⁵⁵ See *U.S. ex rel Sanders, et al. v. Allison Engine Company, Inc.*, Docket No. 10-3818, U.S. Circuit Court of Appeals for the Sixth Circuit.

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The Editorial Board of *The Health Lawyer* is pleased to provide these updates of presentations made at the Annual Emerging Issues in Healthcare Law Conference, held in New Orleans, February 2011. This is an additional benefit provided to Section members to keep you apprised of new developments in healthcare law. We hope that you find these updates useful. *The Health Lawyer* intends to publish additional updates in the February 2012 issue.

Update to 2011 Emerging Issues Conference Presentation

“THE ACA: WE HAD THE AUDACITY...NOW WHAT?”

Submitted by
Susan Feigin Harris, Esq.
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A Baker's Dozen of Key Highlights From The ACO Final Rule

With the release of the final rule governing Accountable Care Organizations (“ACO”s) under the Medicare Shared Savings Program (“MSSP”) (“Final Rule”), the Centers for Medicare & Medicaid Services (“CMS”) sought to address healthcare industry concerns reflected in over 1,320 public comments to the April 7, 2011 proposed rule.

Implementing Section 3022 of the Patient Protection and Affordable Care Act (“PPACA”), the Final Rule, which was published in the November 2, 2011, Federal Register, includes “significant modifications” aimed at reducing “the burden and cost for participating ACOs” by CMS. It has been widely heralded as a step in the right direction by the healthcare community.

The October 20 republication release of the CMS Final Rule was accompanied by an array of related issuances that highlight the Administration’s multi-agency approach to the MSSP.

- An interim final rule with comment period (“IFR”) on fraud and abuse waivers jointly issued by CMS and the Office of Inspector General (“OIG”) of the U.S. Department of Health and Human Services (“HHS”). This rule was also published in the Federal Register on November 2, which was also the date the rule took effect. Comments are due 60 days after publication, on January 3, 2012.
- A final Statement of Antitrust Enforcement Policy jointly released by the Federal Trade Commission (“FTC”) and the U.S. Department of Justice (“DOJ”).
- A final Fact Sheet (2011-11) issued by the Internal Revenue Service (“IRS”) on tax-exempt organizations participating in the MSSP.

- A Notice from CMS announcing the Advance Payment Model and soliciting applications to participate in the initiative. This Notice was also published in the November 2 Federal Register.

Underscoring the Administration’s commitment to achieving the triple aim of “better health, better healthcare and reduced expenditures through continuous improvement,” the modifications outlined in the 695-page Final Rule clearly signal CMS’s steadfast support of ACOs as vehicles for transforming the delivery of healthcare in the United States.

The following report by the Baker Hostetler National Healthcare Team provides a “Baker’s Dozen” overview of key changes from the Final Rule and related issuances.

1. Assignment of Beneficiaries

In a welcome change for the healthcare industry, ACOs now will receive quarterly prospective assignment of beneficiaries from the Medicare program with final membership reconciliation to occur based on each beneficiary’s utilization of primary care services from ACO providers during the performance year.

2. Shared Savings and Losses

Many potential participants had expressed concern over the original structure of ACOs because the transition to bearing financial risk for many was too quick, coupled with the significant investment and uncertainties of return. The proposed rule provided for two shared savings models known as Track 1 and Track 2: Under the one-sided risk model (Track 1), ACOs would share savings only for the first two years and thereafter share savings and losses. Under the two-sided risk model (Track 2), ACOs would share in the savings and losses for all years. Under the Final Rule, the two-sided risk provision for year three under Track 1 is eliminated. This, CMS believes, will provide a “gentler on-ramp” for organizations seeking to participate, while organizations that are better equipped to accept risk have a distinct track. As a result, the one-sided risk model has become a shared “savings-only” track without financial risk to the ACO for the initial contract period.

To further encourage participation, ACOs in both the one-sided and two-sided models will receive shared savings for the first dollar after the minimum savings percentage is

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exceeded (minimum savings rate or “MSR”). This is in contrast to the proposed rule, where sharing only occurred above a two percent threshold once the MSR was achieved. CMS, however, chose not to increase the basic sharing ratios (50 percent allocated for providers in Track 1 ACOs and 60 percent allocated for providers in Track 2 ACOs).

In another change from the proposed rule, CMS eliminated the annual 25 percent withhold of earned bonuses.

3. Repayment of Shared Losses

In the proposed rule, CMS required ACOs to repay any shared losses to the agency within 30 days of receipt of notification of the shared losses. The Final Rule has extended the repayment period to 90 days, which should assist with the cash flow of ACOs.

