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For the Record

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Roy Snell

Compliance Lessons from the Johnny Depp/Amber Heard Trial

As anyone who has watched or read the news lately knows, actors Johnny Depp and Amber Heard sued each other for defamation. The trial was televised and coverage seemed to be nonstop. During the trial, as people will do in civil lawsuits, each side called witnesses. Johnny Depp's lawyers seemed to have gone to some trouble to find experts that were mature, clear communicators, understood the facts, were experienced in the subject matter, and had testified many times in court. On the other hand, Amber Heard's attorneys seemed to pick people who were emotionally unsuited for the court room, unclear communicators, not as experienced with the subject matter, not as familiar with the facts, and looked like they were testifying in court for the first time. Please excuse my sweeping generalizations, which are often… slightly inaccurate but primarily true. The bottom line is that millions of dollars and professional and personal reputations were on the line.

How does this relate to compliance programs? Well, we occasionally have millions of dollars and our reputation on the line too. When we conduct our own investigations or are being prosecuted, we sometimes select lawyers, auditors, and consultants that we know and are generally familiar with the subject matter rather than finding the best in the country. You win cases more often when your people know more about the problem than the opposition. You gain the respect of your leadership when your people know more about the problem than the people who are trying to make you look bad. I believe you occasionally save money in the long run with more expensive experts because they take less time to get the job done. And when it comes to settlements, I absolutely believe you will save money, in the settlement amount, if you pick the best from the entire population rather than picking the best from the people you know.

I would talk to people you know who work in the field. Ask them who has the best reputation. Look for videos of potential experts speaking. If they have no videos of them involved in presentations or participating in an expert panel you should be concerned. The expert you want is very active in their profession, certified, well known, writes articles and speaks regularly. That's how you find people at the top of their class.

Another way to get leads on experts is to find a past conference on the subject matter that you are interested in. Look at the brochure for names of people to call. Do not limit yourself to the general session speakers but

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do pay close attention to them. Find the national professional association for that expertise and call the association's office. I would ask to speak to the CEO but if you can't get them right away, try the lead conference planner. Lead conference planners not only know who the best experts are, they know who the experts think is the best. One thing I would be leery of and not put much stock in is awards given to these experts. Most of the awards that I have seen given out are not based on the things I would consider important and many of them have money flowing from the award receiver to the organization giving the award.

Leadership gets very nervous during big investigations. They trust the people who make the most sense. They want the people making the most sense to be from their side. All you have to do to gain the confidence of leadership is to spend as much time finding your experts as Johnny Depp's team did and not as little time as Amber Heard's team appeared to have taken.

Prepare for Battle: Understanding and Responding to the CMS Audit Contractor Enforcement Landscape

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Anna M. Grizzle / Lauren Gaffney

Healthcare fraud enforcement continues to generate a significant amount of attention due to the large recoveries announced each year by the Department of Justice (DOJ). In Fiscal Year 2021 alone, the DOJ announced $5.6 billion in settlements and judgments from civil cases involving fraud and false claims.[1] While healthcare companies should take steps to avoid the pitfalls leading to these settlements and judgments, DOJ actions are not the only enforcement threat. Claims audits by government contractors are increasing and also pose significant risks if action is not taken to address and ensure appropriate coding and billing.

The Centers for Medicare and Medicaid Services (CMS) has several program integrity audit programs to protect against fraud, waste, and abuse. The agency commonly uses third-party contractors to augment the agency's own efforts to audit Medicare and Medicaid coding and billing by Providers and suppliers (collectively, Providers). Audited Providers may include physicians and allied health Providers, hospitals, pharmacies, durable medical equipment (DME) Providers, and other professionals and entities that bill federal health care programs.

Auditors may review claims bills and/or conduct medical record reviews, and reviews may be electronically automated or done manually. While it may appear the auditors are performing the same task of simply reviewing claims, each auditor was established for a specific purpose, and the results of their activities can vary. Therefore, it is important to understand the purposes of each audit contractor and what to expect when faced with a Medicare or Medicaid audit as well as the potential ramifications of and ability to challenge a negative audit finding.

Types of Medicare Contractor Audits

The most common types of federal health care program audits include Targeted Probe & Educate (TPE), Supplemental Medical Review Contractor (SMRC), Unified Program Integrity Contractor (UPIC), and Comprehensive Error Rate Testing (CERT) audits, but there are other types of audits that Medicare and Medicaid Providers may encounter (for example, quality of care issues are handled by quality improvement organizations (QIOs) and state agencies).[2] TPE, SMRC, and CERT audits were suspended by CMS due to the COVID-19 emergency, however the agency recently resumed these audit programs.[3] Proper preparation for the most common types of audits can decrease the administrative burden and costs on a Provider or supplier when they are inevitably faced with an audit.

Targeted Probe and Educate (TPE) Program

TPE audits provide targeted one-on-one help to Providers to reduce claim denials and appeals.[4] These audits can result in penalties, so TPE audits must be taken seriously. The TPE audit is intended to increase the accuracy of billing in very specific areas. Medicare Administrative Contactors (MACs) use data analysis to identify Providers who have high claim error rates or unusual billing practices, and items and services that have high national error rates and are a financial risk to Medicare.[5] Examples of common claim errors include incomplete encounter notes, missing signature of the certifying physician, insufficient medical necessity documentation, and missing or incomplete certifications or recertifications.[6] If a problem fails to improve after three rounds of education sessions, the Provider is referred to CMS for next steps. This may include 100% prepayment review, extrapolation, referral to a Recovery Auditor, revocation of the Provider's billing privileges, or other action.[7]

If chosen for the TPE program, the Provider will receive a "Notice of Review" letter from its MAC requesting 20–40 claims for each health care service or item under review. TPE audits typically involve the review of 20–40 claims per Provider, per item or service. This is considered a round, and the Provider has up to three rounds of review, which may be prepayment or post-payment. The MAC will review these 20–40 claims and the supporting medical records submitted by the Provider. If compliant, the Provider will not be reviewed again for at least one year on the selected topic unless significant changes in Provider billing are detected. A Provider may be subject to multiple TPE probes at the same time.

If some or all of the claims are denied, the Provider may receive a "Final Results Letter" and will be invited to a one-on-one education session (usually held via teleconference or webinar) specific to the Provider's practice.[8] During the education session, the MAC will review the improper claims and teach the Provider how to correctly bill for the specific items and services found to be improperly billed. When a Provider is moved to an additional round of TPE review, the MAC may begin sending documentation requests for claims with dates of service no earlier than 45 days after the previous post-probe one-on-one education. The goal is to give the Provider time to make changes based on the education received prior to being subjected to additional review.[9] MACs may refer suspected fraud, waste, and abuse to UPICs at any time in the process.

If issues remain after the third round, the MAC will refer the Provider to CMS.[10] CMS may revoke the Provider's billing privileges.[11] Once a matter has been referred to CMS, the appeals process follows the Medicare appeals process. If the appeals results are not available at the time a Provider progresses to the second

or third round of TPE, but are available when the Provider is referred to CMS, CMS will take these results into consideration when determining the need for additional action. If, after appeals, a Provider's adjusted error rate indicates no need for additional review, CMS will make that recommendation, but the Provider will continue to be monitored by the MAC as if they passed the TPE review and had been released from review.

Although a large number of TPE audits are conducted each year and should be taken seriously, only a small percentage fail all three rounds of review. From October 2018 through September 2019, approximately 13,500 Providers were started on TPE with approximately 435,000 claims reviewed. Of these, less than 2% of Providers failed all three rounds of TPE.[12] CMS reports approximately 90,000 intra- and post-probe educational contacts occurred, including phone calls, face-to-face visits, webinar/e-visits, emails, and letters.[13]

Unified Program Integrity Contractor (UPIC) Audits

The UPIC is responsible for preventing, detecting and deterring fraud, waste and abuse in both the Medicare and Medicaid programs, and is the only contractor type that reviews both Medicare *and* Medicaid claims in this context.[14] This means UPIC audits are initiated only when there is a concern of potential fraud, waste and abuse, and should therefore be taken very seriously. UPICs conduct both prepayment medical reviews and postpayment audits. UPIC audits can have serious consequences, such as high-dollar extrapolated overpayment demands, payment suspensions, and referral to law enforcement for additional review.

UPIC audits often begin following data mining used by the UPIC to uncover "inexplicable aberrancies" indicating potentially fraudulent billing. The UPIC will also pursue leads based on information collected during beneficiary interviews, referrals from MACs, CMS, the Office of Inspector General for Health and Human Services (HHS OIG), beneficiaries, Providers, suppliers, state Medicaid Fraud Control Units, and others.[15]

The first sign of a UPIC audit is typically a site visit and/or a documentation request. Providers typically have 30 days to respond to the UPIC's request for documents, but UPICs have been known to grant extensions for good cause when requested. Providers must carefully review any UPIC documentation request to fully understand the scope of the documents being requested and the focus of the UPIC's review. For example, Providers should ask if the request is focused on medical records, or does the request also include business documents such as contracts with Providers or schedules.

Providers should likewise take note of the number of medical records being requested. If the request is for a small number of claims, typically less than ten post-payment claims, the UPIC is more than likely conducing a *probe sample*. Probe samples may result in an education letter informing the Provider by letter of questionable or improper practices and the correct procedure to be followed with supporting references to Medicare guidance, additional documentation requests (ADRs), or an audit finding with overpayments referred to the MAC for collection. Probe samples, coupled with beneficiary interviews can result in payment suspensions, 100% prepayment review and subsequent document requests, including a postpayment request for a statistically valid random sample of claims, if the UPIC finds "credible allegations of fraud."

If the request is for thirty or more claims, the UPIC is likely reviewing these claims in connection with what it will call a *statistically valid random sample.* In this circumstance, the Provider will receive

an overpayment demand from its MAC, which may be extrapolated. Likewise, if an overpayment is found, the UPIC will share that information with CMS, and if relevant, the state Medicaid agency. UPICs may also refer cases to the DOJ, HHS OIG, and to state Medicaid Fraud Control Units for civil or criminal prosecution. For Medicare, the UPIC may initiate recovery of overpayments and may refer discovered overpayments to the MAC for recoupment. For Medicaid, if CMS approves of the UPIC's findings, the matter is referred to the state Medicaid agency for recoupment.

Supplemental Medical Review Contractor (SMRC) Audits

The stated purpose of the SMRC is to "provide support for a variety of tasks aimed at lowering the improper payment rates and increasing efficiencies of the medical review functions of the Medicare and Medicaid programs."[16] The SMRC reviews Medicare Part A, Part B, and DME claims and medical records and supporting documentation under postpayment reviews to see if claims comply with the program's requirements. The SMRC is intended to be a "centralized medical review [] resource that can perform large volume [medical review] nationally."[17]

The current nationwide SMRC is Noridian Healthcare Solutions.[18] The focus of the reviews includes, but is not limited to, issues identified by CMS internal data analysis, the Comprehensive Error Rate Testing (CERT) program, professional organizations and other Federal agencies, such as the OIG or Government Accountability Office (GAO) and comparative billing reports. A list of the SMRC's current projects can be found on the Noridian website.[19] Providers should review the list regularly and, if the Provider fits into one of the current SMRC project categories, the Provider should ensure its documentation and coding are compliant with billing requirements and guidance.

Typically, Providers are targeted for an SMRC audit if CMS data shows the Provider is an outlier in billing when compared to the national average. An SMRC audit is initiated when Noridian sends a provider an ADR. Providers and suppliers are given 45 days to respond to the SMRC's initial request; however extensions may be granted to Providers that submit an extension request to SMRC prior to the end of the specified timeframe.[20] Once the SMRC receives the requested documentation, it has 30 days to conduct its review. When the review is complete, the Provider will receive a Final Review Results Letter from the SMRC. The Provider has 14 days to request another review. Within 30 days of the Final Review Results letter, the Provider may submit additional documentation for review by the SMRC. The SMRC has 30 days from the date of receipt of that documentation to conduct its review of the additional documents, and will send the Provider an Updated Final Review Results Letter.

