
Health Care Fraud

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Director

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Remarks of James B. Comey, Deputy Attorney General, delivered to the American Bar Association, May 13, 2004	1
Department of Justice's Office of Legal Counsel Opinion	8
By Steven G. Bradbury	
Criminal Prosecutions under HIPAA	21
By Peter A. Winn	
Anatomy of a Nursing Home Case	28
By Paul S. Weidenfeld, Joseph A. Aluise, and Dorothy Manning Taylor	
Enforcement of Health Care Kickback Prohibitions Through the Civil False Claims Act: Recent Trends	36
By Jonathan L. Diesenhaus and Laura F. Laemmler	
Internet Pharmacies and the Unlawful Distribution of Controlled Substances	43
By Charlotte J. Mapes	
The Medshares Bankruptcy: Bankruptcy, Fraud, and Patience	50
By Barbara Zoccola	

Remarks of James B. Comey, Deputy Attorney General

*Delivered to the American Bar Association
14th Annual Institute on Health Care Fraud
2004
New Orleans, Louisiana
May 13, 2004*

I appreciate this opportunity to address the 14th Annual National Institute on Health Care Fraud and to be here as a representative of the talented and hardworking men and women of the Department of Justice. I thank our Program Chair, Gabe Imperato, and other members of the planning committee for allowing me this opportunity to speak to you today.

This morning, my colleagues from the Civil and Criminal Divisions provided you with some strategic and practical points in dealing with global settlements, as well as an overview of the trends and the Department's efforts in connection with enforcement under the False Claims Act and the *qui tam* statute. Their remarks will prove to be a valuable guide to you as you navigate among the various components of the Department. I also want to add my voice to theirs to acknowledge our close working relationship with the HHS Office of Inspector General, the Centers for Medicare and Medicaid Services, the HHS Office of General Counsel, the other federal agencies affected by health care fraud, and with our State law enforcement partners at the National Association of Attorneys General and the National Association of Medicaid Fraud Control Units. I am particularly pleased that so many of these groups are represented here at this conference.

I'd like to spend my brief time with you today discussing two main topics: First: I want to discuss the Department's recent reaffirmation of health care fraud as a top white collar crime priority. Second, I'd like to discuss an issue that has generated more than its share of confusion and misinterpretation: our policies concerning waiver of the work product protection and attorney-client privilege in the context of your client's cooperation with our criminal and civil investigations.

In September, 2002, President Bush spoke to

our Corporate Fraud Task Force regarding the Administration's commitment to root out and punish corporate wrongdoers. In the context of financial and accounting fraud, the President stated that: "a few dishonest individuals have hurt the reputations of many good and honest corporations and their executives. They've hurt workers who committed their lives to building the companies that hired them ... For the sake of our free market, corporate criminals must pay a price."

This statement applies with equal force to those in the health care community who commit fraud against the taxpayers of this country. But health care fraud carries with it an added and regrettable dimension: greed and malfeasance in the health care arena can, and often does, harm our nation's most vulnerable citizens – our elderly and our poor. The elderly resident of a sub-standard nursing facility, the high school honor student able to obtain dangerous prescription drugs from an internet pharmacy, the cancer patient receiving diluted drugs from a greedy pharmacist, or the cardiac patient receiving unnecessary surgery, all share one common experience: they each suffered, and some of them *died*, at the hands of a health care provider who placed profit ahead of their patients' vital health care concerns.

I know that today I'm addressing the nation's most seasoned and knowledgeable health care lawyers. And I know that, collectively, you perhaps have seen every conceivable health care fraud scheme. But I'm sure you were as appalled as I to learn that a Missouri pharmacist, for the sake of increasing his bottom line profits, diluted the cancer treatment drugs on which the lives of his customers depended. This pharmacist confessed to diluting in excess of 60 different drugs beginning in 1992 until his arrest in August of 2001, and his actions affected approximately 400 physicians, 4,200 patients, and 98,000 prescriptions.

I know you were as *appalled* as I to learn that a La Mesa, California, high school honors student and athlete died at home from an overdose of Vicodin that he ordered from an internet

pharmacy. This so-called "pharmacy" required only that the teenager complete a simple questionnaire, request his drug of choice, and then pay both a "doctor consultation fee" and the fee for the prescription drugs. No one verified his age. No one verified his medical condition. Instead, doctors were paid only to sign prescriptions. One doctor admitted at trial that he never even reviewed the questionnaires that were submitted by the customers of the site and another doctor signed so many prescriptions in a day that he admitted to falling asleep while signing them.

I know you were as *appalled* as I to learn that physicians lied when telling healthy patients they required cardiac surgery, all for the sake of billing Medicare and other insurers for the surgeries and increasing the profitability of the hospital for which they worked. That is precisely the scheme uncovered in Redding, California, involving a major and otherwise well-known hospital.

I know you were as *appalled* as I to learn that a major medical device company would allow a "stent-graft" device for treatment of certain aneurysms to remain on the market when it knew full well that it could malfunction and cause harm to patients.

I know you were as *appalled* as I to learn that people apparently agreed to undergo expensive outpatient surgeries in exchange for a few hundred dollars—all to further a scheme to bill their insurance companies for the surgeries. That's right, people going under the knife in exchange for the payment of a few hundred dollars, and clinics performing surgeries for the sole purpose of billing insurance companies! That is precisely the scheme we now are investigating, involving multiple clinics in the Los Angeles area, multiple insurer victims, and patients from throughout the nation.

And I am sure you were as *appalled* as I to hear allegations that a wealthy nursing home operator here in Louisiana diverted funds from his three facilities to support a lavish lifestyle while denying his elderly patients items necessary for their care and well-being. While he was making numerous and costly improvements to his \$4 million estate, he was cutting every conceivable corner on patient care, causing the residents of his nursing facilities to suffer in silence—a situation that all too often is the hallmark of elder care.

I know that a large part of this conference is devoted to the False Claims Act and other

remedies intended to recoup money to the victimized government health care programs. I also know that defense counsel assert, often vigorously, that the Justice Department should play no role in some of these matters. We often hear the argument that these are regulatory issues; that the identified wrongs should be dealt with administratively; that licensing authorities should be left alone to impose only their remedies; and that the DOJ is ill-suited to understand the nuances of the practice of medicine and should defer to others. I disagree.

Put simply, I believe that it is of paramount importance that the Department use every tool at its disposal to assure the health and safety of the consumers of the nation's health care system. When physicians and pharmacists abuse the privileges of their professions and deal drugs over the internet, they will continue to be treated by the Department as what they are—drug dealers, not health professionals. When greedy nursing home operators ignore repeated citations, choosing to treat fines as a cost of doing business and not as a penalty for their wanton neglect, they should be treated as what they are—recidivists who unnecessarily risk the lives of our most vulnerable citizens. When hospitals and clinics perform invasive and dangerous procedures on unsuspecting patients, all for the sake of profit, they should *not* be accorded the same deference that so many honest health professionals have worked hard to earn.

That is why the Department of Justice, through the Civil and Criminal Divisions, through the U.S. Attorneys' Offices, through the Federal Bureau of Investigation, and through the Drug Enforcement Administration, is fully committed to the fair and vigorous enforcement of the various laws at our disposal to deal with those companies and individuals that steal from the taxpayers and inflict this suffering on their patients and families. The Department's commitment to effective health care fraud enforcement is driven by our mandate that wrongdoers be brought to justice, the need to deter conduct which threatens our safety and welfare, and the need to protect the diminishing resources of the Medicare Trust Fund, state Medicaid programs, and other government health programs.

Indeed, protecting the resources of that Trust Fund is one of our most vital missions. As you know, the majority of our cases in this area

involve bad acts that are purely economic in nature. Most of these cases are brought by the Department under the False Claims Act. However, other enforcement tools—and ones we are using with greater frequency—are the remedies available to us under the Anti-Kickback and Stark statutes. These laws were enacted by Congress to insure that patients receive the care that is medically required, free from the distortion that often occurs when referral fees or other untoward incentives are offered for the referral of patients. Medical decisions should be dictated by patients needs, and not by bottom lines of medical providers.

Because we think the Anti-Kickback and Stark statutes play a vital role in protecting the integrity of our health system, it continues to be the position of the Department of Justice and the Department of Health and Human Services that violations of these laws also may form a basis for liability under the False Claims Act. In fact, we have had tremendous success asserting this position in various courts.

For all these reasons, the Department recently reaffirmed its longstanding commitment to health care fraud enforcement. I offer the earlier illustrations to underline why the Attorney General considers health care fraud, like corporate fraud, to be a top priority in the Department's efforts to tackle white collar crime. Indeed, just two weeks ago, at a meeting of United States Attorneys, the Associate Attorney General, Robert McCallum, asked each of the United States' Attorneys to make health care fraud a top priority in their offices, and they've responded enthusiastically.

You heard this morning that we've already been quite active in this area. Since Congress created the Health Care Fraud and Abuse Control Program in 1996, the Justice Department, working with the Department of Health and Human Services, and our other state and federal colleagues, has returned more than \$4.5 billion to the Medicare Trust Fund. As many of you know all too well, either because you represent whistle blowers or you represent the entity on whom the whistle was blown, False Claims Act cases alleging fraud against government health care program now substantially outnumber those alleging fraud against the Departments of Defense, Interior, and other government entities. In just the past three years, recoveries under the False Claims Act in matters involving health care fraud accounted for 81% of total False Claims Act

recoveries, or nearly \$3.7 billion for that period. As you heard, last year alone, we tallied a record \$1.6 billion in recoveries for health care fraud cases and Department of Justice prosecutors obtained 437 health care related criminal convictions.

The future holds new challenges for us. As you've read, a new prescription drug benefit is to be added to the Medicare program in 2006. This new and costly benefit will undoubtedly present many opportunities for fraud and abuse. In fact, we've already seen some of that conduct. You've likely heard of the successes enjoyed by the Department in pharmaceutical fraud matters. These cases have resulted in numerous criminal convictions and over \$1.6 billion in restitution and penalties—arising in large part from the pricing and marketing efforts of the some in the pharmaceutical industry. The insight gleaned from these cases was instrumental in leading us to establish a Department initiative to combat fraud and abuse arising from prescription drugs and internet prescribing practices, which Karen Morrisette from the Department's Criminal Division outlined to you this morning. As you heard, we are endeavoring to be ahead of the curve on these matters, both to assure the integrity of the Medicare Trust Fund and to protect the health of our citizens.

I'd like to spend the remainder of my time with you this afternoon discussing an issue that has generated tremendous sound and fury, while at the same time generating a great deal of confusion: That is the Department's policies on requests for waivers of the work product protection and attorney-client privilege in the context of cooperation during our investigations of corporate wrongdoing. This is an issue that comes up frequently in our health care fraud enforcement efforts, as our investigations focus on schemes that are increasingly sophisticated and complex, and often span an entire industry.

As you know, the Department's *Principles of Federal Prosecution of Business Organizations*, known to some as the Thompson Memo, provide guidance to prosecutors making the important decision of whether to criminally charge a corporation. The *Principles* set forth many factors to consider, one of which is whether and to what extent the corporation cooperated with the Government's investigation. In evaluating cooperation, the *Principles* tell prosecutors that they may consider whether the corporation turned

over any internal investigation it may have conducted, and whether it waived applicable work product and/or attorney-client protections.

In addition to the *Principles* encouraging and rewarding cooperation, the Sentencing Commission's organizational sentencing guidelines also encourage and reward cooperation. As you probably know, the organizational guidelines permit a corporation to reduce its punishment by lowering its culpability score through full and thorough cooperation. We understand the term "cooperation" to mean, as courts have, cooperation that discloses all pertinent information, specifically, information that is sufficient for the Government to identify the individuals responsible for the criminal conduct and to understand its full scope.

As an aside, let me note that rewarding cooperation is a good thing. Cooperation reflects that the corporation is looking to clean house—to change its culture, which may be a culture of wrongdoing, to a culture of corporate good citizenship. Cooperation enables the Government to gather the facts before they're stale. Cooperation assists the Government in fully investigating the wrongdoing and figuring out who the wrongdoers are. It also assists us in minimizing victims losses and husbanding resources so we can give folks money back through restitution. Rewarding cooperation facilitates all of these important things.

What constitutes thorough cooperation will necessarily vary in every case. At a minimum, it must be recognized that if a corporation has learned precisely what happened and who is responsible, then they have to turn this over to the Government if they wish to make a claim that they've cooperated and deserve either the benefit of cooperation in the charging decision or a reduced culpability score. The bottom line is that for a corporation to get credit for cooperation, it must help the Government catch the crooks. Sometimes a corporation can provide cooperation without waiving any privileges. Sometimes, in order to fully cooperate and disclose all the facts, a corporation will have to make some waiver because it has gathered the facts through privileged interviews and the protected work product of counsel.

How a corporation discloses the facts will vary, and that's where the rubber hits the road. The Government does not require any particular

method so long as the cooperation is thorough—all pertinent facts are disclosed, including the identification of all culpable individuals, all relevant documents, and all witnesses with relevant information.

Let me give you an example. Cooperation is thorough if the corporation arranges a detailed briefing and voluntarily provides relevant documents and the results of witness interviews. It's also thorough if the corporation provides a general briefing, coupled with identifying relevant witnesses and bringing them in so the Government can hear from the witnesses themselves. Depending upon the nature and type of disclosure, some work product protection may have to be waived because frequently, although not always, the corporation has gathered pertinent facts through an investigation by counsel that included witness interviews which constitute work product protected materials under the law.

Occasionally, a corporation, nevertheless, can provide the Government with a thorough briefing of all the relevant facts without waiving work product protection. But it's fair to say that more often than not, a corporation that has chosen to cooperate will necessarily have to waive its work product protection to some extent to supply the Government with thorough information.

Several important points need to be made here because this waiver issue, ever since the time of the so-called "Holder Memo," the precursor to the Thompson Memo, has generated a lot of ink—mostly by our brothers and sisters in the defense bar—whom we love dearly. First, the Government does not require the corporation to waive work product protection. It is the corporation's decision and that entity's alone to seek leniency by disclosing all relevant facts to the Government. This is the decision that the corporation makes in the context of trying to persuade us not to file charges or to minimize punishment under the guidelines if charged.

In either context, if the facts can be fully disclosed without a waiver, the Department of Justice does not require a waiver as a full measure of cooperation, and the Holder and Thompson Memos make this quite clear. However, if the full facts are only available through access to protected items such as information contained in detailed notes taken during the witness interviews, the corporation will have to decide whether to waive its work product protection in order to have

thoroughly cooperated.

I should also note, though, that waivers can, in many instances, be limited or partial, or limited by subject matter, and let me offer you a couple of examples that we've encountered to highlight this point. Let's say a hospital chain goes into the office of one of our United States Attorneys and says that "we've uncovered a cost report fraud and Medicare has overpaid us by one billion dollars. We know exactly what happened, how it happened, and who was responsible, but we know this from the interviews our lawyers conducted and they're covered by our work product protection. We don't want to waive the protection, so we're not prepared to tell you anything more." And that's it. I think everybody in this room would agree that this disclosure does not constitute the thorough cooperation that the guidelines envision for the corporation to be rewarded.

Now another example—a different example—a company goes into a United States Attorney's Office and says "we've uncovered a crime. There was systemic upcoding in our radiology department for the last three years. We've conducted an internal investigation. We don't want to turn over the notes to you or the report, but we will bring in all the witnesses you'll need to figure out what happened and who was responsible, and we'll make sure the witnesses make full disclosures to you." So long as the corporation follows through with that promise, that cooperation will be full and thorough, and worthy of full credit.

On the other hand, several of the witnesses may decline to be interviewed by the Government, even if they're flown in by the corporation, or they may invoke their Fifth Amendment rights. As a result, if we cannot fully reconstruct the crime or gather sufficient information against those responsible, we're going to turn to the corporation and ask for the notes of their interviews.

Now some might say, well, why don't you guys just immunize the witnesses and not ask for any waiver. The answer is simple. We don't want to immunize those who may have done the deed, who may be culpable and perhaps are even the most culpable, and we're going to look to the corporation to fill in the missing information. The corporation will then have to decide whether to waive work product protection. If it does not waive and the investigation is stymied, or we have

to immunize high-level officials, I can tell you right now the Government is unlikely to view that as sufficient cooperation to merit either leniency in our charging decision or credit through the guidelines at sentencing.

And these examples, I hope, also highlight a very important distinction between work product protection and the traditional attorney-client privilege. In all the materials I've read on this issue, most of it criticizing former Deputies Attorney General, they tend to conflate the two and not recognize the tremendous significance in our investigative work between the two. There's a significant difference because we recognize that the attorney-client privilege is a different animal and is a traditionally protected zone to facilitate communication between client and lawyer. And indeed the Department's policy specifically notes that the waiver of the core privilege, the attorney-client privilege—and I'm careful *not* to use the word "privilege" when I talk about work product—it's a doctrine of a protection—that waiver of the privilege will rarely be necessary when a corporation is cooperating with the Government. And even when we deal with work product material, I should be clear, the Government is almost never seeking counsel's mental impressions of those witness interviews. We want the facts, and as I'm sure any experienced member of the defense bar can tell you, they know how to keep mental impressions and strategy out of their notes of witness interviews. We recognize that the notes of the interview reflect, to some extent, the questions asked by an attorney, and, therefore, they give away the direction or the strategy of the lawyer to some limited extent. But the disclosure of the interview notes is a minimal intrusion on the protection and may be necessary if the corporation wants credit, either through leniency or through reduced culpability score.

I've heard a few complaints from the defense bar that prosecutors routinely ask for waiver, but I don't see evidence of such a widespread practice. If defense counsel mean that prosecutors routinely ask corporations to cooperate and to furnish the Government with all the information known to them about the criminal activity, I certainly hope that is going on. Corporations are unique entities that enjoy many privileges. The Department expects them to conduct their affairs in a scrupulously honest fashion and maintain effective compliance programs that deter and detect any misconduct. When misconduct is

discovered, the Department expects corporations to self-report to law enforcement, including any regulators, to investigate the misconduct, to discipline any wrongdoers, and to cooperate fully with Government investigations. Cooperation doesn't just mean complying with subpoenas. It means—and I hate to sound like a broken record—telling the Government what the corporation knows about what happened, who did it, and how they did it. In short, we expect cooperating corporations to help us catch the bad guys.

If a corporation can do that without a waiver, prosecutors should give them the opportunity to do that. If questions are fully answered without a waiver, prosecutors should consider that to be meaningful cooperation in evaluating all factors in making the charging decision. If a corporation wishes to go farther and share work product and privileged materials in order to enhance the Government's investigation, so much the better. Whether a corporation's failure to cooperate at all, or failure to waive, will result in a charges being brought, is a separate issue that can only be answered by evaluating all the factors.

I'm also aware of contentions by some in the defense bar that waivers will interfere with their ability to investigate the wrongdoing because employees won't agree to be interviewed if they know the information they provide or their "statement" is likely to be turned over to the Government. I don't agree, and we have not seen that happen.

Experienced attorneys routinely advise an employee that the interview is covered *only* by the corporation's attorney-client privilege and that the corporation could decide to waive it. Indeed, many corporations have regulatory obligations to make disclosure of information learned in such interviews. A corporation also has the ability to require an employee to cooperate with its counsel on pain of dismissal. On many occasions, employees who have stolen from corporations willingly confess when confronted by counsel, even though they realize that the consequences will likely be loss of employment, and possible referral to the authorities. To be sure, employees who have engaged in criminal activity may decline to be interviewed. But the fear that the interview might be disclosed to the Government (as opposed to getting the employee in trouble with the corporation) has little impact. In any event, that possibility does not change the fact

that, in order to fully cooperate, a corporation has to help the Government solve the crime.

Let's face it: Corporations self-report and waive the privilege all the time without being requested to do so by the Government. When corporations are victimized by employees, they conduct an internal investigation and frequently decide to *voluntarily* furnish the evidence to the authorities and seek prosecution. There is no parade of horrors conjured up by the defense bar when, on their own initiative, they waive the attorney-client privilege or work product protection.

We've seen no credible evidence that corporations will refrain from conducting internal investigations because, in order to obtain leniency for cooperating, they might be asked to waive a privilege. Many corporations have regulatory obligations to investigate and find out the facts. In some instances, there may also be a fiduciary obligation to investigate. If the corporation is under criminal investigation, its attorneys need to uncover and learn the facts to adequately represent the corporation. In addition, one must remember that waiver of the privilege is voluntary and may only be necessary if the corporation chooses to cooperate to obtain leniency from the Government and/or the Court. In short, I have a hard time imagining that a corporation would refrain from conducting an internal investigation because of some fear that they'll have to share the results of it with the Government.

There are also those who contend that the so-called "requirement"—and there is none—that corporations waive the privilege, will discourage implementation of compliance programs, and aggressive efforts to deter and detect fraud. I cannot believe that a corporation will not seek to prevent criminal activity—for which it will be liable—because, if it does occur, and it is discovered by the Government, the corporation might seek to waive the privilege to obtain leniency from the Government or the Court.

Some corporations have come to us and asserted the terms of a joint defense agreement with an employee, claiming it is the only way employees would speak to it, and then claiming that the corporation can't waive the privilege even if it would otherwise want to. Frankly, it's hard for me to understand why a corporation would ever enter into a joint defense agreement because doing so may prevent it from making the disclosures it

must make if it is in a regulated industry, or may wish to make to a prosecutor.