4. Quality Performance Standards

Another major criticism of the proposed rule was the complexity surrounding the quality performance standards, which acted as a disincentive for many potential participants. The proposed rule contained 65 different measures across five domains. CMS, in the Final Rule, sought to streamline the measures to remove “certain redundant, operationally complex, or burdensome measures.” The Final Rule greatly simplifies the quality performance standards, reducing them to 33 measures across four domains. For instance, the Final Rule combined the care coordination and patient safety domains to better align with other CMS value-based purchasing initiatives and the National Quality Strategy and to emphasize the importance of ambulatory patient safety and care coordination. The Final Rule also adjusts the phase-in period, beginning with a primarily pay-for-reporting methodology and moving, over the participation period, to pay-for-performance. As a result, to earn shared savings in the first performance year, providers will be required to report across all four quality domains. In the second and third performance years, ACOs will share savings based on reporting and performance in the 33 quality measures.

5. Governance and Legal Structure

While acknowledging multiple comments seeking permission for ACO participants to form a new entity by contract, CMS remained steadfast in its position that each ACO must be an entity that is capable of:

- Receiving and distributing shared savings;
- Repaying shared losses, if applicable;
- Establishing, reporting and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including the quality performance standards; and

- Performing the other ACO functions identified in PPACA.

While CMS did emphasize that a new entity may not be needed, it made clear that there must be an entity, with a taxpayer identification number, that otherwise meets program requirements.

Governance flexibility was a big winner in the Final Rule. While PPACA requires a mechanism for shared governance, it does not proscribe how this occurs. The proposed rule outlining the initial governance requirements contained rigid, and often cumbersome, governance structures and were considered governance micromanagement by many. CMS recognized this and created a much more flexible approach to governance. For instance, CMS altered its requirement that each ACO participant be a member of the ACO’s governing body and that there be proportionate control among participants. Instead, CMS acknowledged that the governing body provides oversight and strategic direction for the ACO, holding management accountable for meeting the goals of the ACO and that members of the governing body shall have a fiduciary duty to put the ACO’s interests before that of any one ACO participant or ACO provider/supplier. CMS reiterated its belief that the governing body be provider-driven, maintaining the requirement that 75 percent control of the ACO’s governing body be held by ACO participants, with an exception for existing entities that qualify under the MSSP, so long as they can demonstrate how they will involve ACO participation in innovative ways and provide for meaningful participation in ACO governance by Medicare beneficiaries.

6. Claims Run-Out Period

CMS proposed using a six-month claims run-out period to calculate the benchmark and actual per-capita beneficiary expenditures for each performance year. However, CMS concluded in the Final Rule that the minimal increased accuracy associated with six months of claims run-out data, as compared to three months of data coupled with an appropriate adjustment for claims anticipated to be received during the period after the third month, did not justify delaying the provision of quality metrics and shared savings reconciliation data to the ACOs. The shorter run-out of claims data, especially in the first year, will significantly aid the cash flow of ACOs. CMS, however, indicated that it will monitor claim submission patterns to avoid gaming through the deliberate delay in submission of claims that would result in an unusual increase. No mechanism was established to reduce the completion adjustment for providers that submit bills on a timely basis. Hence, some argument may be made that prompt submission of invoices could harm a provider.

7. Electronic Health Records

In the Final Rule, CMS has decided not to finalize the requirement that at least 50 percent of an ACO's primary care physicians be "meaningful EHR users" as that term is defined in the federal electronic health record ("EHR") financial incentive program regulations, 42 C.F.R. § 495.4, by the start of the second performance year in order to continue participation in the MSSP. This is partly in response to commenters who expressed concern that the 50 percent meaningful EHR use requirement was set too high, given the current lack of experience with the EHR incentive program, especially in the areas of smaller, less integrated or rural physician practices. Instead, EHR participation will remain a key quality measure under the MSSP. Under the Final Rule, the quality measure, "Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment" will be given double the weight proposed initially by CMS to stress the importance of EHR adoption among ACOs.

8. Start Dates and Agreement Period

In response to comments requesting additional flexibility in the start date of the MSSP, the Final Rule establishes two application periods for the first year – April 1, 2012, or July 1, 2012. All ACOs that start in 2012 will have agreement periods that terminate at the end of 2015, as follows:

- April 1, 2012, Start Date – First performance year is 21 months, ending on December 31, 2013. Agreement period is three performance years, ending on December 31, 2015.
- July 1, 2012, Start Date – First performance year is 18 months, ending on December 31, 2013. Agreement period is three performance years, ending on December 31, 2015.