Alternately, after the initial Final Review Results letter, the Provider may request a discussion and education session with the SMRC. The discussion and education session is conducted within 14 days of the request and the Provider will have 14 days from the date of that discussion and education session to submit additional documentation. The SMRC then has 14 days to review the submitted additional documentation and will send the Provider an Updated Final Review Results Letter.[21]

Providers who do not comply with the SMRC's requests may be referred to CMS. The SMRC will notify CMS of any identified improper payment and noncompliance within the documentation requests. The MAC may initiate claims adjustments and/or overpayment recoupment actions through the standard recovery process. At this point, Providers may determine

whether to initiate the appeals process outlined below.

Comprehensive Error Rate Testing (CERT) Audits

Unlike the other audits discussed in this article, selection for a CERT audit is random. The CERT auditor conducts post-payment review of medical records for Medicare Parts A and B and DME to test the accuracy of the Medicare Fee-For-Service program. The CERT establishes the error rates for estimates of improper program payments and findings are extrapolated to the universe of fee-for-service claims to determine the improper payment rate.[22]

The CERT process begins with the selection of a large universe of claims randomly selected for review during a reporting period. The auditor selects a statistically valid random sample of claims to review for improper payment under Medicare fee-for-service. The CERT may request records from both the billing Provider and the referring Providers who ordered the items or services. The CERT documentation requests identify the requested documents to be submitted within 45 calendar days of the request. However, the CERT program has the discretion to grant extensions to Providers who need more time to comply with the request. If records are not produced, the CERT will determine an improper payment occurred.

The CERT reviewers will assign improper payment categories to claims where underpayments or overpayments are found. These categories include: insufficient documentation supporting the claim; incorrect coding; lack of medical necessity (as determined by Medicare program requirements); no documentation; or other. In all cases of improper payment, the CERT will notify the MAC, who may recoup any overpayments. The CERT determination appeals process follows the process for Medicare claims appeals for Medicare fee-for-service.

Actions Resulting From Adverse Audit Results

CMS and its contractors have an array of tools to recoup overpayments and address program integrity concerns in connection with adverse audit results. As discussed below, some of the most powerful tools available to CMS and its contractors include the ability to demand extrapolated overpayments, impose prepayment audits, impose payment suspensions, refer Providers to other government agencies and revoke a Provider's enrollment in the Medicare program.

Extrapolation

After an overpayment determination is made, the contractor must assess an overpayment. The identified overpayments are referred to the MAC who sends the demand letter and ultimately recoups the overpayment amount (subject to the appeal rights discussed below). The assessment of an overpayment depends upon the type of sample used when identifying the beneficiary claims for inclusion in the review. If a limited sample or limited sub-sample of claims was chosen for review then the contractor can (1) seek recoupment of the actual overpayment for the claims reviewed; or (2) conduct an expanded review so that statistical sampling may be used.[23]

Congress has authorized Medicare contractors to use extrapolation to determine overpayments only if there is a determination that: (1) there is a sustained or high level of payment error; or (2) documented educational intervention has failed to correct the payment error.[24] This determination is not subject to administrative or judicial review.[25]

The MPIM has established a framework based upon this statute dictating when extrapolation should be used. Specifically, a contractor "shall use statistical sampling

when it has been determined that a sustained or high level of payment error exists."[26] Further, the use of statistical sampling "may be used after documented intervention has failed to correct the payment error" such as in TPE audits where educational efforts have failed.[27] For purposes of extrapolation, a "sustained or high level of payment error" shall be determined to exist through a variety of means, including, but not limited to:

- High error rate determinations by the contractor or by other medical reviews (*i.e.*, greater than or equal to 50 percent from a previous pre- or post-payment review);
- Provider history (*i.e.*, prior history of non-compliance for similar billing issues, or a history of non-compliant billing practices);
- CMS approval provided in connection to a payment suspension;
- Information from law enforcement investigations;
- Allegations of wrongdoing by current or former employees of a Provider; and/or
- Audits or evaluations conducted by HHS OIG.

When an overpayment determination includes extrapolation, this means the contractor has used a sample of submitted claims to extrapolate the results of the review to a large universe of claims to estimate an overpayment amount. While an overpayment for actual claims denial amounts is typically small, the overpayment amount can quickly balloon into hundreds of thousands or millions of dollars when the error rate is applied across the entire claims "universe," which generally consists of a year or more of claims. When the Provider is subject to an extrapolated overpayment demand, the importance of appealing the denial of each individual claim in the sample becomes imperative. Although each individual claim may represent a low dollar amount, it will represent a significant dollar amount after it is extrapolated. Thus, if extrapolation is upheld, each overturned individual claim will result in a significant reduction in the extrapolated overpayment amount.

While the decision to use extrapolation is not appealable, the sampling methodology and extrapolation calculations are subject to appeal, and Providers can seek to have extrapolation overturned. Statistical extrapolation used in estimations of overpayments must follow the requirements and process outlined in Chapter 8 of the MPIM. CMS affords its contractors significant leeway to make errors in their statistical sampling methodology, but Providers should consider whether the cumulative impact of otherwise allowable errors was enough to render the statistical extrapolation invalid. Through the Medicare appeals process outlined below, Providers have successfully argued the statistical sampling methodology was invalid and should be set aside.

Prepayment Review

Over the past several years, many Providers have experienced a sharp increase in the number of prepayment reviews received from MACs and other CMS contractors based upon data analysis or prior unfavorable audits. A targeted Provider-specific prepayment review occurs "only when there is the likelihood of sustained or high level of payment error." The MPIM recognizes the seriousness of a prepayment review explaining that "MACs shall deal with serious problems using the most substantial administrative sanctions available, such as 100 percent prepayment review of claims."[28]

Prepayment reviews can include a small "probe" sample of generally 20–40 potential problem claims to validate if there is a problem, requiring additional review up to 100% prepayment review. Even if the review is a probe sample, the MAC will institute an edit to flag all claims for review until the probe sample records

are submitted. For Providers with a high volume of claims, this can generate a significant number of ADRs that must be addressed.

CMS considers 100% prepayment review to be appropriate when a Provider has a prolonged time period of non-compliance with CMS policies, which is established through past education attempts and the historic improper payment rate.[29] A MAC must notify CMS in advance of placing a Provider on 100% prepayment review. Notably, no UPIC may initiate a 100% prepayment review without CMS approval.[30]

In conducting a prepayment review, a contractor will issue ADRs to a Provider. The Provider must timely respond to these requests, which is typically 45 calendar days. If the ADR is from the UPIC, the Provider typically has 30 calendar days to respond.[31] The MPIM specifically states, in the context of prepayment reviews, that "the reviewer shall not grant extensions to Providers who need more time to comply with the request."[32] As such, no extensions will apply in extenuating circumstances that the contractor deems good cause (*e.g.*, natural disasters).[33]

While the claims decisions of the claims under review can be appealed, the decision to institute a prepayment review is not appealable and can often be a time-consuming and burdensome process if a significant number of claims are reviewed. Likewise, prepayment review can adversely impact a Provider's cash flow as it can take 90–120 days or more for the contractor to review and approve each the claim. For the contractor to terminate the prepayment review, the Provider must provide sufficient documentation to support the claims. The Provider should carefully review all applicable regulations and guidance for the claims at issue to ensure the claims are supportive. Open dialogue with the audit contractor may also be helpful in understanding the contractor's concerns.

Payment Suspension

Coupled with the increase in audit contractors and audit activity, CMS and its contractors are also choosing payment suspensions as the first line of defense to address potential billing irregularities and overpayments.[34] Although CMS has assured Providers it will exercise its payment authority "judiciously" and will remain "mindful of the impact that payment suspensions may have upon a Provider,"[35] payment suspensions have become increasingly commonplace following an audit-related records request. A payment suspension, especially when coupled with a prepayment review, can have a devastating impact on a Provider's cash flow and, therefore, its long-term operational and financial sustainability.

A payment suspension may be used where there is:

(1) reliable information that an overpayment exists, but the amount of the overpayment is not yet determined;
(2) reliable information that the payments to be made may not be correct;
(3) reliable information that the Provider failed to furnish records and other essential information necessary to determine the amounts due to the Provider; and
(4) in cases of suspected fraud, a payment suspension may be used when there is a credible allegation of fraud.[36]

Most frequently, Providers first learn of a payment suspension through a notice letter, but there are instances where the suspension becomes effective prior to the Provider receiving notice. When prior notice is "appropriate," Providers are to be given at least 15 calendar days' prior notice before the payment suspension is effectuated.[37] However, advance notice of the suspension is not required if, among other reasons, the payment suspension request is a "fraud" suspension. In instances of a "credible allegation of fraud," the Provider will receive notice

concurrent with the implementation of the payment suspension, but not later than five calendar days after the payment suspension is imposed.

Payment suspensions can remain in place for many months, but must be re-evaluated every 180 days to confirm that the suspension continues to be appropriate. Providers have an opportunity to submit a rebuttal statement in opposition to the imposition of a payment suspension, but there is no appeals process available. If the payment suspension is lifted, the Provider will receive the payments held during the time of the suspension. However, this delayed payment is little comfort to a Provider dealing with a payment suspension who is receiving no payment during the pendency of the investigation.

Referrals to Other Agencies

To achieve its stated program integrity goals, CMS has granted its contractors wide authority to refer Providers to other agencies where appropriate. For example, the MAC has broad authority, including in the case of a TPE audit, to refer suspected fraudulent Providers to the UPIC.[38] The UPIC is, in turn, required to refer investigations to law enforcement when it has substantiated allegations of fraud including, but not limited to, documented allegations that a Provider: (1) engaged in a pattern of improper billing, (2) submitted improper claims with suspected knowledge of their falsity, or (3) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity.[39] Unless otherwise instructed by CMS, the UPIC would refer a Provider to HHS OIG, Office of Investigations under these circumstances.[40] The UPIC also is permitted to refer cases to law enforcement and the DOJ. Additionally, the UPIC must refer cases of apparent unethical or improper practices or unprofessional contact to state licensing authorities, medical boards, the QIO, or professional societies for review and possible disciplinary actions.[41]

Medicare Revocation

Any audit (including prepayment audits) can result in the revocation of a Provider's enrollment in the Medicare program. Under 42 C.F.R. § 424.535, CMS is authorized to revoke Medicare billing privileges for twenty enumerated reasons, including failure to respond to requests for medical records.[42] This type of revocation may occur when a Provider fails to respond to an audit request—such as a medical records request from the MAC or other contractor. CMS will revoke a Provider's Medicare enrollment even when the failure to respond to a request is inadvertent—for example, when a Provider fails to update its address in PECOS and fails to receive the requests.

Additionally, under 42 C.F.R. § 424.535(a)(8)(ii), CMS has the authority to revoke a currently enrolled Provider's Medicare billing privileges if CMS determines the Provider has a pattern or practice of submitting claims that fail to meet Medicare requirements.[43] In making this determination, CMS considers, as appropriate or applicable, the following: (1) the percentage of submitted claims that were denied during the period under consideration, (2) whether the Provider has any history of final adverse actions and the nature of such actions, (3) the type of billing non-compliance and the specific facts surrounding the non-compliance, and (4) any other information regarding the Provider that CMS deems relevant.[44] This type of revocation most often follows an audit where the contractor alleges the Provider performed poorly. There is no objective test of what constitutes a "pattern or practice" of submitting claims that fail to meet Medicare requirements. Although a revocation may be appealed, its impact can be far-reaching and have a devastating impact on Providers.

Addressing Issues Through an Audit Response Plan and Appealing Adverse Results

Due to the significant potential negative impact of audits and the actions that can result from them, Providers should redouble their efforts to ensure effective compliance programs are in place. Providers should proactively evaluate their compliance programs to ensure they are capable of detecting any potential billing issues. Providers should also ensure they are facilitating a culture of open communication for the reporting of any billing concerns. An effective compliance program should also provide relevant staff members with the necessary training on coding and billing requirements to help the organization with ongoing monitoring and assessment of risks.

