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Table of Contents

Providers and Patients Pay the Price When CMS Plays Doctor

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On October 30, 2015, the U.S. Department of Justice (DOJ) announced that it settled False Claims Act (FCA) allegations against hundreds of hospitals based on Medicare claims that allegedly did not comply with a National Coverage Determination (NCD) for implantable cardiac defibrillators.[1] Among other things, the DOJ investigation of defibrillator claims exposed the significant FCA risk for hospitals and physicians when a Medicare NCD is inconsistent with accepted standards of medical practice.

As counsel for health systems involved in the investigation, the authors observed this coverage gap first-hand. DOJ attorneys leading the investigation consulted with preeminent cardiologists and recognized that Medicare policy did not cover several categories of defibrillator implants that were considered the standard of care. During its five-year investigation, DOJ began a dialogue with the medical community and the Centers for Medicare & Medicaid Services (CMS) about the contours of that coverage gap, which persists today.

This article's purpose is to advance that dialogue, to make suggestions for CMS to consider to avoid unintended coverage gaps in national coverage policies, and to explore how coverage gaps create FCA risk for hospitals and physicians.

The article poses a hypothetical clinical scenario to demonstrate the practical implications of one such coverage gap that is familiar to many hospitals and cardiologists. We then review the DOJ's defibrillator investigation and settlement as a prelude to addressing, more generally, the increased FCA risk that arises when CMS' coverage policies erode or eliminate the role of physician judgment.

Setting the Stage

Imagine the following scenario: you rush your 75-year-old father to the emergency room because he has chest pain and difficulty

breathing. Following an angioplasty with stent insertion, your father's cardiologist advises him, based on his clinical history and worsening heart failure symptoms, to undergo implantation of a cardiac device called a CRTD.[2] Implanted in the chest, a CRTD functions as both a defibrillator to prevent sudden death from a lethal fast heart rhythm and a pacemaker that improves function in a weak heart. Your father's physician believes that the CRTD could save his life.

But before the surgery can proceed, your father is informed that Medicare will not pay the bill.[3] The implantation will cost more than $25,000, and it is not covered by Medicare under these circumstances, irrespective of the physician's determination of medical necessity.[4]

Your father, or the hospital, would have to pay for the CRT-D surgery, a medically necessary, potentially life-saving procedure.[5] If the hospital were to submit a claim to Medicare for a CRT-D in this scenario, the hospital may be alleged to have engaged in fraud.

This is one common example of a situation involving implantation of a cardiac defibrillating device that is recommended under professional medical guidelines but is not covered by Medicare's ten-year old NCD (NCD #20.4) for implantable cardioverter defibrillators (ICDs), which contains the exclusive indications for coverage.[6] This example demonstrates the financial hardship for the beneficiary—and the potential liability for unwary providers—when an expensive, medically necessary service is not covered by Medicare.[7]

DOJ Defibrillator Investigation and Settlement

In its October 2015 press release about the defibrillator settlements, DOJ announced it settled FCA allegations with 457 hospitals in 43 states.[8] The settlements total more than $250 million, and more settlements may be in the pipeline.

The qui tam relators who filed the action were a cardiac nurse and a health care reimbursement consultant. They named as defendants virtually all of the 457 hospitals covered by the settlement.[9] Obviously, these individuals did not have personal knowledge of the cardiac programs or billing compliance procedures of all of those hospitals. Rather, the relators honed in on the highly technical details of an old NCD, alleged that noncompliance with the NCD's exclusive coverage criteria constituted fraud, and ultimately obtained $38 million as a result.[10]

Divergence of Standard of Care from NCD

When DOJ intervened in the action, prosecutors recognized that modern medical guidelines have diverged dramatically from the medical necessity criteria in the NCD, which was last revised in 2005.[11] DOJ conferred with leading cardiologists and defense counsel and developed proposed settlement guidelines that *excluded* many categories of defibrillator claims—like the hypothetical CRT-D scenario above—that may have violated the technical requirements of Medicare's coverage criteria but were consistent with accepted standards of medical practice.[12]

In the end, DOJ's probe primarily targeted, and undoubtedly significantly reduced the number of, implants that both fail to comply with the Medicare NCD and *also* are not medically indicated by evidence-based standards of medical practice.[13]

The defibrillator NCD remains in effect, however, and it still fails to cover implants that DOJ implicitly recognized as medically appropriate.[14] And there is reason for concern that the publicity surrounding the defibrillator settlement, as well as the award of more than $38 million to the two relators who filed the qui tam action, could inspire copycat lawsuits brought by other relators who have little incentive to exercise the discretion and relative restraint shown by DOJ during the defibrillator investigation.

Data Mining Versus Physician Judgment

It is understood that DOJ employed data mining to refine the relators' allegations. With some exceptions, the defibrillator NCD precludes coverage of a defibrillator implant within three months of a coronary angioplasty or bypass, or within 40 days after an acute myocardial infarction (a heart attack).[15] Thus, the NCD creates mandatory "waiting periods" during which, with limited exceptions, Medicare has deemed any defibrillator implant to be *not* medically necessary, irrespective of applicable professional guidelines and the medical judgment of the beneficiary's physician.

Data mining can be an especially useful enforcement tool when a Medicare coverage policy, such as the defibrillator NCD, establishes the exclusive medical indications for coverage and allows no room for a physician's determination of medical necessity.

Relying on coding data, DOJ generated lists of defibrillator procedures from 2003 through 2010 involving beneficiaries who had recently experienced myocardial infarction, angioplasty, or bypass surgery. Once the appropriate codes were identified, the task of identifying suspect claims associated with the required waiting periods under NCD #20.4 could not have been difficult.

By all accounts, however, CMS had not previously undertaken any such review or provider education about the waiting periods; it had consistently paid defibrillator claims without cross-checking them against billing codes for procedures and diagnoses triggering the NCD's waiting periods.

As noted, however, DOJ's settlement approach did not rest solely on data mining; it adopted clinical review protocols that reflected the realities of modern medical practice.[16] Even DOJ's press release announcing the defibrillator settlement referenced DOJ's respect for physician judgment.[17] Nevertheless, a hospital submitting claims to Medicare for defibrillator procedures may not rely on the physician's judgment

alone, because the NCD does not currently incorporate all of the professional guidelines that physicians follow.

With heightened awareness of this issue in the wake of the DOJ settlement, the mandatory waiting periods in the NCD still may be fertile ground for FCA allegations or audit findings based purely on data mining.

How to Close Unintended Coverage Gaps in Medicare NCDs

Many NCDs contain an exclusive list of medical indications that support coverage for an item or service. In addition to the defibrillator NCD (#20.4), other examples include the NCDs for cardiac pacemakers (#20.8) and balloon angioplasties (#20.7). Items and services furnished for non-listed indications are deemed to be not "reasonable and necessary."[18]

Notwithstanding the "snapshot-in-time" specificity reflected in the clinical criteria articulated in many NCDs, CMS is not required to update its coverage policies.[19] Coverage gaps can arise over time as professional standards evolve, particularly for cutting-edge technologies and complex medical procedures, unless policies are updated.

CMS could avoid unintended coverage gaps by: (1) regularly updating medical necessity criteria in coverage policies; (2) incorporating a sunset clause in coverage policies that involve complex medical treatments (e.g., "this policy will expire within three years"); *and* (3) recognizing a "safety-valve" exception that allows payment on a claim based on a physician's determination of medical need in accordance with established professional guidelines.

The defibrillator NCD, for example, has no expiration date and allows coverage only for indications that had been studied in clinical trials before 2005, when NCD #20.4 was last revised. More than 200,000 patients receive defibrillator implants each year in the United States, and many of them have well-documented medical indications that simply had not been studied in clinical trials ten years ago.[20] Those patients are left out.

Since 2005, hundreds of new studies have been conducted related to defibrillators, leading to *four* significant revisions of the cardiology community's professional guidelines for implantation of defibrillating devices.[21] While medical science marches on, the defibrillator NCD remains frozen in time.

Returning to the CRTD hypothetical above, the currently accepted standard of care calls for performing the CRT-D implant without waiting 90 days after the patient's angioplasty, as Medicare policy requires, provided the patient has been diagnosed with heart failure and has other clinical conditions recognized in professional guidelines.[22]

The *Journal of the American College of Cardiology* has advised cardiologists of the discrepancy between the standard of care and CMS' view of medical necessity. In April 2012, the *Journal* described specific clinical scenarios when the defibrillator NCD departs from "more flexible, nimble, and updated published guidelines . . . based on evolving medical evidence and created by committees of experts":

> It is these published and vetted pathways that have precedence in guiding physicians regarding who requires an ICD and when it should be implanted. The NCD[] should be updated to reflect these dynamic documents or consider ceding authority to them.[23]

In January 2014, as the government's investigation became widely known, the *Journal* again warned physicians that, in some cases, NCD #20.4 is inconsistent with the currently accepted standard of care under professional guidelines, and called for legislative action.[24]

Likewise, on November 3, 2015, the Heart Rhythm Society (HRS) issued a press release stating:

> [The defibrillator investigation] highlights the prevalent gap that exists between Medicare coverage requirements and current evidence-based clinical practice.[25]

The defibrillator NCD thus denies coverage for important and potentially life-saving procedures that are now widely recommended under evidence-based professional guidelines. To avoid this type of coverage gap, in the defibrillator policy and others, CMS could resolve to routinely update medical necessity policies, incorporate sunset clauses, and adopt safety-valve provisions based on the treating physician's medical judgment and professional guidelines.