The Final Rule provides that ACOs will be eligible to receive Physician Quality Reporting System ("PQRS") incentive payments for each calendar year in which they fully and completely report the Group Practice Reporting Option ("GPRO") measures, regardless of their start date. According to the agency, "this will provide ACOs that join the program in April or July 2012 with some working capital in advance of the completion of the first ACO performance year, regardless of their ability to generate shared savings."

9. Eligible Entities

CMS has created an eligibility pathway for federally qualified health centers ("FQHC"s) and rural health clinics ("RHC"s) to both form and participate in ACOs under the Final Rule. These organizations will be required to provide a list of practitioners to CMS who directly render primary care services in their facilities so that beneficiaries may be assigned on the basis of utilization of their services.

10. Advance Payment Model

With the release of the Final Rule, CMS also issued a notice announcing the Advance Payment Model initiative

aimed at encouraging participation by physician-owned organizations, critical access and rural providers in the MSSP. Designed to assist in defraying upfront infrastructure costs and "to smooth cash flow concerns," selected participants will receive a prepaid advance on future shared savings earned by the ACO. Only ACOs that make application for and enter the MSSP in 2012 will be eligible for the advance payments.

11. Antitrust Issues

Concurrent with the promulgation of the Final Rule, the FTC and the Antitrust Division of the DOJ revised their approach to antitrust guidance for ACOs. Notably, the Agencies jettisoned the burdensome mandatory antitrust review originally proposed as a prerequisite to entry into the MSSP for ACOs with large market shares. Antitrust review is now voluntary, and the Agencies provided guidance for how ACOs can, if they choose, obtain expedited review. The final policy statement of the Agencies, "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program," differs from its proposed policy statement in another significant way: the policy statement now applies to all collaborations among otherwise independent providers, not only those formed prior to March 23, 2010.

In the final statement, the Agencies retain from the proposed statement the explicit recognition that CMS's eligibility criteria for ACOs are sufficiently consistent with the indicia of clinical integration that such arrangements are presumptively bona fide and will not be considered anticompetitive shams subject to automatic (or "per se") illegality under the antitrust laws. Thus, the Agencies agree to afford ACOs that meet CMS's criteria the more flexible and forgiving "rule of reason" treatment. The Statement explicitly recognizes that the Agencies have not identified specific criteria required to establish clinical integration, but rather have avoided prescribing how integration should take place.

The Statement also provides a safety zone for certain ACOs unlikely to raise significant competitive concerns, and describes conduct ACOs generally should avoid.

12. Fraud and Abuse Waivers

In conjunction with the Final Rule, CMS and the OIG have published an IFR that establishes waivers of the application of the Ethics in Patient Referral Act physician self-referral law ("Stark Law"), federal Anti-Kickback Statute ("AKS"), and certain civil monetary penalties ("CMP") law provisions to ACOs. The IFR expands the three waivers set forth in the proposed rules to the following five waivers:

- **ACO Pre-Participation Waiver.** This new waiver of the Stark Law, AKS and gainsharing CMP applies for a maximum one-year period to start-up arrangements that predate an ACO's participation agreement in the MSSP. Start-up arrangements are defined as items, services, facilities or goods used to create or develop an

continued on page 36

ACO, and examples are furnished in the IFR. The IFR precludes application of the waiver if the parties to the arrangement include drug and device manufacturers, distributors, durable medical equipment suppliers or home health agencies.

- **ACO Participation Waiver.** This waiver of the Stark Law, AKS and gainsharing CMP, which was included in the proposed rule, applies to any arrangement reasonably related to the purposes of the MSSP as determined by an ACO's governing body. The "reasonably related" language replaces the "necessary for and directly related to ACO purposes" provision set forth in the proposed rule. The waiver starts on the effective date of the MSSP participation agreement and ends six months after termination, unless the agreement is terminated by CMS, in which case the waiver ends on the date of termination.
- **Shared Savings Distribution Waiver.** This waiver of the Stark Law, AKS and gainsharing CMP, which was included in the proposed rule, applies to the distribution or use of shared savings earned by the ACO during the term of the MSSP participation agreement. The shared savings must be: (1) distributed to or among the ACO's ACO participants, its ACO providers/suppliers or individuals in this category during the year in which the shared savings were earned; or (2) used for activities that are reasonably related to the purposes of the MSSP. With respect to the gainsharing CMP, payments may not be made knowingly to induce a physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.
- **Compliance with the Stark Law Waiver.** This waiver, which was included in the proposed rule, provides that the gainsharing CMP and AKS are waived with respect to any financial relationship reasonably related to the purposes of the MSSP between or among the ACO, its ACO participants and its ACO providers/suppliers that meets an exception set forth in the Stark Law.

