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The Use of Extrapolation Under the 60-Day Report and Repay Requirement

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As nearly every attorney working in health law is aware, the Centers for Medicare & Medicaid Services (CMS) recently issued its final rule on reporting and repaying identified overpayments under Medicare Parts A and B. The final rule was issued on February 12, 2016, nearly six years after the repayment obligation was passed into law under the Affordable Care Act (ACA).[1] While the statutory requirement to repay any identified overpayments within 60 days has been effective since the ACA took effect, providers have lacked clarity on CMS' final interpretation of certain key terms within the statute.

Briefly, some of the highlights from the final rule are:

- The 60-day repayment clock will begin to run only after the provider has identified the overpayment and quantified the amount, so long as the provider exercises reasonable diligence in doing so.
- Reasonable diligence includes both proactive compliance activities designed to detect overpayments and reactive investigations designed to quantify overpayments in response to credible information.
- In nearly all circumstances, investigation and repayment should be completed within eight months—six months for investigation and 60 days (two months) for reporting and repaying after identification.
- Failure to exercise reasonable diligence causes the 60-day repayment clock to reference

back to the date the provider received credible information of the overpayment.

- The lookback period for making repayment is six years from the date of reporting and repaying (formerly proposed to be ten years).

As many commentators have noted, the final rule retreats from some of the most onerous aspects of CMS' original proposal. That does not mean that the final rule is easy to comply with, nor does it mean there are no hidden pitfalls for providers to stumble into if care is not taken.

One such potential danger relates to the interplay between the 60-day report and repay requirement (60-Day Rule) and the contractor audits many providers encounter on a routine basis. The final rule makes clear that unfavorable determinations made by Medicare contractors as part of an audit may serve as credible information triggering further investigation by the audited provider.[2] CMS grants a small amount of leeway in exercising reasonable diligence at the conclusion of an audit, allowing providers to complete the administrative appeals process before investigating other possible overpayments on the same issue.[3] The risks associated with the 60-Day Rule are compounded, however, when the contractor audit uses statistical sampling and extrapolates the results of the audit.

Extrapolation is one of the most punitive tools available to CMS. It reduces the burden on the contractors to actually review medical records submitted by providers and maximizes the return on a contractor's auditing efforts. It also significantly impairs a provider's ability to successfully appeal the entire amount of an unfavorable determination by tying large amounts of alleged overpayments to a relatively small number of claims on a proportional basis. Only the specifically identified claims may be appealed. The immense power of extrapolation is recognized, and limited somewhat, by the requirement that certain findings be made before a contractor can use extrapolation for assessing an overpayment.[4] Notwithstanding this limitation, extrapolation continues to be used by contractors and, increasingly, by the U.S. Department of Health and Human Services Office of Inspector General (OIG) in its provider audits. Thus, the interplay between extrapolation and the 60-Day Rule bears closer examination.

The Prevalence of Extrapolation in Audits

As noted, extrapolation is a tool that continues to be used by contractors in assessing overpayments against providers under the Medicare program. Once, it was a tool almost exclusively used by the Zone Program Integrity Contractors (ZPICs).[5] Tasked with identifying fraud, waste, and abuse, the ZPICs were a relatively natural fit for using such a tool. Gradually, however, other contractors have utilized extrapolation for the purposes of identifying overpayments, including Medicare Administrative Contractors (MACs). Even Recovery Auditors are ostensibly granted the ability to use extrapolation, though only under approval from CMS.

In addition to Medicare contractors, OIG has ramped up its use of sampling and extrapolation in its Medicare compliance reviews as well. The majority of compliance reviews issued by OIG over the past year have incorporated extrapolation of at least some issues for the purpose of quantifying the final overpayment amount. OIG's use of extrapolation is potentially more problematic for providers than when used by Medicare contractors because OIG does not appear to be limited in using the tool only under certain circumstances (e.g., in the event of a high or sustained error rate) and because OIG merely "recommends" that a provider refund the alleged overpayment amount.

While possible, it would be foolhardy for a provider to simply ignore OIG's recommendation to refund the alleged overpayment. OIG's role outside of the usual claims review and auditing process becomes significant if the provider disagrees with OIG's findings and wishes to appeal. Where extrapolation is used, the provider can only appeal those claims specifically denied, and only after making a very careful refund to the MAC in which each denied claim is identified in order to preserve future appeal rights. The provider has no means of challenging the entire alleged overpayment and must instead rely on the contractor to apply any denied claims reversed on appeal to a proportional amount of the extrapolated overpayment.

The other prevalent use of extrapolation is by providers conducting internal audits that result in voluntary refunds. By using statistical sampling and extrapolation, providers can use the efficiencies of the methodology to their advantage, eliminating the need for 100% claim review. It also can enable providers to refund overpayments related to billing errors with a high rate of occurrence without simply resorting to refunding all such claims. Generally speaking, when a provider makes a voluntary refund, the question of appealing is not an issue, making extrapolation all the more attractive.

Impact on the 60-Day Rule on Extrapolations Conducted by the Government

With respect to Medicare contractor audits, the most important element of the 60-Day Rule is the fact that the audit results serve as credible information about a possible overpayment. Therefore, depending on the nature of the overpayment identified during the audit, a provider may have a duty to investigate with reasonable diligence. For extrapolations, the population of claims covered by the audit may help reduce the scope of any follow-up investigation, but the contractors remain limited to the four-year reopening period for conducting their own audits.[6] Since providers are required under the final rule to look back for six years,[7] providers may be forced to conduct further investigations going back an additional two (or more) years, even when the contractor uses extrapolation. However, a provider also has the right to appeal the audit results, which tolls the provider's responsibility to investigate until the appeals are concluded.

For OIG audits, all audit reports trigger the need for providers to make at least some amount of "voluntary" repayment. However with respect to audits involving extrapolation, a provider's rights and responsibilities get significantly more complicated and correspondingly less clear. The fact that a repayment that flows from an OIG audit is technically voluntary does not eliminate a provider's right to appeal any specifically identified claims.[8] (Convincing the MAC of that, and figuring out when the appeal rights and related deadlines begin, can unfortunately be a murky exercise in persistent communication.)

OIG audits also come with the complication of the three-year recovery period.[9] In its audits using extrapolation over the past year, OIG has limited its repayment recommendations to the three calendar years preceding the release of the audit report, regardless of how far back the actual claims audited go. This creates much confusion over which claims are actually included in the recommended repayment, both in terms of specifically denied claims and extrapolated amounts. For providers seeking to appeal some, but not all, of the claims alleged to be overpaid, this creates yet another obstacle to exercising those rights.

Impact of 60-Day Rule on Provider Use of Extrapolation

Extrapolation is generally used by providers when an internal audit is conducted and uncovers a fairly widespread issue requiring repayment. By using extrapolation, the provider reduces the amount of resources it must devote to actually quantifying the problem. The final rule provides useful parameters for conducting such extrapolations by establishing the six-year lookback period and setting a timeframe for finalizing a report and making repayment.

Given the heightened risks associated with failure to adhere to the 60-Day Rule (i.e., False Claims Act liability), providers may be inclined to be overly cautious, especially in light of the final rule's affirmation that appeal rights exist even for those claims repaid voluntarily. This may lead providers to make overly inclusive or even unnecessary reports and repayments. However, using extrapolation for such repayments could leave providers without the ability to effectively appeal the repayments once they are made, since only specifically identified claims that are repaid may be appealed.

However, providers may not repay a subset of claims from a sample that should be extrapolated and then appeal those repayments, thereby tolling the requirement to make further repayment.[10] Though not explicitly stated, it is likely that

CMS recognizes the risk of allowing such appeals considering the current status of the administrative appeals process at the Administrative Law Judge (ALJ) level. Under usual circumstances, allowing providers to seek an appeal determination on a subset of claims prior to initiating full repayment would have minimal risk for the government, but given the current multi-year delay for providers seeking an ALJ hearing, such a process would risk losing the entire amount of claims due to be repaid as the lookback period expired while the appeals remain pending.

Conclusion

The processes and expectations established under the 60-Day Rule certainly have greater clarity since the release of the final rule. The provisions of the 60-Day Rule establish the necessary parameters for providers to avoid running afoul of the requirement to report and repay accidentally, even as they create situations where a contractor audit of a single year of claims can trigger a provider's investigation of an additional five years' worth of claims.

More troubling problems arise when extrapolation is used with denials involving subject determinations of medical necessity. For such cases, including determinations of whether inpatient care was appropriate or a patient was covered for inpatient rehabilitation services, the use of extrapolation is arguably inappropriate due to the variable facts of each claim. This has not stopped contractors or OIG from using extrapolation to seek recovery of large overpayments against providers. Given the subjective nature of the reviews involved in determinations of medical necessity, such audits can prove very exasperating to a provider. In these instances, a provider may choose to hold out for contractor audits to identify any alleged overpayments, thereby avoiding the need to use extrapolation in an internal audit and potentially impairing any right to challenge the determination on appeal.

Thus, while the clarifications provided by CMS under the final rule are useful in assisting providers with complying with the 60-Day Rule, there remain a number of opportunities for providers to make costly mistakes. The final rule makes it explicitly clear that providers are now subject to a requirement to follow up on contractor audits with investigations of their own to determine if other related overpayments exist. The extension of the reopening timeframe for providers making repayments under the 60-Day Rule opens providers to risks associated with audits, particularly extrapolated ones that are necessarily limited to either the three-year recovery period or the four-year reopening window.

Furthermore, the implications of the 60-Day Rule for providers subject to extrapolated audits are multiplied by the very nature of extrapolation. As with all extrapolations, inaccuracy in determining the applicable error rate and double-counting are risks. These can be amplified when the provider is placed under a duty to further investigate the matter. With extrapolated audits, appeals are more difficult and time-consuming, and they carry higher stakes in the form of proportional amounts of the extrapolated overpayment tied to each specifically identified claim at issue.

Luckily, the 60-Day Rule also clarifies the impact of administrative appeals on providers' duty to follow up on contested audit findings. The one silver lining for providers tied to the appeals backlog is the potential for their duty to make further inquiries into audit results, extrapolated or not, to be delayed (or extinguished) while appealed denials are pending. This one benefit, however, does little to offset the significant hurdles providers face in all aspects of the current auditing environment: appeal delays, extrapolation, and the burden of the 60-Day Rule.

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1 *See* 81 Fed. Reg. 7,654-7,684 (Feb. 12, 2016). CMS issued a separate Final Rule on the 60-day repayment requirement for Medicare Parts C and D overpayments in 2014. *See* 79 Fed. Reg. 29,844 (May 23, 2014). CMS has not issued rules with respect to Medicaid overpayments.

2 *See* 81 Fed. Reg. at 7,667.

3 *See id.* at 7,668.