The Intersection of FCA Liability and Medical Necessity Policies

When exclusive coverage policies diverge from accepted standards of medical practice, hospitals and physicians can face FCA risk even when their services are medically necessary. A medical service must be reasonable and necessary to be covered by Medicare.[26] An item or service that is not "reasonable and necessary" is "excluded from coverage" by Medicare.[27]

As a result, medical necessity is a condition of Medicare payment.[28] When CMS or one of its claims-processing contractors publishes fixed medical necessity criteria, meeting the criteria becomes a condition of payment. Claims that do not comply with the coverage criteria, and therefore do not meet the conditions of payment, may be alleged to be facially false claims under the FCA, under the theory that the services are listed on the claims as "covered" when allegedly they are "non-covered" services, or under other theories of liability.[29]

CMS establishes medical necessity policies in NCDs, Local Coverage Determinations (LCDs), regulations, and interpretive manuals.

NCDs

NCDs reflect a national policy regarding the medical necessity of a particular item or service.[30] Adopted almost universally by Medicare Advantage plans, Medicaid plans, and private health benefit plans, NCDs set forth "the conditions for which an item or service is considered to be covered (or not covered)" based on CMS' review of clinical trials and professional guidelines, among other things.[31]

"Absolute" Words

Not all NCDs are created equal. Some allow for Medicare Administrative Contractors (MACs) to use discretion when making individual claim determinations, allowing MACs to give deference to the treating physician's judgment and professional determination.[32] Other NCDs are absolute—that is, the NCD criteria are the exclusive method to establish medical necessity, and MACs have no discretion to defer to physician judgment.[33]

According to the Medicare Program Integrity Manual, Section 13.1.1, "contractors have no authority to deviate from [an] NCD if *absolute words such as 'never' or 'only if' are used* in the policy." This instruction also applies to LCDs[34] and Interpretative Manuals.[35]

Under this framework, a provider is expected to scour these materials for "absolute words." In their absence, a hospital might seek a MAC's approval to deviate from the otherwise applicable coverage policy based on the treating physician's judgment of the medical necessity of a particular service for a given patient. But when absolute words are used, CMS has spoken the final word on medical necessity.

Despite the significant consequences of the distinction between absolute NCDs and other types of NCDs, the NCD Manual does not always clearly identify which NCDs are absolute.

Detailed Clinical Criteria for Coverage

Complicating compliance efforts still more, many NCDs, including the defibrillator NCD, as well as those for cardiac pacemakers (#20.8), and balloon angioplasties (#20.7), contain complex clinical criteria that are not capable of being screened by typical coding software. In many instances, only a physician can review and apply the specified criteria on a case-by-case basis. Additionally, NCDs may require data collection or participation in a clinical study as a condition of coverage (Coverage with Evidence Development). Such NCDs are vulnerable to the same type of data-driven fraud allegations that have proven so lucrative to the relators and the government in the recent defibrillator settlements.

Difficult to Challenge

While CMS does solicit public comment on proposed NCDs, NCDs are exempt from notice and comment rulemaking requirements under the Administrative Procedure Act (APA).[36] Therefore, NCDs may not be challenged on the ground that CMS failed to comply with the APA.[37]

And while a patient (but not a provider) may appeal a denial of coverage on the ground that an NCD is inconsistent with the standard of care, an NCD is binding nationally on all contractors and Administrative Law Judges (ALJs).[38] Consequently, the NCD is strictly applied as written, and neither a contractor nor an ALJ may override an NCD to allow coverage based on the treating physician's medical opinion or the standard of care, if different from the NCD.[39] While a patient could pursue a higher-level administrative appeal, or might seek to challenge an NCD or LCD in a direct action in federal court, such options are generally impractical due to cost, delay, and futility.[40]

LCDs

CMS also delegates authority to MACs to issue LCDs in the absence of any applicable NCD.[41] A provider that knowingly submits a claim for services that are not covered or permitted by an applicable LCD also may be found liable under the FCA.[42]

In *United States ex rel. Ryan v. Lederman*, for example, the U.S. District Court for the Eastern District of New York concluded that Dr. Lederman, an oncologist, submitted "false" claims for radiation therapy for cancer below the neck because an LCD described the therapy as "investigational."[43] To the extent Lederman believed the radiation therapy was covered because it was medically necessary and reasonable, he was "mistaken," according to the court:[44]

> It is up to HHS and its designees . . . to decide which types of treatment will be covered. As one court put it in denying a defendant's motion to dismiss a False Claims Act case, '[if] physician determinations' of reasonableness and necessity 'controlled claim payment, there would be no need for a claim reimbursement process at all.'[45]

Regulations and Manuals

CMS also promulgates medical necessity policies in regulations and Interpretative Manuals (such as the Medicare Benefit Policy Manual, Claims Processing Manual, Provider Reimbursement Manual, and Program Integrity Manual). Depending on the policy at issue, the role of physicians' medical judgment in determining medical necessity can vary.

As one significant example, CMS' policy regarding the medical necessity of inpatient admissions is largely a creature of evolving regulations and manual guidance, as opposed to coverage statements in NCDs or LCDs. In the inpatient admission context, CMS' policy statements and regulations purport to defer to the treating physician as the authority on medical necessity.[46]

In practice, however, the agency exerts substantial control over admissions decisions. Most hospitals have experienced that influence through historical Recovery Audit Contractor reviews or FCA investigations challenging the medical necessity of inpatient admissions. The treating physician's judgment in these cases sometimes seems cast aside as if inconsequential.

This apparent disregard of physicians' medical judgment in such cases impacts not only the providers submitting the claims, but also the patients seeking the care recommended to them by their physicians. In 2015, the Second Circuit found in *Barrows v. Burwell* that a putative class of Medicare beneficiaries stated a plausible claim that CMS' usurpation of the physician's role had deprived them of a property right to be classified as "inpatients," in violation of the Due Process Clause of the U.S. Constitution.[47] Reversing dismissal, the court held that the complaint "contains plausible allegations that, increasingly, *admission decisions are not left to the discretion or judgment of the treating physician*" and are instead controlled by CMS.[48]

Concluding Thoughts

The recently announced defibrillator settlements have brought attention to medical necessity policies of CMS that leave no room for the treating physician's medical judgment, and highlighted how an NCD or other coverage policy that is inconsistent with the prevailing standard of care can translate into FCA risk for providers and a loss of valuable Medicare benefits for patients.

It is well known that CMS may not "exercise any supervision or control over the practice of medicine."[49] Yet medical necessity policies that fail to keep pace with the standard of care may significantly interfere in the practice of medicine, as more providers and patients must confront the expense of medically necessary services—such as the CRTD implant in the opening hypothetical—that Medicare does not cover. The authors have offered suggestions to remedy inadvertent coverage gaps in NCDs and other medical necessity policies. For now, providers must remain vigilant to screen Medicare claims carefully to ensure the services provided are consistent with CMS coverage criteria, knowing the coverage criteria may be different from the professional guidelines that physicians routinely follow.

1 DOJ Press Release, *Nearly 500 Hospitals Pay United States More Than $250 Million to Resolve False Claims Act Allegations Related to Implantation of Cardiac Devices* (Oct. 30, 2015), *available at* www.justice.gov/opa/pr/nearly-500-hospitals-pay-united-states-more-250-million-resolve-false-claims-act-allegations.

2 A CRT-D, which stands for Cardiac Resynchronization Therapy with Defibrillator, is a specialized type of implantable cardiac defibrillator. The hypothetical patient's history includes a year-long clinical history of an enlarged weak heart, reduced heart function, certain cardiac rhythm abnormalities, and worsening heart failure symptoms despite optimal therapy with cardiac medications.

3 Under the Medicare National Coverage Determination for Implantable Automatic Defibrillators (NCD #20.4), a CRT-D implant within three months of an angioplasty is a non-covered procedure, unless the patient falls within two limited exceptions that may allow for coverage (involving cardiac arrest or sustained ventricular tachyarrhythmia).

4 *See id.*

5 *See Int'l Rehabilitative Sciences Inc. v. Sebelius*, 688 F.3d 994, 998 (9th Cir. 2012) (noting Medicare providers bear the cost of coverage denials unless they first provide advance written notice to the beneficiary, which shifts the cost to the beneficiary). A patient is informed of non-covered charges with either an Advance Beneficiary Notice of Noncoverage (ABN) for outpatient services or a Hospital Issued Notice of Noncoverage (HINN) for inpatient services. See 42 C.F.R. § 411.404; Medicare Claims Processing Manual (CMS Pub. No. 100-04), ch. 30, § 50.1 [ABNs] and ch. 1, § 150.2 [HINNs].

6 *See The Disconnect Between the Guidelines, the Appropriate Use Criteria, and Reimbursement Coverage Decisions*, 63 J. Am. C. Cardiology 12-14 (Jan. 7, 2014); Heart Rhythm Society Statement in Response to the *U.S. Department of Justice Settlements Related to Billing of Implantable Cardiac Defibrillators* (Nov. 3, 2015), *available at* www.hrsonline.org/News/Press-Releases/20154/11/US-DoJ-Settlements-Related-to-Billing-of-Implantable-Cardiac-Defibrillators-ICDs.

7 Failure to issue an ABN or HINN, or to bill a Medicare beneficiary for the cost of a procedure that the provider knows is non-covered, also may implicate the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(2)) and the Patient Inducement Civil Monetary Penalties law (42 U.S.C. § 1320a-7a(a)(5)). This risk only compounds the hospital's predicament—unless the patient qualifies for financial relief under the hospital's charity care policy, the hospital must bill the patient for the cost of the procedure, creating a significant financial burden for the Medicare beneficiary.

8 DOJ Press Release, *see supra* note 1.

9 *Id.*

10 *Id.*

11 *See* Department of Justice ICD Investigation, Medical Review Guidelines/Resolution Model (Resolution Model).