Providers should immediately respond to any reports of potential non-compliance by investigating and taking corrective action as necessary. Providers should also proactively assess their current practices and confirm they are following all Medicare policies and procedures, including any applicable coverage decisions, when billing Medicare claims. Finally, the organization should self-audit when issues are identified internally and institute corrective action when incorrect coding and billing are identified and when medical record documentation does not support claims. This should include making refunds to a payor if overpayments are identified.

Developing an Audit Response Plan

Considering the increase in audit contractors and audit activity, Providers should also anticipate being the target of an audit and take steps to prepare for this eventuality. Providers can ensure an audit response is successful by developing a process for responding to audit requests. A multi-disciplinary committee (with representation across departments such as medical records, billing, medical staff, nursing administration, case management, utilization review, compliance and legal) is recommended to assist in drafting policies and procedures for responding to audit requests. This committee can assist in evaluating all possible records needed to support a claim, and where and how such records may be quickly located.

After the committee is assembled, the committee should be tasked with developing the audit response policies and procedures. These policies and procedures should anticipate the different types of requests and the response plan for each type of audit. For example, because of the potential impact of UPIC audits, employees should be trained to recognize a UPIC audit and distinguish it from other more routine audit requests. A process for responding to both record requests and onsite reviews also should be included. The policies and procedures should also designate a point person to be responsible for any audit response and require all audit requests to be immediately forwarded to this individual. A reference guide to potential sources of records is also helpful for inclusion to ensure there are no gaps in a response.

After the policies and procedures are developed, the Provider's staff should receive training on the processes. The staff receiving training should include any individuals who may receive an audit request, such as the billing team who may receive ADRs and the mailroom staff who may process incoming mail. This training is crucial in ensuring that the processes are followed in any audit.

Responding to an Audit

When an audit request is received or an auditor appears onsite, the audit response plan is put into action. The designated individual should serve as a point of contact with any audit contractor to coordinate the audit response. Written audit requests should be directed to the designated

individual to begin the process of assembling information for the response. If the audit contractor appears onsite, the designated individual should answer questions regarding where records are located, assist in coordinating any requested interviews, and be present for these interviews.

The Provider's legal counsel also should be contacted if an auditor appears onsite. Legal counsel then can assist in interfacing with the auditors and can monitor and document the audit process, including being present during interviews and assisting in document collection. If staff interviews are conducted, Providers should prepare an interview summary to document the information shared with the auditor. Sometimes Providers may learn auditors have interviewed beneficiaries or staff members outside of the office. If this occurs, the Provider should conduct its own interview to learn the topics discussed so the Provider will have an understanding of the audit focus and any potential concerns that may arise from the interview.

When providing documentation in response to an audit request, the Provider must ensure complete documentation is provided to the auditor to support the billed services. The response should not be rushed by the auditor; the Provider should proceed deliberately to collect all relevant documentation. The Provider should carefully review the audit request and consider whether records outside of the specific date range of the requests, such as physician orders for a therapy visit covered by the request or a certification for hospice care, should be provided to support all billing requirements. Providers should retain or request a copy of all documents provided to an audit. It is also best practice to include a cover letter with the audit response memorializing the documents collected to have a record of the information provided.

The Provider should consider and be cognizant of any response deadlines. If responses are not submitted within the deadline, the auditor may deny the claim and issue a negative finding. Providers needing additional time to respond to an audit should immediately request an extension and document this request and any response.

Appealing Adverse Results

Providers often disagree with a negative audit finding and decide to challenge the results through the Medicare appeals process.[45] Appeals of adverse results allow Providers to receive payment for previously denied claims, and if extrapolation is used, often significantly lowers the damages amounts. Successful appeals also reduce the audit error rate, which is important as future audit targets are often based on past audit results. For these reasons, Providers should be prepared to appeal any negative audit result and analyze every denied claim to determine if there are procedural and substantive grounds to appeal.

Subject matter experts, such as coding consultants and medical reviewers, can provide assistance in developing these arguments. If extrapolation is used, Providers should analyze the methodology with the assistance of a statistician to determine if there are valid appeal grounds. It is well established that "a Provider can . . . challenge the statistical validity of both the sample and the extrapolation."[46] "Courts have sanctioned [CMS's] right to use [random sampling and extrapolation], but reserved to challengers the right to challenge the mechanics of the procedure."[47] This is because an overpayment demand based on statistically invalid methods violates the Provider's right to due process.[48]

The five levels of the Medicare appeals process are: (1) redetermination from the MAC; (2) reconsideration from a Qualified Independent Contractor (QIC); (3) appeal to an administrative law judge (ALJ); (4) appeal to the Medicare Appeals Council Department Appeals Board (DAB); and

(5) appeal to a federal district court. Each level of the appeals process has different deadlines and requirements. Therefore, it is important to review the requirements as soon as an adverse decision is received to ensure appeal rights are preserved.

Redetermination. The first level of appeal is a redetermination in which a Provider can request that its MAC conduct a redetermination or review of the initial determination.[49] The redetermination request consists of a written request to the MAC seeking a review of the claims determinations and, if applicable, the sampling methodology used to calculate the overpayment demand. In the request, the Provider "must explain why it disagrees with the contractor's determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination."[50] This statutory provision thus allows a Provider to include additional records or other evidence to support a Provider's position.

This request must be filed within 120 days of the initial determination.[51] For prepayment audits and certain ADR audits, the initial determination is included on the remittance advices providing notice of payment. If the audit was a postpayment audit, such as a UPIC or SMRC, the MAC will issue a letter noting that it has made an "initial determination" and demand payment within thirty (30) days of receipt of the recommendation.

If the amount is not repaid within thirty (30) days, interest will be assessed on the overpayment amount, and the MAC may initiate recoupment proceedings by offsetting payments owed to the Provider until the overpayment is fully recouped.[52] If a Provider seeks redetermination within forty-two (42) days of the initial determination, recoupment is stayed pending the issuance of the redetermination decision.[53] Interest continues to accrue, however, and is payable if an unfavorable decision occurs. The redetermination decision is generally issued within sixty (60) days of the request.[54]

Reconsideration. If the redetermination is partially or fully unfavorable, Provider can request a reconsideration conducted by a QIC.[55] A reconsideration is "an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim."[56] The Provider must request a reconsideration within 180 days of receipt of the decision on redetermination.[57] However, if the reconsideration request is submitted within sixty (60) days of the redetermination decision, recoupment is stayed until the reconsideration decision is issued.[58] Interest will continue to accrue. Similar to the redetermination request, the reconsideration request is a written request "providing "evidence and allegations of fact or law related to the issue in dispute and explain why [the Provider] disagrees with the initial determination, including the redetermination." If extrapolation was used, the written request should provide evidence explaining why the sampling methodology is invalid. Additional records or other evidence can be submitted, including any missing documentation identified in the redetermination decision.[59] Importantly, any evidence not submitted with the reconsideration request will not be considered at a subsequent level of appeal absent good cause for why the evidence was not previously submitted.[60] The reconsideration decision is generally issued within sixty (60) days of the request.[61] After the reconsideration decision is rendered, recoupment is not stayed under any circumstances, even if additional levels of appeal are pursued.

ALJ Review. If the reconsideration decision remains unfavorable, Providers can request a hearing before an ALJ within 60 days of receiving the QIC's reconsideration decision.[62] The ALJ hearing is the first opportunity in the Medicare appeals process when a Provider can present oral

testimony, including testimony from experts, and other arguments to support its position. This is often the appeals level where Providers see the best results due to this ability to present oral testimony.

The request for an ALJ hearing must be made in writing and include the reasons the Provider disagrees with the QIC decision.[63] If the use of statistical sampling and extrapolation is being appealed, the request for an ALJ hearing include specific information of each sample claim being appealed and assert the reasons the Provider disagrees with how the statistical sample or extrapolation was conducted.[64]

The ALJ conducts a *de novo* review and issues a decision based upon a review of the record from both the lower levels and the ALJ.[65] No new evidence may be submitted at this stage absent good cause for failing to submit at a lower level.[66] The ALJ hearing may be conducted in-person, by video-telephone conference or by telephone with the most common method being by telephone.[67] While CMS and its contractors may join the hearing as a party, they typically only participate in a hearing. This prohibits the Provider from calling CMS or its contractors as a witness or conducting a cross-examination of CMS or its contractors.[68]

DAB Review. A party that has received an unfavorable ALJ hearing may seek review by the DAB.[69] A request must be submitted within sixty (60) days of the ALJ decision and must identify the portions of the ALJ decision with which the Provider disagrees and provide in support of the Provider's position.[70] While oral argument is granted only under limited circumstances, the parties will be given an opportunity to file briefs or other written statements.[71] In addition to the Provider seeking a DAB review, the DAB on its own motion or based upon a referral from CMS or its contractors may determine to review the ALJ decision.[72] The DAB conducts a de novo review and issues a final decision within 90 days of the request for review.[73]

Federal District Court. If the DAB affirms the decision, Providers can seek federal court review within 60 days of receipt of the DAB decision.[74]

Conclusion

Audit activity by CMS contractors is a cost of doing business for Providers. Understanding the roles of each auditor and the potential ramifications of negative findings helps Providers take the proactive steps needed to position themselves for a positive audit result. A robust compliance program and audit response process in particular mitigate the risk of a bad audit result by allowing Providers to implement processes to ensure accurate coding and billing and a complete response to any audit request. But even if a negative audit finding occurs, Providers can still achieve a successful result by preparing a thorough appeal to challenge the findings.

Endnotes

1. *https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year* (accessed June 5, 2022).
2. *See* CMS, "Medicare Program Integrity Manual" (Pub. 100-08), (hereinafter "MPIM"), Chapter 1, Section 1.3.6, (accessed May 31, 2022).
3. CMS, "Comprehensive Error Rate Testing (CERT)," *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Improper-Payment-Measurement-Programs/CERT* (accessed May 31, 2022); CMS, MLN Connects, Aug. 12, 2021, *https://www.cms.gov/files/document/2021-08-12-mlnc.pdf* (accessed May 31, 2022); CMS, "Coronavirus Disease 2019 (COVID-19) Provider Burden Relief Frequently Asked Questions (FAQs)," *https://www.cms.gov/files/document/Provider-burden-relief-faqs.pdf* (accessed May 31, 2022).
4. *See https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Targeted-Probe-and-EducateTPE* (last accessed June 6, 2022).
5. *See* MPIM, Chapter 3, Section 3.2.5 (last accessed June 5, 2022).
6. *See https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/*

Medicare-FFS-Compliance-Programs/Medical-Review/Targeted-Probe-and-EducateTPE (last accessed June 5, 2022).