4 *See* 42 U.S.C. § 1395ddd(f)(3). Contractors may only use extrapolation where a finding is made that: (1) a "sustained or high" error rate exists; or (2) "documented educational intervention" has failed to correct payment errors. The finding of a sustained or high error rate is not appealable.

5 Formerly, the Program Safeguard Contractors, or PSCs.

6 *See* 42 C.F.R. § 405.980(b).

7 *See* 81 Fed Reg. at 7,671.

8 *See id.* at 7,668.

9 *See* 42 C.F.R. § 1395gg(b); *see also* Medicare Financial Management Manual, CMS Pub. 100-06, Ch. 3, § 80. The statutory provision limiting liability was revised in 2013 to extend for five calendar years, but the Medicare manuals have never been revised and still limit liability to three calendar years. OIG continues to refer to the "three-year recovery period."

10 *See* 81 Fed. Reg. at 7,668.

Chair's Column

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As I write this column, the leadership team of the Fraud and Abuse Practice Group (F&A PG), like those of the other AHLA PGs, is busy wrapping up Fiscal Year 2015-2016 and planning for the next year. That means we're lining up next year's leadership rosters, wrapping up this year's projects, and beginning to set our goals for next year.

So, it seems like a good time to revisit the many benefits that our PG has worked hard all year to provide to you, our members. I'm often asked whether it's worthwhile to join our PG and, if so, why. My simple answer is that our PG provides a variety of products and materials to keep you up-to-date on all the developments associated with health care fraud and abuse laws. For example:

Assuming that you have your email preferences set appropriately, you will receive from our PG, throughout the year, email alerts on enforcement activities such as settlements, judicial opinions, and indictments, all of which are drafted by our Enforcement Committee volunteers. You also will receive compliance email alerts from us, which focus more on prospective compliance issues, such as new guidance from the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), all of which are drafted by our Compliance Committee volunteers. And our Advisory Opinions Task Force generates timely summaries of HHS-OIG's Advisory Opinions, as well as the Centers for Medicare & Medicaid Service's Stark Advisory Opinions, which also are sent to members by email. If you are a member of the PG and are not receiving these, check your email preferences on the AHLA website or contact AHLA staff.

In addition to these email alerts, which tend to be fairly short so as to be timely and easily digestible, our PG also publishes a number of Member Briefings and Executive Summaries, which provide more-detailed analysis of fraud and abuse developments. Last summer, for example, we issued a very insightful Executive Summary drafted by one of our volunteers on the second Fourth Circuit decision in the *Tuomey* case. We also coordinate with other PGs to bring you Member Briefings and Executive Summaries that are generated by them but are of interest to our members as well.

In addition to these analyses that are sent to you via email, our PG also provides broader resources that are available exclusively to F&A PG members through our website. For many years we have maintained a 50-State Survey of fraud and abuse laws, which contains a summary of each state's (and DC's) fraud and abuse statutes. More recent additions to the website have included the Stark Law Toolkit, which provides various resources relating to the Stark Law and the Self-Referral Disclosure Protocol, and the similar Anti-Kickback Statute (AKS) Toolkit, which we were excited to launch recently. In addition to information regarding the statute and regulations, the AKS Toolkit contains analyses of relevant court opinions. Plans already are being implemented to update and to add case law analyses to the Stark Law toolkit, as well.

You already know about our newsletters, of course, because you're reading this column in our second newsletter issued this fiscal year. The newsletter articles are particularly valuable, because they give the authors and readers an opportunity to dive deeply into specific angles of fraud and abuse law and to explore their practical implications. As such, the articles reflect the diversity of the fraud and abuse practice around the nation.

But not everything we do is transmitted by email or posted to the website. We also sponsor webinars on a variety of fraud and abuse topics of interest, focusing on compliance and enforcement. This past year, we sponsored an unprecedented ten-part series of compliance webinars, each of which focused on a different part of the health care industry and the compliance challenges specific to that part of the industry. In past years, we have sponsored "boot camp" webinar series designed to provide a solid foundation of fraud and abuse knowledge for attorneys new to the practice of health care law. While participation in these webinars is not limited to F&A PG members, we do provide a discount to our members. In addition, we co-sponsor a number of webinars with other PGs, so our members also get the benefit of discounted participation in those co-sponsored webinars as well.

As you can see, our entire PG, including most importantly our many volunteers, put a great deal of effort into making sure you, the member, get value out of your membership. But there's always room to improve. If you think of something else we could be doing that would add value to your practice, or something you think we could do better, please don't hesitate to contact me at lweidenfeld@jonesday.com. And if you'd like to get involved in any of these many volunteer opportunities—and every item I listed above relied on the efforts of numerous volunteers—don't be shy about letting me know that, too.

Sincerely,

Laura

Resolving the Split(s): The FCA's Implied Certification Theory and the *Escobar* Case

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On December 4, 2015, the U.S. Supreme Court granted the petition for writ of certiorari in *Universal Health Services, Inc. v. United States ex rel. Escobar*.[1] Specifically, the Court granted certiorari on the following two questions: (1) whether the "implied certification" theory of legal falsity under the federal False Claims Act (FCA) is viable; and (2) if so, whether a claim for reimbursement can be "legally false" under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment.[2] The Court's opinion in *Escobar* (likely to be released in the summer of 2016) is set to resolve a deep and long-standing circuit split on both the viability and (if it is found viable) the proper scope of the FCA's implied certification theory. This article discusses the FCA's implied certification theory, the circuit split that has developed surrounding that theory, and the *Escobar* case that may finally resolve that split.

The FCA's Implied Certification Theory

Factual vs. Legal Falsity

The FCA makes it unlawful to, among other things, knowingly present (or cause to be presented) a "false or fraudulent" claim for government reimbursement.[3] A claim can be "false" under the FCA if it is either *factually* false or *legally* false.[4] "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government…."[5] In the health care context, a factually false claim can be most easily described using the following hypothetical: Dr. Jones submits a claim for reimbursement to Medicare. On its face, the claim says, "Dr. Jones saw Patient X on Day Y." If Patient X does not exist, or if Dr. Jones did not actually perform the services on Day Y, then the claim is factually false and the government can bring a claim against Dr. Jones under the FCA.[6]

On the other hand, "a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment."[7] Using a variation of the Dr. Jones hypothetical, above, an example of a legally false claim in the health care context is as follows: Dr. Jones submits a claim for reimbursement to Medicare. On its face, the claim says, "Dr. Jones saw Patient X on Date Y." Dr. Jones did actually see and provide care for Patient X on Date Y; however, Patient X was referred to Dr. Jones in exchange for an illegal kickback in violation of the Anti-Kickback Statute (AKS).[8] Although Dr. Jones performed the services for which he claims reimbursement, the government could bring a claim against Dr. Jones under the FCA on the grounds that the claim is "legally false," because the government would not have reimbursed Dr. Jones if it had known about his payment of illegal kickbacks.[9] FCA liability for a legally false claim is based on a "false certification" theory of liability.[10]

Types of Legal Falsity—Express and Implied

Within the general "false certification" theory of liability are two "sub-types" of false certifications: express and implied.[11] Under the "express certification" theory, "an entity is liable under the FCA for falsely certifying its compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds."[12] For example, each year, as part of the cost reports that hospitals must submit to the Centers for Medicare & Medicaid Services (CMS), CMS requires a hospital officer or administrator to expressly certify that—to the best of his or her "knowledge and belief"—the cost report is true and correct, that the officer or administrator is "familiar" with the health care laws and regulations, and that "the services identified in [the] cost report were provided in compliance with such laws and regulations."[13] Thus, a hospital's failure to comply with this express certification can lead to FCA liability.[14]

The "implied certification" theory, on the other hand, imposes liability "when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment. Thus, an implied false certification theory of liability is premised 'on the notion that the *act of submitting a claim* for reimbursement itself *implies* compliance with governing federal rules that are a precondition to payment.'"[15] Historically, a common example of the implied certification theory in the health care context was the government's and the courts' imposition of FCA liability where a provider submitted claims that were "tainted" by an illegal kickback. Although the Affordable Care Act of 2010 (ACA) amended the AKS to make all AKS violations per se false claims for purposes of the FCA, many courts, prior to the ACA, had found that claims tainted by an illegal kickback constituted false claims under the FCA under the implied certification theory (i.e., by submitting a claim, a health care provider is implying compliance with all applicable rules, including those prohibiting kickbacks).[16]

The Current Circuit Split

Currently, the federal circuit courts are split on *both* the viability and the proper scope of the implied certification theory.

The Viability of the Implied Certification Theory

Up until now, the federal circuits have not been able to agree even on the most fundamental question related to the implied certification theory: whether it is viable in the first place. Indeed, the Seventh Circuit recently rejected the implied certification theory outright.

In *United States v. Sanford-Brown, Ltd.*, the qui tam relator, a former Director of Education at Sanford-Brown College, alleged that the college had made false certifications as part of the college's acceptance of federal subsidies from the U.S. Department of Education under the Higher Education Act.[17] Specifically, the relator argued that the school had engaged in many instances of inappropriate recruiting and retention practices in violation of the Program Participation Agreement (PPA) entered into by all institutions of higher education receiving federal funding.[18]

In dismissing the relator's claims, the Seventh Circuit held that "[g]ood-faith entry into the PPA is the condition of payment necessary to be eligible for subsidies under the U.S. Department of Education's subsidies program."[19] Thus, "[a]bsent evidence of fraud before entry, nonperformance after entry into an agreement for government subsidies does not impose liability under the FCA."[20] Stating that it would be unreasonable to hold that the school's ability to receive payments required "continued compliance with the thousands of pages of federal statutes and regulations incorporated by reference into the PPA," the court dismissed the idea that the college had impliedly certified such compliance.[21]

The Proper Scope of the Implied Certification Theory

Although the majority of circuit courts have accepted the viability of the implied certification theory, those courts are split on the proper scope of the theory. Specifically, the Second, Third, Sixth, and Tenth Circuits all recognize that a federal government contractor impliedly certifies compliance with a statute, regulation, or contractual provision for purposes of FCA "falsity" *only if* the government expressly conditions payment on such compliance; in other words, the legal obligation in question must be explicitly designated as a condition of payment.[22]

The Second Circuit's decision in *Mikes v. Strauss* serves as the seminal case for this proposition. There, the court noted that "[s]ince the [False Claims] Act is restitutionary and aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced the government's decision to pay."[23] Thus, with respect to the implied certification theory, the court held that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid."[24]

By contrast, the First, Fourth, and DC Circuits do not require a condition of payment to be expressly and clearly identified when applying the implied certification theory.[25] Indeed, these courts have found "implied conditions of payment" that are not expressly enumerated in the text of a relevant statute, regulation, or contract. For example, in *U.S. ex rel. Hutcheson v. Blackstone*, the First Circuit explicitly rejected the decision in *Mikes*—holding that a hospital that had submitted provider agreements and cost reports to Medicare certifying compliance with the AKS, while simultaneously engaging in a kickback scheme, had violated the FCA.[26] The court did not care to distinguish between "express" and "implied" conditions of payment; rather, the court instead opined that the forms submitted by the hospital stated with clear specificity that compliance with the AKS was a precondition to payment, and that failure to comply with the AKS meant that the hospital could not seek reimbursement from the Medicare program.[27]

The *Escobar* Case

In the current case before the Supreme Court, a teenage girl, Yarushka Rivera, received behavioral health services from staff members at a clinic operated by Arbour Counseling Services in Lawrence, MA (Arbour) after experiencing behavioral problems at school.[28]

The Arbour clinic participates in the Massachusetts Medicaid program (MassHealth) and bills MassHealth for services rendered by its staff.[29] Yaruska's parents, the relators in this case, met with the counselor's supervisor after receiving reports from their daughter that the counseling sessions were not beneficial to her.[30] Based upon their meetings with the supervisor and additional inquiry, the parents became convinced that the supervisor was not exercising any direct supervision over his counselors, and, in addition, learned that none of the Arbour counselors who treated Yarushka were appropriately licensed.