In any event, how a joint defense agreement will affect a corporation's ability to cooperate will vary in every case. If the joint defense agreement puts the corporation in a position where it is unable to make full disclosure about the criminal activity, then no credit for cooperation will be factored into the Government's charging decision, and it will get no credit for that cooperation under the guidelines. On the other hand, a corporation may learn only some things pursuant to a joint defense agreement and still be able to make a full disclosure to the Government of all relevant information in a sufficient manner to qualify for cooperation credit.

Now, I suspect that some of you are not representing clients in criminal matters. Your experience with the Justice Department is in the realm of the False Claims Act. While it's true that the federal sentencing guidelines are not in play in such matters, the Department nevertheless, and for all the reasons I have stated, fully expects the complete and truthful cooperation of your client with our investigations. At the end of the day, our civil attorneys have a variety of remedies at their disposal. If wrongdoing is established and we attempt to amicably resolve our differences without resort to litigation, your client will be in a far better position as one who was cooperative and open, rather than one who threw up roadblocks whenever the opportunity presented itself.

In closing, I'd like to thank you again for extending this invitation to me and allowing me to come here to beautiful New Orleans to reaffirm the strong commitment of the Department of Justice to root out and prosecute health care fraud. This is a high priority for us in the Department and I hope my presence here today underscores that fact. I thank you for your hard work in putting this conference together and, I look forward to working with you in the future to assure that the Medicare program has sufficient resources for *our* care when we become eligible!



U.S. Department of Justice

Office of Legal Counsel

Office of the Principal Deputy Assistant Attorney General

Washington, D.C. 20530

June 1, 2005

MEMORANDUM FOR

ALEX M. AZAR II

GENERAL COUNSEL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

TIMOTHY J. COLEMAN

SENIOR COUNSEL TO THE DEPUTY ATTORNEY GENERAL

Re: Scope of Criminal Enforcement Under 42 U.S.C. §1320d-6

You have asked jointly for our opinion concerning the scope of 42 U.S.C. § 1320d-6 (2000), the criminal enforcement provision of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 ("HIPAA"). Specifically, you have asked, first, whether the only persons who may be directly liable under section 1320d-6 are those persons to whom the substantive requirements of the subtitle, as set forth in the regulations promulgated thereunder, apply—i.e., health plans, health care clearinghouses, certain health care providers, and Medicare prescription drug card sponsors—or whether this provision may also render directly liable other persons, particularly those who obtain protected health information in a manner that causes a person to whom the substantive requirements of the subtitle apply to release the information in violation of that law. We

conclude that health plans, health care clearinghouses, those health care providers specified in the statute, and Medicare prescription drug card sponsors may be prosecuted for violations of section 1320d-6. In addition, depending on the facts of a given case, certain directors, officers, and employees of these entities may be liable directly under section 1320d-6, in accordance with general principles of corporate criminal liability, as these principles are developed in the course of particular prosecutions. Other persons may not be liable directly under this provision. The liability of persons for conduct that may not be prosecuted directly under section 1320d-6 will be determined by principles of aiding and abetting liability and of conspiracy liability. Second, you have asked whether the "knowingly" element of section 1320d-6 requires only proof of knowledge of the facts that constitute the offense or whether this element also requires

proof of knowledge that the conduct was contrary to the statute or regulations. We conclude that "knowingly" refers only to knowledge of the facts that constitute the offense.¹

¹ In reaching the conclusions discussed below, we have considered the views expressed in your submissions concerning the questions you have asked. See Letter for Jack L. Goldsmith III, Assistant Attorney General, Office of Legal Counsel, from Paul B. Murphy, Associate Deputy Attorney General, *Re: Request for Office of Legal Counsel Opinion on the Scope of the Criminal Medical Records Privacy Statute*, 42 U.S.C. § 1320d-6 (Jan. 16, 2004); Letter for Jack L. Goldsmith III, Assistant Attorney General, Office of Legal Counsel from Alex M. Azar II, General Counsel, Department of Health and Human Services, *Re: Request by the Office of Legal Counsel for HHS Views on 42 U.S.C. § 1320d-6* (Mar. 18, 2004); Memorandum for Jack L. Goldsmith III, Assistant Attorney General, Office of Legal Counsel, from Christopher A. Wray, Assistant Attorney General, Criminal Division, *Re: Criminal Division Position on the Scope of the Criminal Medical Records Privacy Statute*, 42 U.S.C. § 1320d-6 (May 27, 2004), attaching Memorandum for File from Ian C. Smith DeWaal, Senior Counsel, Criminal Division, *Re: CRM response to HHS-OGC Letter* (May 20, 2004); Letter for Dan Levin, Acting Assistant Attorney General, Office of Legal Counsel, from Alex M. Azar II, General Counsel, Department of Health and Human Services (Aug. 6, 2004); Electronic mail with attachment for John C. Demers, Attorney-Adviser, Office of Legal Counsel, from Ian C. Smith DeWaal, Senior Counsel, Criminal Division, *Re: 42 U.S.C. 1320d-6* (Nov. 15, 2004); Letter for John C. Demers, Attorney-Adviser, Office of Legal Counsel, from Paula M. Stannard, Deputy General Counsel, Department of Health and Human Services (Dec. 21, 2004); Letter for John C. Demers, Attorney-Adviser, Office of Legal Counsel, from Paula M. Stannard, Deputy General Counsel, Department of Health and Human Services, *Re: Scope of Enforcement Under 42 U.S.C. § 1320d-6; Draft Opinion of December 17, 2004 - Request for Comments* (Dec. 23, 2004); Memorandum for File from Ian C. Smith DeWaal, Senior Counsel, Criminal Division, *Re: Comments on the Revised OLC Draft Opinion on the HIPAA Criminal Medical Privacy Statute* (transmitted February 18, 2005); Memorandum for Steven G. Bradbury, Principal Deputy Assistant Attorney General, Office of Legal Counsel, from John McKay, United States Attorney for the Western District of Washington, *Re: Scope of Criminal Prosecutions under HIPAA* (Mar. 17, 2005); Memorandum for Steven G. Bradbury, Principal Deputy Assistant Attorney General, Office of Legal Counsel, from

I.

Congress enacted the Administrative Simplification provisions of HIPAA to improve "the efficiency and effectiveness of the health care system" by providing for the "establishment of standards and requirements for the electronic transmission of certain health information." 42 U.S.C. § 1320d note. These provisions added a new "Part C: Administrative Simplification" to Title XI of the Social Security Act and have been codified at 42 U.S.C. §§ 1320d-1320d-8. Part C directs the Secretary of the Department of Health and Human Services ("HHS") to "adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically." *Id.* § 1320d-2(a)(1); *see also id.* § 1320d-2(b)(1) requiring the Secretary to adopt standards concerning unique health identifiers; *id.* 1320d-2(c)(1) (same with respect to code sets); *id.* § 1320d-29(d)(1) (same with respect to security); *id.* § 1320d-2(e)(1) (same with respect to electronic signatures); *id.* § 1320d-2(f) (same with respect to transfer of information among health plans). Various provisions of this part further specify the standards to be adopted, the factors the Secretary must consider, the procedures for promulgating the standards, and the timetable for their adoption. *Id.* §§ 1320d-1 to 1320d-3. Pursuant to this authority, the Secretary has adopted standards and specifications for implementing them. *See* 45 C.F.R. pts. 160-164 (2004).

Section 1320d-1 specifies the persons to whom the standards apply:

Any standard adopted under this part shall

Michael Sullivan, United States Attorney for the District of Massachusetts, *Re: Scope of Criminal Prosecutions under HIPAA* (Mar. 20, 2005); Letter for John C. Demers, Attorney-Adviser, Office of Legal Counsel, from Paula M. Stannard, Deputy General Counsel, Department of Health and Human Services, *Re: Scope of 42 U.S.C. § 1320d-6* (May 5, 2005). We appreciate the thoroughness and thoughtfulness of these submissions.

apply, in whole and in part, to the following persons:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1320d-2(a)(1) of this title.

Id. § 1320d-1; *see also* 45 C.F.R. § 160.102(a) (with respect to general administrative requirements "[e]xcept as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to" the entities listed in section 1320d-1); *id.* § 162.100 (same with respect to additional administrative requirements); *id.* § 164.104 (same with respect to security and privacy regulations). The regulations refer to each of these three groups of persons as a "covered entity." *Id.* § 160.103. To this list of persons to whom the standards apply, Congress later added Medicare prescription drug card sponsors. *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 101(a)(2), 117 Stat. 2071, 2144 ("For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of title XI and all regulatory provisions promulgated thereunder. . . ."), codified at 42 U.S.C.A. § 1395w-141 (h)(6) (West 2004).

Various statutes and regulations define these four categories of covered entities. A "prescription drug card sponsor" is "any nongovernmental entity that the Secretary [of HHS] determines to be appropriate to offer an endorsed discount card program," including "a pharmaceutical benefit management company" and "an insurer." 42 U.S.C.A. § 1395w-141(h)(1)(A). A "health plan" is "an individual or group plan that provides, or pays the cost of, medical care . . ." *Id.* § 1320d(5). A "health care clearinghouse" is an "entity that processes or facilitates the processing of

nonstandard data elements of health information into standard data elements." *Id.* § 1320d(2). Finally, a "health care provider" is any "person furnishing health care services or supplies," including a "provider of services" and a "provider of medical or other health services." *Id.* § 1320d(3). These latter two terms are further defined in 42 U.S.C. § 1395x. A "provider of services" is a "hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, [or] hospice program . . ." *Id.* § 1395x(u). And a "provider of medical and other health services" is any person who provides any of a long list of such services, including "physicians' services," "services and supplies . . . furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills," "outpatient physical therapy services," "qualified psychologist services," "clinical social worker services," and certain services "performed by a nurse practitioner or clinical nurse specialist." *Id.* § 1395x(s). These health care providers only qualify as covered entities if they "transmit[] any health information in electronic form in connection with" certain transactions described in section 1320d-2. *Id.* § 1320d-1(a)(3). The regulations further define the covered entities. *See* 45 C.F.R. § 160.103.

These covered entities must comply with the regulations promulgated pursuant to Part C. Section 1320d-4 requires compliance with the regulations within a certain time period by "each person to whom the standard or implementation specification [adopted or established under sections 1320d-1 and 1320d-2] applies." 42 U.S.C. § 1320d-4(b). Failure to comply with the regulations may render the covered entity either civilly or criminally liable.

The statute grants to the Secretary of HHS the authority for civil enforcement of the standards. Section 1320d-5(a) states, "Except as provided in subsection (b) of this section,

the Secretary shall impose on any person who violates a provision of this part a penalty of not more than \$100 for each such violation. . . ." *Id.* § 1320d-5(a)(1). Subsection (b) provides for three exceptions. First, a civil "penalty may not be imposed . . . with respect to an act if the act constitutes an offense punishable under" the criminal enforcement provision. *Id.* § 1320d-5(b)(1). Second, a civil "penalty may not be imposed . . . with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision." *Id.* § 1320d-5(b)(2). Third, a civil "penalty may not be imposed . . . if the failure to comply was due to reasonable cause and not to willful neglect; and the failure to comply is corrected" within a specified period of time. *Id.* § 1320d-5(b)(3).

The statute prescribes criminal sanctions only for those violations of the standards that involve the disclosure of "unique health identifiers," *id.* § 1320d-6(a), or of "individually identifiable health information," *id.*, that is, that subset of health information that, *inter alia*, "identifies the individual" or "with respect to which there is a reasonable basis to believe that the information can be used to identify the individual," *id.* § 1320d(6). More specifically, section 1320d-6(a) provides:

A person who knowingly and in violation of this part—

(1) uses or causes to be used a unique health identifier;

(2) obtains individually identifiable health information relating to an individual;

or

(3) discloses individually identifiable health information to another person, shall be punished as provided in subsection (b) of this section.

Id. § 1320d-6(a). Subsection (b) sets forth a tiered penalty scheme. A violation of

subsection (a) is punishable generally as a misdemeanor by a fine of not more than \$50,000 and/or imprisonment for not more than one year. *Id.* § 1320d-6(b)(1). Certain aggravating circumstances may make the offense a felony. Subsection (b)(2) provides for a maximum penalty of a \$100,000 fine and/or five-year imprisonment for violations committed under false pretenses. *Id.* § 1320d-6(b)(2). And subsection (b)(3) reserves the statute's highest penalties—a fine of not more than \$250,000 and/or imprisonment of not more than ten years—for those offenses committed "with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm." *Id.* § 1320d-6(b)(3).

II.

A.

We address first which persons may be prosecuted under the criminal enforcement provision, section 1320d-6. Specifically, we address whether section 1320d-6 renders liable only covered entities or whether the provision applies to any person who does an act described in that provision, including, in particular, a person who obtains protected health information in a manner that causes a covered entity to violate the statute or regulations. We conclude that an analysis of liability under section 1320d-6 must begin with covered entities, the only persons to whom the standards apply. If the covered entity is not an individual, general principles of corporate criminal liability will determine the entity's liability and that of individuals within the entity, including directors, officers and employees. Finally, certain conduct of these individuals and that of other persons outside the covered entity, including of recipients of protected information, may be prosecuted in accordance with principles of aiding and abetting liability and of conspiracy liability.

We begin with the language of the statute. *See Liparota v. United States*, 471 U.S. 419, 424 (1985) ("The definition of the elements of

a criminal offense is entrusted to the legislature, particularly in the case of federal crimes, which are solely the creatures of statute."). Section 1320d-6(a) states that:

A person who knowingly and in violation of this part—

- (1) uses or causes to be used a unique health identifier;
 - (2) obtains individually identifiable health information relating to an individual;
- or
- (3) discloses individually identifiable health information to another person, shall be punished as provided in subsection (b) of this section.

42 U.S.C. 9 1320d-6(a). Because Congress enacted the Administrative Simplification provisions for the express purpose of facilitating the use of health identifiers and the acquisition and disclosure of health information, an act listed in subsections (a)(1) to (a)(3) must be done "in violation of this part" in order to constitute a criminal offense. The phrase "this part" refers to "Part C—Administrative Simplification," codified at sections 1320d to 1320d-8. Section 1320d-1(a) makes clear that the standards promulgated under Part C apply only to covered entities: "Applicability. Any standard adopted under this part shall apply, in whole or in part, to the following persons: (1) A health plan. (2) A health care clearinghouse. (3) [Certain] health care provider[s]." *Id.* § 1320d-1(a); *see also* 45 C.F.R. § 160.102(a); *id.* § 162.100; *id.* § 164.104; Exec. Order No. 13,181, 65 F.R. 81,321 (Dec. 20, 2000), *reprinted in* 42 U.S.C. 1320d-2 note ("HIPPA applies only to 'covered entities,' such as health care plans, providers, and clearinghouses. HIPAA regulations therefore do not apply to other organizations and individuals that gain access to protected health information. . . ."). Congress expanded this list to include Medicare prescription drug card sponsors "for purposes of applying part C[s]" Administrative Simplification provisions. 42 U.S.C.A. § 1395w-141 (h)(6). And these

provisions require only "each person to whom the standard or implementation specification applies"—i.e., the covered entities—to comply with it. *Id.* § 1320d-4(b). Because Part C makes the standards applicable only to covered entities and because it mandates compliance only by covered entities, only a covered entity may do one of the three listed acts "in violation of this part." Other persons cannot violate Part C directly because the part simply does not apply to them. When the covered entity is not an individual, principles of corporate criminal liability discussed *infra* will determine when a covered entity has violated Part C and when these violations can be attributed to individuals in the entity.²

That the statute criminalizes the "obtain[ing]" of individually identifiable health information in violation of Part C, *id.* 1320d-6(a)(2), in addition to its disclosure, does not convince us that our reading of section 1320d-6 according to its plain terms is incorrect. It could be argued that by including a distinct prohibition on obtaining health information, the law was intended to reach the acquisition of health information by a person who is not a covered entity but who "obtains" it from such an entity in a manner that causes the entity to violate Part C. *Id.* Further examining the statute and the regulations, however, reveals that the inclusion of section 1320d-6(a)(2) merely reflects the fact that the statute and the regulations limit the acquisition, as well as the disclosure and use, of information by covered entities. Those sections of the statute authorizing the Secretary of HHS to promulgate regulations speak broadly of adopting standards, *inter alia*, "for transactions," "providing for a standard unique health identifier," and concerning "security." *See id.* § 1320d-2. They do not speak only of regulations governing the "use" and "disclosure" of information; the language used in these

² We express no opinion in this memorandum as to whether any particular person or entity may qualify as a covered entity for purposes of liability under sections 1320d-5 or 1320d-6.

provisions easily encompasses the acquisition of information.³ Pursuant to this authority, the Secretary has promulgated regulations governing the acquisition of certain information by a covered entity. *See, e.g.*, 45 C.F.R. § 164.502(b)(1) ("When a health care clearinghouse creates or *receives* protected health information. . . .") (emphasis added); *id.* § 164.502(b)(1) ("When using or disclosing protected health information *or when requesting protected health information from another covered entity . . .*") (emphasis added); *id.* § 164.514(d)(4)(I) ("A covered entity must limit *any request* for protected health information to that which is reasonably necessary. . . .") (emphasis added). Failure to comply with these regulations may render a covered entity liable for "obtain[ing] individually identifiable health information" "in violation of this part." 42 U.S.C.

³ The only statutory section cast in terms of "use" and "disclosure" is the requirement that the Secretary submit to Congress "recommendations on standards with respect to the privacy of individually identifiable health information . . . address[ing] at least . . . the uses and disclosures of such information. . . ." *Id.* § 1320d-2 note. But as discussed above, this quoted language is not found in the main provisions of HIPAA that grant the Secretary authority to promulgate regulations; those provisions use broader terminology that easily includes the authority to regulate the acquisition of information. *See id.* § 1320d-2. Instead, this section solicited recommendations for further legislation concerning health privacy, facilitated congressional oversight of the privacy rules the Secretary developed, and required the Secretary to issue such rules if Congress did not act on the recommendations within a certain time period; it is not a restriction of the authority given elsewhere in the statute. *See infra* n. 12. And on its face this provision does not purport to describe the extent of the Secretary's authority, as it requires the privacy recommendations to address "*at least*" the "uses" and "disclosures" of covered information. *Id.* 1320d-2 note (emphasis added); *see also id.* (same with respect to the privacy regulations). Finally, a rule "address[ing]" the "disclosure" of information may well regulate the acquisition of information by a covered entity because obtaining information generally involves the "disclosure" of it by another person. The provision's use of the noun "disclosure," therefore, does not help to answer the question before us.

§ 1320d-6(a)(2).⁴

The difference between the language used in the civil enforcement provision and that used in the criminal enforcement provision does not support a broader reading of section 1320d-6. The civil enforcement provision makes liable "any person who violates a provision of this part." *Id.* § 1320d-5(a)(1). The criminal enforcement provision makes it a crime to do certain acts "knowingly and in violation of this part." *Id.* § 1320d-6(a). To be sure, the statute must be read as a whole and variations in the language of closely related provisions should be given effect if possible. *See Bryan v. United States*, 524 U.S. 184, 191-93 (1998) (interpreting the requirement that an act be done "willfully" in one subsection of the statute by reference to the "knowingly" requirement contained in other subsections of the same statute). Here, however, the difference in phrasing used in the two provisions does not constitute a basis for concluding that section 1320d-6 reaches persons who are not, or are not part of, a covered entity. Section 1320d-6's use of "in violation of," as opposed to "who violates," reflects only the difference in the scope of the conduct proscribed by the two sections. Section 1320d-5 is phrased as it is—"any person who violates a provision of this part"—because a violation of any of the standards subjects the violator to civil penalties. *See* 42 U.S.C. § 1320d-5(a). In contrast, criminal punishment is restricted to those violations of the standards—specified in subsections (a)(1) to (a)(3)—that involve the improper use, acquisition, or disclosure of

⁴ Nor does the inclusion of "causes to be used" as well as "use" in section 1320d-6(a)(1) compel us to conclude—contrary to the plain language of the statute—that the provision renders liable entities that are not covered by the regulations but that "cause" a covered entity to "use" unique health identifiers in violation of the part. This language is better read to cover those instances in which a covered entity causes, in violation of the part, another person to use a unique health identifier, but where the covered entity itself did not use the identifier in an unauthorized manner.

individually identifiable health information or unique health identifiers. *See id.*

§ 1320d-6(a). Section 1320d-6(a) makes liable a person who "uses or causes to be used," "obtains," or "discloses" such health information. *Id.* Having described the prohibited acts using present tense verbs, the provision could not retain the "violates this part" formulation; instead, it uses "in violation of this part" to make clear that only those uses, acquisitions, and disclosures in a manner contrary to the regulations are illegal. The difference in language between section 1320d-5 and section 1320d-6 is thus best understood as nothing more than a grammatical accommodation resulting from the need to describe the acts for which section 1320d-6 prescribes criminal liability.⁵

Although we conclude that Part C applies only to covered entities, we do not read the term "person" at the beginning of section 1320d-6 to mean "covered entity." Such a reading would not only be contrary to the language of that provision but also create tension with other parts of the statute that appear to use the term broadly, *see, e.g., id.* 1320d-6(a)(3) (prohibiting "disclos[ures] to another person"), and with the Dictionary Act, codified at 1 U.S.C. § 1 (2000), which sets forth a presumptively broad definition of person wherever the term is used in the

United States code⁶ a definition presumptively applicable here because the defined terms specific to Part C do not include the term "person." *See* 42 U.S.C. § 1320d. We conclude only that the phrase "in violation of this part" restricts the universe of persons who may be prosecuted directly. Section 1320d-6 provides criminal penalties for "person[s]" who perform the listed acts "knowingly" and "in violation of this part." *Id.* § 1320d-6. The "in violation of this part" limitation on the scope of liability—like the "knowingly" requirement—is distinct from the definition of "person." It describes that subset of persons who may be held liable, provided that the other elements of the offense are also satisfied. Under this reading of the statute, section 1320d-6(a)(3) continues to make "covered entities" liable for disclosure to *any* "person."