7. *See* MPIM, Chapter 3, Section 3.2.5 (last accessed June 5, 2022).
8. The MAC may send the Final Results Letter before or after the final one-on-one education call. *See https://www.cms.gov/files/document/updated-tpe-qas.pdf*.
9. If a Provider declines to schedule education within a reasonable time after receiving the education offer, subsequent reviews will be for claims with dates of service no earlier than 45 days from the one-on-one post probe education offer. *See https://www.cms.gov/files/document/updated-tpe-qas.pdf*.
10. MPIM, Chapter 3, Section 3.2.5.
11. 42 C.F.R. § 424.535(a)(8)(ii).
12. *See https://www.cms.gov/files/document/updated-tpe-qas.pdf*. This percentage is based on all Providers who started round one of TPE and those who have completed all three rounds. Providers still on review were not counted.
13. *Id*.
14. *See* MPIM Section 4.2.2.1. UPICs replaced the Zone Program Integrity Contractors (ZPICs) and Program Safeguard Contractors (PSCs).
15. *Id*.
16. *See* MPIM, Chapter 1, Section 1.3.1 (last accessed June 4, 2022).
17. *Id*.
18. *See https://www.noridiansmrc.com/* (last accessed June 4, 2022).
19. *See https://www.noridiansmrc.com/current-projects/* (last accessed June 4, 2022).
20. *See https://www.noridiansmrc.com/documentation-requests/how-to-respond-to-an-adr/* (last accessed June 4, 2022).
21. Noridian provides a helpful flowchart of the SMRC review process: *https://www.noridiansmrc.com/documentation-requests/Provider-compliance-group-pcg-medical-review-process-flowchart/* (last accessed June 4, 2022).
22. *See* Medicare Program Integrity Manual, Chapter 12, Section 12.1.
23. MPIM, Chapter 8, Section 8.2.
24. 42 U.S.C. § 1395ddd(f)(3)(A).
25. 42 U.S.C. § 1395ddd(f)(3)(A).
26. MPIM, Chapter 8, Section 8.4.1.4 (emphasis added).
27. MPIM, Chapter 8, Section 8.4.1.4 (emphasis added).
28. *See* MPIM, Chapter 3, Section 3.1.
29. MPIM, Chapter 3, Section 3.4. Note that "prolonged time period of non-compliance" is not defined.
30. MPIM, Chapter 3, Section 3.4.
31. 42 C.F.R. § 405.903.
32. MPIM, Chapter 3, Section 3.2.3.2.
33. 42 C.F.R. § 405.903.
34. Payment suspensions can, but are not required to, be coupled with a 100% pre-payment review. If a prepayment review is not conducted, a post-payment review will be performed on the universe of claims adjudicated for payment during the payment suspension, prior to the issuance of the overpayment determination. *See* MPIM Chapter 8, § 8.3.
35. 76 Fed. Reg. 5862, 5929–30 (Feb. 2, 2011).
36. 42 C.F.R. § 405.371.
37. Day one begins the calendar day after the notice is mailed, so in practice, Providers typically receive less than 15 days notice. *See* MPIM Chapter 8, § 8.3.
38. MPIM, Chapter 3, Section 3.2.5.
39. MPIM, Chapter 4, Section 4.9.
40. MPIM, Chapter 4, Section 4.9.
41. MPIM, Chapter 4, Section 4.9.4.1.
42. *See* 42 C.F.R. § 424.535(a)(10).
43. *See* 42 C.F.R. § 424.535(a)(8)(ii); *See also* MPIM, Chapter 3, Section 3.2.5.
44. 42 C.F.R. § 424.535(a)(8)(ii).
45. *See* 42 U.S.C. § 1395ff(a)-(b); 42 C.F.R., Part 405, Subpart I. For Medicaid claims, the appeals process is determined at the state level.
46. *Chaves County Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 916 (D.C. Cir. 1991).
47. *County Ambulance Serv., Inc. v. Thompson*, 218 F. Supp. 2d 309, 314 (E.D.N.Y. 2002) (quoting the ALJ's decision); *see also* HCFA Ruling 86-1 at 9 (discussing the procedure after a "decision issued on appeal contains a finding that the sampling methodology was not valid").
48. *See Chaves*, 931 F.2d at 922 (noting extrapolation comports with due process "so long as the extrapolation is made from a representative sample and is statistically significant"); *Daytona Beach Gen. Hosp., Inc. v. Weinberger*, 435 F. Supp. 891, 900 (M.D. Fla. 1977) (concluding "the procedure used making a finding based on 10% of the total cases upon which recoupment was made denied the plaintiff due process").
49. 42 C.F.R. § 405.940.
50. *Id*. § 405.946(a).
51. *Id*. § 405.942(a).
52. *Id.* § 405.378.
53. *Id*. § 405.379. While the regulations allow for forty-two (42) days before recoupment begins, the MAC's initial determination letter will request that the appeal be filed within thirty (30) days to avoid recoupment, which allows the MAC a few days to process the redetermination and implement the recoupment stay.
54. *Id*. § 405.950(a).
55. *Id*. § 405.960.
56. *Id*. § 405.960.
57. *Id*. § 405.962(a).
58. *Id*. § 405.379.
59. *Id*. § 405.966(a)(1).
60. *Id*. § 405.966(a)(2).
61. *Id.* § 405. 970.
62. *Id*. § 405.1002(a).

63. *Id.* § 405.1014.
64. *Id.*
65. *Id.* § 405.1000(c).
66. *Id.* §§ 405.1014(a), 1028.
67. *Id.* § 405.1000(b).
68. *Id.* § 405.1010(c).
69. *Id.* § 405.1100.
70. *Id.* §§ 405.1102, 1112(b).
71. *Id.* §§ 405.1120; 1124.
72. *Id.* § 405.1101.
73. *Id.* § 405.1100(c).
74. 42 U.S.C. § 1395ff; 42 C.F.R. § 405.1130.

Considerations for Self-Disclosure: Who, What, Where and When? Guidelines for Compliance Professionals

Gabriel Imperato

Voluntary self-disclosure of a potential overpayment matter or other noncompliant activity may be mandated by law under certain circumstances (and therefore not "voluntary") and/or potentially be advisable (if not mandated by law) and offer protections too significant to pass up under the circumstances. Self-disclosures can be a useful option for not only overpayment matters, but a wide array of noncompliant activity, including misconduct and substantial violations of law which have financial liability associated with the misconduct. However, in considering the options for self-disclosure a provider or supplier should carefully evaluate the relevant pros and cons of each situation, as well as the most appropriate agency entry point for the self-disclosure. Careful consideration may lead to the conclusion that self-disclosure may not even be warranted, but this determination should be made after a careful and thorough analysis, taking into consideration the facts and applicable legal considerations, best practices, the risk of non-disclosure and ultimately the advice of experienced counsel for these matters. The basic objective of a self-disclosure is to secure a release from liability from the government (and therefore protection from qui tam litigation under the False Claims Act) for a defined scope of conduct for a negotiated amount in damages and penalties.

A self-disclosure can be made to the Office of Inspector General of the Department of Health and Human Services (OIG); the Centers for Medicare & Medicaid Services (CMS); or the Department of Justice, U.S. Attorney's Office (DOJ), or even the Attorney General of the state Medicaid program. There are no hard and fast rules, and the specific and precise factual and legal circumstances of each potential disclosure matter will dictate whether, and when, to self-disclose, and which agency will be the best choice to receive an

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initial self-disclosure. Regardless of which agency receives the disclosure, all the relevant agencies typically coordinate with each other to assess the warranted criminal and civil liability of the specific matter disclosed. A self-disclosure should be complete and transparent to protect the self-disclosing party from an allegation that key facts or circumstances were withheld or concealed from the disclosure.

Deciding Whether to Make a Self-Disclosure

In deciding whether and how to make a self-disclosure, health care organizations should generally engage in the following process:

- Investigate and evaluate the report of overpayment and/or noncompliant activity and/or potential misconduct.
  - ❑ At first identification of possible noncompliant activity, consider the necessity of preserving and collecting all potentially relevant documents, both hard copy and electronic information, and issuing a "hold notification" within the organization so no relevant hard copy or electronic information is dissipated.[1]
  - ❑ Consider having persons unconnected to the potential noncompliant activity conduct an internal investigation of the matter including review of relevant documents and other information (*i.e.*, representatives of the organization's compliance department and/or independent consultants directed by counsel).[2]
  - ❑ An individual or entity that becomes aware that it is retaining Federal or State funds to which it is not entitled is obligated to return those funds, even if receiving the funds was a result of a mistake or error.[3]

Comment: The general process of making a self-disclosure consists of identifying the problematic conduct through investigation, fixing the conduct to prevent it from recurring, quantifying any damages associated with the past noncompliant activity, and making a timely, complete, and transparent disclosure. The identification of an overpayment and any misconduct giving rise to overpayment and/or penalties creates exposure for an organization (or individual) to a whistleblower action and allegations under the False Claims Act (FCA). These circumstances can place an organization under significant pressure to seek a release from this exposure to liability by making an appropriate self-disclosure to the appropriate government agency.

- Consider with counsel the benefits and risks of making a self-disclosure.
  - ❑ Evaluate the potential advantages including: the release from liability; creating good will with the government that may foster agency leniency towards the organization; limiting the possibility and disruption of a government-directed investigation; expediting the time it takes to formally resolve the matter; avoiding serious criminal liability; minimizing civil exposure; neutralizing whistleblower suits; (but not eliminating the risk of these cases), reducing overall penalties; and reducing treble damages to 1.5× or 2× the single damage amounts.
  - ❑ Evaluate the potential disadvantages including: financial loss associated with repayments and pre-disclosure internal investigations; potential increased government scrutiny of the self-disclosed matter to verify facts; no upfront commitment by the government agencies of immunity against liability and damages and penalties;[4] and resulting penalties for conduct that may have remained undiscovered.

Comment: The reality for health care organizations may be that disclosure is not all that "voluntary," but may be a legal obligation and/or essential in today's enforcement and litigation environment in order to avoid greater criminal, civil and/or administrative liability.[5] The cost

of settling a self-disclosure liability is generally only a third of the cost associated with defending and settling the same liability in the context of a government criminal or civil enforcement action.

If Self-Disclosure Is Elected

If after considering the advantages and disadvantages of self-disclosure the provider or supplier decides to self-disclose, consider to which entity or agency the self-disclosure should be made: OIG, CMS and/or DOJ or State Agency for Medicaid Program matters.

Submitting the Self-Disclosure Through the HHS OIG-SDP

- Providers and suppliers should recognize that participation in the OIG-SDP is contingent upon acknowledgement of a potential violation of criminal, civil or administrative laws, full cooperation throughout the process, and complete disclosure of the facts and circumstances surrounding the violation. The OIG promotes provider self-evaluation and self-disclosure, encouraging openness and cooperation through use of its SDP. The April 17, 2013 OIG-SDP as amended November 8, 2021 supersedes the initial October 30, 1998 Provider Self-Disclosure Protocol at 63 Fed. Reg. 58399.
  - A unique feature of the OIG-SDP is its prior commitment under ordinary circumstances to resolve the self-disclosed liability with a release from program exclusion liability and Civil Money Penalties without imposing corporate integrity obligations and the availability, in most situations, of a multiplier of 1.5 of the single damages instead of double or triple damages.[6]
  - The self-disclosing party must make a good faith determination that the conduct in question potentially violates Federal, criminal, civil, or administrative laws aimed at health care programs. However, OIG will not accept disclosure of a matter that involves only liability under the physician self-referral (Stark) law in the absence of a colorable Anti-Kickback Statute violation that exceeds $100,000.00 in damages.[7]
  - Determine whether the matter has a "colorable" Anti-kickback violation.

Comment: The Anti-Kickback Statute (AKS) makes it a felony for a person to knowingly and willfully offer, pay, solicit, or receive anything of value in return for a referral, or to induce generation of business reimbursable under a Federal health care programs.[8] Furthermore, a person does not need actual knowledge of the law or specific intent to commit a violation of the AKS.[9] Thus, a violation occurs when the person knowingly engages in the prohibited conduct, not necessarily if and when the person knows he/she is violating the anti-kickback statutory provisions. It may never be prudent to concede or admit that individuals and/or the organization had the "intent" to violate the AKS. A self-disclosure, however, must be based on a potential violation of the AKS, without necessarily an admission of liability. A claim that includes items and services resulting from a violation [of 42 U.S.C. § 1320a-7b(g)] constitutes a false and fraudulent claim for purposes of the FCA.[10]

- If the matter at issue has the potential to violate the AKS, determine whether any statutory exceptions apply, 42 U.S.C. § 1320a-7b(b)(3), or whether the matter fits an applicable safe harbor, 42 C.F.R. § 1001.952.
- Ascertain whether the matter disclosed carries the minimum settlement amount of $100,000.00 necessary to resolve the matter through the OIG SDP.[11]

Comment: The provider should disclose mere billing errors and overpayments not suggestive of fraudulent conduct to the entity that processes the claims and issues payment on behalf of the government agency responsible for that particular Federal health care program

(*e.g.*, Medicare fiscal agent or Medicare Administrative Contractor—"MAC" or State Medicaid Program).[12]

– A provider that uncovers misconduct or an ongoing fraud scheme within its organization should consider a more immediate preliminary disclosure to the appropriate government law enforcement agency, *i.e.*, OIG-HHS and/or Department of Justice, with the expectation of a more complete disclosure upon completion of the internal investigation of the matter.[13]

Comment: Failure to return a known overpayment within sixty (60) days from the date of identification is actionable by whistleblowers under the FCA.[14] Providers may also take advantage of the FCA, which states that a self-disclosure made within 30 days after obtaining the information may limit damages to double damages rather than treble damages.[15] The application of this disclosure incentive varies from case to case, and consultation with counsel is recommended before relying on this FCA statutory provision for self-disclosure.