For example, one of the counselors "held herself out as a psychologist with a Ph.D.",[31] which turned out to be factually inaccurate.[32] Eventually, Yarushka's school informed her parents that she would not be permitted to return to school unless she was receiving treatment from a psychiatrist.[33] The parents reported this requirement to the purported psychologist, who in turn referred Yarushka to yet another counselor at Arbour. As Yarushka's parents later would discover, however, this new counselor was not a licensed psychiatrist, but, rather, was a licensed nurse who did not even work under the supervision of the sole psychiatrist on the staff at Arbour's Lawrence location.[34]

After diagnosing Yarushka with bipolar disorder, the nurse prescribed medication that Yarushka did not tolerate well, and she experienced a seizure resulting in her hospitalization. Although Yarushka temporarily stopped taking the medication, she resumed her treatment following a conversation between her parents and the Arbour supervisor. Approximately six months thereafter, Yarushka suffered another seizure and died.[35]

Yarushka's parents first took their complaints to state regulatory agencies, including the Massachusetts Department of Public Health (DPH).[36] DPH's investigation largely validated the parents' allegations regarding Arbour, and found that "23 therapists were not licensed for independent practice and also . . . not licensed in their discipline."[37] In addition, DPH found that Arbour had no documentation that its staff practiced with any appropriate clinical supervision. Arbour entered into a plan of corrective action in order to resolve the deficiencies. In addition, some of the counselors and the supervisor for Yarushka's treatment individually entered into consent agreements with their separate, applicable licensing agencies, and one agreed to pay a $1,000 civil penalty.[38]

Dissatisfied with the administrative remedies, Yarushka's parents filed a complaint under both the federal and Massachusetts FCAs.[39] They alleged that, by submitting claims for services performed by the unlicensed and unqualified counselors, supervisor, and psychiatrist, Arbour had falsely certified that the staff members possessed legally required qualifications and licenses to render the services for which compensation from the government was sought. Specifically, their complaint alleged that: (1) the lack of supervision over clinic caregivers was in violation of MassHealth regulations; and (2) the clinic violated the staff composition requirements contained in those regulations, because it did not employ a board-certified or board-eligible psychiatrist or licensed psychologist.[40]

The district court dismissed the relators' complaint in its entirety by drawing a distinction between "conditions of payment" and "conditions of participation."[41] It acknowledged that deficiencies in staff qualifications, licensing, and supervision had occurred in the course of Yarushka's treatment, but held that those deficiencies involved conditions of participation in the Medicaid program, for which the appropriate remedy would be to seek Arbour's removal from the Medicaid program.

On appeal, the First Circuit applied the standard it had set in a 2011 case: "[W]hether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment."[42] Building on its reasoning from *Blackstone*, the First Circuit repeated its contention that such preconditions of payment need not be "expressly designated."[43] Rather, said the court, "the question whether a given requirement constitutes a precondition to payment is a 'fact-intensive and context-specific inquiry."[44]

Applying such inquiry in the *Escobar* case, the court then concluded that the MassHealth regulations "pertaining to staff supervision and core staffing at satellite centers is a condition of payment," and that the relators' "carefully compiled information" showed "noncompliance with conditions of payment . . . sufficient to establish the falsity of a claim," without addressing whether the FCA "embraces a distinction between conditions of payment and conditions of participation."[45]

Conclusion

The Supreme Court granted certiorari in the *Escobar* case on December 4, 2015, heard oral arguments on April 19, 2016, and is expected to issue an opinion in the case sometime in the summer of 2016. The issues currently before the Court allow it to resolve the circuit split regarding the viability of the implied certification theory, as well as the split regarding the theory's proper scope (if it is deemed viable in the first place). Whether the Court decides to expand, restrain, or altogether eliminate the implied certification theory, its decision in *Escobar* will likely have a significant impact on health care providers' potential liability under the FCA going forward.

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1 Case No. 15-7.
2 Petition for Certiorari, at p. ii.
3 31 U.S.C. § 3729(a)(1)(A).
4 *U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011).
5 *Id.*
6 In this example, of course, FCA liability might be the least of Dr. Jones' concerns, as this hypothetical conduct could lead to criminal liability.
7 *Wilkins*, 659 F.3d at 305.
8 42 U.S.C. § 1320a-7b.
9 Once again, FCA liability might be the least of Dr. Jones' concerns, as the AKS is a criminal statute carrying with it the possibility of up to five years' imprisonment.
10 *Wilkins*, 659 F.3d at 305.
11 *Id.*
12 *Id.* (citing *Rodriguez v. Our Lady of Lourdes Med. Ctr.,* 552 F.3d 297, 303 (3d Cir. 2008)).
13 Centers for Medicare & Medicaid Services, Form CMS-2552-10, *available at* www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3P240f.pdf.
14 *See U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998).
15 *Wilkins*, 659 F.3d at 305 (quoting *Mikes v. Straus,* 274 F.3d 687, 699 (2d Cir. 2001)) (emphasis added).
16 *See, e.g., U.S. ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211, 1223 (10th Cir. 2008); *see also, McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005).

17 788 F.3d 696, 700 (7th Cir. 2015).
18 *Id.*
19 *Id.* at 711.
20 *Id.*
21 *Id.* (explicitly stating that the court rejects the "doctrine of implied false certification" and joins the Fifth Circuit's decision in *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir. 2010)). Although the Seventh Circuit states that it is "joining" the Fifth Circuit in rejecting the implied certification theory, the Fifth Circuit has actually never explicitly rejected the implied certification theory, although it has not explicitly adopted it either. Both parties to the *Escobar* case acknowledge this in their respective briefs before the Supreme Court. *See* Cert. Petition at p. 29, n.7, and Brief in Opposition to Cert. Petition at pp. 26-27.
22 *See Mikes v. Strauss*, 274 F.3d 687, 702 (2d. Cir. 2001); *U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011); *U.S. ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211 (10th Cir. 2008) ("Based on the fact that the government has established a detailed administrative mechanism for managing Medicare participation, we are compelled to conclude that although the government considers substantial compliance a condition of ongoing Medicare *participation*, it does not require perfect compliance as an absolute condition to receiving Medicare *payments* for services rendered").
23 *Mikes,* 274 F.3d at 697.
24 *Id.* at 700 (emphasis added).
25 *See U.S. ex rel. Hutcheson v. Blackstone*, 647 F.3d 377, 386-88 (1st Cir. 2011) (expressly acknowledging disagreement with the Second Circuit in *Mikes*); *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 636 (4th Cir. 2015); *United States v. Science Applications Int'l Corp. (SAIC)*, 626 F.3d 1257 (D.C. Cir. 2010) (noting disagreement with the Second Circuit in *Mikes* and holding that "to establish the existence of a 'false or fraudulent' claim on the basis of implied certification of a contractual condition, the FCA plaintiff – here the government – must show that the contractor withheld information about its noncompliance with material contractual requirements").
26 647 F.3d at 395.
27 *Id.*
28 *U.S. ex rel. Escobar v. Universal Health Services, Inc.,* 780 F.3d 504 (1st Cir. 2015).
29 Petition for Certiorari, at 6.
30 *Id.*
31 *Id.*
32 *Id.*
33 *Id.*
34 *Id.*
35 *Id.*
36 *Id.* at 8.
37 *Id.* at 9.
38 *Id.*
39 *Id.* at 10.
40 *Id.* at 7.
41 *Id.* at 11.
42 *U.S. ex rel. Escobar v. Universal Health Services, Inc*, 780 F.3d 504, 512 (1st Cir. 2015) (citing *New York v. Amgen, Inc.*, 652 F.3d 103, 110 (1st Cir. 2011)).
43 *Id.*
44 *Id.* at 512-13 (quoting *Amgen*, 652 F.3d at 111).
45 *Id.* at 517.

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Fraud, Abuse, and Enforcement Trends in SNF Therapy Billing

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Over the last decade, the federal government has increasingly scrutinized how skilled nursing facilities (SNFs) bill for physical therapy, occupational therapy, and speech language pathology services (collectively, therapy services). It seems this trend will continue, as the U.S. Department of Health and Human Services Office of Inspector General (OIG) highlighted SNF therapy billing as one of its areas of focus in the Fiscal Year (FY) 2016 Work Plan, and issued *two* scathing reports in 2015 related to SNF therapy billing. This governmental focus also is evident in the number of recent enforcement actions related to SNF therapy billing, culminating in the January 2016 $125 million settlement between Kindred/Rehabcare and the U.S. government to resolve False Claims Act (FCA) allegations related to improper SNF therapy billing.

Background

The Medicare Part A SNF benefit covers skilled nursing care, therapy services, and other services.[1] To qualify for the SNF benefit, a beneficiary must be admitted to the SNF within 30 days of an inpatient hospital stay that lasted at least three consecutive days.[2] Except for certain specifically excluded services, SNFs must submit to Medicare all claims for the services that its residents receive, including all therapy services. SNFs are paid on the basis of a prospective payment system (PPS) that covers all costs of furnishing covered SNF services.

During a Part A stay, an SNF must periodically assess each beneficiary and assign them to a resource utilization group (RUG), which determines how much Medicare pays the SNF each day for the beneficiary's care.[3] There are 66 RUGs grouped into eight categories. Two categories are for therapy RUGs, and the remaining six categories are for non-therapy RUGs.