12 *See id.*

13 DOJ articulated multiple categories of defibrillator claims that were excluded from settlement demands, notwithstanding their noncompliance with coverage criteria under the defibrillator NCD. *Id.*

14 *Id.*

15 NCD #20.4.

16 *See* Resolution Model, *supra* note 11

17 *See* DOJ Press Release, *supra* note 1.

18 *See* 68 Fed. Reg. 55634, 55635 (Sept. 26, 2003) (explaining CMS' use of NCDs to prescribe the conditions under which particular items or services will be considered "reasonable and necessary").

19 CMS aspires to maintain current policies, stating that NCDs "will be revised based on the most recent medical and other scientific and technical evidence available to CMS." NCD Manual, Foreword.

20 *See* 2013 *HRS/ACC/AHA Expert Consensus Statement on the Use of Implantable Cardioverter-Defibrillator Therapy in Patients Who Are Not Included or Not Well Represented in Clinical Trials* (*Expert Consensus Statement*), 64 J. Am. C. Cardiology 1143 (Sept. 16, 2014).

21 *See id.; ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities*, 51 J. Am. C. Cardiology 2085 (May 27, 2008); 2012 *ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities*, 61 J. Am. C. Cardiology, at e6 (Jan. 22, 2013); *ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy*, 61 J. Am. C. Cardiology 1318 (Mar. 26, 2013).

22 *See supra* note 2; *Expert Consensus Statement, supra* note 20, at 1158.

23 *The Federal Audit of Implantable Cardioverter-Defibrillator Implants: Lessons Learned*, 59 J. Am. C. Cardiology 1270-74 (Apr. 3, 2012).

24 *The Disconnect Between the Guidelines, the Appropriate Use Criteria, and Reimbursement Coverage Decisions*, 63 J. Am. C. Cardiology 12-14 (Jan. 7, 2014).

25 Heart Rhythm Society Statement in Response to the U.S. Department of Justice Settlements Related to Billing of Implantable Cardiac Defibrillators (Nov. 3, 2015), *available at* www.hrsonline.org/News/Press-Releases/20154/11/US-DoJ-Settlements-Related-to-Billing-of-Implantable-Cardiac-Defibrillators-ICDs.

26 *See* Social Security Act § 1862(a)(1)(A), codified at 42 U.S.C. § 1395(a)(1)(A).

27 *See* 42 C.F.R. § 411.15(k).

28 A state Medicaid agency also may limit coverage based on medical necessity. *See* 42 C.F.R. § 440.230.

29 *See, e.g., United States ex rel. v. Fresenius Med. Care Holdings, Inc.,* No. CIV. A. 09-10179-GAO, 2012 WL 8667597, at *1 (D. Mass. Mar. 6, 2012) (denying a motion to dismiss an FCA complaint alleging that Fresenius performed Hepatitis B tests more frequently than allowed under the applicable NCD); *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 894 (N.D. Cal. 2009) (denying motion to dismiss FCA complaint based on promotion of off-label use of Natrecor, noting the manufacturer came close to "conceding" the falsity of claims submitted after Medicare published an NCD in 2006 stating off-label use was not medically necessary).

30 *See* 42 U.S.C. § 1395ff(f)(1)(B) (definition of an NCD); 68 Fed. Reg. 55634, 55635 (Sept. 26, 2003).

31 Medicare Program Integrity Manual, § 13.1.1.

32 *Id.*

33 *Id.*

34 *Id.* § 13.5.4.

35 *Id.* § 13.1.2.

36 5 U.S.C. § 553. *See* 42 U.S.C. § 1395hh(a)(2).

37 *See* 42 U.S.C. § 1395ff(f)(1)(a)(ii); Revised Process for Making National Coverage Determinations, 78 Fed. Reg. 48164 (Aug. 7, 2013).

38 *See* 42 U.S.C. § 1395ff(f)(1)(a)(i) (providing that NCDs "shall not be reviewed by any administrative law judge"); 42 C.F.R. § 405.1060(a)(4) ("An NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs, and the MAC."); *id.* § 405.1060(b)(1) ("An ALJ may not disregard, set aside, or otherwise review an NCD."); *accord* Medicare Program Integrity Manual, § 13.1.1; *United States ex rel. Modglin v. DJO Global Inc.*, 48 F. Supp. 3d 1362, 1373 (C.D. Cal. 2014).

39 *See id.*

40 *See* 42 U.S.C. § 1395ff(f)(3); *California Clinical Lab. Ass'n v. Sec'y of Health & Human Servs.*, No. 14-CV-0673 (KBJ), 2015 WL 2393571, at *9 (D.D.C. May 20, 2015) (holding Medicare beneficiary lacked standing to challenge validity of LCD that restricted coverage for "pharmacogenomic testing," despite treating physician's judgment that the testing was medically necessary); *Woodfill v. Sec'y of Health & Human Servs.*, 557 F. App'x 473, 474 (6th Cir.) (applying NCD as written to deny coverage for implantable infusion pump and refusing to consider the wisdom of the coverage policy), *cert. denied sub nom. Woodfill v. Burwell,* 135 S. Ct. 246 (2014).

41 *See* 42 U.S.C. § 1395ff(f)(2)(B) (definition of LCD).

42 *See, e.g., United States ex rel. Ryan v. Lederman,* No. 04–CV–2483, 2014 WL 1910096, at *4 (E.D.N.Y. May 13, 2014).

43 *Id.*

44 *Id.* at *5.

45 *Id.* at *6 (citing *United States v. Vascular Solutions, Inc.,* Case No. 1:10-cv-00883-SS, ECF No. 44, at *7 (W.D. Tex. Mar. 7, 2013)).

46 *See, e.g.*, 42 C.F.R. § 424.10(a) ("The physician decides upon admissions . . . and determines the length of stay."); *see also* 42 C.F.R. § 412.3(d)(3), as finalized in the CY 2016 Hospital OPPS Final Rule, 80 Fed. Reg. 70298, 70602 (Nov. 13, 2015) (stating, in the context of Medicare's controversial Two-Midnight Rule, that admissions where the admitting physician does not expect a patient's stay to span two midnights may nevertheless be payable on a case-by-case basis, "based on the clinical judgment of the admitting physician and medical record support for that determination").

47 *See Barrows v. Burwell*, 777 F.3d 106, 114 (2d Cir. 2015).

48 *Id.* at 115 (emphasis added).

49 *See* 42 U.S.C. § 1395.

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Chair's Column

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Although this newsletter will be published in the beginning of 2016, I am writing this column a few days after Thanksgiving. My reflections over the past week about the things for which I am grateful are beginning to overlap with some early thoughts about what I'd like to accomplish in 2016. A common theme in both is: volunteerism.

I'm grateful to all the volunteers who have made this newsletter possible, as well as those who make the many other projects we undertake in the Fraud and Abuse Practice Group (Fraud PG) possible. The wonderful staff of AHLA assists us tremendously with the logistics of publishing the newsletters, but the newsletter content is almost entirely volunteer-driven. These volunteers include, of course, the authors of the articles contained in this newsletter. They all spent valuable time submitting their proposals, and then drafting and revising their articles for distribution to, and consumption by, their peers—each of our 2600+ members—plus the colleagues with whom those members choose to share the articles. This process required significant time and energy from each of them. True, these authors receive the benefit of having another publication issued in their name and read by many peers, but let's be honest—the inconvenience of working to an externally mandated deadline, which is impervious to client and other demands, can be significant. I suspect that at one point in time, each of the authors had second thoughts about whether committing to submit the article was really such a good idea—ultimately, though, each of them met their commitment.

Once submitted, the articles are carefully reviewed and edited by other volunteers, who include our lead coordinators Susan Kratz, Mike Paulhus, and Bob Brennan, and Fraud PG Vice Chair of Publications Joe Kahn. With each issue of the newsletter, these volunteers take seriously their mission to make sure that all of the articles meet the high bar set by AHLA for its publications. The task of carefully reviewing and editing the articles typically requires a significant level of commitment by them in terms of time and energy. And they don't even get a byline in return!

I hope you'll agree that the efforts of all these volunteers are well-spent, and that you personally benefit from the articles included in this newsletter. And remember, this newsletter is but one of the many benefits that our PG offers to our members throughout the year. Every benefit you receive—newsletters, email alerts, access to the 50-State Survey and various toolkits, and webinars—requires many hours of work behind the scenes, most of it by volunteers. That's the mission of AHLA, after all—to provide high-quality, ongoing education and information to our members. But it does take a lot of time and effort by many of your peers to continue fulfilling that mission, day in and day out.

As you look forward into 2016, I urge you not only to be grateful for the efforts of all our volunteers, but also to consider whether and how you can contribute to our PG community and thus benefit both your peers and yourself. Will that take the form of submitting a proposal for an article in the next newsletter? Suggesting a topic for a webinar? Helping review and/or edit email alerts published by the Compliance Committee or Enforcement Committee? Or even submitting your name for consideration as a PG leader? By doing any of these, or by taking advantage of any number of other volunteer opportunities, you can help our PG fulfill its mission of providing high-quality information and education to your colleagues. At the same time, you will benefit yourself, whether by learning a topic relevant to your own practice in greater depth by writing or speaking about it, by collaborating and getting to know other colleagues from across the country, or by getting more recognition for your expertise.

We all have limited time, and we each must limit our volunteer commitments to those we can actually fulfill not only in a timely fashion, but also at the same high-quality level that we would give our clients. Our volunteer contributions, though, can be particularly rewarding. Please consider how you can contribute, and then respond to the volunteer requests where you think best. We look forward to working not only for you but with you in 2016!