– Submit the self-disclosure following the OIG SDP, which can also be used as a guideline for self-disclosure to DOJ or other agencies or wherever else there are no specific guidelines or a protocol:
  - ❑ Submit a complete description of the conduct being disclosed in accordance with the OIG-SDP, which requires disclosure of basic information, including: the name, address, PIN, tax ID number, and disclosure of pertinent relationships and names and addresses of any related entities, and all other requested information.
  - ❑ Submit a description of the provider's internal investigation findings, or a commitment regarding when it will be completed, including the nature and extent of the improper or illegal activity and the circumstances of identification and corrective action related to the matter.
  - ❑ Submit an estimate of the damages to Federal health care programs and the methodology used to calculate that amount, or a commitment regarding when the provider will complete such an assessment, in accordance with the Self-Assessment Guidelines listed in the OIG-SDP. This self-assessment may be performed at the same time as the internal investigation, or commenced after the scope of noncompliance with program requirements has been established.

Comment: A provider must be in a position to complete the investigation and damages assessment within three months of submission to the OIG-SDP under normal circumstances.[16]

  - ❑ Submit a certification stating that, to the best of the individual's knowledge, the report contains truthful information and is based on a good faith effort to assist OIG in its inquiry and verification of the disclosed matter.

Comment: After receiving a self-disclosure, the OIG confers with DOJ and even other affected agencies to ensure that those agencies are aware of each disclosure before the OIG accepts a provider into the SDP. An acceptance into the OIG-SDP will suspend the obligation to report and return an overpayment within sixty (60) days of identification until a resolution of the self-disclosed matters.[17] The OIG also typically presents its review of the SDP matter to DOJ before the OIG resolves the matter. Ultimately, the OIG's agreement to resolve an SDP matter is not binding upon DOJ, but as a practical matter has typically been reviewed and authorized by DOJ.[18] Additionally, the provider may request the participation of a representative of DOJ or a local U. S. Attorney's Office in settlement discussions if it is determined this is necessary or desirable in order to resolve potential parallel liability under the FCA or other laws.

  - ❑ Submit the self-disclosure to OIG's Web site at: *https://oig.hhs.gov/compliance/*

self-disclosure-info/provider-self-disclosure-protocol/ and mail it to Assistant Inspector General for Investigative Operations, Office of Inspector General, Department of Health and Human Services, 330 Independence Avenue, S.W., Cohen Building, Room 5409, Washington, DC 20201.

Stark Self-Referral Disclosures

The CMS Self-Referral Disclosure Protocol (SRDP) was revised March 27, 2017 and is open to all health care providers and suppliers, whether individuals or entities, and is not limited to any particular industry, medical specialty, or type of service. The SRDP is available online at: *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf*.

- In deciding whether to self-disclose under CMS' SRDP over OIG's SDP, consider the following:
  - The SRDP is intended to facilitate the resolution of only matters that, in the disclosing party's reasonable assessment, are actual or potential violations of the physician self-referral (Stark) law. As stated above, the OIG's SDP will not apply to disclosure of a matter that involves only liability under the Stark law in the absence of a colorable AKS violation.[19] Thus, for matters dealing purely with Stark law issues, only the CMS' SRDP is available. In the event a matter could be disclosed under both protocols, disclosing parties must choose, and should not disclose the same conduct under both CMS' SRDP and OIG's SDP. A potential Stark violation alone should be disclosed through the CMS SRDP. A Stark violation with a corresponding colorable AKS violation with damages of at least $100,000.00 can be disclosed through the OIG SDP.
  - The Stark law essentially prohibits certain physician self-referrals, which can be in the form of physician requests for an item or service and/or establishing a plan of care that involves furnishing certain designated health services under the statute.[20] The Stark law has a series of exceptions that generally apply to ownership interests, 42 U.S.C. § 1395nn(c), and/or compensation arrangements, 42 U.S.C. § 1395nn(e).

Comment: The Stark law is a civil law and strict liability statute and does not assess a parties' intent, and the conduct in question is defined as lawful, but only if it falls within an exception. The AKS is primarily a criminal law, requires intent, and the conduct could still be considered lawful even if it does not meet any statutory exceptions or regulatory safe harbors.[21] Thus, circumstances may arise where intentional inducement of referrals could be lawful under a Stark law exception, but at the same time violate the AKS. These are issues and assessments which should be addressed with competent and experienced counsel.

- CMS will coordinate, as necessary, with the OIG and DOJ, and may refer the matter to law enforcement for consideration under its criminal and/or civil authorities.[22]
- The deadline for reporting and returning overpayments is the later of: (1) 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable.[23]
- An acceptance into the SPDP will suspend the obligation to report and return an overpayment within sixty (60) days of identification until a resolution of the self-disclosed matter.[24]
- Submit the self-disclosure following the requirements of CMS' SRDP:
  - Submit a description of actual or potential violations, including the specific information requested in the SRDP.
  - Submit the findings of a full examination including financial analysis,

providing the specific information requested in the SRDP.

- Include with all submissions a signed certification stating that, to the best of the individual's knowledge, the information provided contains truthful information and is based on a good faith effort to bring the matter to CMS' attention for the purpose of resolving any potential liabilities relating to the physician self-referral law.
- Submit the disclosure electronically to *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol/*. In addition, the disclosing party may submit an original and one copy by mail to the Division of Technical Payment Policy, ATTN: Provider and Supplier Self-Disclosure, Centers for Medicare & Medicaid Services, 7500 Security Blvd., Mailstop C4-25-02, Baltimore, MD 21224-1850.

❑ Be prepared to give CMS access to all financial statements, notes, disclosures, and other supporting documents and the names of any physicians potentially involved in potential violations of the Stark Law.

❑ Be aware that CMS may consider the following factors in reducing the amounts otherwise due and owing: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party.[25]

❑ The time to complete the resolution of a self-disclosure under the SRDP will vary and depend to a large degree on the quality and thoroughness of the submissions received and the backlog of those matters being handled by CMS. The SRDP has delayed numerous notices of acceptance into the SRDP for time periods that exceed any applicable statute of limitation. This situation will usually warrant consideration of a request to withdraw from the SRDP once a submitter is notified of acceptance into the SRDP.

Making a Self-Disclosure to the Department of Justice

Like the OIG, DOJ is a law enforcement agency. However, unlike the OIG and CMS, DOJ does not have a formal protocol for a provider or supplier to follow in making a self-disclosure. DOJ has criminal jurisdiction and also civil authority under the FCA. Thus, the FCA raises another basis for liability the provider should be aware of when going through the investigation, determination and disclosure process:

– The FCA makes it illegal for any person who: (1) knowingly presents or causes the presentment of a false or fraudulent claim; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to get a false or fraudulent claim paid; (3) conspires to do either of the above prohibitions; (4) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government.[26] The existence of a "known overpayment" without repayment within sixty (60) days from identification is enough to cause a violation, even without concealment of the known overpayment (*i.e.*, liability for inaction).[27]

Comment: The DOJ generally considers self-disclosed matters in line with its typical process for resolution of FCA liability

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Foreign Influence Investigation Leads to International Compliance Program

Donnetta Horseman

The H. Lee Moffitt Cancer Center and Research Institute, Inc. (Moffitt)[1] was established by the Florida legislation in 1981. It is named after H. Lee Moffitt, former speaker of the Florida House of Representatives, who lobbied to have it created and funded by the cigarette tax. Moffitt opened in 1986 and quickly earned its National Cancer Institute (NCI) designation through innovative breakthrough research. Moffitt is centrally located in Tampa, Florida with several satellites and partnerships throughout the state.

In December 2019, Moffitt's CEO and 5 others resigned or were terminated after a foreign influence investigation. This investigation was by far, the hardest and most impactful compliance investigation of my 15-year career as a compliance officer.

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Where the Story Begins

Moffitt entered a brotherhood institutionship agreement with Tianjin Medical University Cancer Institute and Hospital (TMUCIH) in 2008. In April 2014, Moffitt entered into a Collaboration Agreement with Tianjin China Taishan Cancer Hospital. I joined Moffitt in October 2014. Through my journey of learning about Moffitt, I read about this collaboration, and saw photos of a building in Tianjin, China that housed the Moffitt logo. I learned that we sent groups of physicians and nurses to Tianjin to teach them about personalized cancer care and hosted groups from TMUCIH at Moffitt on a regular basis. My assessment at that time was that this relationship created very little compliance risk for the organization. At the time, I was also learning about export control compliance, which presented several risks for a research institution like Moffitt.

What Are Export Controls?

Export controls are laws and regulations put in place by the federal government to control the release of equipment, chemical or biological materials, information, technology, software code or services to foreign countries. Activities that are subject to export controls include proprietary research, development, use technology, international agreements, defense services, international shipping, international travel, and certain activities prohibited by the Office of Foreign Asset Controls (OFAC). The regulations include comprehensive lists of items and technological information that are "controlled," which are items and information that cannot be exported to foreign countries without authorization or a license from the U.S. government.

The three U.S. agencies responsible for export controls are the Department of State Directorate of Defense Trade Control (DDTC), the Department of Commerce Bureau of Industry and Security (BIS), and the Department of Treasury Office of Foreign Asset Controls (OFAC).

An export is the controlled transfer of technology, information, equipment, software or services to a foreign person in the U.S. or abroad. There are two main types of exports. Physical exports involve hand carrying, shipping or transmitting technical data or technology to another country. Deemed exports involve the visual release or other inspection, or oral or written exchanges that reveal EAR-controlled technology or source code to a foreign person regardless of location. Export controls do not apply to "fundamental research." "Fundamental research means research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons."[2] The research is not "fundamental research" if sponsor approval is required prior to publication, publication of the results of the project are restricted, other access and dissemination restrictions are in the agreement, or the project dictates citizenship of project team members.

It became evident that as a research institute and hospital, we needed to conduct an export control risk assessment to determine what activities may be subject to export control regulations. Below is an excerpt from the risk assessment identifying specific risks and recommendations.

Risk	Recommendation	Risk Level
Foreign National on site (visas)	Conduct a review of all Moffitt sponsored visas using Visual Compliance.	High
International Shipping	Monitor international shipping daily to ensure compliance.	High
Research Collaborations	Review all grants and contracts that contain export control language or that have an international component. Screen all international parties using Visual Compliance.	High
Agreements	Review all agreements with export control language or international parties and screen using Visual Compliance.	High
Equipment	Review access to equipment and technology by foreign nationals. Comprise a list of Moffitt owned equipment and its associated export classification.	High
Access to Moffitt Systems	Enact a policy to block access to Moffitt systems from comprehensively sanctioned countries.	High
Biologicals	Review all biological protocols to ensure compliance	Medium
International Travel	An International Travel Authorization form was introduced in Spring of 2020. It has been effective in creating oversight of international travel. Update the form and require clean laptop loaners for Team Members traveling to specific countries of concern. Implement and enforce specific compliance activities for Team Members traveling to Cuba.	Low

While learning and educating the organization about export control compliance, other international compliance risks began to surface.

The NIH and Foreign Talent Programs

In January 2018, an article titled, "What is China's Thousand Talents Plan?" published in *Nature*,[3] described China's Thousand Talent Plan as a "scheme to bring leading Chinese scientists, academics and entrepreneurs living abroad back to China." The scheme later grew to include foreign scientists. The benefits of being a Thousand Talent awardee often included a starting bonus, annual salary, free housing, meal allowances, relocation compensation, lab space and personnel, and substantial funding for research abroad. In exchange, the awardee is expected to train personnel, author papers, develop intellectual property and apply for grants and patents in China. China's foreign talent programs also include a commitment from the awardee to work full or part time in China for several years.

In August 2018, the National Institutes of Health (NIH) issued letters to 10,000 research individuals and entities regarding threats to the integrity of U.S. biomedical research from foreign entities noting three areas of concerns: diversion of intellectual property, sharing of confidential information on grant applications by NIH peer reviewers, and failure of researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from foreign institutions and governments. In October 2018, the NIH sent inquiry letters to more than 70 academic institutions citing potential noncompliance with NIH policies regarding disclosure of outside research support and relevant affiliations. The letter, as illustrated below, directed the institutions to conduct investigations into specific investigators whom NIH believed to be in noncompliance and to provide complete copies of any foreign grants and contracts within 30–60 days.