We have considered other laws using the phrase "in violation of." None of these laws supports the view that, as used in 42 U.S.C. § 1320d-6, the phrase should be read more expansively than we conclude. For instance, several of these laws apply to the public generally, and, accordingly, do not shed light on whether section 1320d-6 allows direct prosecutions of persons other than those to whom the substantive requirements of HIPAA's Part C apply. *See, e.g.,* 18 U.S.C. § 547 (2000) ("Whoever receives or deposits merchandise in any building upon the boundary line between the United States and any foreign country, or carries merchandise through the same, *in violation of law. . . .*") (emphasis added); 18 U.S.C.A. § 1590 (West Supp. 2004) ("Whoever knowingly recruits, harbors, transports, provides, or obtains by any means, any person for labor or services *in violation of this chapter. . . .*") (emphasis added). And the phrasing of other laws makes it clear that "in violation of" describes an item

⁵ At most, the difference in phrasing between section 1320d-5 and section 1320d-6 would render the statute ambiguous. If that were the case, it might be appropriate to apply the rule of lenity and conclude that the statute is best read not to subject to direct prosecution persons other than covered entities and those rendered liable by general principles of corporate criminal liability. *See Rewis v. United States*, 401 U.S. 808, 812 (1971) ("[A]mbiguity concerning the ambit of criminal statutes should be resolved in favor of lenity."). But as the language of the statute unambiguously compels the same result, we do not apply the rule of lenity here. *See Chapman v. United States*, 500 U.S. 453, 463 (1991) ("The rule of lenity . . . is not applicable unless there is a grievous ambiguity or uncertainty in the language and structure of the Act. . . .") (citation and quotation omitted).

⁶ "In determining the meaning of any Act of Congress, unless the context indicates otherwise—the word[] person[] . . . include[s] corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." 1 U.S.C. § 1.

involved in the prohibited act, as opposed to the act itself. For instance, 18 U.S.C. § 2113(c) (2000) penalizes "[w]hoever receives . . . property . . . which has been taken . . . in violation of subsection (b). . . ." *Id.* In this case, the placement of the phrase "in violation of" following the word "which" makes plain that the phrase describes only the property, a reading confirmed by the provision's use of the passive "has been taken." *Id.*; see also 18 U.S.C. § 1170(b) (2000) ("Whoever knowingly sells, purchases, uses for profit, or transports for sale or profit any Native American cultural items obtained in violation of the Native American Grave Protection and Repatriation Act. . . .") (emphasis added). In contrast, the phrase "in violation of" in section 1320d-6 does not modify the type of health care information involved in the offense; rather, it relates directly to the acts prohibited by the provision (i.e., "uses or causes to be used," "obtains," or "discloses"). Finally, we have reviewed the cases interpreting these and other potentially analogous provisions and have found none that would cause us to read section 1320d-6 in any way other than in accordance with its plain meaning.⁷

⁷ Consistent with our reading of 42 U.S.C. § 1320d-6, the Sixth Circuit has held that the Video Privacy Protection Act's ("VPPA") creation of a cause of action for "[a]ny person aggrieved by any act of a person in violation of this section," 18 U.S.C. § 2710(c)(1) (2000), allows suits against only video tape service providers and not against all persons. See *Daniel v. Cantrell*, 375 F.3d 377, 382-84 (6th Cir. 2004). In that case, the plaintiff had sued several persons who were not video tape service providers, alleging that they had violated the privacy right in his video rental records given him by the statute. Similar to section 1320d-6, the VPPA cause of action provision refers to acts of "a person in violation of this section." 18 U.S.C. § 2710(c)(1). The court reasoned that because the operative provision of the VPPA provides that "[a] video tape service provider who knowingly discloses . . . personally identifiable information . . . shall be liable," *id.* § 2710(b), only such providers could be "in violation of" the statute. See *Daniel*, 375 F.3d at 383-84. Accordingly, despite the use of the broad term "person" in section 2710(c)(1), only video tape service providers

We conclude, therefore, that an assessment of liability under section 1320d-6 must begin with covered entities. The statute and regulations determine which individuals and entities qualify as a "covered entity." See 42 U.S.C. § 1320d; *id.* § 1395w-141(h)(1); *id.* § 1395x; 45 C.F.R. § 160.103.⁸ A health care provider, is any "person furnishing health care services or supplies," and will be either an individual or an entity. 42 U.S.C. § 1320d(3); see also *id.* § 1395x. In contrast, a "health care clearinghouse," "health plan," and Medicare "prescription drug card sponsor" will virtually never be an individual. See *id.* § 1320d(2) & (5); *id.* § 1395w-141(h)(1)(A). When the covered entity is not an individual, principles of corporate criminal liability will determine the entity's liability and the potential liability of particular individuals who act for the entity. Although we do not elaborate these principles here, in general, the conduct of an entity's agents may be imputed to the entity when the agents act within the scope of their employment, and the criminal intent of agents may be imputed to the entity when the agents act on its behalf. See Kathleen F. Brickley, *Corporate Criminal Liability* §§ 3-4 (2d ed. 1992). In addition, we recognize that, at least in limited circumstances, the criminal liability of the entity has been attributed to individuals in

may be sued under that section. See 375 F.3d at 383-84.

⁸ The statute and regulations do not limit the actions for which a covered entity may be held liable to those activities that render the person a covered entity. Once a person is a covered entity, he must "comply with [an applicable] standard of specification," 42 U.S.C. § 1320d-4(b)(1)(A) and "may not use or disclose protected health information, except as permitted or required by" the regulations, 45 C.F.R. § 164.502. Thus, a physician who is a covered entity in part because he transmits certain health care information electronically must not disclose such protected information, either electronically or otherwise, except as authorized by the regulations. And a physician who is a covered entity must comply with the standards with respect to protected information concerning both his own patients and those patients he is not treating.

managerial roles, including, at times, to individuals with no direct involvement in the offense. *See id.* § 5.⁹ Consistent with these general principles, it may be that such individuals in particular cases may be prosecuted directly under section 1320d-6.

Other conduct that may not be prosecuted under section 1320d-6 directly may be prosecuted according to principles either of aiding and abetting liability or of conspiracy liability.¹⁰ The aiding and abetting statute renders "punishable as a principal" anyone who "commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission" and anyone who "willfully causes an act to be done which if directly performed by him or another would be an offense against the United States." 18 U.S.C. § 2 (2000). And the conspiracy statute prescribes punishment "if two or more persons conspire . . . to commit any offense against the United States . . . and one or more of such persons do any act to effect the object of the conspiracy." 18 U.S.C. § 371 (2000).¹¹ Further discussion of

⁹ "Many regulatory statutes . . . make corporate officials vulnerable to prosecution for criminal conduct in which they did not personally participate and about which they had no personal knowledge." *Id.* § 5.01; *see also United States v. Jorgensen*, 144 F.3d 550, 559-60 (8th Cir. 1998) (applying the principle that "a corporate officer who is in a responsible relationship to an activity within a company that violates provisions of . . . federal . . . laws . . . can be held criminally responsible even though that officer did not personally engage in that activity" in the context of a statute that required proof of "intent to defraud" when the defendant possessed the requisite intent) (quotations and citations omitted).

¹⁰ Depending on the specific facts and circumstances, such conduct may also be punishable under other federal laws. *See, e.g.*, 18 U.S.C. § 1028 (2000 & West Supp. 2004) (identity theft); *id.* § 1030 (2000 & West Supp. 2004) (fraudulent access of a computer).

¹¹ For instance, an individual who is not a covered entity who aids or conspires with a covered entity in the use of protected health information in a manner not authorized by the regulations (e.g., to establish a

corporate criminal liability, aiding and abetting liability, and conspiracy liability in the absence of a specific factual context would be unfruitful, particularly because the contours of these legal principles may vary by jurisdiction. Accordingly, we leave the scope of criminal liability under these principles for consideration in the ordinary course of prosecutions.¹²

fraudulent billing scheme) could be charged under section 2 or section 371 of title 18.

¹² We note that conduct punishable under section 1320d-6 may also be punishable under state law and render a person liable in tort. *See generally* Peter A. Winn, *Confidentiality in Cyberspace: The HIPAA Privacy Rules and the Common Law*, 33 Rutgers L.J. 617 (2002). When Congress enacted HIPAA, it was concerned that state statutory and common law provided inadequate and uneven protection for health information. Congress sought to create a nationwide floor for such protection. *See* Preamble, Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule Preamble"), 65 Fed. Reg. 82,462, 82,463-64 (Dec. 28, 2000). Thus, HIPAA's privacy rules preempt only those contrary state laws that are less stringent than the applicable federal privacy rules. *See* 42 U.S.C. § 1320d-7(a)(2)(B); 45 C.F.R. § 160.203 ("A standard, requirement, or implementation specification . . . that is contrary to a provision of State law preempts the provision of State law . . . except if . . . (b) [t]he provision of State law relates to the privacy of individually identifiable health information and is more stringent than" the federal standard.). All other criminal and civil liability for breaches of a duty concerning the privacy of health information that existed prior to HIPAA remains after its passage.

Although HIPAA charged the Secretary with promulgating transactional and security standards and defined the entities that would be subject to these standards, Congress did not intend the law to be its last word on the matter of health information privacy. Unable to resolve disagreements among members over the proper privacy safeguards, Congress instructed the Secretary, in HIPAA, to submit "detailed recommendations on standards with respect to the privacy of individually identifiable health information." 42 U.S.C. § 1320d-2 note; *see Winn, supra*, at 639-40 ("The Rules themselves were the product of a circuitous method devised by Congress when enacting HIPAA to break a legislative deadlock over the issue of national health privacy standards."). And Congress instructed the Secretary to issue regulations concerning

B.

We address next whether the "knowingly" element of the offense set forth in 42 U.S.C. § 1320d-6 requires the Government to prove only knowledge of the facts that constitute the offense or whether this element also requires proof that the defendant knew that the act violated the law. We conclude that the "knowingly" element is best read, consistent with its ordinary meaning, to require only proof of knowledge of the facts that constitute the offense.

We begin again with the text of 42 U.S.C. § 1320d-6(a). *See Liparota*, 471 U.S. at 424.

A person who knowingly and in violation of this part—

- (1) uses or causes to be used a unique health identifier;
 - (2) obtains individually identifiable health information relating to an individual;
- or
- (3) discloses individually identifiable health information to another person, shall be punished as provided in subsection (b) of this section.

42 U.S.C. § 1320d-6(a). A plain reading of the text indicates that a person need not know that commission of an act described in subsections (a)(1) to (a)(3) violates the law in

such privacy standards if "legislation governing [these] standards" was not enacted by a certain date. 42 U.S.C. § 1320d-2 note. When Congress did not meet the self-imposed deadline to expand privacy protections, the Secretary promulgated the privacy regulations. *See* Privacy Rule Preamble, 65 Fed. Reg. at 82,469-70. These rules are, by necessity, based on the authority found in the existing HIPAA legislation, which states that "any standard adopted under this part shall apply, in whole or in part, to" the covered entities, 42 U.S.C. § 1320d-1(a), and mandates compliance by "each person to whom the standard or implementation specification applies," *id.* § 1320d-4(b). Congress, of course, remains free to expand these protections and the liability of persons other than covered entities.

order to satisfy the "knowingly" element of the offense. Section 1320d-6 makes the requirements that the act be done "knowingly" and that it be done "in violation of this part" two distinct requirements. *Id.* § 1320d-6. These two elements do not modify each other; rather, they independently modify "uses or causes to be used," "obtains" and "discloses." For example, defendants will be guilty of an offense if they both "knowingly" "disclose[] individually identifiable health information" and they "in violation of this part" "disclose[] individually identifiable health information." The view that the statute requires proof of knowledge of the law effectively reads "knowingly" to refer to the "violation of this part." But this reading is contrary to the plain language of the statute, which sets forth these terms as two separate elements each independently modifying the third element, i.e., one of the listed acts. Accordingly, to incur criminal liability, a defendant need have knowledge only of those facts that constitute the offense.

Our reading of the "knowingly" element of the offense comports with the usual understanding of the term. The Supreme Court has stated that "unless the text of the statute dictates a different result, the term 'knowingly' merely requires proof of knowledge of the facts that constitute the offense." *Bryan*, 524 U.S. at 193 (footnote omitted) ("[T]he term 'knowingly' does not necessarily have any reference to a culpable state of mind or to knowledge of the law."). As set forth above, the text of section 1320d-6 does not "dictate[] a different result." *Bryan*, 524 U.S. at 193. In fact, its text dictates an interpretation consistent with the ordinary understanding of "knowingly" as referring only to "knowledge of the facts that constitute the offense." *Id.*

The plain meaning of the "knowingly" element of section 1320d-6 must control, "at least where the disposition required by the text is not absurd." *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000). We consider whether our reading of the criminal provision is absurd in

light of the possible exception to civil liability for reasonable ignorance of the law. Sections 1320d-5 and 1320d-6 operate in a complementary fashion, covering mutually exclusive conduct. *See* 42 U.S.C. § 1320d-5(b)(1) (excepting from civil penalties an act that "constitutes an offense punishable under section 1320d-6 of this title").¹³ The civil enforcement section provides, "A penalty may not be imposed . . . if . . . the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision." *Id.* § 1320d-5 (b)(2). Section 1320d-5 therefore may be read to premise civil liability on knowledge that the act in question violated the applicable standard, not just on knowledge that the particular act occurred.¹⁴ If civil sanctions (of fines up to \$100) may be avoided by establishing reasonable ignorance of the law, it might at first blush appear to be an absurd result to conclude that the significantly more serious criminal punishments (of fines up to \$250,000 and imprisonment of up to ten years) may not be similarly excused.

The absurd results canon of construction is "rarely invoke[d] . . . to override unambiguous legislation." *Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 459 (2002); *Public Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 470-71 (1989) (Kennedy, J.,

concurring) (noting that the canon is limited "to situations where the result of applying the plain language would be, in a genuine sense, absurd, i.e., where it is quite impossible that Congress could have intended the result, and where the alleged absurdity is so clear as to be obvious to most anyone."). Applying the usual definition of "knowingly" here does not yield an absurd result, and certainly not one so absurd that it would cause us to read the statute contrary to its plain meaning. The argument that the statute should not be read so as to impose criminal punishment on the basis of a lesser degree of intent than that required for civil sanction would be more compelling if sections 1320d-5 and 1320d-6 covered the same acts. But they do not. *See* 42 U.S.C. § 1320d-5(b)(1). Civil sanctions may be imposed for violations of a wide variety of regulations. For these violations, the statute provides a maximum \$100 fine and sets forth certain exceptions to liability. *See id.* § 1320d-5 ("General penalty for failure to comply with requirements and standards").¹⁵ In contrast, of all the possible violations of the regulations, section 1320d-6 carves out a limited set and subjects them to criminal punishment. Such punishment is reserved for violations involving "unique health identifiers" and "individually identifiable health information." *See id.* § 1320d-6 ("Wrongful disclosure of individually identifiable health information"). Thus, the statute reflects a heightened concern for violations that intrude upon the medical privacy of individuals. In light of this concern, there is nothing obviously absurd about the statute's allowing a defense of reasonable ignorance of the law for those regulatory violations subject to civil penalty,

¹³ Thus, the Secretary may not impose civil sanctions for the commission of an act that subjects a person to the possibility of criminal prosecution, regardless of whether the person is in fact punished criminally.

¹⁴ This is not the only possible reading of subsection 1320d-5(b)(2). This subsection is headed "Noncompliance not discovered," and the language of the provision—"the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision"—could be read to refer to ignorance of the facts that constitute the violation, rather than ignorance of the law. 42 U.S.C. § 1320d-5(b)(2). But to answer the questions you have asked, we need not decide which reading is better.

¹⁵ In addition to the exception noted above, section 1320d-b(b) contains another defense to liability where "(i) the failure to comply was due to reasonable cause and not to willful neglect; and (ii) the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred." *Id.* § 1320d-5(b)(3).

but withholding this defense with respect to those violations that threaten the privacy of individuals. Accordingly, even reading section 1320d-6 in light of section 1320d-5(b)'s exception to civil liability for reasonable ignorance of the law gives us no reason to doubt that the plain and ordinary meaning of the "knowingly" element of section 1320d-6 is the correct one.

Nor is it proper to apply here the exception to the usual meaning of "knowingly" exemplified by *Liparota*. See 471 U.S. at 424-28. *Liparota* is the case cited by the Supreme Court in *Bryan* as an example of the exception to the rule—when "the text of the statute dictates a different result"—that "knowingly" refers to the facts that constitute the offense and not to the law. 524 U.S. at 193 & n.15. In *Liparota*, the Supreme Court held that a statute forbidding fraudulent use of food stamps required proof of knowledge that the use was unauthorized. See 471 U.S. at 433. The statute in that case read: "whoever knowingly uses, transfers, acquires, alters, or possesses coupons or authorization cards in any manner not authorized by this chapter or the regulations issued pursuant to this chapter" shall be guilty of a criminal offense. See *id.* at 420-21 n.1 (quoting 7 U.S.C. § 2024(b)(1)). This language is at least ambiguous; "knowingly" may modify, for example, either only the verb "uses" or it may modify the entire verbal phrase "uses . . . in any manner not authorized." *Id.*; see *id.* at 424 (The "interpretations proffered by both parties accord with congressional intent. . . . [T]he words themselves provide little guidance. Either interpretation would accord with ordinary usage."); *id.* at 424 n.7 (referring to the statutory language and noting that "[o]ne treatise has aptly summed up the *ambiguity* in an analogous situation.") (emphasis added). But see *Bryan*, 524 U.S. at 193 n.15 (citations omitted) (In *Liparota*, "we concluded that both the term 'knowing' . . . and the term 'knowingly' . . . literally referred to knowledge of the law as well as knowledge of the relevant facts."). The Supreme Court then considered the presumption that criminal

statutes contain a *mens rea* element,¹⁶ applied the rule of lenity, and rested its interpretation, in large part, on the concern that the contrary reading would "criminalize a broad range of apparently innocent conduct." See *Liparota*, 471 U.S. at 426-27.

Here, the "knowingly" element of section 1320d-6 is not ambiguous, see *supra*; thus, it would be inappropriate to resort to the rule of lenity. See *Chapman v. United States*, 500 U.S. 453, 463 (1991) ("The rule of lenity . . . is not applicable unless there is a grievous ambiguity or uncertainty in the language and structure of the Act. . . .") (citation and quotation omitted). Moreover, our interpretation of "knowingly" does not dispense with the *mens rea* requirement of section 1320d-6 and create a strict liability offense; satisfaction of the "knowingly" element will still require proof that the defendant knew the facts that constitute the offense. See *Staples v. United States*, 511 U.S. 600, 622 n.3 (1994) (Ginsburg, J., concurring) (quotations and citations omitted) ("The *mens rea* presumption requires knowledge only of the facts that make the defendant's conduct illegal, lest it conflict with the related presumption, deeply rooted in the American legal system, that, ordinarily, ignorance of the law or a mistake of law is no defense to criminal prosecution."). Finally, the concern expressed in *Liparota* about criminalizing a broad swath of seemingly innocent conduct is less present here. The statute in *Liparota* criminalized the unauthorized use of food stamps by any participant in the program, as well as by any person who might come in possession of these stamps. See 471 U.S. at 426-27. In contrast, section 1320d-6, as we conclude above, applies directly to covered

¹⁶ "[C]riminal offenses requiring no *mens rea* have a 'generally disfavored status.'" *Liparota*, 471 U.S. at 426 (quoting *United States v. United States Gypsum Co.*, 438 U.S. 422, 438 (1978)); *Staples v. United States*, 511 U.S. 600, 606 (1994) ("[S]ome indication of congressional intent, express or implied, is required to dispense with *mens rea* as an element of a crime.").

entities. These covered entities—health plans, health care clearinghouses, certain health care providers, and Medicare prescription drug card sponsors—are likely well aware that the health care business they conduct is heavily regulated by HIPAA and other laws. To the extent that some concern remains, it is insufficient to override the plain meaning of the statute. Accordingly, *Liparota* provides no support for giving "knowingly" in section 1320d-6 a meaning different from its usual understanding as referring only to knowledge of the facts that constitute the offense.

For the foregoing reasons, we conclude that covered entities and those persons rendered accountable by general principles of corporate criminal liability may be prosecuted directly under 42 U.S.C. § 1320d-6 and that the "knowingly" element of the offense set forth in that provision requires only proof of knowledge of the facts that constitute the offense.

Please let us know if we may be of further assistance.