- **Waiver for Patient Incentives.** This new waiver waives the CMP and AKS for items or services provided by an ACO, its ACO participants or its ACO providers/suppliers to beneficiaries at free or below market prices. The items or services must advance the goals of preventive care, adherence to treatment, drug, or follow-up care regimes or management of a chronic disease or condition. The items and services must be in-kind incentives related to the care of the patient and may not include financial incentives such as waiving or reducing patient cost-sharing amounts.

Finally, the IFR solicits comments on various issues, including whether to impose commercial reasonableness or fair market value requirements on the arrangements in the ACO pre-participation and participation waivers.

13. Tax-Exempt Organization Participation

In conjunction with the issuance of the Final Rule, the IRS released Fact Sheet 2011-11, confirming that although CMS's final regulations differed from the proposed regulations, the IRS discussion in Notice 2011-20 continues to reflect the IRS position with respect to participation in ACOs by tax-exempt organizations. The IRS clarified that it is sufficient for the written agreement to set forth the methodology for determining an ACO's allocation of shared savings payments, rather than specifying a precise share or exact amount. Also, whether an ACO's termination from the MSSP would jeopardize the tax-exempt status of a participant will depend on all facts and circumstances. Similarly, ownership interests in an ACO need not be directly proportional to capital contributions, nor is an ACO required to always distribute shared savings payments in proportion to such ownership interests. Finally, the IRS confirmed that its 2007 memorandum relating to EHRs applies to a charitable organization participating in the MSSP through an ACO.

Editor's Note: for more detailed information about the ACO Final Rule, see the Health Law Section eSource Special Editions on the subject, at www.americanbar.org/groups/health-law/publications.html.

Update to: How Many Ways Can One Skin a COI?

DHHS/PHS/NIH Financial Conflict of Interest Regulations Finalized

Michael M. Schmidt, Esq.
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Denver, Colorado

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The Law Practice of Stephen Chris Pappas
The Woodlands, TX

This article updates a presentation on financial conflicts of interest made by Chris Pappas and Michael M. Schmidt (moderated by Robyn Shapiro) entitled *How Many Ways Can One Skin a COI?* A part of the presentation addressed a proposed rule published in 2010 pertaining to financial conflicts of interest (“FCOI”s) (75 Fed. Reg. 28688 et. Seq. May 21, 2010) (“Proposed Rule”).

These proposed revisions would modify the existing regulations by (among other proposed revisions): expanding the scope of the FCOI to include Small Business Innovation Research and Small Business Technology Transfer (“SBIR/STTR”) program Phase I applications; amending the definition of significant financial interest (“SFI”) to include a disclosure threshold of \$5,000 for any payments or equity; excluding income from government or higher education for seminars, lectures, teaching, or service on advisory panels; making institutions responsible for defining FCOIs and whether a SFI relates to any Public Health Service (“PHS”) funding; requiring disclosures of any SFIs that are related to an investigator’s institutional responsibilities; enhancing the information on an FCOI reported by the institution to the PHS awarding component; and requiring that before spending funds for PHS-supported research the institution post on a publicly accessible Web site information on SFIs of senior/key personnel.

The Department of Health and Human Services (“HHS”) published the Final Rule in the Federal Register

at 76 Fed. Reg. 53256-53293 (August 25, 2011) (the “Final Rule”). Although not included in the Proposed Rule, the Final Rule requires institutions to require investigators to complete training related to the FCOI and/or other FCOI-related requirements every four years or immediately under the circumstances. Also, the Final Rule materially modified certain definitions and operating rules in the Proposed Rule. However, the Final Rule reversed the Proposed Rule by continuing the current exclusion from reporting FCOIs for SBIR Programs. The Final Rule also clarified that institutions may use their own policies and procedures to comply with the Final Rule.

The Final Rule considered, but did not address, the non-financial conflicts of interest and institutional conflicts of interest that may impact research objectivity. HHS also declined to harmonize the monetary thresholds for disclosures of FCOI used by other agencies, such as the National Science Foundation and the Food and Drug Administration (“FDA”).