The therapy RUGs are each divided into five levels: ultra-high, very high, high, medium, and low. An SNF must categorize each beneficiary into one of these levels primarily on the basis of the amount of therapy provided during a seven-day assessment period.[4] The more therapy a beneficiary receives during the assessment period, the higher the RUG level the beneficiary is placed into. In addition, RUGs are generally divided by the amount of assistance a beneficiary needs with certain activities of daily living (ADLs). A beneficiary who needs high levels of assistance is categorized into a RUG with a high ADL score, whereas a beneficiary who needs less assistance is categorized into a RUG with a lower ADL score. Payment rates for therapy RUGs are typically higher than for non-therapy RUGs, and payment rates increase as the level of therapy increases and as the ADL score increases.

This system incentivizes SNFs to place beneficiaries into the highest therapy RUG possible in order to be paid at the highest rate, while providing the minimum amount of therapy necessary to qualify for each RUG. In a story published on August 16, 2015, the *Wall Street Journal*[5] describes the results of an analysis it conducted on SNF billing patterns between 2001 and 2013, which found that the use of the ultra-high category of rehabilitative therapy reimbursement increased from 7% of patient days in 2002 to 54% of patient days in 2013. CMS, in comments to the proposed FY 2015 SNF PPS Rule,[6] noted that the percentage of SNF residents classified into ultra-high rehabilitation groups has increased "rather steadily." CMS also observed that many patients are receiving the minimum minutes of therapy to qualify for a given RUG.

Recent data supports these estimations. On March 9, 2016, CMS published a fact sheet, "Medicare Skilled Nursing Facility (SNF) Transparency Data (CY2013),"[7] which summarizes CMS' analysis of payment information on 15,055 SNFs, over 2.5 million stays, and almost $27 billion in Medicare payments for 2013. The data regarding RUG utilization shows that the top RUGs in terms of both payment amount and numbers of days were ultra-high RUGs. Furthermore, a majority of SNFs had assessments that showed therapy provided within 10 minutes of meeting the *minimum* thresholds for ultra-high or very high rehabilitation RUGs.

Under these circumstances, it is easy to see why enforcement agencies and qui tam relators alike are continuing to focus on SNF therapy billing.

OIG FY 2016 Work Plan

For several years, OIG has expressed suspicion about the ever-increasing numbers of SNF residents placed into higher, and thus more expensive, therapy RUG levels. In its FY 2015 Work Plan, OIG noted that Medicare Part A billing was a topic of interest and that OIG intended to explore therapy utilization trends. Similarly, in the 2014 Work Plan, OIG indicated that its prior work reflected that SNFs "increasingly billed for the highest level of therapy even though beneficiary characteristics remained unchanged."

OIG's focus on SNF therapy billing will continue in 2016. The FY 2016 Work Plan[8] includes a focus on SNF PPS requirements related to therapy billing. Specifically, OIG states that:

> We will review compliance with various aspects of the skilled nursing facility (SNF) prospective payment system, including the documentation requirement in support of the claims paid by Medicare. Prior OIG reviews have found that Medicare payments for therapy greatly exceeded SNF's cost for therapy. In addition, we have

found that SNFs have increasingly billed for the highest level of therapy even though key beneficiary characteristics remained largely the same. We will determine whether SNF claims were paid in accordance with Federal laws and regulations. All documentation requirements specified in 42 CFR § 483.20 must be met to ensure that SNF care is reasonable and necessary. (77 Fed. Reg. 46214, 78 Fed. Reg. 47936). Such SNF documentation includes (1) a physician order at the time of admission for the resident's immediate care (2) a comprehensive assessment, and (3) a comprehensive plan of care prepared by an interdisciplinary team that includes the attending physician, a registered nurse, and other appropriate staff. Prior OIG audits, investigations, and inspections have identified areas at risk for noncompliance with SNF Medicare billing requirements. (OAS; W-00-15-35744; various reviews; expected issue date: FY 2016; work in progress).[9]

September 2015 OIG Report: OEI-02-13-00610

In September 2015, OIG released its report, "The Medicare Payment System for Skilled Nursing Facilities Needs to be Evaluated."[10] This was the fifth report issued in five years by OIG related to billings for therapy services in SNFs. In this report, OIG's stated objectives were to: (1) compare Medicare payments to SNF costs for therapy; (2) determine the extent to which SNF billing and key beneficiary characteristics changed from FYs 2011 to 2013; and (3) determine the extent to which changes in SNF billing affected Medicare payments.

According to the report, the difference between Medicare payments and SNFs' costs for therapy, combined with the current payment method, creates an incentive for SNFs to bill for higher levels of therapy than necessary. Increased SNF billings for therapy resulted in $1.1 billion in Medicare payments in FYs 2012 and 2013.The report also makes recommendations for changes to the SNF reimbursement system and offers guidance to CMS on the reforms OIG believes should be implemented:

1. *Evaluate the extent to which Medicare payment rates for therapy should be reduced*. CMS should reduce the base rate for therapy; analyze how to set an appropriate new base rate; and take steps to develop a legislative proposal, including a proposal that could seek to eliminate the market-basket update.
2. *Change the method of paying for therapy.* CMS should "accelerate its efforts to develop and implement a new method of paying for therapy that relies on beneficiary characteristics or care needs."
3. *Adjust Medicare payments to eliminate the effect of case mix creep*.
4. *Strengthen oversight of SNF billing*.

CMS concurred with all of OIG's recommendations, and noted that, as part of the SNF PPS Payment Model Research Project, it had "reviewed past research studies and policy issues related to SNF PPS therapy and options for improving or replacing the current system of paying for SNF therapy services," and that the findings from that research were being used "as a guide to identify potential models suitable for further analysis of the entire SNF PPS system." With respect to OIG's recommendations, CMS:

1. Acknowledged that additional statutory authority would be required in order for CMS to address the recommendation that Medicare payment rates for therapy be reduced, but noted that the President's FY 2016 budget included a legislative proposal requiring a reduction to the market basket updates for SNF payment rates.
2. Commented again that the results of the SNF PPS Model Research Project would be used to "inform changes to the current method of paying for therapy."
3. Noted that it has the authority to adjust payment rates if it determines that changes in overall payments to SNFs across the SNF payment system are unrelated to changes in beneficiaries' characteristics, and stated that it "will consider various approaches to adjust payments once such a determination is made."
4. Agreed that it will work to monitor SNF billing "and target SNFs that rarely bill for changes in therapy or frequently use therapy assessments incorrectly for education and claims review."

June 2015 OIG Report: OEI-02-13-00611

OIG released a separate report in June 2015 entitled "Skilled Nursing Facility Billing for Changes in Therapy: Improvements Are Needed."[11]

In this report, OIG analyzes billing by SNFs for changes in therapy under recently implemented Medicare policies. These policies, implemented in FYs 2011 and 2012, were designed to address concerns that SNF billing failed to adequately reflect changes in the amount of therapy that occurred during a beneficiary's Medicare Part A stay. Specifically, CMS introduced three types of assessments to capture when SNF beneficiaries: (1) started therapy (the start-of-therapy assessment); (2) ended therapy (the end-of-therapy assessment); and (3) decreased or increased therapy (the change-of-therapy assessment). Under these policies, the choice of assessment determines when the SNF begins billing for the therapy and for changes in therapy during a beneficiary's stay. Because these assessments were intended to capture changes in a beneficiary's therapy more quickly than scheduled assessments, CMS' ultimate goal was that SNF billing and Medicare payments would be better aligned. OIG reviewed these new policies to determine whether this goal was achieved. OIG analyzed paid SNF Medicare claims with dates of services in FYs 2010 through 2013 for: (1) changes

in therapy under the new policies; (2) the use of assessments for decreases and increases in therapy; and (3) how often SNFs used the new therapy assessments incorrectly.

OIG's analysis of billing for changes in therapy found that under the recently implemented billing policies, SNFs slightly increased their billing for changes in therapy (by only 4%). SNFs most commonly billed for changes in the level of therapy, and less commonly billed for a therapy RUG followed by a non-therapy RUG. OIG also found that SNFs used assessments very differently when decreasing therapy than when increasing it, costing Medicare $143 million over two years. Further, SNFs frequently used the new start-of-therapy assessment incorrectly.

According to OIG, to better ensure that beneficiaries are receiving the needed amount of therapy and that Medicare is paying appropriately, CMS should accelerate efforts to implement a new method for paying SNFs for therapy. In the meantime, OIG recommends that CMS: (1) reduce the financial incentive for SNFs to use assessments differently when decreasing and increasing therapy; and (2) strengthen the oversight of SNF billing for changes in therapy.

CMS agrees with these recommendations, noting that it is working on identifying potential alternatives to the current SNF payment methodology. CMS also states it will increase monitoring of SNF billing for changes in therapy and will target for education and claims review the SNFs that rarely bill for changes in therapy or that often use therapy assessments incorrectly.

Recent Enforcement Actions

With the opportunities for abuse inherent in the SNF therapy billing system, and the consequent governmental scrutiny, it is not surprising that there have been increased enforcement actions related to SNF therapy billing, including a recent FCA case that resulted in the largest settlement of its kind. Importantly, the government has not only gone after the therapy providers who provide the medically unreasonable or unnecessary services, but also the SNFs who submit claims for those services.

Kindred/Rehabcare[12]

In January 2016, Kindred Healthcare Inc. and its subsidiary RehabCare Group Inc. settled a $125 million whistleblower lawsuit with the federal government for allegedly improperly placing patients in the highest therapy RUGs.[13] In addition to RehabCare, settlements also were reached with four SNFs for their role in submitting claims to Medicare for therapy provided by RehabCare, including: a $3.9 million settlement with Wingate Healthcare Inc. and 16 of its facilities; a $2.2 million settlement with THI of Pennsylvania at Broomall LLC and THI of Texas at Fort Worth LLC; a $1.375 million settlement with Essex Group Management and two of its facilities; and a $750,000 settlement with Frederick County, Maryland, which formerly operated the Citizens Care SNF.

The underlying suit claimed that RehabCare routinely scheduled SNF residents for higher levels of therapy than needed, resulting in therapy services that were not reasonable or necessary, or that never occurred. The company also allegedly scheduled patients for therapy after they were recommended to be discharged, and reported that services had been provided when residents were asleep or unable to undergo therapy.

RehabCare is the nation's largest skilled therapy provider, contracting with more than 1,000 facilities in 44 states. Kindred purchased RehabCare in 2011.

SavaSeniorCare[14]

On October 29, 2015, the U.S. Department of Justice (DOJ) announced that the government intervened in three FCA lawsuits and filed a consolidated complaint against SavaSeniorCare LLC and related entities (Sava) alleging that Sava knowingly and routinely submitted false claims to Medicare for rehabilitation therapy services that were not medically reasonable and necessary.[15] Sava operates approximately 200 SNFs in 23 states.