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Criminal Prosecutions under HIPAA

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This article is about criminal prosecutions for violations of the Standards for Privacy of Individually Identifiable Health Information, commonly referred to as the "HIPAA Rules." It examines three questions: (1) who, given the language in the statute, is subject to criminal prosecution for a knowing violation of the Rules, (2) how a recent legal opinion by the Office of Legal Counsel of the Department of Justice (the OLC Opinion) appears to limit the scope of HIPAA criminal prosecutions, and (3) how another criminal statute, 18 U.S.C. § 2(b), works in conjunction with HIPAA's criminal provisions to still permit prosecutions of many individuals, in spite of the problems with direct prosecutions identified in the OLC Opinion.

The HIPAA Rules were promulgated pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The Rules apply, as a direct matter, to "covered entities"—defined to be health care payers, health care clearinghouses and health care providers who transmit health information in electronic form in connection with standardized transactions governed by the Administrative Simplification Provisions of HIPAA.¹ In general, except as otherwise required by law or where there is express authorization by the patient, covered entities are prohibited from disclosing a patient's personally identifiable health information or PHI, for any purpose other than treatment, payment, or health care oversight.

Most covered entities are artificial persons—corporations and partnerships.² As a practical matter, the employees of covered entities, who are not covered entities themselves, need access to PHI to do their jobs. Likewise, covered entities share PHI with each other, and provide access to PHI to medical billing companies, pharmacy benefit management companies, utilization review and management companies, accounting firms and lawyers, and others who perform important and legitimate services for covered entities. This last group of entities are called "business associates" under the Rules.

Recognizing the existence and necessity of widespread information sharing in the health care industry, the Rules also protect the confidentiality PHI when it is disclosed downstream to employees and to business associates. Covered entities are required to train their employees to use proper care to maintain the confidentiality of PHI, and are required to sanction appropriately any employee who fails to do so.³ Likewise, a covered entity is prohibited from transmitting PHI downstream to any business associate until the business associate enters into a written contract guaranteeing that it will provide the same level of confidentiality for PHI as the covered entity itself is required to provide under the Rules.⁴ This

² Virtually all health care payers, of course, are corporations, as are most institutional health care providers such as hospitals and clinics. Even most individual physicians operate through separately incorporated professional associations.

³ 42 C.F.R. § 164.530(b) (training requirements for employees with respect to the requirements of the HIPAA Rules); 42 C.F.R. § 164.530(e) (requirement that covered entities sanction employees who fail to comply with the requirements of the HIPAA Rules).

⁴ 42 C.F.R. § 164.504(e)(2)(ii)(A) (covered entities may not disclose protected health information to such third party contractors without first entering into a business associate agreement with the covered entity where the third party company, or business associate must promise not to use or further disclose PHI inconsistent with the terms of the HIPAA Rules). Note that other assurances or requirements of law may

¹ 42 U.S.C. § 1320d-1(a); 45 C.F.R. Parts 160 and 164. In the Medicare Prescription Drug Improvement and Modernization Act of 2003, Congress added to the list of "covered entities" Medicare prescription drug card sponsors. Pub. L. No. 108-173, § 101(a)(2), 117 Stat. 2071, 2144 (2003), codified at 42 U.S.C. § 1395w-141(h)(6) (West 2004).

combination of direct regulation of covered entities with indirect regulation of downstream disclosures to employees and business associates is intended to create a "chain of trust," protecting the privacy and confidentiality of PHI throughout the entire health care system.

The chain of trust imposed by the HIPAA Rules is based on the way the common law tort system protected health information prior to the enactment of the HIPAA Rules. Common law tort liability for breach of confidentiality applies not only to doctors, but to downstream users with duties of confidentiality, as well.⁵ While the HIPAA Rules did not substantially alter the nature of the *duties* established under prior law, the *penalties* imposed are different. HIPAA does not provide for a private cause of action. Instead, it provides for civil monetary penalties,⁶ and the possibility of criminal prosecution.

The civil monetary penalties are imposed by the Office for Civil Rights of the Department of Health and Human Services ("OCR"), and are imposed in an administrative proceeding. These administrative sanctions are limited to \$100 per violation, with a maximum penalty of \$25,000 for each calendar year. OCR interprets its authority to bring civil monetary penalty actions as limited *to covered entities only*; and, to date, it has engaged only in "educational" efforts and has not brought a single enforcement proceeding pursuant to its civil monetary penalty authority.⁷ On the other hand, HIPAA's criminal provisions are enforced by the Department of Justice, which has brought at least

substitute for an agreement where the covered entity and the business associate are both a government entity, 42 C.F.R. § 164.504(e)(3)(i), or if the business associate is required by law to perform a function or activity on behalf of, or provide services to, a covered entity. 42 C.F.R. § 164.504(e)(3)(ii).

⁵ *De May v. Roberts*, 9 N.W. 146 (Mich. 1881) (holding not only a doctor liable for breach of confidentiality, but finding liability for his "assistant" as well). For the scope of common law liability for wrongful downstream disclosures of PHI, see Winn, *Confidentiality in Cyberspace: the HIPAA Privacy Rules and the Common Law*, 33 RUTGERS L. J. 617 (2002).

⁶ 42 U.S.C. § 1320d-5.

⁷ *Id.*

one successful prosecution of an individual, and has several active investigations pending. Criminal penalties under HIPAA range from a fine of up to \$50,000 and imprisonment for up to one year for a simple violation; to a fine of up to \$100,000 and imprisonment for up to five years for an offense committed under false pretenses; and to a fine of up to \$250,000 and imprisonment for up to ten years for an offense committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, gain or malicious harm.⁸

Unfortunately, when health care lawyers attempt to understand how the HIPAA criminal penalties work, they are faced with a criminal statute that is not exactly a model of clarity. The language of Section 1320d-6 reads as follows:

A person who knowingly and in violation of this part —

- (1) uses or causes to be used a unique health identifier;
- (2) obtains individually identifiable health information relating to an individual; or
- (3) discloses individual identifiable health information to another person, shall be punished as provided in subsection (b) of this section.

How broadly does this language apply? According to the language of the statute, criminal liability under Section 1320d-6 extends to "a person" who "obtains or discloses" individually identifiable health information "in violation of this part." "This part" refers to the administrative simplification provisions of HIPAA, under which

⁸ 42 U.S.C. § 1320d-6

A person described in subsection (a) of this section shall—

- (1) be fined not more than \$50,000, imprisoned not more than 1 year, or both; and
- (2) if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and
- (3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both.

the Health Privacy Rules were promulgated. Accordingly, it would appear that in order to "obtain or disclose" individually identifiable health information "in violation of this part" one would first have to be subject to "this part." While, by definition, a covered entity would be subject to "this part," who, if anyone else, would?

One reading of the statute would be to approach Section 1320d-6 narrowly, as applying only to those entities who are *directly* responsible for protecting personal health information under HIPAA—that is, to covered entities alone. On this view, employees of covered entities and their business associates would not be subject to prosecution under Section 1320d-6 even if they otherwise violated the statute by intentionally disclosing protected health information in violation of the HIPAA Rules. Under this line of thought, an employee might be fired, and a business associate might have its contract terminated, but neither would go to jail for the violation.

A second reading would be to read Section 1320d-6 as covering persons in the chain of trust, who have undertaken, either as a condition of their employment or through a business associate contract, to be subject to HIPAA's duties of confidentiality. On this reading, a violation of their duties of confidentiality by employees or by business associates would constitute a violation of "this part," and would subject them to criminal prosecution like covered entities.

The third reading would read Section 1320d-6 more broadly, to cover any person who "caused" a violation of "this part"—that is, not only covered entities, employees and business associates, but any persons in or outside the chain of trust who caused an improper disclosure of PHI. This broad reading of the statute is supported by the statutory prohibition on wrongfully "obtaining" PHI, language which would make little sense if Congress intended the law to be restricted to covered entities alone.

A recent opinion issued by the Office of Legal Counsel of the Department of Justice (the "OLC") has provided some guidance as to the scope of Section 1320d-6.⁹ OLC opinions are not legally

binding on the judiciary, but are binding on all executive branch agencies, including prosecutors at the Department of Justice. The OLC Opinion addresses the question: which persons may be prosecuted for direct liability under Section 1320d-6? More specifically, it addresses the question of whether section 1320d-6 renders liable only those specifically listed covered entities in HIPAA, or whether the provision applies to any person who obtains protected health information in a manner that *causes* a covered entity to violate the statute or regulations, in which case liability would extend to a universe larger than covered entities. Indirectly, the OLC Opinion also addresses the extent to which employees and business associates of covered entities can be prosecuted for violations of Section 1320d-6.

The OLC concludes that "liability under Section 1320d-6 must begin with covered entities, the only persons to whom the standards apply." While it also notes that "depending on the facts of a given case, certain directors, officers and employees of these entities may also be liable directly under Section 1320d-6, in accordance with general principles of corporate criminal liability," OLC specifically *rejects* an interpretation of Section 1320d-6 which would make directly liable a person who obtains protected health information in a manner that *causes* a covered entity to violate the statute or regulations. In other words, the OLC Opinion agrees with interpretation number one, specifically rejects interpretation number three, and suggests that the scope of liability under interpretation number two may be very narrow indeed. In reaching this conclusion, the OLC Opinion interprets the scope of the criminal statute as having the same scope as the scope of HHS' administrative enforcement powers.

As a practical matter, the OLC Opinion forecloses the use of Section 1320d-6, *operating by itself*, for the prosecution of anyone other than a fairly narrow group of entities—and an even narrower group of individuals—for the bad acts described in Section 1320d-6. However, other criminal statutes, operating in conjunction with Section 1320d-6, may still reach a significant portion of these bad acts. The OLC Opinion carefully limits itself to discussing who can be prosecuted for *directly* violating Section 1320d-6, but leaves open the possibility that employees and business associates could still be prosecuted in other ways. In this respect, the OLC Opinion

⁹ A copy of the OLC Opinion has been included in this Bulletin. It can also be found at: http://www.usdoj.gov/olc/hipaa_final.htm.

states that "[t]he liability of persons for conduct that may not be prosecuted directly under section 1320d-6 will be determined by principles of aiding and abetting liability and conspiracy liability." In this context, the OLC Opinion specifically quotes 18 U.S.C. § 2 which renders "punishable as a principal" anyone who "willfully causes an act to be done which if directly performed by him or another would be an offense against the United States." *Id.* The scope of such *indirect* criminal liability the OLC leaves open "for consideration [by courts] in the ordinary course of prosecutions."

Of the various criminal statutes mentioned in the OLC Opinion to enable indirect prosecutions of Section 1320d-6, 18 U.S.C. Section 2(b) is probably the most important. Section 2(b) is a codification of the common law maxim *qui facit per alium facit per se*: "He who acts through another, acts himself." As such, Section 2(b) is the means by which the federal statutory criminal system currently holds responsible parties responsible for their conduct, even if they act through the agency of others.¹⁰

Title 18 U.S.C. § 2(b) reads as follows: "Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal."

As originally enacted in 1948, 18 U.S.C. § 2(b) provided that "whoever willfully causes an act to be done which if directly performed by him would be an offense against the United States, is punishable as a principal." 62 Stat. 684 (1948). In 1951, Congress added the words "or another" to the statute. The Senate Report accompanying the proposed amendment, explained the purpose of the amendment as follows:

This section is intended to clarify and make certain the intent to punish aiders and abettors regardless of the fact that they may be

¹⁰ Reported decisions applying this principle date from the famous 16th Century decision reported by Edmund Plowden, *The Queen v. Saunders and Archer*, 2 Plowd. 473, 474 (1575, 1816 Edition) (a poisoner who acts through an unwitting intermediary, can still be prosecuted as the principal for "causing" the poisoning to take place); see *United States v. Ruffin*, 613 F.2d 408, 413 (2d Cir. 1979), quoting *United States v. Lester*, 373 F.2d 68, 72 (6th Cir. 1966), citing *United States v. Gooding*, 25 U.S. (12 Wheat.) 460 (1827).

incapable of committing the specific violation which they are charged to have aided and abetted. Some criminal statutes of title 18 are limited in terms to officers and employees of the Government, judges, judicial officers, witnesses, officers or employees or persons connected with national banks or member banks.

Section 2(b) of title 18 is limited by the phrase "which if directly performed by him would be an offense against the United States," to persons capable of committing the specific offense. . . . It has been argued that one who is not a bank officer or employee cannot be a principal offender in violation of section 656 or 657 of title 18 and that, therefore, persons not bank officers or employees cannot be prosecuted as principals under section 2(g). Criminal statutes should be definite and certain.¹¹

It thus seems clear that when it enacted the 1951 amendment to Section 2(b), Congress intended to "to . . . make certain the intent to punish (persons embraced within Section 2) . . . regardless of the fact that they may be incapable of committing the specific violation."¹²

Like the bank fraud statutes enumerated in the legislative history of Section 2(b), Section 1320d-6 is also a *capacity* statute, in which direct liability is restricted to those types of entities specifically covered in the statute, itself. However, when Congress amended Section 2(b) in 1951, it made sure that the limitations of capacity statutes would not prevent the law from holding agents responsible for their deliberate misconduct, at least when such agents derived their capacity to violate the statute from the agency relationship itself. Unlike its sister statute, Section 2(a), which applies to "aiding and abetting," Section 2(b) permits prosecution of an agent for the commission of a crime, even when the principal may be entirely innocent of wrongdoing. In such a case, Section 2(b) treats the agent, himself, as the principal.

¹¹ 1951 U.S. Code Cong. serv. 2578, 2583.

¹² S. Rep. No. 1020, 82nd Cong., 1st Sess., 1951 U.S. Code Cong. and Admin. Serv. 2578, p. 2583. (1951 U.S. Code Cong. Service pp. 2578, 2583. See generally, 52 ALR Fed. 769).

With this in mind, if an employee of a covered entity intentionally caused a disclosure of a patient's confidential health information, which action, if directly performed by another—that is, the covered entity—would be an offense against the United States, then the employee is punishable as a principal—that is, as if the covered entity, itself, had performed the act. An employee may not be, according to the OLC Opinion, within the category of persons to whom the criminal statute directly applies. The employee could, however, be punishable as a principal under Section 2(b) if they committed an act which would be an offense *if committed directly by the covered entity*. Under section 2(b), it is not necessary that the employee action cause the covered entity to commit any crime—that is to confuse liability under section 2(b) with the vicarious liability of an employer for a wrong committed by an employee. It is not even necessary for the actions of the employee to render the covered entity vicariously liable in tort. The covered entity could be completely innocent of all civil or criminal liability. All that is necessary under the language of section 2(b) to render an employee subject to criminal prosecution is for the employee to have caused an act to take place which, if it had been directly committed by another, would be an offense against the United States.

Of course, in order to commit an act which would be a crime if committed by the entity with the capacity to do so, one ordinarily needs to be in some relationship with that entity. In order to wrongfully disclose protected health information, one would need to have access to that information in the first place, and to get access to that information one usually would need to be in the chain of trust under HIPAA. Thus, liability under Section 2(b) usually extends to agents.

Section 2(b) extends the capacity of the principal to commit a crime downstream to the agent. If the employee caused an act to take place which violated Section 1320d-6, the employee would assume the capacity of the covered entity to be prosecuted under Section 1320d-6.

While no court has yet decided a case involving Section 2(b) in the context of a Section 1320d-6 prosecution, case law involving similar capacity statutes shows that courts frequently have permitted prosecutors to use Section 2(b) to prosecute persons who, while lacking the capacity to violate a criminal a statute *directly*, nevertheless have misused their agency

relationships with persons with the requisite capacity to violate statutes ostensibly applicable only to their principals. When this occurs, Section 2(b) has permitted the agents to be prosecuted as if they were principals with the requisite capacity to violate the law directly themselves.

An example of a successful use of the "or another" prong of Section 2(b) may be found in *United States v. Scannapieco*.¹³ In this case the Fifth Circuit upheld the conviction of a firearms dealer's *employee* under 18 U.S.C. § 2(b) for causing a violation of 18 U.S.C. § 922 which prohibits a firearms *dealer* from selling and delivering a firearm to a buyer who was not an authorized person under the statute. The conviction was upheld despite the fact that the *dealer* was not present and was in no way responsible for the illegal sale and the consequent violation of the law. Section 2(b) permitted the prosecution of the employee for having knowingly "caused an act to be done"—the sale of firearms to an unauthorized person—which "if directly performed by another" (*i.e.*, the dealer) would be a violation of 18 U.S.C. § 922. Thus, even though the employee was not a licensed dealer himself and was therefore not himself capable of directly committing the act forbidden by the statute which applied only to *dealers*, Section 2(b) permitted the employee to be prosecuted as if he were the dealer—that is, the principal. The Fifth Circuit wrote as follows:

[S]ince the 1951 amendment to 18 U.S.C. § 2(b), an accused may be convicted as a causer even though not himself legally capable of personally committing the act forbidden by federal statute.¹⁴

Likewise, the Ninth Circuit reached the same result on similar facts in *United States v. Armstrong*,¹⁵ a case in which the defendant presented false information to a gun dealer in connection with his purchases of handguns who was ultimately charged with causing false entries to be made on a federal firearms transaction

¹³ 611 F.2d 619 (5th Cir. 1980).

¹⁴ *Scannapieco*, 611 F.2d at 620-21, citing *United States v. Lester*, 363 F.2d 68 (6th Cir. 1966).

¹⁵ 898 F.2d 734, 740 (9th Cir. 1990).

record, even though the gun dealer was innocent.¹⁶ In the context of this case, the principles underlying Section 2(b) were so little questioned that liability under Section 2(b) was not litigated. Rather, the litigation dealt only with the question of whether Section 2(b) needed to be specifically alleged in the indictment. The Ninth Circuit ruled that Section 2(b) was implied in every indictment and did not have to be specifically alleged.

Section 2(b) has also been successfully used in the context of cases involving illegal payments by employer to members of Unions. In *United States v. Inciso*,¹⁷ a labor union official was charged with violating a federal statute¹⁸ which made it a crime for any "representative" of employees to receive any money or other thing of value from the employer of such employees. The court held that the word "representative" included the labor union, but not the employee of the Union. Nevertheless, the court determined that the union employee could be prosecuted under Section 2(b) because he caused the labor union to receive unlawful funds from the employer.

Thus, Section 2(b) appears to permit an agent to be prosecuted for "causing" an act which does not *directly* violate the law, as long as it would be a crime if another (*i.e.*, the agent's principal) had directly committed the offense. This is true even though the principal may have been entirely innocent of any misconduct. Where there is a capacity statute, Section 2(b) downstreams to the agent the principal's capacity to commit a crime. Even if the agent could not otherwise be prosecuted as a direct matter under Section 1320a-7, if a covered entity has the legal capacity to violate the criminal statute, Section 2(b) permits the agents and employees of the covered entity to be charged as well.

¹⁶ *Id.* at 739. ("Section 2 does not define a substantive offense, but rather 'describes the kinds of individuals who can be held responsible for a crime; it defines the degree of criminal responsibility which will be attributed to a particular individual. The nature of the crime itself must be determined by reference to some other statute.'")(citing *United States v. Grubb*, 469 F. Supp. 991, 996 (E.D.Pa.1979)); accord *United States v. Kegler*, 724 F.2d 190, 200-01 (D.C.Cir.1984).

¹⁷ 292 F.2d 374 (7th Cir. 1961).

¹⁸ 29 U.S.C.A. § 186(b).

It must be said that the broad scope of Section 2 comes with a caveat. In the context of Section 2 prosecutions, courts have sometimes rejected as "unseemly and unwise" what they believe to be attempts by the executive branch "to bring in through the back door a criminal liability so plainly and facially eschewed in the statute creating the offense."¹⁹ In *United States v. Shear*, the government brought a criminal prosecution of both the employer and an employee for an OSHA violation which resulted in the death of another employee.²⁰ The underlying OSHA statute applied expressly only to *employers*. While upholding the conviction of the employer, the court overturned the conviction of the employee, finding that the express purpose of the statute was to protect employees by holding *only* employers liable. Under these circumstances, the court held that prosecution of a person in the class of victims was inappropriate and analogous to the prosecution of a willing "victim" for aiding and abetting a violation of the Mann Act.²¹

In the context of a potential Section 1320d-6 prosecution, the question whether the *Shear* limitations would prohibit the use of Section 2(b) to prosecute an employee or an agent of a covered entity comes down to the question of whether, when it enacted Section 1320d-6, Congress intended that *only* covered entities be prosecuted under the statute and *no other types of persons*. Even the OLC opinion does not go this far. However, in light of the *Shear* admonition that the executive branch may not use the broad scope of Section 2(b) to "legislate new crimes," prosecutors should be very careful not to stray from Congress' purpose in enacting Section 1320d-6 when charging persons other than the covered entities themselves.

There is little question that Congress enacted Section 1320d-6 to protect confidential patient information. Few covered entities have ever intentionally engaged in breaches of patient confidentiality. Most egregious breaches have been committed by employees of covered entities,

¹⁹ *United States v. Shear*, 962 F.2d 488, 496 (5th Cir. 1992).