In gratitude,

Laura

Stark, the False Claims Act, and the Transition to Outcome-Based Reimbursement

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Stark Law violations have long served as the basis of False Claims Act (FCA) cases. *Tuomey* and *Halifax* have been widely discussed and cited as the quintessential cases that fit in this category. This year brought other significant settlements, and drove home with a vengeance the potential FCA liability that can result from these violations. These cases raise important considerations for providers as they shift to compensation models that consider—at least in part—quality metrics.

United States ex rel. Drakeford v. Tuomey Healthcare System

Tuomey's procedural history has been widely explored. In short, Tuomey entered into compensation agreements with certain local physicians that were found to violate the Stark Law because they took into account the value of projected referrals.[1] While the doctors in question previously performed outpatient surgical procedures at Tuomey, they had begun to perform such surgical procedures at their own offices or off site.[2] Because of its concerns of lost revenue, Tuomey enticed several local physicians to enter into part-time employment agreements. The agreements had several contractual terms that were not necessarily standard in physician employment agreements, including ten-year terms with no "without cause" termination provision; part-time, partial services; total exclusivity; and full-time benefits for part-time employees.[3] Under the agreements, the physicians' salaries were adjusted from year to year based on the amount of services rendered in the previous year, but the bulk of their salary was in the form of a productivity bonus, equaling 80% of their collections for the year.[4] In addition, the physicians received an incentive bonus of up to 7% of the productivity bonus.[5] In exchange, the physicians agreed to perform all of their outpatient surgical procedures exclusively at the hospital.[6] Notably, these arrangements were reviewed by outside counsel who concluded they likely violated the Stark Law, but Tuomey proceeded with them nonetheless.

The government intervened. Following the first jury trial, the district court granted a new trial on the FCA claim following certain testimonial issues, but entered judgment for the government on its equitable claims.[7] The Fourth Circuit reversed and remanded, finding a Stark Law violation was a common factual issue "necessary to the resolution of both the equitable claims and the FCA claim."[8] Following the second trial, the jury concluded that Tuomey knew the agreements would result in false claims, and found that Tuomey submitted 21,730 claims to Medicare that were "false" due to the compensation arrangements, resulting in a verdict against Tuomey in excess of $237 million.[9]

Tuomey appealed again, arguing the compensation agreements did not, on their face, take into account the volume or value of anticipated referrals.[10] The Fourth Circuit rejected this argument, finding that the lower court considered the contracts as they were actually implemented—taking into account the volume or value of referrals by varying physicians' salaries on the basis of the facility fees they generated.[11] The court based its decision on two key findings. First, the physicians were paid a base salary that was adjusted based on their collections from the previous year.[12] Second, the physicians' productivity bonus made up the bulk of their compensation, equaling 80% of their collections.[13] Because these collections were tied to procedures that the physicians were required to perform at the hospital, the court determined that the compensation agreements took into account the volume or value of their referrals.

United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center

In this intervened qui tam, the government argued that the Halifax Medical Center's bonus provisions, which provided that each physician would receive a portion of a total bonus pool that was equal to 15% of the operating margin of the overall medical oncology program, violated the Stark Law.[14] The bonus received by each physician was determined by dividing the total billings of all six physicians for services personally performed, by each physician's individual billings.[15]

The hospital in turn argued that the employees qualified for the bona-fide employee exception and that the bonus was permitted if based on the services personally performed by the physician.[16] The court, citing the initial *Tuomey* decision, disagreed, observing that when a physician personally performs a service, any related facility fee may be regarded as a fee for a referral of that patient.[17] The court concluded that whenever a physician is identified as the operating physician on a Medicare claim form, that physician has made a referral to the hospital of a designated health service under Stark.[18]

Columbus Regional, North Broward, and *Adventist*

Because they were settled in advance of any litigation and prior to the United States intervening, these cases provide less fodder for close analysis than *Tuomey* and *Halifax*. Nonetheless, they provide important insights in understanding how payments to physicians may be considered improper.

United States ex rel. Barker v. Columbus Regional Healthcare System

The Columbus Regional settlement agreement filed with the court[19] sets forth certain "covered conduct" alleged to have occurred in violation of the Stark Law. This includes "improper salary and medical directorship payments" to a physician, Dr. Pippas, who was named in the complaint. Interestingly, the settlement agreement also resolves liability related to other financial relationships that were disclosed pursuant to the Centers for Medicare & Medicaid Services' Stark self-referral disclosure protocol, suggesting that Columbus Regional was aware of at least some potential Stark Law violations during the time of the allegedly improper relationship with Pippas. The complaints offer additional details with regard to the alleged improper salary and medical directorship payments to Pippas. In particular, the government based its claim that Pippas' compensation violated the Stark Law on the fact that his compensation was paid at or above the 90th percentile for similar physicians, the fair market value (FMV) of his compensation was not reviewed for a four-year period, and he was being paid, in part and received credit under the compensation plan, for work relative value units performed by the other physician.

United States ex rel. Reilly v. North Broward Hospital District

In this action, originally filed in April 2010, the relator—a physician who reportedly spurned employment at North Broward—initially focused on financial relationships with three cardiologists and two orthopedic surgeons. The relator alleged that the compensation for those physicians was in excess of the 90th percentile for physicians in their specialties and that the "net operating revenue" of these physicians outstripped their "expenses" and those of their practices.[20] The relator claimed that this was made up for by referrals to North Broward, and that North Broward secretly tracked the volume and value of these referrals as "Physician Practice Contribution Margins" at each North Broward hospital and clinic. Subsequent amendments to relator's complaint added significant detail—likely gleaned from the five-year investigation conducted by the United States—and named additional physicians (eventually totaling 16) and practice lines as well as alleging the existence of sham medical directorship agreements. These allegations followed a similar pattern of payments in excess of the 90th percentile that were made without regard for FMV. Eventually North Broward paid $69.5 million to settle allegations involving compensation for "nine employed physicians that exceeded the fair market value of their services."[21]

United States ex rel. Payne and *United States ex rel. Dorsey v. Adventist Health System*

In *Adventist*, three former employees brought a qui tam action alleging that physicians were paid excessive compensation to lock in their patient referrals to Adventist-owned health care facilities. The complaint alleged Adventist implemented a corporate policy encouraging and directing facilities to purchase physician practices and/or employ physicians to control patient referrals. The complaint also alleged that, to keep the physicians from terminating their contracts, Adventist provided each physician with excessive compensation, perks, and benefits.

The complaint identified a 2012 analysis that revealed more than 50 physicians employed by Adventist were receiving compensation that could not be considered "commercially reasonable" based on Medical Group Management Association (MGMA) reviews, and that Adventist knew that 35% of the physicians were paid salaries that exceeded the 90th percentile of the MGMA standard for comparable physicians, yet many of these physicians fell below the 50th percentile for personal work productivity.

While most of the excessive compensation was provided for in the physician agreements, the complaint alleged that some of the excessive compensation came from bonuses and perks that were not provided for in the physician agreements. According to the complaint, one doctor had his lease payments for his BMW and Mustang paid for by Adventist. Another doctor ran an independent private practice outside of his work for Adventist for which Adventist assumed all costs, including staff and equipment. Yet another, required

under his contract to "devote substantially all of his/her professional time and attention to [his] practice," allegedly worked just 20-24 hours per week and took more than 50 days off a year, while still taking his full base salary. Adventist ultimately paid $115 million to settle these claims.[22]

The (Slow) Move to Value- and Outcome-Based Compensation Models

Currently, most physician compensation models are based on either a fixed-salary or gross- or net-revenue basis, along with various incentives and productivity bonuses.[23] The primary factors in determining physician compensation include regional market factors and compensation surveys, particularly those conducted by the MGMA. FMV requirements typically require a physician's income to be similar to the earnings of others in their specialty area with comparable experience and skills,[24] and as a result there is unlikely to be wide variations in compensation models.

The U.S. Department of Health and Human Services (HHS) has set a goal of "tying 30 percent of Medicare fee-for-service payments to quality or value through alternative payment models by 2016 and 50 percent by 2018. HHS has also set a goal of tying 85 percent of all Medicare fee-for-service payments to quality or value by 2016 and 90 percent by 2018."[25] As Medicare reimbursement shifts from a straight-forward, fee-for-service model to provide incentives for quality of care, improved patient experience, and cost reductions, physician employment agreements are beginning to reflect this new emphasis.[26] Additionally, medical practices have internal motivations for providing these value-based incentives as they allow a practice to place an emphasis on quality service and cost efficiency.[27] This shift of emphasizing quality over volume of services performed represents a significant change in physician compensation.[28]

As with traditional fee-for-service models, however, hospitals face unique challenges in ensuring that so-called value-based compensation complies with Stark. Although Medicare implemented a number of programs experimenting with physician compensation in the past, large-scale implementation did not occur until after the passage of the Affordable Care Act (ACA) in March 2010.[29] In many ways, the ACA served as a reaction to "the unrestrained growth of Medicare expenditures without a corresponding increase in quality outcomes."[30] The lack of broad payer implementation has led the shift to value-based payments to proceed at a somewhat glacial pace. In 2013, incentive payments relating to value objectives made up 3% to 5% of the total compensation of employed physicians with an expected increase of up to 7% to 10% to occur in following years.[31]

The first large-scale attempt to compensate physicians under a value-based model occurred with the Medicare Physician Group Practice (PGP) demonstration—beginning in April 2005 and ending in March 2010. The PGP demonstration project employed a shared savings model to encourage cost efficiency. Participating physicians were allowed to retain a portion of savings achieved by reducing costs and increasing quality of care for a defined population of Medicare recipients.[32] This payment structure still relies on the traditional fee-for-service model, but value-based incentives offer additional rewards for reducing costs.[33]

One value-based model endorsed by the ACA is the Accountable Care Organization (ACO). ACOs provide coordinated, accountable care, and ease the burden on over-utilized Medicare resources by creating incentives for quality and efficiency across a network of providers. ACO providers are allowed to share in the savings created by the coordinated care offered by the ACO. Importantly, however, in creating the ACO model, Congress recognized the potential for conflict with Stark and the Anti-Kickback Statute (AKS), and under the ACA provided HHS the power to waive such liability for ACOs.[34]

Under a typical management model that takes quality or value metrics into account, health care providers will contract with a physician or group of physicians to meet certain defined metrics relating to reducing the cost of providing health care.[35] The arrangement can be structured as a cost-savings committee of physicians, or can include all physicians who practice in a particular specialty at a facility.[36] Physicians are usually paid for their services under a traditional compensation model, such as an hourly rate payment model, but also receive bonuses for achieving certain cost-reduction benchmarks that comply with HHS Office of Inspector General guidance on gainsharing arrangements.[37]

Germaine to all of these models is the identification of quality metrics. These metrics vary by provider. They can include so-called outcome metrics, including payments related to the Physician Quality Reporting System and other pay-for-quality payments. They also include "process metrics" such as electronic medical record completeness, diagnosis accuracy, and attendance and completion of education and training sessions. Metrics related to patient satisfaction and community involvement also can be included under the broad heading of "quality."