In a similar development, on May 25, 2011 the FDA released a new draft guidance entitled *Guidance for Clinical Investigators, Industry and FDA Staff: Financial Disclosure by Clinical Investigators*. While the main thrust of the 2011 Guidance remains similar to that of the 2001 Guidance (*Guidance for Industry: Financial Disclosure by Clinical Investigators*) which it will replace, the current draft Guidance indicates that the FDA will enhance its focus and increase the degree of scrutiny regarding the matter of conflicts of interest in clinical research. The 2011 draft Guidance includes more detailed disclosure of financial interests and requires more explicit processes for the management of potential conflicts. Importantly, the 2011 draft Guidance revises the FDA’s standard for due diligence in collecting financial information from various parties. It is clear that clinical investigators, clinical research institutions and industry must go beyond just going through the motions of collecting disclosure forms and establish explicit, transparent, objective and meaningful processes to enforce strong conflict of interest policies in order to comply with FDA regulations.

The articles published in *The Health Lawyer* reflect the opinions of the authors.
We welcome articles with differing points of view.



13TH ANNUAL CONFERENCE ON EMERGING ISSUES IN HEALTHCARE LAW

February 22-25, 2012

Hilton San Diego Bayfront, San Diego, CA

The Emerging Issues in Healthcare Law Conference is a program you do not want to miss! This conference is an excellent way to network with your colleagues, learn more about the ABA, and become more involved in Section activities. There will be 20+ hours of CLE programming on the most timely and important issues facing today's healthcare attorney as well as three conference receptions and your choice of fourteen Interest Group/Task Force lunches. In addition, the Health Law Section's Council will meet immediately after the conference and all conference attendees are welcome to attend!

The full conference brochure will be available to all Health Law Section members. In the meantime, please see below for a list of activities and programs. If you have any questions, please contact Amy Alder, Senior Meeting Planner, with any questions at amy.alder@americanbar.org. To register now, please visit www.americanbar.org/health.

We look forward to seeing you in February!

Wednesday, February 22, 2012

- 8:30am – 5:00pm Registration
- 9:00am – 12:30pm Breast Cancer Legal Advocacy Workshop
- 12:45pm – 5:00pm Leading Through Change: The Role of Attorneys in Supporting and Guiding System Change through Strategic Management of Conflict
- 1:00 pm – 4:00pm Hospital-Physician Contracting Fundamentals Workshop
- 4:30pm – 5:30pm Young Lawyers Division Open Meeting
- 5:00pm – 6:00pm Diversity Reception
- 6:00pm – 7:30pm Joint Reception with Young Lawyers

Thursday, February 23, 2012

- 7:00am – 5:00pm Registration
- 7:00am – 8:30am Continental Breakfast
- 7:50am – 8:00am Welcome from your EMI Planning Committee Chairs
- 8:00am – 9:30am The Marriage of Quality and Reimbursement: A Match Made in Heaven or a Shotgun Wedding?
- 9:40am – 10:55am **Concurrent Interest Group CLE Sessions**
 - 1) Parlez-vous Kickback? – The Application of the Foreign Corrupt Practices Act to the Healthcare Arena
 - 2) Predictive Modeling: CMS' New Innovative Approach to Claims Review

- 9:40am – 10:55am *(continued)* **Concurrent Interest Group CLE Sessions**
 - 3) ICD-10 Transition: What Health Lawyers Need to Know
- 11:05am – 12:35pm Medicaid Fraud Enforcement: What the States Are Doing and How Providers Are Responding
- 12:50pm – 2:00pm Interest Group Lunches
- 2:15pm – 3:45pm PPACA in 2012: Are We There Yet?
- 3:55pm – 5:10pm **Concurrent Interest Group CLE Sessions**
 - 1) What's Inside This Pretty Box? Compliance Issues in Due Diligence
 - 2) HIPAA Breach Notification – Case Studies on What to Do and When to Report
 - 3) Are Hospitals Doing Enough: Charity Care Disclosures and Public Reactions
- 5:20pm – 6:20pm Business Meetings
- 6:30pm – 8:00pm Reception Honoring Program Faculty and Planning Committee Members

Friday, February 24, 2012

- 7:30am – 4:00pm Registration
- 7:30am – 9:00am Continental Breakfast
- 8:00am – 9:00am Ethical Issues for Healthcare Attorneys In The Land of Overpayment Disclosures, Provider Financial Relationships and HIPAA Violations
- 9:15am – 9:30am State of the Section Address