Sava allegedly set aggressive, prospective corporate targets for the highest Medicare reimbursement rates to significantly increase Sava's revenues without regard for patients' actual clinical needs, and then pressured its staff to meet those goals. Sava also allegedly delayed discharging patients from its facilities, even though the patients were medically ready to be discharged, in order to increase its Medicare payments.

Rousseau Management[16]

On April 30, 2015, an SNF operator in Maine, Rousseau Management Inc., entered into an agreement with the United States to pay $300,000 to resolve allegations concerning inflated Medicare claims for therapy provided by its subcontractor, RehabCare Group East Inc. (RehabCare).

Rousseau allegedly failed to take sufficient steps to prevent RehabCare from engaging in a pattern and practice of providing high levels of therapy that were not reasonable or necessary during assessment reference periods, and/or failed to prevent other RehabCare practices designed to inflate Medicare reimbursement, including: (1) presumptively placing patients in the highest reimbursement level, rather than using individualized evaluations to determine the level of care most suitable for each patient's clinical needs; (2) planning the minimum number of minutes of therapy required to bill at the highest reimbursement level while discouraging the provision of therapy in amounts beyond that minimum threshold; (3) arbitrarily shifting the number of minutes of planned therapy between therapy disciplines to ensure targeted reimbursement levels were achieved; (4)

reporting that time spent on initial evaluations was therapy time; and (5) reporting that time spent providing unskilled palliative care was time spent on skilled therapy.

HCR Manorcare[17]

On April 21, 2015, DOJ announced that the government had intervened in three FCA lawsuits and filed a consolidated complaint against HCR ManorCare alleging that ManorCare knowingly and routinely submitted false claims to Medicare and Tricare for rehabilitation therapy services that were not medically reasonable and necessary. ManorCare operates approximately 281 SNFs in 30 states.

ManorCare allegedly exerted pressure on SNF administrators and rehabilitation therapists to meet unrealistic financial goals that resulted in the provision of medically unreasonable and unnecessary services to Medicare and Tricare patients, by setting set prospective billing goals designed to significantly increase revenues without regard to patients' actual clinical needs, and threatened to terminate SNF managers and therapists if they did not administer the additional treatments necessary to qualify for the highest Medicare payments. ManorCare also allegedly increased its Medicare payments by keeping patients in its facilities even though they were medically ready to be discharged.

Ross Manor[18]

A Maine SNF, Ross Manor, entered into an agreement with the United States to pay $1.2 million to resolve allegations concerning inflated Medicare claims for rehabilitation therapy to resolve claims for therapy purportedly provided by its subcontractor, RehabCare Group East Inc. The settlement resolved allegations that Ross Manor caused the submission of claims to Medicare that sought inflated amounts of reimbursement based on the provision of unreasonable or unnecessary rehabilitation therapy.

ArchCare[19]

The Catholic Health Care System, also known as ArchCare, entered into an agreement concerning claims for therapy purportedly provided by its subcontractor, Physical and Occupational Rehabilitation Therapy and Speech-Pathology Services PLLC, an affiliate of RehabCare Group East Inc. (RehabCare) and Kindred Healthcare Inc. Allegedly, ArchCare's facilities failed to take sufficient steps to prevent RehabCare from engaging in a pattern and practice of providing high levels of therapy that were not reasonable or necessary during assessment reference periods, when ArchCare was required to report to Medicare the amount of therapy it was providing to its patients. ArchCare billed Medicare patients at the highest therapy reimbursement level, but RehabCare then provided less therapy to those same patients outside the assessment reference periods, when the facilities were not required to report to Medicare the amount of provided therapy. As a result of this practice by RehabCare, ArchCare frequently billed Medicare for its patients' care at the highest therapy-based levels, even though the patients often were not receiving therapy at those levels.

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1 42 U.S.C. §§ 1395d(a)(2)(A) and 1395x(i).
2 42 C.F.R. § 409.30(a)(1) and (b)(1).
3 CMS, *Long-Term Care Facility Resident Assessment Instrument User's Manual*, ver. 3.0 (RAI Manual 3.0), May 2013, § 1.3.
4 CMS, RAI Manual 3.0, § 6.6.
5 Christopher Weaver, Anna Wilde Mathews, and Tom McGinty, *How Medicare Rewards Copious Nursing-Home Therapy*, The Wall Street Journal, Aug. 16, 2015, *available at* www.wsj.com/articles/how-medicare-rewards-copious-nursing-home-therapy-1439778701 (last visited May 23, 2016).
6 *See* 79 Fed. Reg. 25767, at 25789 (May 06, 2014).
7 *Available at* www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-09.html.
8 *Available at* www.oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf.
9 OIG FY 2016 Work Plan.
10 OEI-02-13-00610. *Available at* http://oig.hhs.gov/oei/reports/oei-02-13-00610.pdf.
11 OEI-02-13-00611. *Available at* http://oig.hhs.gov/oei/reports/oei-02-13-00611.pdf.
12 Nation's Largest Nursing Home Therapy Provider, Kindred/Rehabcare, to pay $125 Million to Resolve False Claims Act Allegations (Jan. 12, 2016). *Available at* www.justice.gov/opa/pr/nation-s-largest-nursing-home-therapy-provider-kindredrehabcare-pay-125-million-resolve-false (last visited May 23, 2016).
13 *United States ex rel. Halpin and Fahey v. Kindred Healthcare, Inc.*, No. 1:11cv12139-RGS (D. Mass.).
14 Government Intervenes in Lawsuits Alleging that Skilled Nursing Chain SavaSeniorcare Provided Medically Unnecessary Therapy (Oct. 29, 2015). *Available at* www.justice.gov/opa/pr/government-intervenes-lawsuits-alleging-skilled-nursing-chain-savaseniorcare-provided (last visited May 23, 2016).
15 *See United States ex rel. Hayward v. SavaSeniorCare, LLC*, No. 3:11-0821 (M.D. Tenn.); *United States ex rel. Scott v. SavaSeniorCare Administrative Services, LLC*, 3:15-0404 (M.D. Tenn.); and *United States ex rel. Kukoyi v. Sava Senior Care, L.L.C.*, No. 3:15-1102 (M.D. Tenn.).
16 Maine Nursing Home Operator to Pay $300,000 to Resolve Allegations Concerning Claims for Rehabilitation Therapy (Apr. 30, 2015). *Available at* www.justice.gov/usao-ma/pr/maine-nursing-home-operator-pay-300000-resolve-allegations-concerning-claims (last visited May 24, 2016).
17 Government Sues Skilled Nursing Chain HCR Manorcare for Allegedly Providing Medically Unnecessary Therapy (Apr. 21, 2015). *Available at* www.justice.gov/opa/pr/government-sues-skilled-nursing-chain-hcr-manorcare-allegedly-providing-medically-unnecessary (last visited May 24, 2016).
18 Maine Nursing Home to Pay $1.2 Million to Resolve Allegations Concerning Rehabilitation Therapy (Mar. 30, 2015). *Available at* www.justice.gov/usao-ma/pr/maine-nursing-home-pay-12-million-resolve-allegations-concerning-rehabilitation-therapy (last visited May 24, 2016).
19 New York Catholic Nursing Chain to Pay $3.5 Million to Resolve Allegations Concerning Claims for Rehabilitation Therapy (Mar. 2, 2015). *Available at* www.justice.gov/usao-ma/pr/new-york-catholic-nursing-chain-pay-35-million-resolve-allegations-concerning-claims (last visited May 24, 2016).

Common Marketing Techniques Come Under Fire

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Introduction

Over the past several years, the U.S. Department of Justice (DOJ) has interpreted the federal Anti-Kickback Statute (AKS) in new ways that implicate standard marketing arrangements commonly used by drug and device manufacturers, and—by extension—downstream purchasers, including physician offices, pharmacies, and hospital systems. Specifically, the government has taken the position that performance-based price concessions, preferred product list (formulary) payments, and sales-related "spiffs"[1] may each represent illegal inducements. Although market share and volume-based discounts and rebates have long been considered permissible, DOJ has begun targeting arrangements it perceives as linking a discount or rebate to specific efforts to grow sales volume, as well as those arrangements in which the government believes the parties have failed to disclose all discount terms. Similarly, despite general acceptance of paying reasonable commissions on product sales, DOJ has contested the use of modest, short-term "spiff" payments to help focus attention on particular products.

It seems obvious that purchasers receiving market share or volume-based price concessions from manufacturers also will be interested in actually re-selling the products, and further that the purchasers and the manufacturers have a mutual interest in working together to market the products. The government's position suggests, however, that these marketing activities are only permissible if they adhere to requirements that are narrow and often quite technical.

This trend is reflected in recent False Claims Act (FCA) case resolutions and settlements, and, as a result, drug and device manufacturers may now question whether these previously widely accepted practices present unacceptable risks going forward. This article summarizes recent cases addressing these issues, as well as the more recent positions taken by the government in some of these cases, and offers practical guidance on how manufacturers might avoid the pitfalls associated with these familiar arrangements going forward.

Joint Marketing Arrangements

Manufacturers frequently engage in joint marketing activities with downstream partners. For example, when a new product is introduced a manufacturer may work with its re-sellers to introduce the product to the sales force. The manufacturer might also provide a limited-time incentive program to boost sales. Recently, such arrangements have faced increased scrutiny.

Historic Support for Discounts

The AKS exception for discounts dates back to its enactment in 1972, and the U.S. Department of Health and Human Services Office of Inspector General (OIG) followed Congress' lead and adopted a discount safe harbor.[2] OIG has emphasized that discounts are "encouraged under the Federal health care programs so long as the Federal health care programs share in the discount where appropriate."[3]

The safe harbor regulations define "discount" broadly to mean a "reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction."[4] Discounts include rebates, which are defined to be "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which are not given at the time of sale."[5] Under this definition, a rebate (including a volume-based price incentive) is a discount as long as the terms of the rebate are fixed in writing at the time of the initial sale.