None of the significant FCA cases cited above focused on payments based on quality metrics. Nonetheless, given the increasing shift to quality-based payments, it is likely that these models will occupy a more prominent place in physician compensation moving forward. While the Stark Law does not bar physician compensation models that take into account quality measures unrelated to the volume or value of services or other business generated by a physician, this shift in compensation models will introduce new uncertainty. So, where are the vulnerabilities?

First, the same overarching concern exists—providers that track and directly factor into compensation the volume or value of referrals will continue to face scrutiny. Simply because a compensation model also considers certain quality metrics will not change the analysis.

In addition, FCA/Stark liability in these new models could arise in a more nuanced manner. For example, if a provider uses quality-based payments to increase the FMV of the compensation arrangement, the quality metrics used must be real and must have value, otherwise the agreement could face the same scrutiny as the physician arrangements in the cases discussed above. In addition, quality metrics have to be objectively measurable. Quality-based payments based on subjective factors or measurement raise the same issues with Stark as other payments based on the subjective decisions of hospital management. Similarly, in addition to being objective, such measurements also must actually be performed and the specified payment increases—or reductions—actually followed.

So what practical steps can providers take in the face of the significant potential FCA liability related to Stark violations, particularly in the face of the shift to quality-based payments? Perhaps the simplest response is to separate the physician compensation and management functions. The bad facts common to the cases discussed above involved hospital management that subjectively set physician compensation, taking into account the volume and value of referrals. Separating these functions, and allowing a group independent of hospital management and knowledgeable in physician compensation rules to assess physician compensation, can eliminate the improper consideration of the volume and value of referrals as well as troubling communications about any such consideration. Because quality metrics increase the number of variables that can be considered in arriving at a compensation number, they have the potential to introduce additional tractability in setting physician compensation. As such, a "firewall" between management and compensation functions may be even more helpful. Of course this is but one approach. What is clear is that providers will be wrestling with these questions in the years to come with the increasing shift to quality-based compensation models.

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1 *United States ex. rel. Drakeford v. Tuomey*, 792 F.3d 364, 370 (4th Cir. 2015).
2 *Id.*
3 *Id.* at 371.
4 *Id.*
5 *Id.*
6 *Id.*
7 *Id.* at 373.
8 *Id.*
9 *Id.* at 370.
10 *Id.* at 379.
11 *Id.*
12 *Id.*
13 *Id.*
14 *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.,* No. 6:09-cv-1002-Orl-31, 2013 WL 6017329,*8 (M.D. Fla. Nov. 13 2013).
15 *Id.* at *3.
16 *Id.*
17 *Id.* at *10.
18 *Id.* at *11.
19 *United States ex rel Barker v. Columbus Reg'l Healthcare Sys..*, M.D. GA Civil Action No. 4-12-cv-108, Amended Complaint (DE 112-1).
20 *United States ex rel Reilly v. North Broward Hosp. Dist..*, S.D. FL. Case No. 0:10-cv-60590, Complaint (DE 2), p. 9-10.
21 *See* www.justice.gov/opa/pr/florida-hospital-district-agrees-pay-united-states-695-million-settle-false-claims-act.
22 *See* www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations.
23 *Physician Compensation Models: The Basics, The Pros, and the Cons, available at* www.nejmcareercenter.org/article/physician-compensation-models-the-basics-the-pros-and-the-cons/ (last visited Nov. 11, 2015).
24 *See id.*
25 *See Health Care Payment and Learning and Action Network, available at* https://innovation.cms.gov/initiatives/Health-Care-Payment-Learning-and-Action-Network/ (last visited Nov. 11, 2015).
26 *See* Jeffrey B. Milburn et. al., *Strategies for Value-Based Physician Compensation, available at* www.mgma.com/Libraries/Assets/Store/Books/8652-excerpt.pdf (last visited Nov. 11, 2015).
27 *Id.*
28 *Id.*
29 Corbin Santo, *Walking a Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 Case W. L. Rev. 1377 (2014).
30 *Id. See also* Elliott Fisher et al., *Health Care Spending, Quality, and Outcomes: More Isn't Always Better,* Dartmouth Inst. for Health Pol'y & Clinical Prac. 2 (2009), *available at* www.dartmouthatlas.org/downloads/reports/Spending_Brief_022709.pdf (last visited Nov. 11, 2015) (finding that higher rates of spending in certain localities were actually associated with a decrease in the quality of care).
31 *See* Milburn, *supra* note 26.
32 *Id.*
33 *Id.* at 1398.
34 Bruce M. Fried et. al., *Accountable Care Organizations: Navigating the Legal Landscape of Shared Savings and Coordinated Care*, 4 J. Health & Life Sci. L. 88 (2010).
35 Robert G. Homchick, *Gainsharing and Physician Incentive Compensation*, AHLA-Papers P10229833 (1998).
36 *Id.*
37 *Id.*

The Growing Use of Statistical Extrapolation to Prove Health Care Fraud in Civil and Criminal Cases

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In a handful of recent cases, federal district courts have begun to approve the U.S. Department of Justice's (DOJ's) use of statistical sampling and extrapolation to prove liability in civil False Claims Act (FCA) cases. The use of statistical sampling to prove and quantify civil liability under the FCA is itself a significant expansion of FCA law that may lead to even more-significant corporate settlements in the health care and life sciences field. It also raises questions—particularly for physicians, executives, and other individuals—about how the government might seek to use this type of evidence in *criminal* health care fraud cases.

This concern is underscored by DOJ's recent release of a memorandum regarding individual accountability for corporate wrongdoing, authored by Deputy Attorney General Sally Quillan Yates (Yates Memo).[1] Because the Yates Memorandum formally shifts DOJ's emphasis to aggressively pursuing criminal charges against individuals involved in corporate wrongdoing, it seems likely that the government's new strategy of using statistical extrapolation evidence to help prove health care fraud cases may find its way into individual prosecutions.

How these two new strategies will intersect in health care-related investigations involving allegations of false claims remains to be seen. However, a trend has emerged in such cases, whereby a company enters into a large civil settlement under the FCA, followed later by criminal prosecution of the individuals responsible for the wrongdoing. A recent example of this trend is the criminal indictment of W. Carl Reichel, a former president of drug maker Warner Chilcott, for allegedly overseeing a kickback scheme. Reichel was indicted after the government agreed to a corporate criminal settlement with a Warner Chilcott subsidiary for $23 million and another $102 million civil settlement under the FCA.[2] This trend provides the backdrop against which the government's use of statistics to prove fraud may be a potent tool for DOJ.

Reliance on extrapolation evidence will be most useful to DOJ in cases focusing on large health care organizations that operate in multiple jurisdictions and deal with extremely high numbers of claims. Increased reliance upon extrapolation evidence raises the most risk for large networks such as hospice care providers, hospitals and hospital groups, nursing homes, dialysis clinics, vein care centers, and eye clinics. It also poses similar concerns for life sciences companies that operate nationwide or even globally, as well as their executives. If DOJ uses statistical sampling to support allegations of large-scale fraud against a health care organization, leverages its investigation to influence the organization to provide information to help the government prosecute employees, and then seeks to use the same evidence against those employees, a number of issues will arise:

- When is the use of statistical sampling and extrapolation in a criminal action against an individual constitutional?
- Will prosecutors use statistical extrapolation to prove health care fraud in criminal cases in ways that do not require proof beyond a reasonable doubt? And,
- Practically speaking, will individuals be able to challenge statistical findings that are based on the government's non-public billing and claims data?

DOJ's Use of Statistical Extrapolation in Civil FCA Cases

In *United States ex rel. Martin v. Life Care Centers of America, Inc.*, a federal district court in Tennessee issued a ruling on September 29, 2015 that approved a new approach for the federal government in FCA cases.[3] DOJ joined in two consolidated civil FCA lawsuits against a company that operated a network of nursing homes in 28 states, alleging that it systematically overstated the complexity of services it provided to residents, thereby overcharging Medicare for them. DOJ sought recovery for more than 150,000 allegedly false claims submitted to Medicare for payment over the course of 54,796 patient admissions. The government indicated that it would advance unifying theories of liability that supported all of its claims. There was one problem, however: in FCA cases, liability attaches when a claim for payment is made, not when the underlying activity alleged to be fraudulent occurs. The government, as plaintiff/intervenor, was obliged to prove the submission of a false claim to the government on each individual occasion when wrongful conduct allegedly occurred. Obviously, *LifeCare* involved allegations of such widespread fraud that doing so on a case-by-case basis was impractical.