²⁰ *Id.*

²¹ See *Gebardi v. United States*, 287 U.S. 112 (1932).

business associates, or outsiders who have hacked into computer systems or stolen paper records. Thus, it would appear that use of Section 2(b) to punish non-covered entities would not stray from Congress' stated purpose for enacting Section 1320d-6. However, a more conservative approach would be to restrict the scope of prosecution to individuals within the chain of trust, who knowingly violate their duties of confidentiality established under the HIPAA Privacy Rules. Under this more conservative approach, unless the facts were particularly egregious, prosecutions would not ordinarily go beyond the scope of the chain of trust established by the HIPAA Privacy Rules and the common law.

In conclusion, while the OLC Opinion appears to restrict the scope of Section 1320d-6 prosecutions to covered entities, this holding is limited to *direct* prosecutions only. Because the government can bring prosecutions under *indirect*

liability theories, the scope of criminal liability for the wrongful disclosure of PHI will ultimately be determined by how another criminal statute, 18 U.S.C. § 2(b), interacts with Section 1320d-6. From the review of existing case law under Section 2(b), prosecutions of employees and business associates of covered entities appear to remain viable, at least to the extent that prosecutors are careful to stay within the original Congressional purpose in enacting Section 1320d-6—to protect the privacy of patient health information—particularly when this information is subject to traditional common law duties of confidentiality as codified by the HIPAA Rules.❖

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Anatomy of a Nursing Home Case

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I. Introduction

In late 1997, Wayne Thurber, a Senior Investigator for the United States Department of Labor, received information that Evangeline Healthcare, Inc. (EHC), a nursing home management company for three nursing homes owned by Melville Borne, Jr. (Borne), was routinely 90 to 120 days behind in payments to vendors. As part of a Labor Department initiative targeting corporations that were chronically late in meeting financial obligations, Thurber initiated a civil investigation into EHC's business practices. Thurber's investigation immediately revealed that Borne was also improperly handling employees' 401(k) contributions. As Thurber continued his investigation into Borne's labor practices, he began to learn much more about Borne's business methods.

Through interviews of Borne's employees and an examination of EHC's books, Thurber learned that Borne regularly diverted large amounts of cash from the nursing homes directly to himself and to a construction company that he wholly owned, Dynastar Development Corporation (Dynastar). Thurber also discovered that, while the nursing home money supported Borne's lavish lifestyle and his construction companies, the nursing homes were left strapped for cash every month and unable to meet even the most basic needs of their residents. Thus, a case which began as a civil investigation into possible labor violations burgeoned into a six year criminal health care fraud investigation case that addressed Borne's intentional failure to care for the residents of his three nursing homes and required the combined resources of three federal agencies.

The investigation exposed pervasive fraudulent business practices by Borne that victimized a vast array of parties ranging from the elderly residents of Borne's nursing homes, nursing home vendors, Borne's business associates, and Borne's own employees. Ultimately, a federal grand jury indicted Borne and Dynastar in a fifty-three count superceding indictment charging the defendants with health care fraud, mail fraud, pension fund fraud, and money laundering. One month before the scheduled trial date, Borne pled guilty to health care fraud and pension fund fraud. The court sentenced Borne to thirty-seven months imprisonment and ordered the forfeiture of nearly \$4 million worth of Borne's and Dynastar's property.

II. Factual background of the health care case

Borne owned several development companies, including codefendant Dynastar, that constructed a variety of projects in Louisiana and elsewhere. These building companies provided a gateway for his entry into the nursing home industry, when one of them began constructing nursing homes in Louisiana and North Carolina. Initially, Borne employed a third party to operate his homes, but he soon realized that nursing homes could generate an enormous cash flow on a monthly basis and that nursing home management companies could control this cash flow. As cash seemed to be something he always lacked, Borne created EHC and began operating his nursing homes first in Louisiana and then in North Carolina. Borne sold his North Carolina nursing homes in 1996. The criminal investigation focused on Borne's management of his three Louisiana nursing homes.

EHC, as management company, maintained complete control over *all* revenues generated by Borne's nursing homes. As revenues were received by EHC, Borne would first pay Dynastar's and his own personal expenses prior to the payment of nursing home expenses. While Dynastar existed as a separate corporate entity, it generated virtually no income. The vast majority of Dynastar's funds were monies diverted from

EHC to Dynastar at the direction of Borne. In this way, Borne forced the nursing homes to depend completely upon EHC to pay their bills, maintain their equipment and properties, supply and staff their facilities, and care for their residents. Thus, nursing home administrators charged with the day-to-day operation of the homes were impotent to countermand choices Borne made on the use of nursing home funds. Despite their protestations, Borne left just enough money in the nursing homes to keep the doors open, without regard to the residents' care, services, or environmental needs.

Nursing homes create cash flow from a variety of sources. Medicare and Medicaid provide the primary source of nursing homes' funds in the form of reimbursements for the room, care, and services provided to residents. Nursing homes also receive room and bed fees directly from residents and payments from other entities, such as private insurers and the Veterans Administration. In order to obtain payments from Medicare and Medicaid, Borne, as owner of the nursing homes, executed Provider Agreements wherein he represented to Medicare and Medicaid that he was aware of all applicable federal and state laws and regulations and that he would provide care, services, and a suitable environment for nursing home residents in accordance with these laws and regulations.

Rather than use nursing home monies as represented in the Provider Agreements, Borne diverted large amounts of cash from the nursing homes to Dynastar. The diverted funds primarily supported the improvement and maintenance of "Annedelle Gardens," Borne's 150 acre personal estate located in Folsom, Louisiana and the development of an assisted living facility located in New Jersey. Borne also made fraudulent representations to the New Jersey Economic Housing Authority and the bond underwriter who managed the public bond offering to fund the construction of Borne's New Jersey assisted living facility.

The grand jury that indicted Borne for health care fraud also charged Borne in connection with his fraudulent conduct in New Jersey. The district court severed the "bond count" into a separate trial, and this charge was dismissed when Borne pled guilty to health care fraud and pension fund fraud. In addition, Dynastar paid Borne an annual six figure salary and reimbursed him for personal expenses and travel. While Borne represented to auditors of Dynastar and EHC that Annedelle

Gardens was "land held for investment," Borne developed the 150 acres as a lavish estate which he had no intention of selling or subdividing. The estate included a residence, a manicured riverside park, an elaborate gazebo, opulent gardens, man-made streams and waterfalls, and ponds stocked with exotic black swans.

As Borne's personal finances and estate flourished, his nursing home residents suffered in appalling living conditions. Left without sufficient funds by EHC to pay their financial obligations, the homes were woefully understaffed and often without essentials such as soap, linens, sheets, wound care supplies, gloves, and disinfectants, all vital in caring for elderly residents. Air conditioners were frequently broken during Louisiana summers. Washing machines would often break down and staff traveled to commercial laundromats with soiled nursing home linens and sheets for periods that sometimes exceeded a week. Whirlpool and lifting equipment was often in such a state of disrepair that larger residents had to go without baths for extended periods of time, resulting in dangerous and unsanitary conditions for these residents. Transportation services for residents to travel to and from medical and dental appointments was often unavailable because the service providers had not been paid in a timely manner. Ice machines at the nursing homes often did not work, and the maintenance of an adequate supply of ice is crucial in caring for elderly residents as it assists in keeping residents hydrated. Borne generally refused to provide funds to quickly repair any of the malfunctioning equipment, and the staff was often forced to purchase items such as ice, sometimes with their own money, from grocery stores over prolonged periods. Even food was sometimes in short supply at Borne's nursing homes. (One child of a nursing home resident recalled a time when nursing home kitchen workers were forced to take up a collection from residents and family members to buy the food they needed for residents' meals, and another family member donated a truckload of greens to a home without enough food.)

Borne's employees alerted him to the conditions at the nursing homes through an almost daily stream of telephone calls, e-mails and faxes, yet Borne remained steadfast in his decision to pay Dynastar's and his own expenses first. Despite Borne's assertions to the contrary to

his staff, the question was not one of insufficient funds being generated by the nursing homes.

In addition to neglecting nursing home residents, Borne also neglected to pay the vendors who provided various services to the residents of his nursing homes. Borne refused to pay his vendors despite receiving reimbursement payments from Medicare and Medicaid, either directly or indirectly, for the services the vendors provided. The vendors were forced to resort to a variety of collection efforts, including retaining collection agencies, hiring attorneys, and filing lawsuits. Despite their efforts, vendors frequently came away with nothing or pennies on the dollar as Borne would even refuse to pay judgments obtained against him and his companies.

III. Health care fraud premised upon failure of care

By enacting the Nursing Home Reform Act (part of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Pub. L. No. 100-203, 101 Stat. 1330 (Dec. 22, 1987), 42 U.S.C. § 1395i-3 (Medicare standards) and 42 U.S.C. § 1396r (Medicaid standards)), Congress created a comprehensive statutory scheme designed to protect the well-being of vulnerable nursing home residents. The statutory scheme makes clear that long term care providers who receive public funds for the care of residents must provide care for the residents in the manner specified by the programs.

In the April 1997 Health Care issue of the *United States Attorneys' Bulletin*, David Hoffman, an Assistant United States Attorney in the Eastern District of Pennsylvania, wrote an article entitled "*The Federal False Claims Act as a Remedy to Poor Care*." The article explained how he developed a civil case against a nursing home wherein "[f]or the first time, the Government invoked the Federal False Claims Act (FCA) in conjunction with the Nursing Home Reform Act (the Act) to remedy the provision of inadequate care that was paid for by Government funds." David Hoffman, *The Federal False Claims Act as a Remedy to Poor Care*, UNITED STATES ATTORNEYS' BULLETIN, Apr. 1997 at 54. United States Attorneys' Offices since have instituted a handful of cases focusing on the care provided in nursing homes. These cases were brought, for the most part, as Affirmative Civil Enforcement actions under the False Claims Act and were premised upon nursing homes' failure to

provide adequate or appropriate care for residents. See Marie-Therese Connolly, Federal Law Enforcement in Long Term Care, 4 J. HEALTH CARE L. & POL'Y 230 (2002). Termed "failure of care cases," the legal theories advanced by civil prosecutors included billing for nonexistent and worthless services, submission of express false certifications, and, to a lesser extent, billing for goods or services that violate a statutory, regulatory, or contractual provision.

On a few occasions, federal prosecutors have charged "failure of care" cases as criminal violations. These criminal prosecutions charged individual nursing home employees for specific harms sustained by individual nursing home residents. *United States v. Crawford*, No. 4:1998CR00219 (E.D. Ark. Mar. 15, 2000) (resulting in conviction); *United States v. Turner*, No. 4:1998CR00215 (E.D. Ark. Mar. 15, 2000) (resulting in conviction); *United States v. Taibi*, No. 01-212 (E.D. Pa. Nov. 21, 2001) (resulting in conviction); *United States v. Bell*, Crim. No. 04-CR-212 (W.D. Pa. Aug. 24, 2004) (disposition pending). Prior to the prosecution of Borne and Dynastar, however, no one had premised a "failure of care" criminal prosecution upon a nursing home owner's systemic failure to provide adequate or appropriate care to all residents of a facility. As we uncovered the extent of Borne's failure to provide care for his residents, we concluded that a criminal charge was the only appropriate resolution of the case. Title 18, United States Code, Section 1347 provided the vehicle for this charge.

Section 1347 states:

Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice – (1) to defraud any health care benefit program; or (2) to obtain, by means of false and fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than ten years, or both.

By executing Provider Agreements with Medicare and Medicaid, Borne represented to these health care benefits programs that he would provide care, services, and a healthy environment for the homes' residents in accordance with all

federal and state laws and regulations. These representations were the cornerstone of the health care fraud charge against Borne, as the indictment alleged that Borne executed these Provider Agreements intending to divert substantial portions of the Medicare and Medicaid reimbursements to Dynastar, and that he never intended to provide the level of care to which he agreed when he signed the Provider Agreements. In fact, as described above, Borne failed to provide meaningful care to his residents.

In addition to Borne's representations in the Provider Agreements, he also signed annual Medicare Cost Reports. The cost reports reconcile reimbursements made by Medicare with expenditures of the nursing home and identify all liabilities incurred by nursing homes in providing services to their residents. In executing the cost reports, Borne expressly represented that all of the services identified therein had been provided in accordance with all applicable state and federal statutes and regulations. He also represented that he had liquidated all liabilities owed to vendors who provided services to the nursing homes and their residents. The indictment alleged that Borne submitted his cost reports knowing that he had diverted the Medicare reimbursement monies to Dynastar rather than use the money to provide appropriate care and reimburse nursing home vendors.

IV. Investigating a failure of care case

The federal investigation of Borne and Dynastar brought together the resources of the Department of Labor, the Department of Health and Human Services, Office of Inspector General, and the Federal Bureau of Investigation. Investigators uncovered several separate, but related frauds committed by Borne: the Section 1347 health care fraud as described above, the pension fund fraud, Borne's fraudulent representations to the New Jersey Economic Housing Authority, and Borne's fraudulent treatment of his nursing home vendors. With respect to the health care fraud, investigators focused upon the following issues: (1) failures in care at the nursing homes, (2) the losses sustained by the financial victims such as Medicare, Medicaid, and the nursing homes' vendors, and (3) the diversion of funds from the homes to EHC and Borne and how Borne ultimately spent the diverted funds.

A. Investigating the failure of care provided to the residents

Three sources provided the bulk of information as to the level of care Borne provided to his nursing home residents.

- The nursing homes' own records.
- The nursing home employees.
- The Louisiana state survey system.

The grand jury subpoenaed relevant nursing homes' records, including nursing assessments, physician's notes/orders, dietary notes, care plans, medication administration records, fluid intake and output records, quality assurance records, therapy notes, resident and family complaints, abuse and/or neglect complaints or incident reports, and others. The list of records sought eclipses several pages, and the actual documents obtained from the nursing homes filled an entire room. It was also discovered that some nursing home administrators and directors of nursing maintained meticulous personal records of their own. The records of these administrators and directors proved particularly useful as they often were kept expressly for the purpose of documenting Borne's refusal to provide them with sufficient funds to properly operate the nursing homes.

The testimony of countless employees corroborated the documentary evidence. Due to the number of employees with relevant information, it was necessary to make strategic choices as to who would be placed before the grand jury. Employees of EHC, who worked most closely with Borne and who were disconnected from the day-to-day care provided at the nursing homes, testified before the grand jury. This allowed us to "lock in" the testimony of witnesses who may have had some personal allegiance to Borne. On the other hand, nursing home administrators, nurses, nurses' aids, and residents' family members generally, and not surprisingly, demonstrated no allegiance toward Borne and viewed the nursing home residents as victims. Consequently, there was no need to parade this long line of witnesses before the grand jury. Instead, their testimony was solidified for trial through interviews.

The Louisiana state survey process built upon the documentary and testimonial aspects of the failure of care case. By virtue of federal regulation, all nursing homes must submit to

annual surveys conducted by state agencies. In addition, all complaints made to the state surveying agency must be documented by the agency and may result in a separate survey. The surveyors are charged with evaluating nursing homes' compliance with all state and federal laws and regulations regarding the provision of long term care. Upon completion of a survey, the nursing homes receive a report which identifies violations. Nursing homes must respond with a plan of correction and remedy the violations within a specified period of time. State survey agents can employ several administrative remedies, which range from fines to revoking a Provider Agreement.

The survey process is often problematic because the quality and commitment of the surveyors varies widely, the surveyors often miss violations, and the results are conclusory in nature. The survey process may also create inferences that substantial quality of care failures do not exist because they are not documented in an annual survey. On the other hand, state surveys can provide valuable information regarding every aspect of the care, services, and environment provided to nursing home residents. Accordingly, we obtained all surveys (both annual and complaint) and all underlying documents which supported the surveyors' findings.

B. Losses to financial victims

The financial victims of Borne's and Dynastar's fraud included Medicare, Medicaid, and vendors of the nursing homes. As part of his scheme to defraud, Borne knowingly diverted Medicare payments intended to reimburse the vendors of the nursing homes for services provided to residents, from EHC to Dynastar. Thus, Borne owed considerable sums to many vendors through consistent delinquency in payment or failure to pay despite promises and representations to the contrary. Vendors' losses were established with documents provided by the vendors (invoices, accounts receivable printouts, collection letters, and lawsuits), testimony of vendor representatives, and the accounts payable documents of the nursing homes and EHC. The investigation focused on the larger vendors of the nursing homes (rehabilitation companies, pharmacies, equipment and supply vendors, and others), and those vendors who had long-standing relationships with Borne's nursing homes testified before the grand jury.

At the time of Borne's fraudulent conduct, Medicare regulations required that nursing homes liquidate all liabilities claimed on their cost reports within one year, and when a nursing home owner submitted a cost report, he certified that he had complied with these regulations. A nursing home that failed to liquidate its liabilities was required to file an amended cost report reflecting the nonliquidated liability. The amended report must reconcile the balance sheet in light of the home's failure to use the Medicare money for its intended purposes, and if properly prepared, it can result in the nursing home owing a significant refund to Medicare.

Borne received large reimbursement payments from Medicare for rehabilitation services, pharmaceuticals, and other services. Because Borne diverted large sums of money from the nursing homes, he failed to liquidate these liabilities. In addition, Borne failed to amend his cost reports with Medicare. A Medicare representative assisted us in determining the amount of money overpaid to Borne by Medicare, based upon the total nonliquidated liabilities. This amount equaled approximately \$2.4 million. This figure provided an approximation of a "loss" to Medicare that resulted from Borne's scheme. However, had Borne proceeded to trial, we would have argued, consistent with our *failure* of care theory, that all of the money Borne obtained from Medicare and Medicaid for the provision of care to residents was fraudulently obtained.

C. The diversion of funds

Borne's scheme to defraud funded his lavish lifestyle and his construction companies. Thus the financial aspect of our case focused on juxtaposing the desperate conditions at the nursing homes with Borne's profligate spending in support of himself and his other projects.

Initially, we obtained, through grand jury subpoena, all of the financial records from the nursing homes, EHC, Dynastar, and Borne. As Borne fraudulently listed Annedelle Gardens as "land held for investment" on the books of Dynastar, these records provided a detailed accounting of Borne's diversion of funds from the nursing homes to EHC to Dynastar and then to himself.

In order to develop a complete picture of Borne's diversion of funds, we sought to

demonstrate how Borne spent the diverted funds. We obtained photographs, invoices, travel records, and credit card statements which detailed the expenditures of the diverted funds. Borne traveled to Italy with nursing home funds to purchase wrought iron gates and statues for his estate. He constructed man made lakes and streams on the estate that fed into an artificial waterfall. He stocked his man-made streams with expensive exotic swans (while stately, much to Borne's disappointment, the swans proved incapable of outmaneuvering the coyotes that roamed the landscape, thus requiring Borne to frequently restock his slow-paddling waterfowl). He funded a Dynastar company jet, paid for an advanced degree from the Harvard School of Business, and spent millions of dollars funding failed Dynastar construction ventures.

Our focus upon how Borne spent diverted funds is not unique to a health care case. Indeed, demonstrating how a fraud defendant uses the proceeds of his crime is integral to many white collar investigations. In our case, Borne's extravagances were underscored by the meager conditions at the nursing homes. While nursing homes did not have sufficient wound care supplies, linens, operable critical equipment, or even soap, Borne was jetting to Italy to purchase items for his personal estate.

V. Pretrial issues

A. Drafting the indictment

The 18 U.S.C. § 1347 charge against Borne and Dynastar represented the first of its kind as it alleged a health care fraud premised upon a nursing home owner's systemic failure to provide care to his residents. In drafting the indictment, we were cognizant of several issues. First, we wanted to insure that the theory of the prosecution was clear. Thus we were careful to discuss the false representations made by Borne to Medicare and Medicaid and describe in detail the documents within which the representations were found. We also explained the level of care he agreed to provide by executing the Provider Agreements and discussed in great detail the substandard care actually provided to the residents. The indictment identified several categories of care failure, such as inadequate staffing, lack of pharmaceuticals, failure to maintain necessary equipment, and lack of nursing, sanitary food, and housekeeping

supplies. The indictment listed specific examples within each of these general categories. By drafting the indictment in such detail, we sought to avoid a notice argument by the defendants when nursing home employees were called to testify regarding the conditions at the nursing homes.

We also wanted to establish how Borne's diversion of funds related to his fraudulent conduct. The indictment emphasized that the diversion was part and parcel of the overarching scheme to defraud. This emphasis tied the properties owned by Dynastar directly to the scheme to defraud, making clear the properties were forfeitable. The indictment also left no doubt that the government's case-in-chief would include evidence of the diversion of nursing home funds by Borne and Dynastar.

Borne's criminal conduct in managing his nursing homes and conducting his construction business was not limited to health care fraud. The indictment also charged: (1) pension fund fraud, in violation of 18 U.S.C. § 664, based upon Borne's failure to timely remit, and improper use of EHC and nursing home employees' 401(k) contributions, (2) mail fraud premised upon Borne's intentional misrepresentations to nursing home vendors, and (3) money laundering. The money laundering charges emphasized that Borne was converting nursing home funds into an asset, in the form of real property, of an unrelated company, Dynastar.

Finally, the indictment included notices of forfeiture relative to Borne's personal residence and Annedelle Gardens. (By the time the grand jury returned the indictment against Borne and Dynastar, Borne had sold all of his nursing homes. Thus EHC possessed no assets to forfeit.) When the grand jury returned the indictment, we immediately filed Notices of Lis Pendens. The Lis Pendens notified the public that Borne's and Dynastar's properties were subject to a forfeiture proceeding and effectively prevented Borne from dissipating his assets prior to resolution of the criminal proceeding.