DOJ's Recent Position On Performance-Based Discounts and Rebates

Price concessions are inherently designed to induce the purchase of a good or service, and thus are fertile ground for AKS activity. Several cases exhibit the government's theory that performance-based discounts or rebates implicate the AKS, and by extension the FCA. An early example appeared in a lawsuit against Bristol-Myers-Squibb.[6] The complaint alleged that stocking allowances, price protection payments, and "market share payments" constituted illegal remuneration under the AKS to the manufacturer's retail pharmacy and wholesale customers.[7]

These same theories received extended treatment in *U.S. ex rel. Banigan v. Organon USA Inc.*[8] In pleadings filed in 2011, the parties argued over whether certain standard rebates offered to purchasers of the antidepressant Remeron were protected. The *Organon* relator alleged that rebates provided to long term care facilities as part of a "switching" program constituted impermissible remuneration under the AKS.[9] The challenged arrangements included flat percentage discounts, market share discounts, conversion rebates, rebates tied to the placement of Remeron on formulary in a preferred position, and rebates for entering into therapeutic interchange agreements.[10] The relator argued that conditioning the discounts on negotiated performance conditions (such as a certain dollar volume or percentage of sales, or inclusion on formulary or preferred lists) removed the payments from regulatory or statutory protection.[11] The relator further

alleged that the discount safe harbor required that all of these terms be disclosed to the government.[12]

The Pharmaceutical Research and Manufacturers of America (PhRMA) filed an amicus brief, noting that the case could have a dramatic impact on discounting and rebate practices long considered standard in the pharmaceutical industry.[13] PhRMA pointed out that the types of market share and performance-based payments at issue in *Organon* were ordinary price concessions, very typical in the industry, that ultimately benefit payers, including federal health care programs.[14] PhRMA also pointed out that formulary programs are common, and that the state Medicaid programs frequently use formularies—and require rebates—in exchange for inclusion on the state's preferred drug list.[15]

In addition, both Organon and PhRMA argued at length that the statutory discount exception and the regulatory discount safe harbor protect price concessions, regardless of whether they are performance-based, so long as the terms of the discount or rebate are transparent.[16] As PhRMA summarized, it is "axiomatic that all discounts are intended to increase the purchase of a given product."[17] Indeed, the limited guidance regarding discounts provided by OIG suggested that the government did not intend to prevent "innocuous, or even beneficial, commercial arrangements."[18]

Although the government declined to intervene in *Organon,* it filed a Statement of Interest to clarify its position on the rebate issue. In its brief, DOJ stated: "Payments to pharmacies for switching patients from one drug to another, and for other efforts to increase a drug's utilization do not qualify as protected price reductions" for purposes of the discount safe harbor or the statutory discount exception.[19] The *Organon* court did not squarely address the rebate issue.[20] The case eventually settled,[21] and DOJ has subsequently taken the position that the resolution supports its theory regarding performance-based price concessions.

In *U.S. ex rel. Lisitza v. Johnson & Johnson*, the court ruled that performance-based rebates paid to long term care facilities predicated on "switching" and "therapeutic interchange" programs for Johnson & Johnson's Risperdal product did not qualify for the statutory discount exception, observing that "[w]hile the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not." [22] The court did not describe the terms and conditions of the rebates that should have been explicated, nor to whom. Nor is it clear why this should have mattered, as transparency around the terms and conditions of a rebate is not an element of the discount safe harbor so long as the buyer is able to accurately calculate and report the *value* of the price concession.[23] Reading between the lines of the court's ruling, it may be that the court was troubled by other, more mundane AKS concerns. For example, the allegations included a large payment for physician data that was of questionable utility and apparently lacked fair market valuation support.[24] Nonetheless, the government continues to rely on *Lisitza* for the proposition that performance-based rebates are inherently problematic.

More recently, DOJ made a similar argument in pleadings filed in connection with *U.S. v. Novartis Pharmaceuticals Corp*.[25] In that case, the government alleged that Novartis paid kickbacks to specialty pharmacies to induce them to switch patients to the Novartis immunosuppressive product, Myfortic, and to recommend it over generic alternatives.[26] Specifically, the government alleged that pharmacies were paid to prescribe Myfortic over generic alternatives that had a lower cost and better safety profile.[27] Similarly, the government alleged that pharmacies were paid to prescribe the Novartis iron chelation drug, Exjade, despite the availability of a putatively safer alternative product for the same condition.[28]

Relying on similar arguments to those raised in the *Organon* matter, Novartis argued that these arrangements were protected by the Discount Safe Harbor and related statutory exceptions.[29] In response, DOJ asserted that multiple "plus" factors were implicated by the Novartis arrangements with specialty pharmacies.[30] Specifically, DOJ alleged that the Exjade arrangements raised concerns regarding patient safety, and potentially undermined independent medical judgment, while the Myfortic arrangements implicated cost and utilization concerns.[31] Despite what appeared to be colorable counterarguments, Novartis chose to settle the matter.[32]

In the recently settled matter of *U.S. ex rel. Herman v. Coloplast Corp*., the relators alleged that volume-based discounts and market share rebates for continence and ostomy supply products sold to durable medical equipment suppliers were not eligible for discount safe harbor or statutory exception protection because the payments were contingent on participation in promotional campaigns.[33] The relators also took the position that "spiff" incentive payments to re-seller sales representatives constituted an improper inducement to sell particular products.[34]

In another recently settled matter, the relators alleged that Respironics, a manufacturer of sleep apnea masks, provided free call center services to medical equipment suppliers that bought its products.[35] Respironics asserted that it had a "good-faith belief that the [call center arrangement] offered a permissible bundled discount of Respironics' masks and resupply services under the appropriate discount safe harbors."[36] DOJ alleged that the program had the potential to compromise the supplier's judgment regarding which products to promote.[37]

Practical Considerations Concerning Marketing Activities

Beyond the positions taken in the above-referenced, and similar, cases, the government has otherwise provided only limited additional guidance regarding marketing activities. Much of the relevant guidance is based on long-standing, more generally applicable AKS principles. Following these general principles, the risk of an enforcement action may be

minimized if an arrangement is structured to avoid certain features that have traditionally triggered the key policy concerns that served as the basis for the AKS. According to OIG guidance, arrangements may be problematic if they:

- Interfere with or subvert independent medical decision making;[38]
- Increase costs to federal health care programs or beneficiaries;[39]
- Shift costs among reimbursement systems, making it difficult for government reimbursement programs to set proper price levels;[40]
- Implicate patient safety or quality of care concerns;[41]
- Result in overutilization or inappropriate utilization of products or services;[42] or
- Result in unfair competition.[43]

OIG has suggested that marketing arrangements may pose less risk when they are "passive in nature"—meaning they do not involve direct contact with federal health care program beneficiaries—or when the individual or entity conducting the marketing activity is not in a "position of public trust" vis-à-vis program beneficiaries.[44]

Counsel analyzing marketing arrangements should thus consider whether one of the parties to the arrangement has the ability to recommend products directly to federal health care program beneficiaries, especially where the party making the recommendation is in a position of trust (i.e., white-coat marketing).[45] Additionally, counsel should consider whether the arrangement includes other features that may draw scrutiny, such as direct billing or payment of "success" fees.[46]

Based on the recent DOJ enforcement actions discussed above, parties crafting marketing arrangements should consider the following:

1. Discount and Rebate Programs

- *De-link discounts from performance obligations.* The cases discussed above underscore that DOJ views price concessions conditioned on gaining market share or providing services with suspicion, and will pursue enforcement actions if the spirit of the discount safe harbor is violated. When the parties contemplate the performance of a service, that service should not be contingent upon or compensated through a discount or rebate, as the government may take the position that an arrangement combining aspects of both a discount and a payment for services does not qualify for protection under either the discount or personal services safe harbors. Instead, the services should be the subject of a separate agreement, under which compensation is based on fair value for bona fide services actually provided.
- *Documentation is critical.* The manufacturer should clearly communicate the customer's reporting obligations and the value of the price concession. As described in OIG Advisory Opinion 13-07, meeting the seller's reporting obligations under the discount safe harbor is straightforward, requiring sellers only to notify the buyer of reporting obligations and provide information sufficient to permit the buyer to calculate the value of the total price concession. Advisory Opinion 13-07 also evinced a more flexible approach to bundled discounts, even where the products are reimbursed under different methodologies. Perhaps recognizing that concern about "shift[ing] costs among reimbursement systems and distort[ing] the trust cost of items" is anachronistic under contemporary reimbursement models, OIG concluded that "discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the program through lower costs."[47]
- *Disclose discount terms.* While there is no statutory or regulatory requirement that the terms and conditions of a price concession be disclosed, failure to memorialize the basis for a discount or rebate (e.g., volume or market-share commitment) may lead enforcement agencies to conclude that the discount is a disguised kickback or a payment for a service (e.g., compensation for "conversion" or "switching" activities, adherence programs, or placement on preferred-product lists).

2. Joint Marketing Activities

- *Written Agreements and Documentation.* In assessing whether a payment represents fair market value for the services performed, the government will inquire into the bona fide nature of the services, whether the services are actually performed, and whether there is a cap on the dollars allocated to the activities. If a party is able to document that services have been performed, and there is reasonable proportionality in the exchange of value, the government is less likely to be interested.
- *Fair market value.* The government is often suspicious of marketing payments, believing that they are used to disguise kickbacks for federal health care program referrals. For this reason, the parties to a joint marketing agreement should be careful to ensure that any payment is fair market value for the services actually provided. One shortcut to achieving this objective is the use of a "rate card" or other preset price list to specify the value of certain common marketing services, such as email communications or box stuffers.
- *Be aware of "plus" factors.* DOJ is far more likely to intervene in an FCA case if it can identify and articulate harm to federal health care programs or federal health care program beneficiaries. For example, in the *Johnson*

& Johnson and *Novartis* cases, the government alleged that the products at issue had significant risk profiles and patient safety concerns that warranted close scrutiny. In the *Organon* and *Novartis* cases, the products at issue raised cost concerns. It is instructive in this regard that the government elected not to intervene in the *Novartis* case with respect to several drug products that presumably did not lend themselves to arguments concerning overutilization, medical necessity, or risk.

3. Key Points Concerning "Spiffs"

The government may be expected to carefully scrutinize "spiff" payments in the following circumstances:

- *Where sales representatives interact directly with federal health care program beneficiaries.* The government believes that such arrangements are inherently problematic, and that a lack of transparency regarding compensation for recommending particular products raises significant "white coat marketing" issues. Even where there is an independent check, as when the item must be approved by a health care professional, DOJ believes the transparency issue raises AKS concerns.
- *Where the arrangement otherwise implicates policy considerations that typically trigger AKS enforcement decisions.* Specifically, the government will consider whether "spiff" payments may contribute to overutilization or excessive cost. For example, in connection with the *Coloplast* matter, the government has suggested publicly that patients may not have ordered ostomy or continence products but for the "spiff" payments.[48]

Conclusion

Overall, manufacturers cannot rely on the long-standing acceptance of common marketing arrangements as insulation from enforcement activity. In light of recent FCA activity, manufacturers should endeavor to structure arrangements in a manner designed to provide clear definition around the types of activities at issue and the basis for price concessions or payment for services.