Because it faced seemingly insurmountable practical barriers to proving each of these claims individually, the government sought to use statistical sampling and extrapolation to prove liability. Specifically, from the 154,621 claims LifeCare made during the years in question, DOJ selected a random subset of 400 claims and analyzed them for fraud, after which it sought to extrapolate the rate of fraud within that subset to the entire universe of claims.

The defendant mounted a vigorous challenge to this method of proof. It argued that allowing DOJ to proceed in that manner would effectively relieve it of its burden under the FCA to prove each element of each claim. Additionally, once the extrapolation was complete for the remaining claims, LifeCare argued, the presentation of such evidence at trial effectively would require the corporate defendant to rebut an inference of fraud, which it believed would impermissibly shift the burden of proof to the defense, in violation of due process.

The district court rejected these defense arguments, noting that such extrapolation has been used in many other contexts and that similar arguments about the uniqueness of individual claims often have been rejected.[4] Regarding whether statistics could carry the government's burden to demonstrate materiality, the court reasoned that the evidence should be admissible for that purpose, with the jury deciding how much weight to attribute to it.[5] The court also rejected LifeCare's due process argument, reasoning that because the defendant would be permitted to present its own evidence to rebut the statistics, its constitutional rights would be protected.[6]

Other courts have adopted *LifeCare*'s approach and have allowed the government to use statistical extrapolation and similar evidence in FCA cases. For example, in *United States ex rel. Paradies v. AseraCare*, DOJ accused AseraCare, a provider of hospice services, of hiding information from physicians to secure certifications of hospice eligibility for patients who were not actually terminally ill.[7] As in *LifeCare,* DOJ used a sampling and extrapolation method to make its case, arguing that it would not be feasible for it to prove individually each specific instance of fraud involved in the scheme. DOJ is seeking more than $200 million in damages from AseraCare based on evidence it presented in relation to a sample of just 123 patients.

One federal district court recently expressed concerns about DOJ's use of statistical sampling and extrapolation in the FCA context. In June 2015, a federal judge in South Carolina rejected an FCA plaintiff's attempt to use statistical extrapolation instead of individualized proof to establish liability in a case against a network of nursing homes.[8] The court acknowledged the "staggering" number of claims at issue, but held that claim-by-claim proof of falsity was required to establish FCA liability. The case currently is on appeal before the Fourth Circuit, which could become the first federal court of appeals to weigh in on the use of statistical sampling to prove fraud.

DOJ's Renewed Emphasis on Criminally Prosecuting Individuals

On September 9, 2015, DOJ released the Yates Memo, which outlines its latest shift in its approach to white collar crime and corporate investigations. The memorandum sets forth "six key steps" toward strengthening its pursuit of individual corporate wrongdoing. The Memo acknowledges the "challenges unique to pursuing individuals for corporate misdeeds," which "make it all the more important that the Department fully leverage its resources to identify culpable individuals at all levels in corporate cases."[9] These principles will apply in any investigation of corporate misconduct, whether criminal or civil.

Going forward, federal prosecutors are not to offer any cooperation credit to corporations under investigation unless the corporation provides all relevant facts about the individuals involved in the corporate misconduct. The Yates Memo specifically mandates that both criminal and civil investigations should focus on individuals from their inception. Through the immediate focus on individuals, DOJ aims to "increase the likelihood that individuals with knowledge of the corporate misconduct will cooperate with the investigation and provide information against individuals higher up in the corporate hierarchy." This reflects DOJ's emphasis on targeting not just individuals, but "high-level executives" as well.[10]

The new guidance also calls for more cooperation between criminal prosecutors and civil enforcement attorneys handling corporate investigations. DOJ is clear that it wants "[e]arly and regular communication between civil attorneys and criminal prosecutors" handling these types of investigations.[11] This approach permits the government to most effectively use the full range of its potential remedies (including incarceration, fines, penalties, restitution to victims, asset seizure, and forfeiture). The Memo explicitly directs DOJ attorneys to be "alert for circumstances where concurrent criminal and civil investigations of individual misconduct should be pursued."[12] Through this emphasis in particular, the Yates Memo will likely lead to more parallel criminal and civil proceedings.

DOJ also has sought to discourage corporate settlement agreements that provide protection from criminal or civil liability for any individuals. In these situations, the Yates Memo directs DOJ attorneys to "take care to preserve the ability to pursue these individuals."[13] In deciding whether to charge an individual, DOJ attorneys are encouraged to prioritize individual accountability over recovering the maximum possible settlement amount. The Yates Memo directs that corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and requires that declinations as to individuals in such cases be memorialized.

The FCA is sure to be at the center of DOJ's efforts to implement these principles in the health care context. DOJ has called the FCA one of the most powerful tools in the multi-agency effort to fight health care fraud nationwide. In the same vein, DOJ also recently announced that its prosecutors will automatically review all new civil whistleblower complaints to determine whether a complaint outlines any criminal conduct.

How DOJ Could Use Statistical Extrapolation and the Yates Memo in Criminal Cases

Considered together, these two strategies—the use of statistics to prove health care fraud liability and DOJ's focus on pursuing criminal prosecutions against individuals involved in corporate misconduct—raise the specter of the use of statistical extrapolation evidence in individual prosecutions. Now that the government has had some success in persuading courts to approve the use of statistical sampling to quantify civil FCA liability, prosecutors may push for an even broader use of statistics in criminal health care fraud cases.

For individuals facing a criminal prosecution, the government could use statistical extrapolation in a number of ways. Several recent health care fraud cases have involved using statistical sampling and extrapolation evidence to prove a massive loss amount at the sentencing phase of the

proceedings.[14] Defendants have challenged the constitutionality of using statistical extrapolation in this way, but with little success.[15] The U.S. Supreme Court's seminal decision in *Apprendi v. New Jersey*[16] has been held not to apply to the calculation of the loss amount under the Sentencing Guidelines.[17] *Apprendi* requires that any fact that increases the penalty for a crime beyond the prescribed statutory minimum be submitted to a jury and proved beyond a reasonable doubt.[18] Because the loss amount will drive the length of the defendant's sentence, a defendant could receive a lengthy sentence based on statistical extrapolation evidence showing a large loss amount if the government can prove that loss amount by a mere preponderance of the evidence, rather than beyond a reasonable doubt.[19]

Courts similarly have held that *Apprendi* does not apply in restitution or forfeiture proceedings.[20] Accordingly, the government can attempt to prove the amount to be paid in restitution or to be forfeited by a preponderance of the evidence, just as it can to prove the loss amount for sentencing purposes.[21] The lower standard of proof in these circumstances paves the way for the use of statistical extrapolation evidence at sentencing and in restitution and forfeiture proceedings. Given the Yates Memo's emphasis on allowing DOJ attorneys to use "the full range of the government's potential remedies" (including civil and criminal forfeiture), the strategies used in civil FCA cases are likely to be the same strategies used in these types of criminal actions.

The Fifth Circuit has recognized "some tension" between the Supreme Court's dicta in *Southern Union Co. v. United States*,[22] and the many cases holding that the Sixth Amendment does not require a jury to find the amount of restitution.[23] In *Southern Union*, the court opined that *Apprendi* should apply to all forms of punishment, including sentences, penalties, and fines. Arguably, when a statute requires restitution based on the loss amount, that restitution is part of a "sentence" and thus falls within *Apprendi* and requires that amount to be submitted to a jury.[24] Thus far, though, courts have not been persuaded and have held that *Apprendi* does not apply to restitution.[25]

There are additional constitutional obstacles to using statistical extrapolation against a defendant in the trial phase. In a trial against a corporate defendant, the government conceivably could attempt to directly prove fraud through the use of statistical extrapolation, given the expanded concept of corporate *mens rea*. It is hard to imagine a criminal trial in which a judge would permit prosecutors to support individual criminal counts based simply on extrapolation, given the government's burden to prove guilt beyond a reasonable doubt as to each individual charge.

But what if the government seeks to use extrapolation to prove intent in less-direct ways? In recent criminal health care fraud cases, the government has presented expert witness testimony that was based on statistical extrapolation to attempt to prove health care fraud. Defendants generally have been unsuccessful in challenging such testimony under Federal Rules of Evidence 403 and 404(b). For example, in *United States v. Tran*,[26] the defendant podiatrist argued that the district court abused its discretion in admitting statistical evidence comparing her prescriptions to other Michigan podiatrists and testimony by an expert pharmacist that her prescriptions raised ethical "red flags." The defendant argued that the statistical data presented by the government, which showed that she prescribed more than twice as much oxycodone as any other Michigan podiatrist, should be excluded as unduly prejudicial and misleading under Rule 403. The Sixth Circuit affirmed the district court's evidentiary ruling, relying on the government's use of statistical evidence in similar cases.[27]

In other circumstances, however, motions to exclude testimony based on statistical extrapolation have found favor. In one case, *United States v. MacKay*,[28] the court opined that statistical extrapolation evidence would have been inadmissible under Rule 403 had the defendant not opened the door at trial. In any event, there are fundamental due process concerns at play when the government chooses a statistical sample and then presents expert witness testimony at a criminal trial based on that sample to prove fraud. As these issues play out at trial, defendants must be sensitive to potential Rule 403 or 404(b) challenges to keeping the government from introducing this evidence.

Finally, the practical concerns for individual defendants who must counter the government's statistical evidence are equally valid. If a prosecutor can work with a corporate employer to settle a large fraud claim based on billing data that an employee or former employee cannot easily access, it puts the individual at an extreme and perhaps insurmountable disadvantage in fighting any criminal charges. An employee of a hospital or hospice care center, for example, is unlikely to have access to her employer's billing data, and is even less likely to have access to government billing data. A manager of a medical device company is equally unlikely to have full access to government billing data or competitor billing data, which prosecutors can use to attempt to show improper billing practices. While some of this information is commercially available through third-party vendors, it is often extremely expensive. It also would be expensive and time-consuming to evaluate each claim within a data set individually. This is particularly problematic given that, once an employee is under indictment, he is likely to lose advancement of legal fees from the employer absent an undertaking.