In December 2018, a working group of the NIH Advisory Committee issued a

Please review these issues and confirm that these investigators and AWARDEE complied with the policies cited above. If any instances of non-compliance are identified or suspected, please also provide a detailed description of the issue and corrective actions taken.

In order for NIH to make informed assessments of possible overcommitment and/or scientific or budgetary overlap, we will need to see complete copies (in original and in English translation) of foreign grants and employment contracts.

I ask that you submit your written response with a copy to the NIH Office of Policy for Extramural Research Administration, ComplianceReview@mail.nih.gov, within the next 30-60 days.

Sincerely,
Michael S. Lauer, MD
cc: IC

report titled, "ACD Working Group Foreign Influences on Research Integrity"[4] further outlining its concerns and providing recommendations for addressing these issues. With the issuance of each of these letters and guidances, we provided education and reminders to our workforce on the importance of current and accurate conflict of interest disclosures and reporting of other support.

The Investigation

Moffitt never received an inquiry letter from NIH but these issues certainly further piqued my interest about Moffitt's relationship with Tianjin, leading me to question those most involved in the relationship. It was during this time that the Vice President (VP) of Clinical Research informed me that he and others at Moffitt were recipients of a Thousand Talent award from TMUCIH and that he had been escorted to a bank in China where he was told money was deposited into an account in his name. He was given a debit card to access the account while he was in China. He stated he did not know how much money was deposited, what the money was for and had never accessed it. He also stated he never signed any agreements or contracts and never received any paperwork. He was told this was an award for his collaboration and partnership with TMUCIH—all of which was coordinated by another senior Moffitt faculty member who happened to be from Tianjin, China, and our CEO's closest collaborator. My compliance officer antennae went all the up.

Over the next several months, we received an educational briefing from the local Federal Bureau of Investigation (FBI) field office on threats from foreign talent programs, engaged outside counsel and learned lessons from our peers at other organizations conducting similar investigations. We interviewed our CEO and Center Director and learned that they also had been recipients of a Thousand Talent award, opened bank accounts and received debit cards from banks in China. Neither individual remembered receiving any paperwork or signing any contracts or agreements. All three leaders who were recipients of the Thousand Talents award were adamant that they never committed to working in China for any period of time.

As part of our investigation, we performed a preliminary email search and found foreign talent program applications for the CEO, Center Director, VP of Clinical Research, and several other senior faculty members. These applications outlined specific benefits to the awardee, including but not limited to:

- Official positions, such as Director of programs, at the foreign institution;
- 300 sq. meters of space for experiments;
- A professional team of 10 researchers, assistant researchers, and technicians;
- Full-time translators with a dedicated office area;
- A residential apartment of 150 sq. meters and a work vehicle;
- A living allowance provided for the term of work equal to approximately $7,800 USD; and
- First class tickets for work trips.

The application also contained an express commitment to start working full time in China within 6 months after the application was approved for a minimum of 3, 6 or 9 months per year for 3 consecutive years. Directly under this work commitment was the applicant's signature. The investigation uncovered that the Moffitt senior faculty member from Tianjin was responsible for recruiting Moffitt leadership into this program. This faculty member was a long time Moffitt researcher and co-inventor of multiple inventions along with our CEO. He worked closely with the

Moffitt leaders to gather the information required for their applications, including copies of their signatures to append to the applications.

Although the investigation was not concluded, we disclosed what we knew so far directly to NIH. The conclusion of the investigation lead to the termination and/or resignation of the CEO, Center Director, VP of Clinical Trials and three other senior faculty members, including the one responsible for recruiting others into the program. We promptly disclosed the matter to the Department of Justice, Office of Inspector General, FBI, and the State of Florida.

Considering their full-time positions at Moffitt, it was impossible for these work commitments to ever be met. Neither the work commitments nor personal payments were properly disclosed to Moffitt. It did not violate Moffitt policies for these individuals to have participated in the Talents programs, or to have other academic positions or research collaborations with Chinese colleagues or institutions. However, under Moffitt policies and NIH regulations, timely disclosure and advance approval is required. Accepting undisclosed personal compensation from TMUCIH represented a conflict of interest (COI). Committing to spend significant professional time and effort on non-Moffitt activities, without permission, also represented a conflict of commitment.

Conflicts of Interest and Commitment

A financial conflict of interest (FCOI) is a financial interest that may create or give the appearance of creating bias or affecting decision making. A research FCOI (RFCOI) exists when an individual's personal financial interest could directly and significantly affect the design, conduct, or reporting of research. A conflict of commitment (COC) exists when an individual's commitment of time and effort to outside activities is inconsistent with the individual's commitment to the institution and/or the institution's interests. An institutional conflict of interest (ICOI) exists when financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, could affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution.

RFCOI rules are grounded in Public Health Service (PHS) regulations[5] promulgated in 2011. Key components of the regulations include:

- Defining significant financial interests (SFI);
- Mandating disclosure and review of SFIs;
- Requiring publication of a COI policy;
- Publishing COI management plans; and
- Requiring training for investigators.

There are no unifying federal regulations governing conflict of commitment. Institutions are subject to varying requirements under state laws and organizational policies. Common components of COC include:

- Outside activities or time away from work;
- Incidental use;
- Prior approvals; and
- Foreign relationships and activities.

COIs and COCs are managed through disclosures, disclosure review, determination of potential or actual conflict, management of the conflict, reporting and ongoing monitoring. Failure to promptly and properly identify or report potential COIs and COCs can create significant compliance risk for both the institution and the individual.

The Fallout

Moffitt Cancer Center became the top news story. Although the investigation did not reveal any loss or threat

to intellectual property, numerous headlines read, "Top exec, researchers resign from Moffitt Cancer Center over the concern of IP theft from China." The Florida Speaker of the House of Representatives convened the Select Committee on The Integrity of Research Institutions[6] to investigate foreign influence in taxpayer-funded research, intellectual property theft and gifts from foreign entities. The result of this work lead to the creation of state of Florida House Bill 7017—Foreign Influence[7] which requires the following:

- All State agencies are required to report any gift, grant, money, or anything of value over $50,000 from a foreign source to the Department of Financial Services within 30 days of receipt;
- Private entities that apply for grants or want to do business with a State agency must disclose financial ties worth more than $50,000 with China, Cuba, Iran, North Korea, Russia, Syria, Venezuela, or their agents;
- The creation of a research integrity office to oversee compliance;
- Rigorous screening of foreign applicants for research and research-related positions, prior to interview, including review of all publications, grants, employment, and education;
- Pre-approval and monitoring of international business travel and provision of detailed annual report listing travelers and foreign institutions visited; and
- Random audits by the Inspector General in order to ensure compliance.

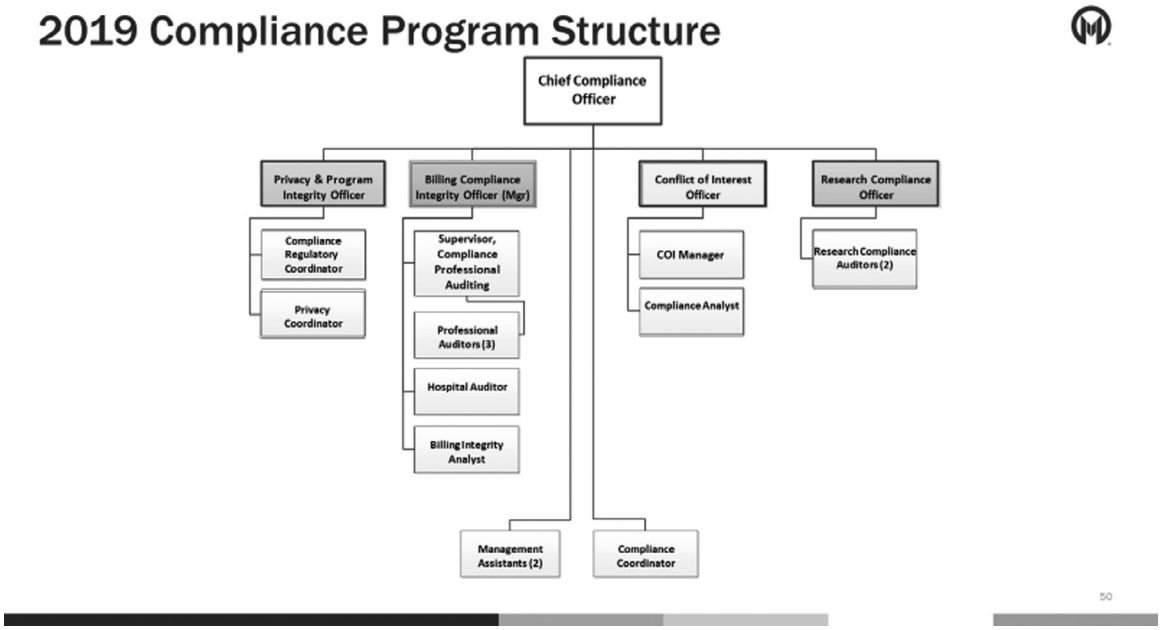
The Recovery

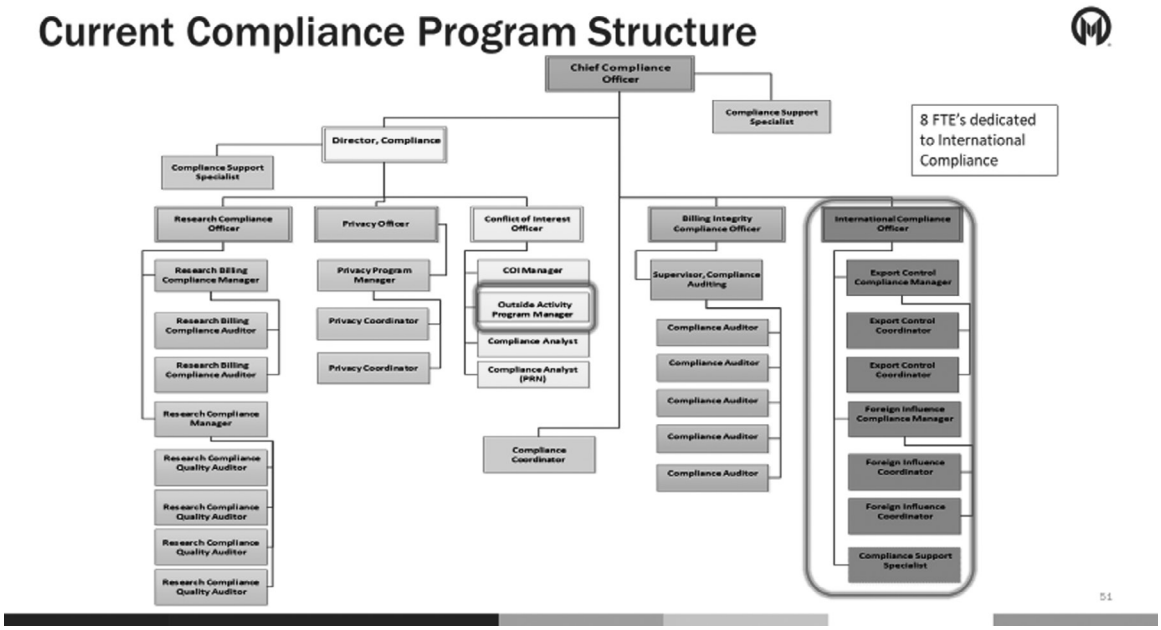
Throughout the investigation, Moffitt took numerous steps to improve oversight and compliance related to foreign influence and export control compliance, including but not limited to:

- Revising the Conflict of Interest in Research policy and disclosure forms;
- Launching a system-wide re-education effort on foreign influence and conflicts of interest;
- Hiring an International Compliance Officer and Export Control Compliance Manager;
- Conducting an export controls risk assessment;
- Implementing an international business travel policy and pre-approval process;
- Improving processes for visa review;
- Implementing a more robust review of international agreements and research collaborations; and
- Revising the Outside Professional Activity policy and developing an electronic reporting system that integrates with the conflict of interest disclosure reporting application.