1 This term, also written as "SPIFF" or "SPIF," is sometimes understood to be an acronym for Sales Promotion Incentive Fund, Special Payment Incentive for Fast Sales, or similar concepts. Generally speaking, a "spiff" refers to a de minimis, short-term sales incentive payment.
2 42 U.S.C. § 1320a–7b(b)(3)(E).
3 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999).
4 42 C.F.R. § 1001.952(h)(5).
5 42 C.F.R. § 1001.952(h)(4).
6 *See* Press Release, Dep't of Justice, *Bristol-Myers-Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing* (Sept. 28, 2007), *available at* www.justice.gov/archive/opa/pr/2007/September/07_civ_782.html.
7 *See id.*
8 No. 07-cv-12153-RWZ (D. Mass. Nov. 16, 2007).
9 *See, e.g.*, Third Am. Compl., *Organon,* 07-cv-12153-RWZ (Sept. 7, 2010) at ¶ 95; *see also* Mem. of Decision, *Organon*, 07-cv-12153-RWZ (June 1, 2012) at 5-6, 16.
10 Third Am. Compl., *Organon*, 07-cv-12153-RWZ at ¶¶ 94-95.
11 Relator's Resp. to Mot. to Dismiss, *Organon*, 07-cv-12153-RWZ (Sept. 22, 2011) at 4-7.
12 Mem. of Decision, *Organon*, 07-cv-12153-RWZ at 29-30.
13 Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America, No. 07-cv-12153-RWZ (D. Mass. Oct. 27, 2011).
14 *See id.* at 1, 4-11.
15 *Id.* at 7–11.
16 *See, e.g., id.* at 13–18.
17 *Id.* at 16.
18 *Id.* (citing *U.S. v. Shaw*, 106 F. Supp. 2d 103, 119 (D. Mass. 2000) (quoting 56 Fed. Reg. 35952 (July 29, 1991)). In Advisory Opinion 98-02, OIG determined that a pricing arrangement whereby a wholesaler received discounted pricing from a pharmaceutical manufacturer in exchange for promotional support activities would not constitute prohibited remuneration under the AKS. OIG reasoned: "Implicit in any manufacturer's discount to a wholesale purchaser is a financial incentive to the wholesale purchaser to increase its retail sales of the discounted product. That financial incentive does not change simply because the Proposed Arrangement conditions the discount on the performance of certain limited activities that directly support the resale of [the discounted products]." OIG Ad. Op. 98-02, at 8 (Apr. 8, 1998).
19 Statement of Interest on Behalf of the United States in Resp. to Defs.' Mots. to Dismiss at 6–9, *United States ex rel. Banigan et al. v. Organon USA Inc., et al.*, No. 07-cv-12153 (D. Mass. Sept. 30, 2010).
20 883 F. Supp. 2d 277 (D. Mass. June 1, 2012).
21 Press Release, N.Y. Atty. Gen. Schneiderman, *A.G. Schneiderman Announces $31 Million Nat'l Medicaid Settlement with Pharmaceutical Company* (Oct. 15, 2014), *available at* www.ag.ny.gov/press-release/ag-schneiderman-announces-31-million-national-medicaid-settlement-pharmaceutical.
22 765 F. Supp. 2d 112, 125 (D. Mass. Feb. 25, 2011).
23 42 C.F.R. § 1001.952(h).
24 Mem. and Order on Def. Johnson and Johnson's Mot. to Dismiss at 20, *Lisitza*, No. 07-cv-10288-RGS (D. Mass. Feb. 25, 2011).
25 No. 11-cv-8196-CM-JCF (S.D.N.Y. filed Nov. 14, 2011).
26 Compl -in-Intervention of United States, No. 11-cv-8196-CM-JCF at ¶¶ 3–4 (S.D.N.Y. Apr. 23, 2013).
27 *Id.*
28 Am. Compl -in-Intervention of United States, No. 11-cv-8196-CM-JCF at ¶¶ 1, 3, 7-10 (S.D.N.Y. Jan. 8, 2014).
29 Joint Pre-Trial Order, No. 11-cv-8196-CM-JCF at 57-62 (S.D.N.Y. June 26, 2015).
30 "Plus" factors refer to policy concerns that sometimes inform enforcement decisions. Such factors include interference with independent medical decision-making and overutilization of product or services, among others.
31 *See id.* at 10-32; *see also* Am. Compl.-in-Intervention of the United States, ¶¶ 60-140, 143-225, No. 11-cv-8196-CM-JCF (S.D.N.Y. Jan. 8, 2014).
32 Press Release, Dep't of Justice, *Manhattan U.S. Atty. Announces $370 Million Civil Fraud Settlement Against Novartis* (Nov. 20, 2015), *available at* www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis.
33 Second Am. Compl, ¶ 123, No. 11-CA-12131 (D. Mass. filed June 01, 2015).
34 *Id.* at ¶¶ 161-68.
35 *U.S. ex rel. Dr. John Doe v. Philips Electronics North America et al.*, No. 14-cv-2077 (D.S.C.).
36 www.dotmed.com/news/story/29891.

37 www.justice.gov/opa/pr/respironics-pay-348-million-allegedly-causing-false-claims-medicare-medicaid-and-tricare.
38 *Special Fraud Alert: Prescription Drug Marketing Schemes* (Aug. 1994), *reprinted in* 59 Fed. Reg. 63,376 (Dec. 19, 1994) (Marketing Schemes); *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731, 23,734 (May 5, 2003) (CPG).
39 Marketing Schemes, *supra* note 35; CPG, *supra* note 35; 56 Fed. Reg. 35,952, 35,978 (July 29, 1991).
40 CPG, *supra* note 35, at 23,734.
41 *Id.*
42 *Id.; see also* OIG Ad. Op. No. 06–16, at 6 (Oct. 3, 2006).
43 OIG Ad. Op. No. 06–16 at 5.
44 56 Fed. Reg. 35952, 35974 (July 29, 1991).
45 OIG Ad. Op. No. 11-08 at 6 (June 21, 2011).
46 *See, e.g.*, OIG Ad. Op. No. 10-23 (Oct. 28, 2010); OIG Ad. Op. No. 99-03 (Mar. 16, 1999); and OIG Ad. Op. No. 98-10 (Aug. 31, 1998).
47 OIG Ad. Op. No. 13-07, at 5 (July 1, 2013).
48 *See* Press Release, Dep't of Justice, *Coloplast Corp. and Liberator Medical Agree to Pay $3.6 Million to Resolve Kickback Allegations* (Dec. 22, 2015), *available at* www.justice.gov/usao-ma/pr/coloplast-corp-and-liberator-medical-agree-pay-36-million-resolve-kickback-allegations.

Fraud and Abuse Practice Group Leadership

Ethical Dilemmas for Attorneys in the Wake of the Yates Memorandum

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On September 9, 2015, Deputy Attorney General Sally Quillian Yates issued a memorandum to all U.S. Department of Justice (DOJ) attorneys titled "Individual Accountability for Corporate Wrongdoing." (Yates Memo).[1] The Yates Memo emphasizes that during an investigation of potentially fraudulent or illegal activity, a company will only receive cooperation credit if it provides DOJ with all relevant facts regarding individual misconduct.

DOJ's focus on individual culpability creates a host of questions counsel must consider when faced with either a potential or actual government investigation, such as:

- Who should conduct the internal investigation?
- When and how can conflicts of interest arise?
- What needs to be told to directors, officers, employees, members, shareholders, or other constituents prior to an interview conducted by an attorney who represents the company?
- When should a company consider recommending and/or paying for separate counsel for employees?

This article addresses a number of potential ethical issues raised by the Yates Memo that defense counsel should consider when representing corporate entities.

A Company Will Only Receive Cooperation Credit If It Provides DOJ with All Relevant Facts Relating to Individual Misconduct

The Yates Memo articulates a DOJ policy initiative to target individuals who may be involved in corporate crimes and to hold them personally accountable for the corporation's misconduct. It attaches cooperation credit to a company's disclosure to DOJ of all relevant facts regarding individual misconduct and cautions that a company will not receive cooperation credit if it picks and chooses what facts to disclose or if it declines to learn of such facts relating to individual wrongdoers.[2] In short, the Yates Memo places an affirmative obligation on a company that desires cooperation credit to internally investigate individuals suspected of misconduct and to report its finding to DOJ regardless of the investigated individual's position, status, or seniority.

In addition to the Yates Memo, DOJ revised Section 9-28.700 of the Principles of Federal Prosecution of Business Organizations (Principles) in 2015. Section 9-28.700 is titled "The Value of Cooperation" and states that if a company meets the threshold requirement of providing DOJ all relevant facts with respect to individuals, it will be *eligible for consideration* for cooperation credit.[3] It reiterates that a company must identify *all* individuals involved in or responsible for the misconduct at issue, regardless of their position, status, or seniority, and must provide to DOJ *all* facts relating to that misconduct in order to be considered for cooperation credit.[4] If a company seeking cooperation credit declines to learn of such facts or to provide DOJ with complete factual information about the individuals involved, its cooperation will not be considered a mitigating factor under this section. In addition, if a company is prosecuted, DOJ will not consider a cooperation-related reduction at sentencing if the company failed to identify all individuals involved in or responsible for the misconduct at issue.[5]

It is clear that DOJ expects each company to proactively investigate its constituents for potential misconduct that may arguably run afoul of government regulations.

What Must a Company Report to the Government?

Does the Yates Memo subtly suggest that a company will receive cooperation credit if it chooses to disclose attorney-client privileged information? DOJ denies that this is a goal of the Yates Memo or is otherwise an expectation of the government. In fact, Section 9-28.700 of the Principles explicitly states: "to be clear, a company is not required to waive its attorney-client privilege and attorney work product protection in order [sic] satisfy this threshold."[6] While the Principles repeatedly remind prosecutors that a company may choose to waive the attorney-client and work product privileges, the government maintains that prosecutors may not credit a company for choosing to waive the privileges or penalize a company for choosing not to waive the privileges.

This leads to the question: What is protected by the attorney-client privilege during the course of an internal investigation? In *Upjohn v. The United States*, the U.S. Supreme Court held that within a corporation or other business organization, the attorney-client privilege applies to all communications to and from an attorney by all employees.[7] The issue presented to the Court in *Upjohn* was whether a company's attorney-client privilege extended to an attorney's communication with all employees or was limited to an attorney's communication with upper management. In describing this dilemma, Justice Rehnquist wrote:

> In a corporation, it may be necessary to glean information relevant to a legal problem from middle management or non-management personnel as well as from top executives. The attorney dealing with a complex legal problem is thus faced with a 'Hobson's choice.' If he interviews employees not having 'the very highest authority,' their communications to him will not be privileged. If, on the other hand, he interviews only those employees with the highest authority, he may find it extremely difficult, if not impossible, to determine what happened.[8]

While the Court concluded that the corporate privilege extends to communications with all employees, it cautioned that protection of the privilege extends only to communications, and not to facts. The client cannot be compelled to answer the question, "What did you say or write to the attorney?" but may not refuse to disclose any relevant fact within his knowledge merely because he incorporated a statement of such fact into a communication to his attorney. The government has seized upon the language in *Upjohn*. As long as the company provides DOJ with all relevant facts relating to all individuals who have engaged in putative misconduct, the company will be eligible for consideration of cooperation credit. On its face, this seems simple. However, the lines between facts and privileged communication can become blurred.