Friday, February 24, 2012 *(continued)*

- 9:30am – 11:00am Fraud and Abuse Enforcement Update – Enforcement Actions Against Individuals
- 11:15 am – 12:30 pm **Concurrent Interest Group CLE Sessions**
- 1) Will Payors Rescue Accountable Care?
 - 2) The Perils and Pitfalls of Careful Drafting: How Stark Has Changed the Risk Calculus
 - 3) Protecting Human Research Subjects: Proposed New Rules
- 12:45pm – 1:55pm Interest Group Lunches
- 2:00pm – 4:30pm Standing Committee on Substance Abuse Business Meeting
- 2:10pm – 3:40pm How Integrated Should We Be? Emerging Physician-Hospital Integration and Alignment Models
- 2:10pm – 3:40pm Law Student Meet and Greet

3:55pm – 5:10pm **Concurrent Interest Group CLE Sessions**

- 1) Provider, Physician and Supplier Obligations to Report and Return Overpayments
- 2) Where Have All the Drugs Gone? Dealing with Drug Shortages
- 3) New Rules Affect Executive Compensation for Tax-Exempt and Governmental Organizations

5:15pm CLE Program Adjourns

Saturday, February 25, 2012

- 8:00am – 11:30am Open Council Meeting
- 12:30pm – 6:00pm 13th Annual Margarita Cup Golf Scramble
- 12:30pm – 6:00pm Temecula Wine Tour
- 7:00pm – 9:00pm Reception Hosted by Section Chair David Johnson

Simeon Carson, Health Law Section, Honored by the ABA CLE Center

Congratulations to the Health Law Section and to Simeon Carson, Associate Director for being recognized and honored by the American Bar Association's Continuing Legal Education ("CLE") Center. The recognition and honor were made at the CLE Center's Appreciation Celebration November 18.

CLE Center staff were asked to nominate an ABA employee who they felt had put forth outstanding efforts as the Center's partner in providing continuing legal education. This honor was to be bestowed on only two individuals; our own **Simeon Carson** was one of the two selected. Congratulations, Simeon!

The Section is also being recognized for **Member Value** – The partner with the highest percentage of sponsoring entity members attending Distance Learning programs. With over 2,000 attendees at Health Law Section webinars, we averaged .9 members attending, providing valuable education to Section members and others in the legal profession.



Left to right: Wanda Workman, Section Director; Earnestine Murphy, Center for Continuing Legal Education; Amy Alder, Senior Meeting Planner; and Simeon Carson, Associate Director.



Join a Health Law Section Task Force—for Free!

The ABA Health Law Section has four task forces that may interest you:

ACO Task Force

Chair, Matthew Jenkins, Partner, Hunton & Williams LLP

The accountable care organization (“ACO”) Task Force was formed to address the myriad issues that surround the development of accountable care organizations, both in response to the provisions of PPACA and the interest of commercial payors in finding new ways to bend the cost curve.

Long-Term Care Task Force

Co-Chair, Michael E. Anderson, Partner, Arent Fox LLP
Co-Chair, Gregory L. Pemberton, Partner, Ice Miller LLP

The Long Term Care Task Force focuses on legal issues for providers and organizations that serve senior and disabled populations in need of long term or chronic care services. As a result, the Task Force addresses many areas of law related to long term care, including reimbursement, corporate governance, labor and employment matters, housing issues, continuing care communities, financing and risk management, to name a few.

Native American Health Task Force

Chair, Rakel Meir, Associate General Counsel, Tufts Health Plan

The Native American Health Task Force examines healthcare issues unique to the Native American population with the goal of improving access to high quality care.

Breast Cancer Task Force

Chair, Shelley K. Hubner, Executive Counsel, Health Net, Inc.

The Breast Cancer Task Force is a pro bono initiative that was developed to lead and implement educational programs to help protect the legal rights of breast cancer patients. A primary mission of the Task Force is to coordinate training sessions for attorneys interested in assisting breast cancer patients who need legal advice related to their diagnosis and treatment.

Sign Me Up!

- | | |
|--|--|
| <input type="checkbox"/> ACO Task Force | <input type="checkbox"/> Long-Term Care Task Force |
| <input type="checkbox"/> Native American Health Task Force | <input type="checkbox"/> Breast Cancer Task Force |

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Return to: American Bar Association Attn: Health Law Section, 321 N. Clark St., Chicago, IL 60654

For more information, contact Simeon Carson, Associate Director at 312-988-5824 or simeon.carson@americanbar.org.



The Section is pleased to welcome the following new members:

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