The International Compliance program has further expanded to support legislative requirements and continues to provide education and implement processes to ensure compliance.

Prior to this investigation, international compliance was not really on my risk radar. As illustrated in the figure below, Moffitt's Compliance Program structure was significantly different from the structure of today's program. Compliance Officers at U.S. based institutions with no international presence should consider how doing business with international organizations and international laws can impact their organizations.


2019 Compliance Program Structure
Chief Compliance Officer
Privacy & Program Integrity Officer
Billing Compliance Integrity Officer (Mgr)
Conflict of Interest Officer
Research Compliance Officer
Compliance Regulatory Coordinator
Privacy Coordinator
Supervisor, Compliance Professional Auditing
Professional Auditors (3)
Hospital Auditor
Billing Integrity Analyst
COI Manager
Compliance Analyst
Research Compliance Auditors (2)
Management Assistants (2)
Compliance Coordinator
50


Current Compliance Program Structure
Chief Compliance Officer
Compliance Support Specialist
8 FTE's dedicated to International Compliance
Director, Compliance
Compliance Support Specialist
Research Compliance Officer
Privacy Officer
Conflict of Interest Officer
Billing Integrity Compliance Officer
International Compliance Officer
Research Billing Compliance Manager
Research Billing Compliance Auditor
Research Billing Compliance Auditor
Research Compliance Manager
Research Compliance Quality Auditor
Research Compliance Quality Auditor
Research Compliance Quality Auditor
Research Compliance Quality Auditor
Privacy Program Manager
Privacy Coordinator
Privacy Coordinator
COI Manager
Outside Activity Program Manager
Compliance Analyst
Compliance Analyst (PRN)
Compliance Coordinator
Supervisor, Compliance Auditing
Compliance Auditor
Compliance Auditor
Compliance Auditor
Compliance Auditor
Compliance Auditor
Export Control Compliance Manager
Export Control Coordinator
Export Control Coordinator
Foreign Influence Compliance Manager
Foreign Influence Coordinator
Foreign Influence Coordinator
Compliance Support Specialist
51

Endnotes

1. *http://www.leg.state.fl.us/statutes/index.cfm?mode=View%20Statutes&SubMenu=1&App_mode=Display_Statute&Search_String=moffitt&URL=1000-1099/1004/Sections/1004.43.html*.
2. *https://www.bis.doc.gov/index.php/documents/regulations-docs/2382-part-734-scope-of-the-export-administration-regulations-1/file*.
3. *https://media.nature.com/original/magazine-assets/d41586-018-00538-z/d41586-018-00538-z.pdf*.
4. *https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences_report.pdf*.
5. *https://www.govinfo.gov/content/pkg/FR-2011-08-25/pdf/2011-21633.pdf*.
6. *https://www.myfloridahouse.gov/sections/committees/committeesdetail.aspx?CommitteeId=3075*.
7. *https://www.flsenate.gov/Session/Bill/2021/7017*.

Paying Employees for Referring Healthcare Business

Kim C. Stanger / Allison Kjellander

Many healthcare employers may want to incentivize or compensate their employees for referring patients to or generating business for the employer, but they (appropriately) fear application of the federal Stark law, Anti-Kickback Statute, and/or the Eliminating Kickbacks in Recovery Act (EKRA). As explained more fully below, however:

- Stark only applies to payments to physicians (or the physician's immediate family members) if the physician refers certain designated health services payable by Medicare or Medicaid; it does not apply to referrals by non-physicians, nor does it apply to referral-based compensation arrangements involving non-DHS referrals.
- The Anti-Kickback Statute contains an exception that permits referral-based compensation to bona fide employees for legitimate services payable by federal healthcare programs.
- EKRA only applies to referrals for recovery homes, clinical treatment facilities, and laboratories.

Importantly, the foregoing only applies to compensation paid to bona fide employees, not to independent contractors or other entities. The following summarizes some of these key laws and limitations when structuring a referral-based compensation structure formula for employees.

Stark Law

The federal Ethics in Patient Referrals Act (Stark) prohibits physicians from referring patients for certain designated health services (DHS) payable by Medicare or Medicaid to entities with which the physician (or a member of the physician's immediate family[1]) has a financial relationship unless the transaction fits within a regulatory safe harbor. (42 U.S.C. § 1395nn; 42 C.F.R. § 411.353). Violations may result in significant penalties and repayments.[2] But the scope of Stark is relatively limited.

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Allison Kjellander is an associate at Holland & Hart. Ally assists buyers, sellers, and operators in the healthcare industry with federal and state regulatory compliance, including physician self-referral laws such as Stark, anti-kickback statutes, civil monetary penalties laws, antitrust, and licensing.

Physicians and Their Family Members

Stark only applies to referrals by physicians.[3] It does not apply to referrals or other business generated by non-physician employees unless the physician is effectively controlling the employees' referrals. (42 C.F.R. § 411.353(a)). Consequently, Stark generally does not prohibit referral-based compensation to employees who are not physicians or immediate family members of physicians.

Referrals for DHS

Stark only applies to referrals[4] by the physician to other entities, which may include an employer; however, it does not apply to services personally performed by the physician. (42 C.F.R. §§ 411.351, definition of *referral*; 411.353(a); and 411.357(c)(4)).

Thus, an employer may always pay an employed physician based on services the physician personally performs. Stark only applies to referrals by physicians for certain DHS[5] payable by Medicare and Medicaid. (42 C.F.R. § 411.353(a)). It does not prohibit a physician from referring non-DHS to her/his employer, including items or services outside the definition of DHS or DHS that are not payable by Medicare or Medicaid.

Bona Fide Employee Safe Harbor

Even if a physician is referring DHS, Stark's "bona fide employee" safe harbor generally excepts:

> Any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:
>
> (1) The employment is for identifiable services.
> (2) The amount of the remuneration under the employment is—
> (i) Consistent with the fair market value of the services; and
> (ii) Except as provided in paragraph …(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.
> (3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.
> (4) Paragraph … (2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).
> (5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of [42 C.F.R.] § 411.354(d)(4).

(42 C.F.R. § 411.357(c), emphasis added). Significantly, the safe harbor only requires that the compensation not vary with the volume or value of "referrals", which is defined as referrals for DHS. (42 C.F.R. § 411.351, definition of *referrals*). In contrast, the safe harbor applicable to independent contractors requires that the compensation not vary with the "volume or value of any referrals or other business generated between the parties", *i.e.*, non-DHS business. (42 C.F.R. § 411.357(d)(1)(v), emphasis added). The net effect is that referral-based compensation may be paid to employed physicians or their immediate family members so long as the compensation formula does not take into account referrals

for DHS;[6] the rules differ for independent contractors.

Directed Referrals

Although an employed physician's compensation formula generally may not vary with the volume or value of referrals for DHS, Stark allows an employer to require an employed (or contracted) physician to refer business to the employer subject to certain limitations:

> a physician's compensation under a bona fide employment relationship, personal service arrangement, or managed care contract [may be] conditioned on the physician's referrals to a particular provider, practitioner, or supplier, [if] all of the following conditions must be met.
>
> (i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.
> (ii) The compensation is consistent with the fair market value of the physician's services.
> (iii) The compensation arrangement otherwise satisfies the requirements of an applicable exception at [42 C.F.R.] § 411.355 or § 411.357.
> (iv) The compensation arrangement complies with both of the following conditions:
> (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.
> (B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.
> (v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, personal service arrangement, or managed care contract.
> (vi) Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5)(i) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

(42 C.F.R. § 411.354(d)(4)).[7] Under this "volume or value" standard, an employer may not require that an employed or contracted physician meet certain quotas as a condition of his or her continued employment or the amount of compensation received, *i.e.*, the employer may not require that an employed or contracted physician refer x number of cases or $y in revenue. (85 FR 77550). In its recent commentary, CMS offered the example of a hospital reviewing a physician's past performance when considering a contract extension:

> if, for example, the hospital increases the physician's compensation in the renewal term only if the physician made a targeted number of referrals for diagnostic testing to the hospital or the designated wholly owned providers and suppliers in the current term, the compensation would not meet the condition at § 411.354(d)(4)(vi). Similarly, if, for example, the hospital refuses to renew the employment arrangement (or terminates it in the current term) unless the value of the physician's diagnostic testing referrals generates sufficient profit to the hospital (or its wholly owned providers and suppliers), the existence of the compensation arrangement would be contingent on the value of the physician's referrals in violation of § 411.354(d)(4)(vi).

(85 FR 77548). On the other hand, the regulation specifically states that "[t]he requirement to make referrals to a particular provider … may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier." (42 CFR § 411.354(d)(4)(vi)). Thus, according to CMS:

> [If] the directed referral requirement … provided for termination of the compensation arrangement if the physician failed to refer 90 percent, for example, of his or her patients to a particular provider, practitioner, or supplier, it would not run afoul of the special rule at § 411.354(d)(4) or jeopardize compliance with the requirement of the applicable exception.

(85 FR 77550, emphasis added). Even in such cases, however, the directed referral requirement must satisfy or account for other conditions in § 411.354(d)(4), including that a physician is not required to direct the referral to the employer if "the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment." (*See id* at § 411.354(d)(4)(iv)(B)).

Group Practice Members

Physician groups have greater latitude in compensating their physicians. Physician groups that satisfy Stark's "group practice" definition[8] may pay their group members (including employed physicians) based on the volume or value of their referrals in two situations. First, "a physician in the group may be paid a share of overall profits that is not directly related to the volume or value of the physician's referrals." (42 C.F.R. § 411.352(i)(1)(i)).

> Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

(*Id.* at § 411.352(i)(1)(ii)). Although not exclusive, the regulations contain certain safe harbors in which the payment of a share of overall profits is deemed not to take into account the volume or value of referrals, *i.e.*, if:

(A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).
(B) Overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.
(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(42 C.F.R. § 411.352(i)(1)(iii)).

Second, "a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services 'incident to'[9] such personally performed services, that is not directly related to the volume or value of the physician's referrals..." (42 C.F.R. § 411.352(i)(2)(i)). A productivity-based compensation model will be deemed not to be based on the volume or value of referrals in the following situations:

(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician.
(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.
(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(*Id.* at 411.3572(i)(2)(ii)).

Stark in Summary

To summarize, Stark generally prohibits paying employed physicians (or their immediate family members) in a manner that varies directly with the volume or value of their referrals for DHS but it may be possible to compensate them based on their referrals for non-DHS. The danger is that employers and those implementing such a compensation arrangement may not understand the distinction and/or become careless. Before you know it, the compensation may factor in referrals for DHS as well as non-DHS resulting in potential Stark violations. Physician groups have greater flexibility and may pay their physician group members a share of overall profits, which profits may be impacted by referrals, subject to certain limits. Alternatively, physician groups may pay physicians based on the "incident to" services they refer in addition to their personally performed services. Finally, Stark allows employers to require physicians to refer patients to an identified entity so long as the directed referral requirement satisfies the requirements in 42 C.F.R. § 411.354(d)(4). Given the nuances, employers should carefully consider the practical compliance challenges before establishing a referral-based compensation formula for employed physicians or their family members.

The Anti-Kickback Statute

Given the relatively narrow scope of Stark, the federal Anti-Kickback Statute (AKS) is often the more relevant hurdle for most employee compensation arrangements, especially compensation for non-physicians. The AKS generally prohibits knowingly and willfully offering, paying, soliciting or receiving any remuneration to induce referrals for items or services payable by federal healthcare programs. (42 U.S.C. § 1320a-7b(b)). Violations may

result in significant criminal, civil, and administrative penalties.[10] The AKS is subject to two significant limitations, however, as described below.