B. Motion practice

Three central pretrial issues arose in this case. First, Borne and Dynastar unsuccessfully sought to cancel the Notices of Lis Pendens described above. Defeating this effort was crucial as it

preserved assets the government ultimately would use to compensate victims.

Next, due to the array of fraudulent activity undertaken by Borne, we submitted an extensive notice of the government's intention to introduce evidence pursuant to Federal Rule of Evidence 404(b). In drafting the motion, we deliberately separated fraudulent conduct uncovered during the investigation that was not related to the frauds charged in the indictment (and thus admissible only pursuant to Rule 404(b)) from uncharged fraudulent conduct that nonetheless was "intrinsic" to the charged schemes to defraud (and thus admissible for any purpose). The 404(b) notice educated the district court as to the facts of the case and the breadth of Borne's fraudulent conduct and described much of the evidence that the defendants would likely find objectionable, thus forcing a pretrial ruling on such evidentiary matters.

The most important pretrial issues were the defendant's motions to dismiss most of the indictment. One of the motions to dismiss attacked the health care fraud charge. This motion claimed that the health care fraud count in the indictment sought to criminalize mere regulatory violations and that the alleged diversion of nursing home monies by Borne created, at best, a civil contract dispute between Medicare and Borne. In its unreported opinion, the court recognized that the health care fraud charge alleged that "Borne and Dynastar perpetrated [a] fraud upon Medicare and Medicaid by misrepresenting what Borne intended to do in operating his nursing homes." *United States v. Melville Borne, Jr. and Dynastar Development, LLC*, No. 03-247 "J", 2003 WL22836059 *1 (E.D. La. Nov. 25, 2003). Further, the court realized that Borne's diversion of funds created more than a mere civil dispute between Medicare and Borne. "[T]he information regarding diversion of funds and regulatory violations in the . . . indictment is relevant and is information which the government hopes to prove at trial." *United States v. Melville Borne, Jr. and Dynastar Development, LLC*, No. 03-247 "J", 2003 WL 22836059 *3 (E.D. La. Nov. 25, 2003). Thus the district court not only denied the motion to dismiss, it also signaled that all evidence of Borne's diversion of funds would be relevant and admissible at trial.

VI. Considerations in preparing for trial

Borne entered his plea of guilty a month before trial was scheduled to begin, thus we had completed most of our trial preparation. We anticipated that the trial against Borne and Dynastar would last approximately six to eight weeks, and that during our case-in-chief we would call around eighty witnesses and introduce at least 1,200 exhibits comprised of 25,000 pages. As such, document and witness management were matters of critical concern.

A. Document management

The various records relating to care that are maintained by nursing homes are voluminous. Combined with records from vendors of the nursing homes, the financial records of the nursing homes, EHC, Dynastar, and Borne, and state survey records, we received in excess of one million pages of documents. As we intended to introduce only a fraction of these documents, document management became one of the more important and difficult aspects of the case.

Because we sought to compile much of the information contained within these documents into summary exhibits, we employed the services of a nontestifying nursing expert with experience in nursing homes to assist us in synthesizing the documents. Her assistance enabled us to identify the crucial documents relating to failure of care that would be admitted at trial, identify witnesses who could testify based upon the documents, and create a series of demonstrative exhibits that compared the shortages at the nursing homes with the extravagance of Borne's and Dynastar's spending habits.

As our courtroom presentation was to be "paperless," each exhibit had to be scanned, marked, and identified for easy retrieval and courtroom use. This process encompassed a master exhibit list, which included a description of the document, the witness through whom the exhibit would be introduced, whether the exhibit would be entered by stipulation, and, if not by stipulation, how the exhibit would be authenticated. Due to the volume of evidence, this process required an enormous amount of time and attention to detail. Beginning the process of document management early in the investigation helped ease the burden of trial preparation.

B. Expert witnesses

To assist us in articulating to the jury the failure of care aspect of the case, we retained a former nursing home administrator as an expert in the field of nursing homes and long term care. The expert had both clinical and administrative experience. She had worked as a nurse, as a director of nursing, and as the administrator of a nursing home. She also had experience as a regional vice president of a chain of nursing homes and as a nursing home executive director and director of operations. In preparing for trial, the expert worked closely with the nontestifying expert and reviewed relevant care-related records received from the nursing homes, the state surveys of the nursing homes, and the testimony of potential care-related witnesses.

The expert could address Borne's failures to provide services, staff, supplies, equipment, and an appropriate environment, and the harm suffered by the residents as a result. The expert also could take the testimonial and documentary evidence at trial and explain how it proved a systemic failure to care for residents. Further, she could explain how a nursing home owner could avoid serious sanction through the state survey process, yet still be guilty of failing to care for his residents.

With regard to the financial evidence within the case, we retained an accountant with expertise in health care accounting principles. The accountant could explain and quantify Borne's diversion of funds and reveal the deceptive nature of his bookkeeping. The expert reviewed all of the financial documents received from the nursing homes, EHC, and Dynastar, and the cost reports. Based upon his healthcare background, the accountant was familiar with Medicare cost reports and could explain the significance of Borne's failure to liquidate the liabilities listed on his cost reports.

The financial expert could also provide important context to Borne's misrepresentations as alleged in the indictment. To begin with, he could trace funds from Medicare to the nursing homes, explain how Medicare expected the money to be spent, and then show how much of the money actually was diverted from the nursing homes and used by Borne and Dynastar. The accountant could explain why Anedelle Gardens should have been considered a personal asset of Borne rather than "land held for investment" by Dynastar, and the importance of this misrepresentation. We also

planned to use the accountant to explain various falsities and fraudulent representations within a number of financial statements of Borne and his companies.

In sum, because Borne perpetrated much of his crimes through fraudulent financial representations, the accounting expert was crucial in piecing together the various items of evidence that revealed these frauds. Due to the volume of evidence reviewed by the accountant, we worked closely with him in creating numerous summary exhibits for use during his testimony.

VII. Conclusion

While the health care fraud charge brought against Melville Borne, Jr. was unique in its use of 18 U.S.C. § 1347, Borne's scheme to defraud was not unusual. He made material misrepresentations to the government for the purpose of obtaining federal funds. Our case was challenging in that it required us to prove a systemic and intentional failure of care of nursing home residents, but, as long as we remained focused on Borne's underlying fraudulent intent, our case maintained its direction and fit nicely within § 1347. In the end, what began as a civil labor investigation revealed an extensive scheme to defraud Medicare and Medicaid that victimized hundreds of elderly nursing home residents. The prosecution resulted in the first criminal conviction of a nursing home owner for failure to care for his residents and sent a message to all nursing home owners that such failure may bring criminal consequences.❖

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Enforcement of Health Care Kickback Prohibitions Through the Civil False Claims Act: Recent Trends

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I. Introduction

Recent federal court decisions have established the civil False Claims Act (FCA), 32 U.S.C. §§ 3729-3731, as an additional and important weapon in the fight against kickbacks, bribes, and other more insidious forms of remuneration intended to induce the referral or recommendation of items or services for federal health care program beneficiaries. Like all consumers of health care goods and services, the federal programs necessarily depend on health care professionals to exercise independent judgment in the best interests of the patient and, in so doing, to play an important role in the allocation of scarce health care resources. State and federal law, as well as ethical canons of the medical profession, have long held that kickbacks, referral fees, and other financial incentives having a tendency to corrupt the judgment of medical

professionals are unlawful and improper. *See United States v. Neufeld*, 908 F. Supp. 491, 496 (S.D. Ohio 1995) ("Taking bribes for referrals . . . is an inherently wrongful activity . . . for which a physician may be disciplined . . . and prosecuted.")

So too, federal common law has long held that contractors and others who obtain a right to bill the federal government through the commission of a crime or similar unlawful act, forfeit their right to benefit from the resulting bargain. Synthesizing these common themes, the government has argued successfully that persons who pay bribes to obtain access to federal health care program business forfeit their right to bill those programs and, accordingly, that FCA liability will attach as a matter of law when a violation of the federal healthcare Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b)(2), or the Social Security Act's (SSA), Pub. L. No. 74-271, 49 Stat. 620 (1935), prohibition against self-referrals results in the submission of claims for program reimbursement.

The United States' recent successes in establishing the viability of the legal theory have produced an increase in law enforcement activity concerning health care kickbacks. Not surprisingly, by reducing legal uncertainty, recent court decisions seem to have triggered a string of FCA settlements in pending cases. The

government successes also appear to have produced an increase in the number of new filings in which *qui tam* relators allege kickback-based theories of FCA liability. Notably, those successes, the increased risk of a *qui tam* filing, and other developments have also spurred a growing number of voluntary disclosures from providers who find they have engaged in illegal kickback schemes. This article describes the legal framework for establishing FCA liability in those cases.

II. Statutory framework

A. The Anti-Kickback Statute

The health care Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b)(2), emanates from congressional concern that payoffs to those who can influence decisions about the delivery of health care goods and services will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. First enacted in 1972 as part of the Social Security Act, the statute was strengthened in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach.

The AKS prohibits any person from "knowingly and willfully" offering or paying "remuneration" in the form of a kickback, bribe, rebate, or anything of value, to induce the recipient to refer, arrange for, or recommend a health care item or service covered under a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). The statute similarly prohibits solicitation and receipt of "remuneration" paid for those purposes. 42 U.S.C. § 1320a-7b(b)(1). Violation of the statute is a felony that can also subject the perpetrator to administrative sanctions, including exclusion from participation in federal health care programs and, as of 1997, civil monetary penalties. *See* 42 U.S.C. § 1320a-7.

To prove a subsection (b)(2) violation, the government must show that the party paying or offering the remuneration intended to induce a referral of health care business. *See United States v. Jain*, 93 F.3d 436, 440-41 (8th Cir. 1996). The crux of the statute is inducement—the statute prohibits health care providers from generating business, *i.e.*, sales or services for which it will bill federal health care programs, by making

payments that Congress determined would compromise the professional judgment of referral sources. Courts construing the statute have determined that such conduct is sufficiently corrupting that the statute is violated if *one* purpose of the remuneration was to induce referrals; it need not be the sole or even the primary purpose for the transaction. *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 30 (1st Cir. 1989) ("[T]he issue of sole versus primary reason for payments is irrelevant since any amount of inducement is illegal."); *see also United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989). The government must also prove that the defendant engaged in the prohibited transaction "knowingly and willfully," *i.e.*, that he or she acted unjustifiably and with knowledge that such conduct was wrongful. *See United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (government need not prove specific knowledge of the statute); *Jain*, 93 F.3d at 441; *cf. Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995) (government must show specific intent to violate "a known legal duty").

Because of the statute's breadth, Congress created statutory exceptions for conduct deemed to be nonabusive, including certain discounts, bona fide wages, certain managed care risk arrangements and, most recently, dealings with federally qualified health centers. In addition, the Department of Health and Human Services, Office of Inspector General (HHS-OIG) issues regulations identifying nonabusive payment practices that will not be subject to criminal prosecution or provide a basis for administrative exclusion. *See* 42 C.F.R. § 1001.952. These "safe harbor" regulations list specific criteria for certain financial relationships between a provider and a referral source that, if met, protect the participants from prosecution regardless of their intent.

B. The physician self-referral prohibition a/k/a the Stark Laws

The Social Security Act also contains prohibitions intended to prevent physicians from profiting from their own referrals. *See* 42 U.S.C. § 1395nn. These provisions, also known as the Stark Laws, prohibit *referrals* for specifically designated services, prohibit *billing* for those services, and prohibit Medicare from *paying* for such services, when the referring physician has a

financial relationship with the entity providing the service and that relationship does not fall within one of the several specified statutory or regulatory exceptions. *See* 42 U.S.C. § 1395nn(a), (g). The statute defines a prohibited "financial relationship" to include both ownership or investment interests in the billing entity and compensation arrangements with the entity. 42 U.S.C. § 1395nn(a)(2). Violation of the statute subjects the referring physician and the entity that bills for the referred service to administrative penalties. It also renders the claim for the unlawfully-referred service subject to denial of payment. 42 U.S.C. § 1395nn(g).

As enacted in 1989, the law now known as Stark I applied only to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992. In 1993 and 1994, Congress extended the prohibitions to ten additional "designated health services" (DHS), including, for example, radiology services, prosthetics, and inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6). This amendment, often referred to as Stark II, became effective January 1, 1995.

The statutory exceptions to the definition of prohibited financial relationships encompass nearly every form of nonabusive relationship between a physician and an entity receiving a referral. *See* 42 U.S.C. §§ 1395nn(b), (c), (d), (e). Most of these exceptions parallel regulatory safe harbors and statutory exceptions to the AKS. For example, some types of physician investments in certain entities, including hospitals, and personal service agreements that meet the indicia of bona fide compensation, fall within exceptions and do not trigger the referral ban. If the parties satisfy the exceptions' criteria, referrals and resulting claims are not prohibited. Generally, the critical elements of these Stark II exceptions are that payments must: (1) be made pursuant to the terms of a written agreement or instrument, (2) represent fair market value for services or property delivered by the physician, and (3) be calculated or established without regard to the value or volume of referrals from the physician to the entity.

The Stark laws were enforceable as of the effective date of the amendments; Congress did not require HHS to promulgate regulations to implement the statute. Although the health care industry urged the agency to suspend enforcement pending regulations, HHS declined to do so. *See*

Physician Ownership and Referral Prohibitions Program Memorandum, HCFA Pub. 60A/B, Transmittal No. AB-95-3 (Jan. 1, 1995), CCH Medicare and Medicaid Guide, 1995-1 Transfer Binder ¶ 43,078. Instead, HHS issued guidance to providers and payment contractors explaining the statute and informed providers that, in the absence of regulations, the statute would be enforced. *Id.*

When the final Stark I regulation was issued in August 1995, the preamble expressly recognized the applicability of much of the regulation to interpret Stark II. *See* 42 C.F.R. §§ 411.350-361 (1996); 60 Fed. Reg. 41,978 (Aug. 14, 1995). On January 4, 2001, HHS issued Phase I of the final regulation interpreting Stark II, further clarifying that statute and its exceptions. *See* 66 Fed. Reg. 856 (Jan. 4, 2001). The Phase I regulations codify mainly definitions of key terms in the statute and regulations. In publishing the Phase I regulations, HHS explained, "where [the regulation] proscribes conduct not previously prohibited," providers have until January 4, 2002, to bring those arrangements into compliance. *Id.* at 862. "*In the meantime, the statute in its entirety remains in full force and effect,*" as did the August 1995 final rule for Stark I. *Id.* (emphasis added).

On March 26, 2004, HHS released as interim final regulations Phase II of the Stark II regulations, which became effective July 26, 2004. *See* 69 Fed. Reg. 16,054 (Mar. 26, 2004). The Phase I and Phase II regulations, together, supersede the 1995 Stark I regulations governing clinical laboratory services and provide regulatory clarification for most of the existing statutory and regulatory exceptions to the statute. *Id.* Final Phase III regulations are expected to be published no later than March 2007.

C. The Civil False Claims Act

While the AKS and Stark laws attempt to rein in the corruption of physicians' and others' medical judgment by prohibiting certain financial relationships that can affect items or services that are reimbursable under federal health care programs, the FCA, 31 U.S.C. §§ 3729-3733, is the government's primary tool to recover losses due to fraud against the United States. *See* S. Rep. No. 345 at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266; *U.S. ex rel. Kelly v. Boeing*, 9 F.3d 743, 745 (9th Cir. 1993). The FCA establishes a civil action for the recovery of damages and penalties from those who submit

false or fraudulent claims to the United States. Congress intended the FCA to be read broadly.

[The FCA] is intended to reach all fraudulent attempts to cause the Government to pay out sums of money or to deliver property or services. Accordingly, a false claim may take many forms, the most common being a *claim for goods or services . . . provided in violation of contract terms, specification, statute, or regulation . . .*

S. Rep. No. 345 at 25, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (emphasis added); *see Shaw v. AAA Eng'g & Drafting*, 213 F.3d 519, 532 (10th Cir. 2000) (relying on legislative history to hold that "FCA liability under § 3729(a)(1) may arise even absent an affirmative or express false statement").

III. FCA liability for violations of the AKS and Stark

The overwhelming weight of federal case law establishes that the appropriate inquiry for a court considering whether the violation of a statute, regulation, or contract provision gives rise to FCA liability is whether a *nexus* exists between that statute, regulation, or contract provision, and the defendant's claim for payment, *i.e.*, whether compliance is a prerequisite to payment or the right to retain payment. FCA liability arises when a person submits to the government a "false or fraudulent" claim for payment or approval, or submits a false record or statement in support of a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1) and (a)(2). Thus, when a person violates applicable statutory, regulatory, or contractual provisions, FCA liability will attach if compliance with such provisions could affect entitlement to payment.

Cases in which courts have found that a knowing failure to comply affects the claimant's right to payment fall into three categories: (1) the items or services for which the claim is submitted were defective, *see, e.g., United States ex rel. Lee v. SmithKline Beecham*, 245 F.3d 1048 (9th Cir. 2001), (2) the claimant falsely expressly certified compliance with applicable requirements, *see, e.g., United States ex rel. Thompson v. Columbia/HCA Healthcare*, 125 F.3d 899, 902 (5th Cir. 1997) (*Thompson II*), and (3) the claimant failed to comply with a statute, regulation, or contract provision that was a prerequisite to payment, *see, e.g., United States ex*

rel. Augustine v. Century Health Services, 289 F.3d 409, 415 (6th Cir. 2002); *United States v. TDC Mgmt. Corp.*, 288 F.3d 421 (D.C.Cir. 2002). Violations of the AKS and the Stark Laws implicate the latter two categories.

A. Express certification

Two Circuit Courts of Appeals have articulated the noncontroversial proposition that an express certification of compliance with law, including the AKS and Stark Laws, can serve as the basis for establishing FCA liability where the certification is a prerequisite to payment. Both cases involved such express certifications on Medicare cost reports. In the first, the Fifth Circuit reversed a prior dismissal and remanded to the district court for further consideration of whether the certification of compliance was a prerequisite to program payment. *See Thompson II*, 125 F.3d at 899; *see also United States ex rel. Thompson v. Columbia/HCA Healthcare*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998) (*Thompson III*) (holding on remand that certification of compliance is a condition of payment under Medicare, applying doctrine of deference to agency expertise). More recently, the Third Circuit found that alleged violations of the AKS could serve as a predicate to FCA liability where a hospital certifies compliance with the statute in its annual cost report. *See United States ex rel. Schmidt v. Zimmer, Inc.* 386 F. 3d 235, 245 (3d Cir. 2004); *see also United States ex rel. Pogue v. Diabetes Treatment Centers of America*, 238 F. Supp. 2d 258, 266 (D.D.C. 2002) (*Pogue II*) (holding in the context of hospital claims that subsequent regulatory developments confirm that compliance with the AKS is a condition of, and material to, Medicare payment).

B. Implied certification

The more significant developments in the case law concerning the AKS and Stark Laws have come in the context of claims that are not the subject of an express certification of compliance. Courts, commentators, and litigants have adopted the short-hand term "implied certification" to describe cases in which FCA liability is based on the knowing violation of a statute, regulation, or contract provision that constitutes a prerequisite to payment. *See, e.g., Augustine*, 289 F.3d at 415.

While the label may be relatively new, the theory of liability is anchored in decades of

federal case law, much of which addresses allegations of defendant-generated government business by means of kickbacks, rigged bids, and other financial conflicts of interest. Regardless of the label applied, presentment of the claim for payment in each such case falsely represents an entitlement to payment that the claimant forfeited by violating a statute, regulation, or contract term that was a prerequisite to payment. In determining whether a particular provision is a prerequisite to payment, courts have used the standard tools of statutory construction—language, legislative history, and purpose.

The plain language of the FCA establishes that liability may attach for the submission of a false claim even in the absence of an express false statement. The statute clearly distinguishes between the "use of a false record or statement to get a false or fraudulent claim paid" (31 U.S.C. § 3729(a)(2)) and the submission of a "false or fraudulent claim for payment or approval" (31 U.S.C. § 3729(a)(1)) without the additional element of a false record or statement. It nevertheless imposes the same liability on both types of violation. *See Shaw*, 213 F.3d at 531-32 (highlighting the distinction between sections (a)(1) and (a)(2)). Moreover, the legislative history of the 1986 FCA amendments indicates that Congress intended the FCA to apply whenever a defendant is ineligible for payment, even if the defendant provided the product or service requested by the government. *See* S. Rep. No. 99-345 at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274 ("claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program"); (false claim "may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specifications, statute, or regulation"). *Id.* at 5274.

At least seven Circuit Courts of Appeal have explicitly recognized implied certification liability, in various contexts, under the FCA. The common theme in each is that FCA liability can be premised on an implied certification of compliance with law, regulation, or contract terms, so long as compliance with that provision or term was a prerequisite to receiving a payment or benefit. *See United States ex rel. Quinn v. Omnicare*, 382 F.3d 432, 442 (3d Cir. 2004); *Augustine*, 289 F.3d at 415; *United States ex rel. Siewick v. Jamieson Sci. & Eng'g.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000); *Shaw*, 213 F.3d at 519;

Ab-Tech Const. v. United States, 31 Fed. Cl. 429 (Fed. Cl. 1994), *aff'd without opinion*, 57 F.3d 1084 (Fed. Cir. 1995); *Murray & Sorrenson v. United States*, 207 F.2d 119, 123 (1st Cir. 1953); *see also United States ex rel. Mikes v. Straus*, 274 F.3d 687, 699-700 (2d Cir. 2001) (endorsing implied certification theory, but limiting its application in certain contexts).