For all of these reasons, the extended use of statistical extrapolation and the Yates Memo will work in tandem to increase the pressure on individuals involved in a health care fraud investigation to plead guilty earlier in the process. Criminal defense attorneys practicing in this space would be wise to track how federal courts treat DOJ's various attempts to prove health care fraud though statistical sampling and extrapolation.

1 Memorandum from Sally Quillian Yates, Deputy Attorney General, U.S. Department of Justice, September 9, 2015, Individual Accountability for Corporate Wrongdoing (hereinafter, Yates Memo), *available at* www.justice.gov/dag/file/769036/download.

2 DOJ Press Release, *Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay $125 Million to Resolve Criminal Liability and False Claims Act Allegations* (Oct. 29, 2015), available at www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million#sthash.3N7qiLQo.dpuf.
3 *United States ex rel. Martin v. Life Care Ctrs. of Am.*, Nos. 08-cv-251, 12-cv-64, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2012).
4 *Id.* at *15.
5 *See id.* at *19.
6 *See id.* at *15.
7 No. 2:12-cv-000245 (N.D. Ala. filed Sept. 20, 2011).
8 *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 12-3466, 2015 WL 3903675 (D.S.C. June 25, 2015).
9 Yates Memo, *supra* note 1, at 2.
10 *Id.* at 4, 2.
11 *Id.* at 4.
12 *Id.* at 5.
13 *Id.* at 5.
14 *See, e.g., United States v. Shannon*, 803 F.3d 778 (6th Cir. 2015).
15 *See, e.g., id.* at 787-88.
16 530 U.S. 466 (2000).
17 *See, e.g., United States v. Lamarre*, 248 F.3d 642, 650 (7th Cir. 2001).
18 *Apprendi*, 530 U.S. at 490.
19 *See, e.g., Shannon,* 803 F.3d at 788.
20 *See, e.g., United States v. Elliott*, No. 13-20560, 2015 WL 327648, at *3-5 (5th Cir. Jan. 27, 2015) (citations omitted).
21 *See, e.g., id.*
22 132 S.Ct. 2344 (2012).
23 *Elliott,* 2015 WL 327648, at *4.
24 *See id.* at *4.
25 *See id.* at *4 fn.14 (citing cases).
26 609 F. App'x 295, 300-01 (6th Cir. 2015).
27 *See id.* at 298 (citing cases).
28 715 F.3d 807, 841-42 (10th Cir. 2013).

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Getting the Most from Health Care Fraud Expert Witnesses: Lawyer and Expert Best Practices

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Health care fraud and abuse cases are often won or lost on the effective use of expert witnesses. As health care fraud cases have become more complex and technical, the scope and use of expert testimony has proliferated, and the successful use of experts is one of the lawyer's most important jobs. False Claims Act, Anti-Kickback Statute, and Stark Law cases all demand various types of experts to assist the trier of fact in understanding the nature of the case, the morass of rules at play, the evidence, and a variety of billing, valuation, contractual, technical, and compliance concepts. Increasingly, expert reports and testimony play a pivotal role in motions for summary judgment, as well as at trial. Experts also are used in "conference room litigation," such as mediations or negotiations between defense counsel and enforcement agencies. This article is the result of interviews with health care fraud litigators and expert witnesses in the field who identified their best practices to produce optimum outcomes for their clients.

The Federal Rules[1]

Expert reports are controlled by the Federal Rules of Civil Procedure 26(a)(2) and 26(b)(4), while the admissibility of expert testimony falls under Federal Rule of Evidence 702. In most cases, the expert must produce a written report that contains "a complete statement of all opinions the witness will express and the reasons and basis for them."[2] The report must be "prepared and signed by the witness,"[3] and it must include the "facts or data considered"[4] in forming the opinions expressed. It must include the expert's compensation, a list of all other expert testimony provided in the past four years, and the witness's qualifications, including a list of all publications authored in the past ten years.[5] Rule 702 allows expert testimony when the expert's scientific, technical, or other specialized knowledge will "assist the trier of fact to understand the evidence or determine a fact in issue."[6] A qualified expert may provide opinion testimony if it is based on significant facts or data, if it is the product of reliable methods, and if the witness has applied the methods reliably to the facts.[7] Under Rule 702, the Judge is the gatekeeper who determines whether the expert report and testimony is admissible. The sanctions for failing to meet the requirements for expert reports and testimony can be drastic, including being excluded entirely.[8]

Attorney Work Product and the 2010 Amendments to Rule 26(a)(2)

The work performed by experts for attorneys and communications between attorneys and experts generally are protected by the work product doctrine. In 2010, Rule 26(a)(2) was amended to clarify what expert material is subject to discovery and what material is off-limits. Notably, the new Rule restricted discovery of draft reports and certain attorney-expert communications. Prior to 2010, attorneys and experts engaged in a variety of inventive and costly strategies to avoid discovery of their work process and draft reports.[9] Rule 26(b)(4)(B) protects draft reports from discovery, and Rule 26(b)(4)(C) protects communications between attorneys and experts, with three crucial exceptions: compensation, facts, or data provided by the attorney, and assumptions the attorney provided and the expert relied on in forming their opinions.[10]

The 2010 amendments made another critical change. Before 2010, the report had to disclose the *data or other information* considered by the expert; after 2010, this changed to the *facts or data* considered by the expert.[11] The purpose of limiting disclosure to "*facts or data*" and not "other information" was to protect counsel's theories and mental impressions from discovery.[12]

Protect Your Work Product

The work product doctrine's protection is not absolute. The best lawyers carefully review the legal concepts and limits with their experts early on, and the best experts telephone counsel if they have any questions. As noted above, communications about the expert's compensation are not protected. This means that billing records may be discoverable. In addition, communications about compensation, including emails discussing retention agreements, may be fair game. Out of an abundance of caution, expert bills should provide enough information for payment by the client, but they should not reflect substantive analysis or opinions. When in any doubt, experts should seek the lawyer's guidance by telephone.

Facts or data provided by counsel that the expert considered to form her opinions should be listed in the expert's report as supporting exhibits, and they may be proactively produced in discovery or subpoenaed by deposing counsel. Experts should rely on the counsel that retained them to prepare any responses to these subpoenas. Communications identifying the facts or data being provided to the expert are not protected; although "further communications about the potential relevance of the facts or data are protected."[13] As a best practice, communications that identify or transmit the fact or data being provided by counsel should avoid commentary or notes on the information. Likewise, care must be taken to avoid any notes or impressions of counsel that may appear on factual documents or data sent to the expert. Transmission of facts or data should be clearly separate (and void of all discussion about the information being

transmitted) from any discussion of the meaning or application of the facts or data sent.

The last category specifically identified as discoverable is assumptions provided by counsel to the expert, which the expert relied on in forming his or her opinions. For example, one expert may opine on billing requirements and records, while another expert in the same case performs data analysis to quantify the number of claims involved and damages. Counsel may instruct the data analysis expert to make certain assumption based on the billing expert's analysis. In such a case, the assumption must be disclosed. Expert reports that rely on an assumption provided by counsel should clearly state this, and the expert should be prepared to discuss the assumptions and how he relied on them. Counsel should prepare the expert to limit his testimony to the actual assumption—not to how it was used in deliberations with counsel.

Additionally, experts must be vigilant to protect their work product and communications with counsel. Discussing the case with outsiders, or in a public place, can breach the protection—experts must never allow this to happen. Similarly, it is important to resist the urge to discuss the expert analysis with colleagues in the field—such as "just bouncing an idea off of someone"—unless this step is vetted by counsel who retained the expert. All documents, facts and data, report drafts, emails, and other communications must be properly secured and protected. This means clean desk rules, locking files for all disks and paper documents, and securing all computers and electronic files. Each page of report drafts, or anything prepared for counsel, should include a header "Prepared at Direction of Counsel—Expert Work Product" or a similar legend. Many experts routinely delete out-of-date drafts and all drafts upon finalization of the report. Counsel should review the work product doctrine and the exceptions when they retain the expert, letting them know any preferences for billing, document handling, and report drafts.

Can Cousin Vinny Write Marisa Tomei's Expert Report?

Having worked through the key federal rules and work product implications of expert retention, it is worth pausing on the sometimes contentious subject of how far a lawyer can permissibly go to "assist" an expert in compiling her report. We all know that Marisa Tomei's expert testimony on tire treads won the case for Cousin Vinny in the movie of the same name. But if Ms. Tomei provided a written expert report of her findings, could Cousin Vinny write it for her? Surprisingly, the answer is yes. The 1993 Federal Rules Committee notes state: "Rule 26(a)(2)(B) does not preclude counsel from providing assistance to experts in preparing reports, and indeed, with experts such as automobile mechanics, this assistance may be needed."[14] Of course, there are many reasons why counsel should avoid writing, or significantly rewriting, the expert's report.

In most cases, the expert must submit a written report that states all opinions to be expressed and the basis for them. The report must be "prepared and signed" by the expert. Courts have excluded the expert report and testimony altogether when they have found that the report was, in fact, prepared by counsel for the expert's signature.[15] More importantly, an expert who feels that he has been "bullied" into a report, who is not completely familiar with his own report, or simply did not put in the time will perform poorly defending opinions and the report at a deposition. A favorite tactic of counsel is to identify words or phrases used by all the experts for the other side, or in the pleadings, and to zero in for intense examination on these as areas that may not have been written by the expert. An expert who is not fully confident in her own report will have trouble establishing credibility of opinions at deposition and trial.