As a result of the *Upjohn* decision, an attorney representing a company in an internal investigation is encouraged to issue "*Upjohn* warnings" during witness interviews. Such warnings may help avoid the potential ethical quandary in which an employee believes the attorney represents the employee, thereby in effect creating a dual representation that may later lead to a conflict between two clients. After the Yates Memo, in False Claims Act (FCA) cases and during government investigations, attorneys need to be even more vigilant about issuing these warnings as the potential for a company and employees to become adverse to each other is increased. An attorney representing a company must explain to all officers, directors, employees, and other organizational constituents that he represents the organization and not the individual. The attorney must explain that the attorney-client privilege belongs to the company, and that the company may choose to waive the privilege and disclose the substance of the interview to third parties. The attorney should tell the interviewee to keep the communication confidential because disclosure of the content of the communication would result in a waiver of the privilege.[9] Failure to give such a warning may result in the individual believing that the investigating attorney represents them and that the attorney will not reveal anything that is said during the course of the interview.

Potential Conflicts of Interest

Encountering a Conflict of Interest

In response to the Yates Memo, how should an attorney act when there is a potential conflict between the personal interests of corporate decision makers and the corporate entity? Rule 1.13 of the Model Rules of Professional Conduct states: "A lawyer employed or retained by an organization represents the organization acting through its duly authorized constituents."[10] When constituents of the organization make decisions for it, the decisions ordinarily must be accepted by the attorney even if their utility or prudence is doubtful. Decisions concerning policy and operations, including ones entailing serious risk, are not in the attorney's province. However, different considerations arise when the attorney knows that the organization may be substantially injured by the action of a constituent that is in violation of the law. In such circumstances, it may be reasonably necessary for the attorney to ask the constituent to reconsider the matter. If that fails, or if the matter is of sufficient seriousness and importance to the organization, it may be reasonably necessary for the attorney to take steps to have the matter reviewed by a higher authority in the organization.[11]

Rule 1.13 explicitly states that an attorney shall not reveal the *results* of an investigation of an alleged violation of law, even if the highest authority that can act on behalf of the organization fails to address the alleged illegal conduct in a timely and appropriate manner and the attorney reasonably believes that the violation is reasonably certain to result in substantial injury to the organization.[12] Thus, if the company does not permit the attorney to reveal the results of an internal investigation, the attorney may not do so. The Yates Memo does not change this. But an attorney who is instructed not to share the results of an investigation with DOJ should be certain that such direction is coming from the highest authority in the organization and not from someone whose individual conduct might be called into question or who might face criminal prosecution. This can create a troublesome dilemma if the board of directors is culpable for the misconduct and thereby instructs the attorney not to reveal the results of the investigation.[13]

When May an Attorney Represent Both the Company and Its Individual Constituents?

Rule 1.13 contemplates that an attorney representing an organization also may represent any of its directors, officers, employees, members, shareholders, or other constituents, subject to the provisions of Rule 1.7, with the caveat that if the

organization's consent to the dual representation is required by Rule 1.7, the consent shall be given by an appropriate official of the organization other than the individual who is to be represented, or by the shareholders.[14] While the rule appears straightforward, its application can be laden with landmines.

Typically, a company will assume that its constituents are acting lawfully and in the company's best interest. Therefore, where there is an allegation of company or constituent misconduct initiated either by the government or a whistleblower, the company is likely to assume that the investigation will confirm that there is no misconduct and will fail to anticipate a potential conflict of interest.

An unwary attorney may initiate an investigation before putting certain safeguards in place. For example, the attorney may assume that no conflicts of interest exist and neglect to remind individuals that they represent the company rather than the individual. The attorney may decide that they can represent the individuals in addition to the entity but neglect to secure waivers. Alternatively, the attorney can put these safeguards in place and have the correct waivers executed only to embark upon an investigation in which they learn that a corporate officer has conducted themselves in a way that is contrary to the law. This inevitably creates a conflict of interest for the attorney who then is ethically obligated to recuse themselves from the investigation. While it is generally preferable to avoid representing both the company and any number of its individual constituents, if it must occur, a recommended practice is to carefully scrutinize any agreement to represent the company and individuals jointly and consider these pitfalls going forward.

Of course, an attorney should consider potential conflicts of interest and issue *Upjohn* warnings in most commercial litigation matters. However, in FCA cases and government investigations where the company has the option to settle and avoid treble damages or criminal penalties if it discloses all relevant information and identifies all culpable individuals, these considerations become critical. In these situations, the attorney must warn individuals and the company about personal exposure and potential criminal prosecution. Moreover, if the attorney discovers individual misconduct, they will likely need to advise the company to report, or at a minimum, consider reporting the individual in exchange for cooperation credit. Thus, unlike typical commercial litigation situations, the Yates Memo has the potential to incentivize a company to turn over its people to protect its financial interests.

When Should a Company Consider Hiring Separate Counsel for Individuals?

There are occasions in which it may be prudent to identify potential individuals who are targets of a whistleblower or government investigation and consider hiring separate counsel for those individuals. While a company is not typically required to hire individual counsel for its constituents

who may be accused of wrongdoing, it may be in its best interest to do so.[15] For example, hiring separate counsel for an employee may increase the individual's good will toward the company. It might encourage cooperation and candor during an investigation. It also has the added benefit of improving the quality of the investigation because the individual can review documents with their own attorney and discuss how best to respond to questions. Finally, it likely aids in morale during an investigation because it sends a message that the company is supporting its people.

Retaining individual counsel should, in theory, not adversely impact a company's posture for cooperation credit. The Principles prohibit prosecutors from taking into account whether a corporation is advancing or reimbursing attorneys' fees or providing counsel to employees, officers, or directors under investigation or indictment when evaluating cooperation.[16] However, it has been noted that the Yates Memo has the potential to lead to unintended consequences, such as encouraging individuals to retain counsel, who may then conclude it is not in their best interest to provide fulsome interviews to company counsel. If this happens and the company is therefore less able to develop a comprehensive factual picture, the question remains as to whether DOJ would provide the company cooperation credit, given that it may not be able to gather all relevant facts.

Should a Company Hire Outside Counsel to Conduct the Investigation?

In light of DOJ's instructions that a company provide it with all relevant information regarding any individual misconduct, regardless of the person's position in the company, it may behoove a company to hire outside counsel to conduct an investigation of suspected misconduct. While general counsel may feel confident that they can conduct a thorough, objective, and unbiased investigation, the retention of outside counsel removes the appearance of bias and contributes to the appearance that the company is committed to thoroughly investigating alleged misconduct.

However, and perhaps more importantly, engaging outside counsel may help with employee morale. It is challenging for attorneys to begin a witness interview by delivering an *Upjohn* warning, essentially putting an employee on notice that the company is investigating individual culpability in exchange for cooperation credit; and, in the next breath, ask that employee to be entirely candid. This becomes particularly difficult for an attorney who has a personal and professional relationship with those employees that, up to that time, has been based upon mutual respect and trust. It is in these instances that outside counsel can protect successful and productive internal working relationships. During an ongoing investigation, an organization needs to continue to function in an environment that is relatively free from distrust and fear. Furthermore, once the investigation is closed, reliance on outside counsel can help to ensure that the investigation did not irreparably fracture the working relationships within the organization. Finally, if the alleged misconduct is based upon legal advice given by in-house counsel, it is advisable to hire outside counsel to conduct the investigation and advise the company on whether to invoke the advice of counsel defense.

Conclusion

Ultimately, the Yates Memo has created additional Hobson's choices for a company and the attorneys representing it. In order to be eligible for consideration for cooperation credit, a company, most likely through its counsel, is required to investigate alleged misconduct and report all relevant facts and identify all culpable individuals to DOJ. In addition, DOJ expects that a company will be able to secure individual cooperation during an investigation despite an attorney's ethical obligation to issue an *Upjohn* warning, which may have a chilling effect on the actual witness interview. The Yates Memo has the potential to create a number of thorny ethical issues for counsel representing corporate defendants. It would be prudent to dust off the ethics rules and refresh the principles found in *Upjohn* before finding oneself on the wrong end of a disqualification motion.

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1 Deputy Attorney General Sally Q. Yates, *Individual Accountability for Corporate Wrongdoing* (Sept. 9, 2015).

2 *Id.*

3 Principles of Federal Prosecution of Business Organizations, USAM 9-28.700.

4 Principles of Federal Prosecution of Business Organizations, USAM 9-28.700.

5 *Id. See also*, U.S.S.G. § 8C2.5(g), cmt. (n. 13) ("A prime test of whether the organization has disclosed all pertinent information" necessary to receive a cooperation-related reduction in its offense level calculation "is whether the information is sufficient … to identify … the individual(s) responsible for the criminal conduct.")

6 *Id.*

7 *Upjohn v. United States*, 449 U.S. 383 (1981).

8 *Upjohn*, 449 U.S. at 391-92.

9 It should go without saying, but the attorney should document that the *Upjohn* warning was delivered and may consider having the individual sign a document acknowledging they received and understood the *Upjohn* warning.

10 Model Rules of Prof'l Conduct R. 1.13.

11 *Id.* at 1.13(b).

12 *Id.* at 1.13(c) and (d).

13 Consider also the situation in which one represents a corporate client at a civil settlement or mediation and the subject of civil or administrative releases for both the company and individuals arises. One should think ahead regarding whether the company representative can effectively make decisions for the corporation divorced from any individual's interests.

14 Model Rules of Prof'l Conduct R. 1.13(d).

15 This analysis assumes that the company is unaware of any corporate misconduct or individual misconduct but receives a report from a whistleblower or notice of a government investigation. The analysis would change if the company discovered an employee's illegal conduct and decided to report it.

16 The Principles of Federal Prosecution, Section 9-28.730. This, however, does not apply if the prosecutor discovers that the retention of individual counsel for an employee is contingent upon directing the employee not to be truthful or to conceal relevant facts. *Id.*

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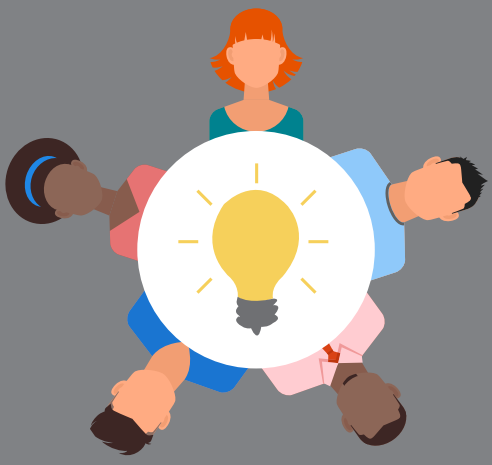

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