Numerous district courts have also recognized the viability of the implied certification theory when a nexus between compliance and payment is established by the statutory, regulatory, or contractual terms at issue. *See, e.g., United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 55 (D. Mass. 2001) (dismissing kickback-related allegations for failure to allege express or implied certification or causal connection between alleged kickbacks and claims); *United States ex rel. Wright v. Cleo Wallace Ctrs.*, 132 F. Supp. 2d 913, 926 (D. Colo. 2000); *United States ex rel. Bryant v. Williams Bldg. Corp.*, 158 F. Supp.2d 1001 (D.S.D. 2001); *United States ex rel. Kneepkins v. Gambro Healthcare*, 115 F. Supp.2d 35, 41-42 (D. Mass. 2000).

While a few courts have approached implied certification theories skeptically and even critically, *see, e.g., United States ex rel. Willard v. Humana Health Plan of Texas*, 336 F.3d 375, 382-83 (5th Cir. 2003) (declining to address *Mikes* standard or to resolve viability of implied certification theory under Fifth Circuit precedent), no court has foreclosed implied certification liability. *See Franklin*, No. CIV.A 96-1165PBS, 2003 WL 22048255, at *7 (D. Mass. Aug. 22, 2003) (noting positive trend in recent case law); *Pogue II*, 238 F. Supp. 2d at 264-65 (finding no court of appeals to have rejected implied certification liability); *Thompson III*, 20 F. Supp. 2d at 1047-48 (commending the "thoughtful analysis" in *United States ex rel. Pogue v. American Healthcorp*, 914 F. Supp. 1507 (M.D. Tenn. 1996) (*Pogue I*), noting potential weakness of the implied certification theory, and nevertheless holding that the text of the Stark Laws renders claims submitted in violation thereof "actionable" under the FCA).

A current controversy in the development of case law in this area surrounds a standard articulated by the Second Circuit in *Mikes*, 274 F.3d at 687. The court held that, in the context of certain qualitative standards imposed on health care providers, an applicable regulation would need to expressly state that compliance was a

condition of payment for FCA liability to attach. *Id.* at 700. The government has since argued that the *Mikes* standard wrongly precludes a court from using all available tools of construction—language, Congressional and regulatory intent, and statutory, regulatory and programmatic structure—to determine whether a defendant's alleged failure to comply with a particular statute or regulation has a sufficient nexus to payment to render him ineligible to receive or retain the payment claimed from the United States, and, if so, whether the totality of the evidence supports the conclusion that the defendant knowingly submitted a false claim.

Notably, no other Court of Appeals to address the issue since *Mikes* has adopted its standard. *See Willard*, 336 F.3d at 375; *Augustine*, 289 F.3d at 416 (adopting *Shaw*). Most recently, in the context of an alleged violation of a health care regulation, the Third Circuit specifically rejected the *Mikes* standard as overly restrictive. *Quinn*, 382 F.3d at 443 ("Even though [the regulation] does not expressly condition payment on compliance with its terms, it hardly can be said that noncompliance with its terms is 'irrelevant to the government's disbursement decisions,'" quoting *Mikes* at 697). *Mikes* incorrectly and unnecessarily purports to establish a rule limiting the scope of implied certification liability, and is particularly inapt when applied in the context of financial conflicts of interest like those prohibited by the AKS and the Stark Laws.

C. Stark violations and implied certification

The Stark Laws provide a straightforward basis for application of the implied certification theory of FCA liability. The statute expressly prohibits the submission of claims for improperly referred services, *see* 42 U.S.C. § 1395nn(a), as well as program payment for those services, *see id.* 1395(g). This preclusion of Medicare coverage for Designated Health Services referred in violation of its prohibition is central to the FCA analysis. Courts addressing the issue have held unanimously that FCA liability will attach to knowing submission of a claim prohibited under the Stark Laws. *See, e.g., United States ex rel. Barrett v. Columbia/HCA Healthcare*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003); *Pogue II*, 238 F. Supp. 2d at 266; *Thompson III*, 20 F. Supp. 2d at 1046.

D. AKS violations and implied certification

Because FCA liability will attach to a defendant's alleged failure to comply with a particular statute or regulation that has a sufficient nexus to payment to render him ineligible to receive or retain the payment claimed from the United States, it follows that a violation of the AKS can give rise to liability under the FCA. As three recent decisions have specifically recognized, compliance with the AKS is a prerequisite to payment of federal funds and therefore can form the basis for an FCA claim. *See United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612 (N.D. Ill. 2003); *United States ex rel. Barrett v. Columbia/HCA Health Care*, 251 F. Supp. 2d 28 (D.D.C. 2003); *Pogue II*, 238 F. Supp. 2d at 266; *see also Franklin*, 2003 WL 22048255 at *7 ("The Court agrees with the government that recent case law supports implied-certification FCA claims in the healthcare context, including kickback-based claims.")

In each case, the United States demonstrated that the Social Security Act, itself, establishes that compliance with the AKS is a prerequisite to a provider's right to receive or retain federal funds. Under the majority view of implied certification—that a defendant submits a false or fraudulent claim when he violates a condition of payment, regardless of whether the provision states on its face that it is a condition of payment—the AKS unquestionably constitutes a proper basis for an FCA violation. Even if the Court were to apply the minority view set forth in *Mikes*—that the "underlying statute or regulation [must] expressly state [] that the provider must comply in order to get paid," 274 F.3d at 700—the United States submits that the plain language of the AKS establishes that compliance is a prerequisite to payment as a matter of law.

Critically, the government has asserted in each of these cases that defendants violated a central provision of the Medicare and Medicaid statutes and that they did so for the purpose of generating claims. *See* 42 U.S.C. § 1320a-7b(b). If the kickback allegations are true, defendants in these cases engaged in conduct proscribed by a criminal statute that establishes a *core term* of those reimbursement schemes. The link between the prohibited conduct (unlawfully inducing physicians to order reimbursable items and services) and the claims at issue (claims to federal health care programs for those very items and services) is apparent on the face of the AKS itself.

The statute establishes that the reimbursement scheme Congress designed for the Medicare program is one in which: (1) kickbacks would not be paid, (2) referrals could not be induced by kickbacks and, thus, (3) claims on such referrals and claims that would fund the kickbacks would not be presented for payment. As a matter of law, under this statutory scheme, compliance with the AKS is a prerequisite to receiving or retaining federal payments.

Conduct that violates the AKS is, by statutory definition, conduct *intended* to induce a referral or affect the decision to order items or services for which *payment* may be made under Medicare or certain other federal health care programs. The statute specifically focuses on paying off referral sources to obtain the opportunity to bill those programs. It is violated only when one purpose of paying kickbacks is to induce another person to refer, arrange for, or recommend referrals for the provision of "any item or service for which *payment* may be made in whole or in part under a Federal [or, prior to 1996, Medicare or Medicaid] health care program." 42 U.S.C. § 1320a-7b(b) (emphasis added); *see also Jain*, 93 F.3d at 441 (intent to induce referral of program-reimbursable business is an element of violation of 42 U.S.C. § 1320a-7b(b)(2)).

In the context of kickbacks paid to physician referral sources, FCA liability premised on a violation of the AKS attaches only when the provider submits a claim to a federal health care program *after*: (1) the provider violated the AKS by paying unlawful remuneration to the referral source in an effort to induce that source to refer, recommend, or arrange for patients to receive reimbursable items or services, (2) the provider received a referral from that source, and (3) the provider submitted a federal health care program claim on behalf of the unlawfully referred patient(s). Consequently, if providers complied with the AKS, no claim resulting from a kickback would ever be presented for payment. Accordingly, whatever view of implied certification a court ultimately adopts, the government argues that FCA liability attaches as a matter of law when a violation of the AKS knowingly results in the submission of a claim for payment under a federal health care program. *See Pogue II*, 238 F. Supp. 2d at 264 (implied certification liability premised on the AKS comports with *Mikes*).

IV. Other legal considerations

Now that the theory of liability has been established, the government, and relators in declined cases, have set out to litigate FCA liability for claims resulting from violations of the AKS and the Stark Laws. A number of legal issues not yet squarely addressed in any one court decision continue to arise in these cases. For example, FCA damages are clear in the context of a claim submitted in violation of the Stark Laws' prohibitions against billing and payment. The FCA damages in a Stark Laws-based case are the amounts paid on the illegally submitted claims. That statute presumes that the services were otherwise reimbursable, but effectively prohibits Medicare coverage nonetheless due to the relationship between the physician and the billing entity.

In an AKS context, however, defendants argue that damages cannot be established where the government receives what it otherwise bargained for—good quality, medically necessary items or services. In measuring loss for sentencing guidelines purposes, two courts have held that the government's losses from health care kickbacks were limited to the amount of the kickback paid in the illegal transaction. *See United States v. Liss*, 265 F.3d 1220 (11th Cir. 2001); *United States v. Vaghela*, 169 F.3d 729, 736 (11th Cir. 1999).

Consistent with the articulation of the theory of implied certification liability described above, the government has argued that, in a civil FCA context, courts should recognize that had the defendant complied with the law, no claim resulting from a kickback would have been submitted and, therefore, no payment would have been made on such a claim. In the context of kickbacks to referring physicians, the government has also asserted that the payment of a bribe to the individual upon whom the programs rely to certify medical necessity vitiates the bribing party's ability to rely on that certification to establish medical necessity. As a result, in a manner consistent with principles applicable in various other civil litigation contexts, the burden would be on the defendant at trial to *establish* that the services rendered were, despite the payment of a kickback, both medically necessary and of sufficient quality to warrant payment from the relevant health care program. The fate of these theories and resolution of these and other issues will define the future course of FCA litigation

involving violations of the AKS and the Stark Laws. ❖

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Internet Pharmacies and the Unlawful Distribution of Controlled Substances

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I. Introduction

The Internet enables us to communicate quickly and efficiently with individuals and businesses all over the world. It provides us with access to vast amounts of information and allows us to conveniently purchase

products without leaving our homes. As much as it permits legitimate commerce and communication, it also provides an avenue for the illegal dissemination of products, including prescription drugs and controlled substances.

At the time the Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 301-397, and the Controlled Substances Act, 21 U.S.C. §§ 801-971, became law, the Internet was either not in existence or not a widely-recognized method of communication and commerce. Even so, the criminal provisions of both statutes are available to prosecute those who distribute prescription drugs and controlled substances over the Internet by fraud or outside the scope of legitimate medical practice. Due to the nature of most criminal Internet pharmaceutical cases, charges of conspiracy and Continuing Criminal Enterprise (CCE), as well as money laundering and forfeiture, may also be appropriate.

E-mail boxes are full of advertisements enticing us to click here to get pharmaceutical drugs, diet drugs, Viagra®, steroids, or narcotics. The most widely prescribed controlled substances, hydrocodone combinations found in Vicodin®, Lortab® and related products, are often advertised on the Internet. Opening these advertisements will lead to a Web site where orders can be placed for the drug of choice, without having to visit a physician or a pharmacy. Completion of a questionnaire may or may not be required. For a price, which may be as much as ten times the cost at a neighborhood pharmacy, these drugs will be delivered right to your home. Chances are that most of these drugs are prescription drugs, and many times they are controlled substances. Sometimes they are counterfeit and oftentimes they are dangerous, especially when a teenager is placing the order so he or she can get high.

II. The operation

Is it legal to operate a Web site such as the one described above? Pharmacist Clayton Fuchs, physician Ricky Joe Nelson and others knew that it was not, and they got caught. Mr. Fuchs, who was convicted of operating a CCE, is currently serving twenty years in federal prison. Nelson is serving a fifty-one month federal sentence.

Clayton Fuchs, an unindicted co-conspirator, operated an internet pharmacy called "NationPharmacy.com" where customers could obtain prescription

and non-prescription drugs. In accord with federal law, all requests for prescription drugs were first reviewed by a physician, defendant Nelson, who either approved or denied the request. Nelson, however, approved 90-95% of all prescription drug requests and did so without ever examining his purported patient. Moreover, the vast majority of filled prescriptions were for hydrocodone, a powerful and addictive pain-killer and a Schedule III controlled substance.

United States v. Nelson, 383 F.3d 1227, 1228 (10th Cir. 2004).

Nelson approved over 4,000 prescriptions for hydrocodone in less than two months, coming periodically to the pharmacy and signing hundreds to thousands of prescriptions at one time. This is exponentially more than he could have written if he had seen and consulted with each patient before issuing a prescription. Nelson did not receive any payment from the customers, but instead was paid by the Web site operator for each prescription approved. The money was wired to an offshore account.

Pharmacists and physicians are usually involved in the operation of domestic Internet pharmacies. Suppliers will only sell pharmaceutical drugs to someone possessing a Drug Enforcement Administration (DEA) registration. In addition, nonmedical opportunists are involved in Internet pharmacy operations, acting as facilitators or organizers by hiring the doctors and pharmacists, and channeling money through a Web site which they often control. Many of the physicians associated with these operations have been terminated by hospitals, are under investigation, or have lost their license in one state and moved to another. They need money and are willing to authorize prescriptions based on a questionnaire.

There are, however, legitimate Internet pharmacies. Many of the major pharmacy chains have Web sites. Prescription drugs and controlled substances can be obtained lawfully from these pharmacies with a valid prescription. These pharmacies ensure they receive a valid prescription and that the physician has a relationship with the patient. Many of them have been certified by the National Association of Boards of Pharmacy

and have a Verified Internet Pharmacy Practice Site (VIPPS) symbol signifying this certification on their Web site.

Some of the uncertified Internet sites advertise that they will provide prescription drugs and controlled substances without a prescription. Some try to make themselves appear legitimate by requiring the customer to complete a questionnaire, which is reviewed by a physician, often many states removed from the customer or the pharmacy that will fill the order. Of course all these services require payment, usually between four and ten times what would normally be charged by your neighborhood pharmacy for the same drug. These sites do not take insurance or third-party payments.

In June 2004, the United States General Accounting Office (GAO) published a report on Internet pharmacies. U.S. GENERAL ACCOUNTING OFFICE, INTERNET PHARMACIES: SOME POSE SAFETY RISKS FOR CONSUMERS, GAO-04-820 (June 17, 2004) available at www.gao.gov/new.items/d04820.pdf. During the course of the investigation, GAO officials selected thirteen pharmaceutical drugs and attempted to make ten purchases of each drug on the Internet without a prescription. Three of the drugs selected were controlled substances: OxyContin®, Percocet®, and Vicodin®/hydrocodone. The GAO investigators selected pharmacies in the United States, Canada, and other foreign sites. They obtained eleven of the thirteen drugs selected, including one shipment of OxyContin® and nine of hydrocodone products. They were unable to obtain any Percocet®.

The GAO identified three types of Internet pharmacies in the report.

- Those operating as traditional drug stores, offering a wide variety of prescription drugs, and requiring a prescription.
- Those selling a limited range of pharmaceutical drugs, usually lifestyle drugs, and requiring the customer to complete a questionnaire.
- Those dispensing drugs without a prescription.

The hydrocodone prescriptions were obtained from Web sites requiring a questionnaire. In testimony before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate, on June 17, 2004, Robert J. Cramer, Managing Director of the Office of Special Investigations for the GAO, discussed the manner in which his investigators obtained hydrocodone products without a prescription through the Internet. For a cost of \$239, including a \$49 consultation fee, the investigator received sixty tablets of hydrocodone which would have cost \$26 at a local pharmacy. Even adding a fee for a doctor visit to obtain the prescription, the price was still two to three times the cost of obtaining the drug lawfully. See GAO-04-892T available at www.gao.gov/new.items/d04892t.pdf.

Distribution of pharmaceuticals and pharmaceutical controlled substances via the Internet is a significant method of diversion of these drugs from the legitimate market directly to drug abusers. Physicians approving hundreds of prescriptions in one day, and individual pharmacies distributing millions of doses of narcotics in a matter of months, makes large quantities of these dangerous controlled substances easily available for abuse. This type of operation enables the hundreds of thousands of individuals who abuse these drugs, including many teenagers, to obtain significant quantities without ever having any direct contact with a medical professional.

III. Theory of prosecution

In order for a consumer to lawfully obtain a pharmaceutical controlled substance, either from a neighborhood "brick and mortar" pharmacy, or an Internet pharmacy, the consumer must obtain a prescription issued for a legitimate medical purpose by a physician within the scope of professional practice. See *United States v. Moore*, 423 U.S. 122 (1975).

The Supreme Court in *Moore* held that a physician could be prosecuted under the criminal provisions of the Controlled Substances Act when that physician acts outside the scope of professional practice. The Court further stated that a physician who acts

outside the scope of professional practice acts "as a large-scale 'pusher' not as a physician." *Id.* at 143. Pharmacists have a responsibility to fill only valid prescriptions. If they knowingly fill an invalid prescription or distribute controlled substances without a prescription, they are subject to prosecution under the Controlled Substances Act.

The language which the Supreme Court adopted in *Moore* comes from a regulation promulgated by the DEA shortly after the Controlled Substances Act was passed in 1970. The regulation, found at 21 C.F.R. § 1306.04(a) states in part:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

Assume someone visits a Web site from their home in Virginia, fills out a questionnaire which goes to a physician in Oklahoma who superficially reviews it and then sends an order to a pharmacist in Florida, who fills it and mails it to you. Is this within the scope of professional practice, for a legitimate medical purpose? The organizations who regulate both physicians and pharmacists say "No" because there is not a valid doctor-patient relationship. The DEA says "No" because there is no valid prescription. So how do you prove this to a jury?

As a prosecutor, you must convince the jury that the conduct of the defendants was unlike any experience they have ever had when obtaining a prescription. Completing a questionnaire which is reviewed by someone the customer has never met, who has never examined or taken a medical history from the customer, or used diagnostic or laboratory testing, is not professional practice. A physician who reviews a questionnaire is also unable to determine that the information on the questionnaire is correct. Physicians like Ricky Joe Nelson are now in federal prison for issuing prescriptions for controlled substances based on a cursory review of a

questionnaire. See *United States v. Nelson*, 383 F.3d 1227 (10th Cir. 2004).

The Federation of State Medical Boards, an organization representing the medical licensing boards of the fifty states and the District of Columbia, has issued *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*. These model guidelines may be found at http://www.fsmb.org/Policy Documents and White Papers/Internet_use_guidelines.htm. Included in the guidelines is the statement, "[t]reatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care."

The National Association of Boards of Pharmacy, an association representing the pharmacy licensing boards of the fifty states and the District of Columbia has created a certification program for Internet pharmacies. In addition, on their consumer page discussing signs of a suspect pharmacy, they state "online pharmacies are suspect if they dispense prescription medications based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination." Available at www.nabp.net/vipps/consumer/faq.asp.

The DEA has also published guidance in this area. In 2001, the DEA, the federal agency that registers physicians and pharmacies authorizing them to dispense controlled substances, published a notice in the Federal Register entitled, "Dispensing and Purchasing Controlled Substances over the Internet." 66 Fed. Reg. 21,181 (Apr. 27, 2001). The notice indicates that consumers must have a valid prescription to obtain controlled substances via the Internet, and in order to obtain controlled substances from foreign sources, they must obtain a DEA registration as an importer.

Is a showing that a Web site disregarded the guidance from organizations representing federal and state licensing boards and regulatory agencies enough to support a prosecution for unlawful distribution of a controlled substance for other than a legitimate medical purpose? Probably not, but it establishes that a physician or pharmacist

should know that their conduct did not conform to proper medical practice as established by regulatory boards and agencies.

As a prosecutor, it will be necessary to demonstrate that a defendant's conduct was outside the scope of professional practice and not for a legitimate medical purpose. This may require the use of an expert witness to review the practices of the defendant and provide an opinion as to whether the conduct was outside the scope of professional practice.

When prosecuting the pharmacist working for the Internet pharmacy, the government must show that the pharmacist knew, or should have known, that the prescriptions filled were not valid. "[I]f the drug-dispensing pharmacist knows that a customer not only lacks a valid prescription but also will not use the drugs for legitimate medical purposes, then section 841 applies in full flower and treats the dispenser like a pusher." *United States v. Limberopoulos*, 26 F.3d 245, 250 (1st Cir. 1994).

As a professional, there are indicators that prescriptions for controlled substances are not valid. Proof that these indicators were present and that the pharmacist knew about them is the kind of evidence that will establish conduct outside the scope of professional practice. These include: lack of a doctor-patient relationship including evidence that the doctor did not have face-to-face contact with the patient or even a telephonic consultation, excessive payments for the drugs, and prescriptions limited to a few selected and highly abused controlled substances.

Individuals without medical training or credentials that facilitate these activities may be charged under this same theory as coconspirators or accomplices. By participating in the conspiracy or aiding and abetting unlawful distribution of controlled substances outside the scope of medical practice, they are equally culpable. *See United States v. Johnson*, 831 F.2d 124 (6th Cir. 1987).