Of course, there are situations in which an expert i.e., data analyst or auto mechanic, needs assistance to produce a report that reflects her work and opinions in understandable terms, and the Federal Rules Advisory Committee notes permit this kind of writing by lawyers.[16] In some cases, time constraints or the typographic abilities of the expert require counsel to polish or produce the report, and this can be appropriate depending on the circumstances. Experts report that counsel often like to rearrange the order of the opinions and report sections, and this generally is acceptable to most experts. Experts should rely on counsel for delivering the report and for any requests for documents subpoenaed by opposing counsel from the expert.

What Kind of Experts Does One Need?

Identifying the types of experts needed is an important part of early case planning. Of course, the type of case will drive this analysis. Health care fraud cases have the potential to require many and varied experts, including, for example:

- False Claims Act cases based on billing issues often rely on coders and billing experts along with compliance and industry practice experts;
- Anti-Kickback Statute and Stark Law cases often require industry standards and valuation experts to help establish or rebut intent and evaluate fair market value and commercial reasonableness;
- Cases based on medical necessity may require clinical experts;
- Statistician experts are important where sampling and extrapolation are applied;
- Cases with large volumes of claims often require data mining experts; and
- Data analysis of claims and damages calculations require experts with data processing, finance, and health care claims knowledge.

Often, cases require a combination of these experts, and making certain that each expert has a designated lane and that they do not conflict with one another is an important role for coordinating counsel.

Vetting Your Expert

Mark Twain said, "An expert is anyone out of town." In health care fraud cases, one has to do a good deal more than find someone from out of town. In fact, paradoxically, the out-of-town "Pro from Dover" may play poorly with a local jury pool. Lawyers must identify experts who are highly qualified in the particular area on which they will opine, and, in health care, this can be fairly narrow.[17] The best lawyers carefully vet their experts, and the best experts expect this vetting.[18] At a minimum, the following steps should be considered:

- Fully review and resolve potential conflicts;
- Perform criminal background check;
- Verify all licenses, credentials, and degrees;
- Check the U.S. Department of Health and Human Services Office of Inspector General's List of Excluded Individuals/ Entities database;[19]
- Review relevant prior testimony and publications;
- Check websites and social media on the expert;
- Use Wayback Machine[20] to view archived websites;
- Secure *and call* expert's references;
- View the expert in person or by video to see how they would present at trial; and
- Ask the expert to explain potential opinions and press on ways he could be challenged to see how the expert holds up to scrutiny.

Shoot at the Same Target

Experts and lawyers agree that the best expert work is the result of clear communication and a full understanding of the issues on which the experts will opine. The best litigators clearly communicate the issues and the opinions they are seeking from the expert as early in the process as possible. The best experts let counsel know exactly what opinions they can and cannot provide and what data and facts they require for their analysis. The best lawyers have a clear but flexible legal strategy early on, factor the role of experts in that strategy, and communicate the strategy to their expert. As one expert explained, "You want to be sure you're shooting at the same target."

Responsiveness also is a key best practice. Newly discovered evidence, or the expert's own analysis, can require review and revision of the opinions to be expressed. Both lawyers and experts should promptly share and address any new information and make sure everyone still has the same understanding of the opinions being offered.

Experts and lawyers agree that effective time management is essential to a productive engagement. Agreeing to a sensible schedule at the outset, meeting deadlines, and leaving ample time to complete the report pays off in the end. Inevitably, conflicts and delays occur, and the best experts and lawyers advise the other immediately and work together to get back on schedule. As the process goes on, lawyers should set milestones to circle back with the expert to the basic opinions and be sure they are still shooting at the same target.

The Expert Whisperers

The best litigators instill confidence in their experts by selecting the right expert, having a clear plan for the expert's role, and communicating effectively. These practitioners share their strategy with the expert and make clear the expert's role in the big picture. Also critical is demonstrating respect for the expert's knowledge and experience as well as encouraging the expert to help identify potential problems or challenges to their opinions or reports.

The best lawyers set and adhere to a sensible schedule, providing data and facts to the expert on a timely basis. They review report drafts and provide meaningful feedback promptly. They also engage in a meaningful dialogue about the expert's analysis and opinion development, always encouraging the expert to identify and address concerns. The best lawyers work synergistically with their experts to produce a report that the expert has full confidence in and reflects his own voice. And the best lawyers recognize that an expert who wholeheartedly believes in his opinions and report will be more credible, reliable, and useful in litigation.

The Best Experts

The best experts instill confidence and credibility in their opinions, reports, and testimony. They do this by only accepting those cases in which they are fully qualified and comfortable with expressing their opinions. The best experts communicate effectively and fully understand the opinions being sought. They carefully review and understand all facts, data, and assumptions provided and perform their own independent analysis using reliable methods to arrive at their opinions. The best experts write clear opinions and reports that reflect their independent analysis, meet the needs of counsel, and help the reader understand the case. Best practices identified by experts include the following:

- Only accepting cases in which they are fully qualified;
- Fully understanding the issues and facts, as well as the opinions being sought;
- Carefully reviewing all facts and data;
- Properly supervising any assistants;

- Conducting independent review of the facts and data, using reliable methods;
- Effectively communicating with counsel about the opinions to be expressed;
- Collaborating with counsel to provide a report;
- Rigorously maintaining all attorney communications in strictest confidence;
- Complying fully with all non-disclosure orders and agreements;
- Securing all files, notes, data, and facts, report drafts as directed by counsel;
- Maintaining all Protected Health Information in accordance with the Health Insurance Portability and Accountability Act Privacy Rule;
- Marking *each page* of all drafts, notes, and other work product as "Prepared at Request of Counsel: Expert Work Product" or as directed by counsel; and
- Maintaining an accurate and complete file and list of all materials considered in preparing the report.

Je ne sais quoi

Lawyers and experts who follow best practices put themselves on the road to providing the best work for their clients. Some lawyers and their clients find experts to be a costly, unwieldy, but essential part of the litigation process. However, the most seasoned experts and lawyers report a *je ne sais quoi* in the best lawyer-expert relationships. They report working relationships that challenge their intellects, engage their analytical and writing skills, embrace their independence and expertise, and allow the expert to create the best expert work in support of the lawyer's strategy. When exceptional lawyers work synergistically with their experts and follow best practices, they produce persuasive, credible, and reliable opinions and testimony, helping achieve the best possible work product for their clients.

**We would like to thank Mary Wickens, JD, CFE (M.K. Wickens PLC, East Lansing, MI) for authoring this article.*

1 This article generally is limited to a discussion of federal civil health care fraud cases, although many of the same concepts will apply in criminal matters and state cases. The Federal Rules of Criminal Procedure, Rule 16(a)(1)(G) govern expert disclosures in criminal cases.
2 Fed. R. Civ. P. 26(a)(2)(B)(i).
3 Fed. R. Civ. P. 26(a)(2)(B).
4 Fed. R. Civ. P. 26(a)(2)(B)(ii).
5 Fed. R. Civ. P. 26(a)(2)(B)(iv)(v)(vi).
6 Fed. R. Evid. 702.
7 *Id.*
8 *See United States ex rel. Paradies v. Aseracare Inc.*, No. 2:12-cv-245-KOB, Doc. 268, (N.D. Ala. Dec. 4, 2014) (excluding testimony in hospice FCA case, because the expert, while qualified in pharmacy and general medicine, did not have hospice-specific experience); s*ee also Numatics Inc. v. Balluff, Inc.* No. 2-13-cv-11049, (E.D. Mich. Dec. 16, 2014) (court excluded expert's report and testimony and criticized lawyers for writing the report in its entirety).
9 The 2010 Committee notes describe their concerns: "The Committee has been told repeatedly that routine discovery into attorney-expert communications and draft reports has had undesirable effects. Costs have risen. Attorneys may employ two sets of experts—one for purposes of consultation and another to testify at trial—because disclosure of their collaborative interactions with expert consultants would reveal their most sensitive and confidential case analyses. At the same time, attorneys often feel compelled to adopt a guarded attitude toward their interaction with testifying experts that impedes effective communication, and experts adopt strategies that protect against discovery but also interfere with their work."
10 Fed. R. Civ. P. 26(b)(4)(C).
11 Jason J. Rawnsley, *The 2010 Amendments to the Expert Discovery Provisions of Rule 26 of the Federal Rules of Civil Procedure: A Brief Reminder,* ABA's Section of Litigation, 2012 Section Annual Conference Apr. 18-20, 2012, *available at* www.americanbar.org/content/dam/aba/administrative/litigation/materials/sac_2012/43-4_2010_amendments_to_rule_26.authcheckdam.pdf (last visited Oct. 22, 2015).
12 *Id.*
13 Fed. R. Civ. P. 26, Advisory Committee's Note 1993.
14 *Id.*
15 *Numatics*, at 4 (excluding the expert because "he did not draft his own report; defense counsel drafted it for him.).
16 Fed. R. Civ. P. 26, Advisory Committee's Note 1993.
17 *United States ex rel. Paradies v. Aseracare Inc.*, No. 2:12-cv-245-KOB, Doc. 268, (N.D. Ala. Dec. 4, 2014 (the court excluded expert Dr. Perri because he merely "recited documentary evidence and testimony" p.20; and because although "highly qualified in . . . pharmacy and general healthcare marketing" he was not qualified *in the hospice industry*" p. 19).
18 Large law firms may have designated staff to perform this function, but it is important for the litigation case team to be involved in the vetting process to be comfortable with the expert. There are commercial services that will provide the legal community with expert background checks for a fee, and these are easily located online.
19 *See* http://oig.hhs.gov/exclusions/exclusions_list.asp (last visited Nov. 5, 2015).
20 *See* https://archive.org/web (last visited Nov. 5, 2015).

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