IV. Charging considerations

The Supreme Court case of *United States v. Moore*, 423 U.S. 122 (1975), established that a physician registered by the DEA may be prosecuted under the criminal provisions of the Controlled Substances Act. Several federal appellate courts have found the same to be true with regard to pharmacists. Although pharmacists are not individually registered with the DEA, they have a corresponding responsibility with the physician.

Charges for Internet organizations do not differ significantly from those levied against any other criminal drug trafficking organization. The basic charge in any case involving controlled substances is the criminal trafficking charge in 21 U.S.C. § 841(a)(1). This is also the foundational charge in any Internet pharmacy case. This charge may be used for every unlawful distribution of a controlled substance, but doing so in a case that involves thousands of transactions would be unwieldy and impractical. The distributions are often grouped by drug and time frame. However, selected distributions, such as those made by undercover investigators, are often charged individually.

When medical professionals with a DEA registration are involved, it is prudent to add to the traditional language of a § 841(a)(1) charge that the individual acted outside the scope of professional practice and not for a legitimate medical purpose. An example of such a charge would be the knowing, intentional, and unlawful distribution of a Schedule III controlled substance containing hydrocodone, outside the scope of professional practice and not for a legitimate medical use in violation of 21 U.S.C. § 841(a)(1).

Conspiracy charges are common in Internet pharmacy cases because there are often multiple individuals involved, both medical professionals and others necessary to facilitate the transactions. These individuals may be charged with a conspiracy to knowingly, intentionally, and unlawfully distribute and possess with intent to distribute controlled substances (specifically list drugs and Schedules) outside the scope of medical practice and not for a legitimate medical

purpose, in violation of 21 U.S.C. §§ 841(a)(1) and 846.

Since the Internet is used to facilitate the unlawful activities, 21 U.S.C. § 843(b) may also be charged. This charge makes it unlawful to use a communication facility in causing or facilitating a violation of the Controlled Substances Act. The maximum statutory penalty for this offense is four years imprisonment.

In many cases, the organizer or leader of the enterprise operating the Internet pharmacy may be charged with operating a CCE under 21 U.S.C. § 848. While this statute provides a mandatory minimum penalty of twenty years imprisonment to life regardless of the controlled substance involved, it can be complicated to prove and does have several elements over and above the normal drug conspiracy charge. This charge was used successfully in prosecuting pharmacist Clayton Fuchs in the Northern District of Texas as mentioned in the introduction to this article. There are five elements required to prove the CCE charge.

- The defendant's conduct must constitute a felony violation of the Controlled Substances Act, 21 U.S.C. § 848(c)(1).
- The conduct must be part of a continuing series of violations, 21 U.S.C. § 848(c)(2).
- The defendant must act in concert with five or more persons, 21 U.S.C. § 848(c)(2)(A).
- The defendant must be the organizer, supervisor, or manager of the criminal activity, 21 U.S.C. § 848(c)(2)(A).
- The defendant must obtain substantial income or resources from this enterprise, 21 U.S.C. § 848(c)(2)(B).

A. Money laundering

Charging money laundering in an Internet pharmacy case can be beneficial in a number of areas. Motive for the crime and showing that the defendants were acting outside the scope of professional practice can often be demonstrated by the movement of large sums of money to offshore banks and the purchase of luxury items. Showing the movement of the money can also demonstrate that the

physician and the pharmacist were not paid by the customer, as is customary in a legitimate transaction. It also shows that payment was made through a Web site and that highly inflated prices were charged for the "medical consultation" and the drugs. These factors help demonstrate that the pharmaceutical drugs were not dispensed for a legitimate medical purpose.

Charges under 18 U.S.C. § 1957, engaging in a monetary transaction greater than \$10,000 derived from a specified unlawful activity, or 18 U.S.C. § 1956(h), conspiracy to launder money, are the provisions most commonly used in these cases, although specific circumstances may dictate other money laundering charges.

B. Forfeiture

Either criminal, 21 U.S.C. § 853, or civil, 21 U.S.C. § 881, forfeiture provisions may be used to divest these internet pharmacy organizations of their ill-gotten gains. This may include forfeiture of homes, offices, and pharmacies where the illegal conduct occurred. Bank accounts, third-party payer accounts, vehicles, and even professional licenses may be subject to forfeiture. Since these organizations take in significant profits, these forfeitures often run into millions of dollars.

V. Sentencing

The statutory penalties for trafficking offenses for controlled substances are found at 21 U.S.C. § 841(b). There are no minimum mandatory penalties for trafficking in any of the pharmaceutical controlled substances. However, if the pharmaceutical is a Schedule I or II controlled substance and the unlawful distribution resulted in death or serious bodily injury, there is a mandatory minimum penalty of twenty years to life imprisonment. Convictions under the CCE provision are subject to at least a twenty year to life term of imprisonment.

Most pharmaceutical controlled substances distributed via the Internet outside the scope of professional medical practice are Schedule III and IV controlled substances. The hydrocodone combination products are

Schedule III, and the diet drugs, including phentermine, are Schedule IV controlled substances. The maximum statutory penalty for a Schedule III controlled substance is five years imprisonment and for Schedule IV it is three years.

Under the United States Sentencing Commission Guidelines, the offense levels for pharmaceutical controlled substances in Schedules III-V are calculated not by total weight, but by units. One tablet or capsule or .5 ml of liquid is equal to one unit. The medical professionals that are prosecuted may also be subject to a two-level upward adjustment for abuse of special position of trust or special skill under U.S.S.G. § 3B1.3.

There is a new provision in the Sentencing Guidelines that relates specifically to controlled substance cases involving the Internet. The Sentencing Guidelines were amended effective November 1, 2004 to include an upward adjustment of two points for an individual who "distributed a controlled substance through mass-marketing by means of interactive computer service." U.S.S.G. § 2D1.1(b)(5).

VI. Conclusion

The Internet is a fast and easy way for those who want to abuse drugs to get them without having to demonstrate a medical need. It is easy to lie on a questionnaire. A college student wants stimulants, like phentermine, to keep awake. Will a legitimate physician prescribe them? Not likely. So they log on to their computer, go to one of hundreds of Web sites offering such drugs, and complete a questionnaire stating that they weigh 200 pounds when their actual weight is 125. A physician in a far away state they have never seen or spoken to "prescribes" phentermine for weight control. How is the doctor reviewing the questionnaire going to know the student only weighs 125 pounds? They do not know. They are causing the distribution of controlled substances outside the scope of professional practice, a criminal violation of the Controlled Substances Act. The pharmacist who fills such a "prescription" is also distributing a controlled substance outside the scope of professional practice.

Internet pharmacy cases are being successfully prosecuted by United States Attorneys' Offices around the country. Such prosecutions can have a substantial impact on the availability of these dangerous drugs to those who abuse them. ❖

ABOUT THE AUTHOR

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The Medshares Bankruptcy: Bankruptcy, Fraud, and Patience

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Health care provider bankruptcies can be complex, and health care fraud suits are sometimes part of the complexity. The limited resources available for distribution to creditors and the priorities established by the Bankruptcy Code will sometimes yield results that seem less than satisfying to some government players. The Medshares bankruptcy case in Memphis is an instance where a cooperative spirit among government attorneys and an abiding patience ultimately yielded a result that the various federal interests found satisfactory.

In 1999, Meridian Corporation, d/b/a Medshares, and its subsidiaries filed 103 Chapter 11 bankruptcy cases in the Western District of Tennessee. Two weeks later, Medshares filed an additional twenty-five cases. The Court consolidated these 128 cases for administration as a single Medshares case. Most of the Medshares corporations operated home health agencies that held Medicare provider agreements with the Centers for Medicare & Medicaid Services (CMS) (the Health and Human Services (HHS) component that administers Medicare). When Medshares filed bankruptcy, it was one of the largest chains of home health providers in the nation. Medicare reimbursement constituted the lion's share of its revenues.

A number of problems contributed to the Medshares bankruptcy. Alarmed by the runaway growth in Medicare expenditures for home health and by the abuses prevalent in the industry, Congress significantly cut Medicare reimbursement for home health services, in the Balanced Budget Act of 1997. These changes triggered many bankruptcy filings by home health agencies across the country, resulting more often than not in shutdowns and liquidations. Other factors leading to the Medshares bankruptcy were specific to Medshares itself. Medshares aggressively expanded, primarily by the acquisition of numerous home health agencies from other companies, but was unable to shoulder

the resulting debt obligations. In fact, Medshares began the process of shutting down many of its home health agencies even before the bankruptcy filing.

The United States was, by far, the largest creditor in the Medshares bankruptcy case. Medshares owed the Internal Revenue Service (IRS) millions of dollars in unpaid taxes and Medicare overpayments. Many of the Medicare overpayments were attributable to the recently-implemented changes in the Medicare law and others arose from Medicare cost-report audits. In addition, Medshares faced a large fraud judgment for a home health agency that it had purchased.

There were health care fraud civil judgments owed by Medshares for alleged actions of its own. In 1998, Van Vincent, an AUSA in the Middle District of Tennessee (Nashville), obtained a judgment against one of the Medshares corporations in *United States ex rel. Doyle and Niemi v. North Central Homecare of Tennessee*, Civ. No. 3:96-0427 (M.D. Tenn. Jan. 30, 1998). Later, Vincent also obtained a judgment against Medshares in *United States ex. rel. A+ Homecare, Inc. v. Medshares Management, Inc., Trevecca Home Health Care, Inc. and Stephen Winters*, Civ. No. 97-0488 (M.D. Tenn. Sept. 13, 2003).

When Medshares filed for bankruptcy, there were also open investigations and pending suits for health care fraud in other jurisdictions. AUSA Bill Siler was working on *United States ex. rel. Cynthia A. Wingfield v. Medshares, Inc.*, Civ. No. 99-2042 (W.D. Tenn. Jan. 15, 1999). In the Western District of Kentucky, AUSA Bill Campbell handled *United States ex. rel. Employees of HJM 1-86 v. Homecare and Hospital Management, Inc.*, Civ. No. 3:99CV0340-H (W.D. Ky. May 26, 1999). AUSA Connie Frogale was working on *United States ex. rel. Dana Hutcherson, Sabra Sherrill, Deborah Javins, and Regina Pettaway v. All-Care Home Health Services of Virginia, Inc.*, Civ. No. 00-1166-A (E.D. Va. Jul. 13, 2000). In the Southern District of Florida, AUSA Barbara Bisno was examining the Medicare claims billing practices of certain Medshares providers in the Miami area, though no formal complaint was filed. Vanessa

Reed, an attorney in the Civil Fraud Division of the Department of Justice (Department), oversaw and coordinated these cases.

The United States has traditionally represented itself as one creditor in the bankruptcy courts, and the courts have consistently recognized the status of the United States as a "unitary creditor." Nonetheless, various federal agencies will have distinct, and sometimes conflicting, stakes in a particular bankruptcy case. CMS, as a payer of health care services through the Medicare program, has a different type of relationship with a bankrupt health care organization than does the IRS.

In the Medshares case, the diverse federal interests could have been at odds at different points, but the cooperative spirit of the various government attorneys involved—those named above, as well as Ford Holman in Nashville, representing the IRS, Raja Sekharan, then with the HHS Office of Inspector General (OIG) in Washington, and Greg Bongiovanni in Atlanta, representing CMS—permitted the United States to present a consistently united front. It was an alignment that ultimately inured to the benefit of all the various federal interests at stake in the Medshares case.

The first task for the government players was to educate each other on the status that their respective claims against Medshares would have under different scenarios in a bankruptcy. CMS, as a payer, and as a party to scores of active Medicare provider agreements with Medshares, had the biggest ongoing stake in the case. It also had the advantage of recouping Medshares' Medicare overpayments, in those instances where the provider continued to operate and to bill the Medicare program, by offsetting against currently owed Medicare reimbursements. Indeed, CMS recouped approximately \$45 million during the bankruptcy process.

In addition, the bankruptcy courts recognize the Medicare provider agreement as an executory contract, a breach of which must be cured if Medshares continues that contract (i.e., CMS must be repaid if Medshares wants to continue as a Medicare provider). Even though CMS had a lot of leverage, it only mattered for those Medshares entities that remained in business. In the event of a Medshares shutdown and liquidation, CMS would hold nothing but a general unsecured claim, the sort of claim that typically receives little, if any, payment.

The IRS faced its own challenges. Because the IRS had not recorded tax liens before the bankruptcy began, the Medshares tax debt was not secured. The priority status of the IRS required payment of most of Medshares' outstanding taxes if Medshares was going to have a reorganization plan confirmed. 11 U.S.C. § 1129. However, if Medshares were to sell its assets, there would be no requirement that the IRS get paid. As for the fraud cases, any judgment or settlement amount would hold the status of an unsecured claim. From the onset of the bankruptcy, it was clear that Medshares was *not* likely to come out of bankruptcy intact. There would either be a sale of portions or all of the Medshares home health empire, or there would be a total shutdown and liquidation.

The most significant player in the Medshares bankruptcy, other than the United States, was National Century Financial Enterprises (NCFE). NCFE was Medshares' secured lender, and it was owed millions of dollars. NCFE had Medshares over a barrel. The financing company had effectively gained operational control of Medshares prior to the bankruptcy filing. NCFE lawyers were actually on-site in the Medshares corporate offices on a daily basis. In addition, NCFE forced Medshares to appoint NCFE's people to the Medshares' Board of Directors.

NCFE continued to fund Medshares after the bankruptcy filings because they had a plan. It was their intention to create a new subsidiary that would purchase Medshares outright. One of NCFE's most significant actions was to force the ouster of Stephen Winters, founder and chief executive officer of Medshares. AUSA Vincent's personal fraud judgment against Winters in the *A+ Homecare* case in Nashville alerted NCFE that HHS could exclude Winters from participation in Medicare. If Winters were excluded from the Medicare program, Medshares would lose its primary stream of income, which would render Medshares worthless to NCFE. Accordingly, Winters was ousted. Winters unsuccessfully appealed the fraud judgment to the Court of Appeals for the Sixth Circuit. Ultimately, the fraud judgment led to Winters' exclusion from participation in the Medicare program for a period of ten years.

NCFE proposed an asset sale from Medshares to NCFE's new subsidiary pursuant to 11 U.S.C. § 363 of the Bankruptcy Code. In a § 363 sale, a debtor sells assets and pays creditors with

proceeds from the sale, in an order of priority outlined in § 1129 of the Code. If the proceeds are insufficient to pay all creditors in full, then those debts go unpaid. NCFE held such tight control that no one else had a meaningful opportunity to make an offer. NCFE refused to allow potential purchasers to examine Medshares financial records to determine if they wanted to make a bid. Ultimately, it took a court order to compel NCFE to open the financial records to other prospective purchasers.

In the initial months of the bankruptcy, NCFE (and to the lesser extent that it had a voice, Medshares itself) attempted to refute CMS' authorities and to undermine CMS' position of power. NCFE maintained that the Medicare payment adjustment process was not recoupment, that a lender's security interest trumped any recoupment process, that Medicare provider agreements were not executory contracts and there was no need to cure overpayments and defaults, and that Medicare overpayment obligations could be expunged in a sale of assets under the Bankruptcy Code. These arguments, all of which were very familiar to CMS, were refuted. NCFE came to understand that they needed to make CMS whole for any Medicare overpayments that occurred in the past if the respective Medicare provider agreements were to advance. Medshares was of little value to anyone without those provider agreements and the substantial payment source that they represented.

Consequently, NCFE offered to repay the Medicare overpayments, but proposed to pay nothing on the IRS debt and the fraud obligations. NCFE knew that bankruptcy law would not compel payments on those accounts in a sale scenario. Here the various U.S. interests had to unite. CMS indicated that if NCFE wanted *any* concessions out of CMS, for example, regarding payment terms, or any forbearance from recouping certain of the providers' Medicare overpayments while the sale was pending, then NCFE needed to make some concessions in favor of the other U.S. interests.

A lengthy period of time went by as the parties attempted to reach acceptable terms. The United States got some breathing room in October 2000, when the era of cost-based reimbursement for home health services ended, and the Medicare home health prospective payment system (PPS) took effect. This new payment methodology greatly reduced the risk of any further Medicare

overpayments being made and Medshares was keeping up with its post-petition federal taxes, so the prospect of additional financial harm to the United States was minimal.

In the meantime, however, rumors started circulating about problems at NCFE. The Federal Bureau of Investigation (FBI) made a well-publicized raid on NCFE's offices. After much speculation, NCFE filed its own bankruptcy case in the Southern District of Ohio. This ended the rounds of negotiations on a sale of Medshares to a new NCFE subsidiary. The prospects for a resolution of the Medshares bankruptcy were at a stalemate. At this point prospective purchasers could approach Medshares unimpeded by NCFE. Several prospective purchasers emerged, though none proposed terms that were acceptable to the United States.

Some of the Medshares providers had no outstanding Medicare overpayments that needed to be cured and others had staggeringly large overpayment balances. Accordingly, the United States encouraged prospective purchasers to focus their sights on those Medshares' providers that had modest overpayment obligations that needed to be cured. However, many of the home health agencies with the largest overpayment obligations also happened to be high-volume operations, and prospective purchasers viewed them as particularly attractive acquisitions.

The CMS attorney was aware that there was a growing pot of money that could be used as an element in the negotiations. As the Medicare program was auditing and settling old cost reports, it became clear that some Medshares providers had been underpaid by Medicare in certain fiscal years. Specifically, there was approximately \$3 million in Medicare underpayments due to defunct Medshares home health providers that had left behind no overpayment balances against which to post the underpayments as recoupment adjustments. In the absence of some approvable arrangement, these funds would have to be paid to Medshares. CMS' attorney suggested that the United States negotiate to keep these underpayments, to be credited as a recovery in several health care fraud cases, for which the United States was otherwise extremely unlikely to recover anything.

Eventually, Intrepid U.S.A., a large, Minneapolis-based health care company that operated home health care providers around the country, emerged to express interest in purchasing

the remaining Medshares providers. Intrepid appreciated the insistence of the United States that its various interests be addressed in any sale negotiation. In return, for some modest concessions by CMS, Intrepid agreed to pay \$18.6 million to CMS at closing, as a cure for the outstanding Medicare overpayments of the home health providers being purchased. Although bankruptcy law did not require it in the context of a sale, Intrepid also agreed to pay \$7 million of Medshares' old tax debts, in installments. The IRS attorney obtained his agency's approval of this proposal. Moreover, Intrepid agreed to support the United States retention of the defunct providers' \$3 million in Medicare underpayments, as a recovery on the fraud cases, and to also sign a corporate integrity agreement with the HHS/OIG.

Intrepid negotiated with NCFE to purchase the latter's secured claim in the Medshares bankruptcy for cash. Intrepid stepped into NCFE's shoes for the purpose of the Medshares bankruptcy, with the purchase of the secured NCFE claim. To gain the support of the creditors' committee for the sale, the parties negotiated to provide the unsecured creditors with a modest recovery from the proposed sale. The only significant opposition to the sale came from Stephen Winters, the ousted former CEO of Medshares, who harbored hopes of regaining control of the company. The United States notified the court that Winters had been excluded from the Medicare program for ten years and that he could have no affiliation with Medshares (ownership, management, employment) without jeopardizing Medshares' relationship with the Medicare program. Winters eventually filed a personal bankruptcy case.

The court approved a § 363 sale of Medshares' assets to Intrepid. DVI, Inc., Intrepid's longtime lender and their intended source of financing for the Medshares acquisition, was in financial trouble. After Intrepid made an initial payment of \$6 million to CMS and began its installment payments to the IRS, DVI's problems reached a crisis point and DVI declared bankruptcy.

Intrepid asked CMS for time in which to locate an alternate source of financing. The Medshares deal had called for Intrepid to complete its \$18.6 million payment obligation to CMS quickly. CMS had not negotiated a deal for installment payments. Nonetheless, in the interest of giving the deal a chance to survive, CMS gave

Intrepid several months in which to locate alternate financing and to complete the repayment of the Medshares overpayments, with an immediate recoupment of those overpayments due if Intrepid missed its deadline.

The entanglement in DVI's financial problems led Intrepid to file Chapter 11 bankruptcy in the District of Minnesota. Intrepid, however, was well aware that recoupment would commence if it did not complete its repayment obligations to CMS. Intrepid located a post-petition source that agreed to lend sufficient funds to cover the CMS obligation. Intrepid asked CMS for one final month's grace to get court approval for the financing and for payment to CMS. CMS made this one last accommodation on the condition that Intrepid become current on some other outstanding Medicare overpayment obligations of its own. Intrepid completed payment of the amount due to CMS.

In the end, after twists and turns, false starts and dead ends, the outcome in the Medshares bankruptcy was a good one for the United States. CMS recouped \$45 million in Medicare overpayments over the course of the case and then received \$18.6 million in payment. The United States retained an additional \$3 million in Medicare underpayment funds and applied them toward the various Medshares health care fraud cases, yielding a significant recovery on the consent judgments that each of the AUSAs had reached with Medshares. Intrepid continues to operate the former Medshares home health agencies under a corporate integrity agreement with the HHS/OIG. The unpaid Medshares tax obligations will be treated in Intrepid's Chapter 11 bankruptcy plan.

The spirit of cooperation and accommodation among the attorneys representing the various federal interests carried the day in the Medshares bankruptcy. The willingness to present a united front in negotiations and in court, to compromise among themselves on individual points, and to abide patiently through unexpected turns in the bankruptcy case, ultimately served the interests of the United States well. ❖

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Notes



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