Federal Healthcare Programs

The federal AKS only applies to referrals for items or services payable by federal healthcare programs; it does not apply to remuneration offered for referrals for private pay business. Employer compensation programs that reward referrals for private pay business—not government program business—should not implicate the AKS. Nevertheless, there are risks in such programs. As with Stark, it may be difficult to implement the program in a way to ensure referrals for federal program business are not factored into the compensation. In addition, the HHS Office of Inspector General (OIG) has cautioned that such "carve out" programs in which remuneration is paid solely for private pay business may have the effect of also inducing federal program business and, therefore, violate the AKS. (*See, e.g.*, OIG Adv. Op. 12-06 at p.6–7).[11]

Bona Fide Employee Exception

More importantly, the AKS expressly excepts "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services." (42 U.S.C. § 1320a-7b(b)(3)(B)). Consistent with the statutory exception, the regulations implementing the AKS contain the following "bona fide employee" safe harbor:

> *Employees*. [For purposes of the AKS], "remuneration" does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of … this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. § 3121(d)(2).

(42 C.F.R. § 1001.952(i)). Under 26 U.S.C. § 1321(d)(2), "any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee." For purposes of this article, we will refer to both the statutory employment exception and the regulatory employment safe harbor as the "employee safe harbor."

OIG, courts, and commenters discussing the employee safe harbor have generally identified two potential issues that must be considered when evaluating application of the safe harbor: (1) whether the person receiving the remuneration is a "bona fide employee"; and (2) whether the remuneration is intended to generate referrals instead of the "furnishing of any item or service" payable by federal health care programs. (*See, e.g.*, D. Romano, *How Safe Are the Safe Harbors? An In-Depth Look at Statutory and Regulatory Exceptions to the Anti-Kickback Statute*, 30 Health Lawyer 1 at 6–8 (12/17)).

1. Bona Fide Employment

Whether a person is a bona fide employee for purposes of the employee safe harbor depends on the common law test for employee-employer relationships. As one court explained,

> Whether a worker is an "employee" is based on "the hiring party's right to control the manner and means [of the work]," which is determined by considering the following factors:
>
> > the skill required; the source of the instrumentalities and tools; the location of the work; the duration of the relationship between the parties; whether

> the hiring party has the right to assign additional projects to the hired party; the extent of the hired party's discretion over when and how long to work; the method of payment; the hired party's role in hiring and paying assistants; whether the work is part of the regular business of the hiring party; whether the hiring party is in business; the provision of employee benefits; and the tax treatment of the hired party.

(*United States v. Vernon*, 723 F.3d 1234, 1271 (11th Cir. 2013), *quoting Nationwide Mut. Ins. Co. v. Darden*, 503 U.S. 318, 323–24, 112 S.Ct. 1344, 1348, 117 L.Ed.2d 581 (1992); *see also United States v. Sanjar*, 876 F.3d 725, 747 (5th Cir. 2017) ("Factors relevant to determining if an employment relationship is bona fide include the manner of payment, whether the work is part of the employer's regular business, and the employer's control over work hours."); *United States v. Crinel*, 2015 U.S. Dist. LEXIS 77773, *13 (listing 13 factors to determine whether an employee relationship exists); *United States v. Halifax Hosp. Med. Ctr.*, 213 WL 6196562 at *6 (M.D. Fla. 2013) (listing 25 factors for determining whether a person is an employee)).

Several courts have held that, no matter how the parties characterize the relationship, the employee safe harbor does not apply if the person receiving the remuneration is really not a bona fide employee under the common law rules for determining employee status. (*See, e.g., United States v. Vernon*, 723 F.3d 1234, 1249–51 (11th Cir. 2013) (no bona fide employment relationship where the purported employee rarely visited the company headquarters, received no oversight or direction from company employees, earned significantly more than other sales representatives in similar jobs, did not have to comply with company policies and procedures, and spent a majority of his time performing non-work related tasks); *United States v. Robinson*, 505 Fed. Appx. 385, 387–88 (5th Cir. 2013) (no bona fide employment where the purported employees did not receive regular paychecks, received no training or direction about marketing, did not have office hours or on-site offices, work was not sufficiently controlled by the company, and received payments solely as a fee or commission for each referral they provided to the company); *United States v. Job*, 387 Fed. Appx. 445, 454 (5th Cir. 2010) (no bona fide employment relationship where the purported employee was not trained, had no set hours, was not required to work fulltime, did not perform work on the employer's premises, split expenses with the employer, and was paid purely by commission)).

2. Remuneration for Providing Covered Services

There is some authority suggesting that the employee safe harbor does not apply if the remuneration is paid for referrals instead of the furnishing of items or services payable by government healthcare programs. In a 1992 letter discussing compensation in the sale of a physician practice, the OIG official included the following footnote:

> We would also note that while the anti-kickback statute contains a statutory exemption for payments made to employees by an employer, the exemption does not cover any and all such payments. Specifically, the statute exempts only payments to employees which are for "the provision of covered items or services". Accordingly, since referrals do not represent covered items or services, payments to employees which are for the purpose of compensating such employees for the referral of patients would likely

> not be covered by the employee exemption.

(Letter from D. McCarty Thornton to T.J. Sullivan dated 12/22/92 (Thornton footnote), available at *https://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm*). Consistent with the Thornton footnote, several courts have held or suggested that the employee exception does not apply if the remuneration is paid for referrals, not for "providing" or "furnishing" covered services. (*See, e.g., United States v. Luis*, 966 F.Supp.2d 1321,1330–31 (S.D. Fla. 2013), *aff'd*, 564 Fed.Appx. 493 (11th Cir. 2014), *rev'd*, 578 U.S. – –, 136 S.Ct. 1083, 194 L.Ed.2d 256 (2016), *and vacated and remanded*, 653 Fed.Appx. 904 (11th Cir. 2016) (defendant allegedly paid nurses to recruit patients); *United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011); *United States v. Starks*, 157 F.3d 833, 839 (11th Cir. 1998); *see also United States v. George*, 900 F.3d 405, 413–14 (7th Cir. 2018); *United States ex rel. Obert–Hong v. Advocate Health Care*, 211 F.Supp.2d 1045, 1050 (N.D.Ill. 2002)).

Nevertheless, most courts and commentators that have considered the issue have expressly rejected the foregoing analysis and authorities and/or upheld referral-based payments to bona fide employees under the employee safe harbor exception. (*See, e.g., Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267 (11th Cir. 2018); *United States v. AIDS Healthcare Found., Inc.*, 262 F.Supp.3d 1353, 1362 (S.D. Fla. 2017); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 U.S. Dist. LEXIS 80160 (N.D. Tex. 2016); *Crinel*, 2015 U.S. Dist. LEXIS 77773; *Hericks v. Lincare, Inc.*, 2014 U.S. Dist. LEXIS 39706, *53–54 at n.17 (E.D. Pa. 2014); *Halifax Hosp.*, 2013 WL 6196562 at *8; *State v. Harden*, 983 So.2d 480 (Fla. 2006); *New Boston Gen. Hosp., Inc. v. Texas Workforce Comm'n*, 47 S.W.3d 34 (Tx.App. 2001)). The analysis in these cases is persuasive for the following reasons:

a. OIG Commentary Approves Commission-Based Compensation.

The 1992 Thornton footnote is hardly authoritative. As one court noted,

> The letter from the Associate General Counsel concerns the acquisition of physician practices by hospitals and the possible payments to those physicians; not only is this letter inapposite to this case, which involves bona fide employees receiving payment from their employer while working for that employer, it is over twenty years old and the author also only suggested in a footnote that payment for referrals of patients would "likely" not be covered by the employee exemption.

(*Hericks*, 2014 U.S. Dist. LEXIS 39706, *53–54 at n.17; *see also Vista Hospice*, 2016 U.S. Dist. LEXIS 80160, *75–76 ("This Court finds [the Thornton footnote's] prediction of likelihood to be the equivalent of dictum, and that, in this Courts' view, in inaccurate.")).

More importantly, the footnote expressly contradicts the OIG's official commentary to its employee safe harbor. When the safe harbor was originally proposed in 1989, the OIG stated:

> <u>This statutory exemption permits an employer to pay an employee in whatever manner he or she chooses for having that employee assist in the solicitation of Medicare or State health care program business</u>. The proposed exemption follows the statute in that it applies only to bona fide employee-employer relationships.
>
> In response to the October 21, 1987 request for comments, many commenters suggested that we broaden the exemption to apply to

> independent contractors paid on a commission basis. We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision. We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts.

(54 FR 3088, 3093 (1/23/89), emphasis added). In its 1991 comments to the final rule, the OIG reaffirmed that the employee safe harbor "permit[s] an employer to pay an employee in whatever manner he or she cho[oses] for having that employee assist in the solicitation of program business ...." (56 FR 35952, 35953 (7/29/91)). Again, the OIG distinguished bona fide employment relationships from independent contractor relationships:

> *Comment*: Many commenters urged the OIG to extend this exception to apply to independent contractors paid on a commission basis. ...
>
> *Response*: We continue to reject this approach because of the existence of widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control. Although two commenters asserted that they could achieve appropriate supervision and control of independent contractors by including restrictive terms in the contract, we cannot expand this provision to cover such relationships unless we can predict with reasonable certainty that they will not be abusive. We are confident that the employer-employee relationship is unlikely to be abusive, in part because the employer is generally fully liable for the actions of its employees and is therefore more motivated to supervise and control them.
>
> ...
>
> *Comment*: One commenter inquired whether a part-time employee paid on a commission-only basis falls within the employee exception.
>
> *Response*: As long as a bona fide employer-employee relationship exists between the part-time employee and the employer, such a relationship falls within the scope of this provision.

(*Id.* at 35981, emphasis added).

It is difficult to reconcile the Thornton footnote with the OIG's official commentary. If the OIG truly intended to backtrack on its published commentary, one would expect that it would have done so in a more official manner rather than sticking the new rule in an indefinite footnote of a letter addressing a different issue. There does not appear to have been any other official OIG pronouncement affirming or expanding the proposition raised in the 1992 Thornton footnote. To the contrary, in Advisory Opinion 07-03, the OIG reaffirmed its 1991 commentary that "the risk of fraud and abuse is typically reduced with bona fide employer-employee relationships, in part because the employer is generally fully liable for the actions of its employees and is thus more motivated to supervise and control them. (*See* 56 Fed. Reg. 35952, 35961 (July 29, 1991))."[12]

Courts have frequently cited the official OIG commentary approving

commission-based employee compensation programs when concluding that the employee safe harbor permits such programs. (*See, e.g., AIDS Healthcare Found.*, 262 F.Supp.3d at 1362; *Vista Hospice*, 2016 U.S. Dist. LEXIS 80160, *77–78; *Harden*, 938 So.2d at 488–89).

b. The Cases That Prohibit Payment for Referrals Are Distinguishable.

The cases most often cited for the proposition that the employee safe harbor does not apply to payments for referrals have markedly distinguishable facts from the typical referral-based employee compensation program. In *Starks*, the defendant paid two non-employees $250 for each patient they referred to the defendant. The 11th Circuit concluded that the employee safe harbor did not apply because:

> even if Starks and Siegel believed that they were bona fide employees, they were not providing "covered items or services." As the government has shown, Starks received payment from Siegel and Future Steps only for referrals and not for any legitimate service for which the Hospital received any Medicare reimbursement. At the same time, persons in either Siegel's or Starks's position could hardly have thought that either Starks or Henry was a bona fide employee; unlike all of Future Steps's other workers, Starks and Henry did not receive regular salary checks at the Hospital. Instead, they clandestinely received their checks (often bearing false category codes) or cash in parking lots and other places outside the Project Support clinic so as to avoid detection by other Project Support workers.

(147 F.3d at 839). Significantly, *Starks* did not address situations in which employees are paid a commission for referrals within the context of a bona fide employment relationship that involved the provision of legitimate patient care services. Later courts have distinguished *Starks* on this basis. For example, the court in *Hericks v. Lincare* noted, "in *Starks*, the individuals received payment from the treatment center only for referrals and not for any legitimate service eligible for Medicare reimbursement. In this case, the employees are employed by Lincare for more than simply referrals." (2014 U.S. Dist. LEXIS 39706, *54 at n.17; *accord AIDS Healthcare Found.*, 262 F.Supp.3d at 1368–69; *Vista Hospice*, 2016 U.S. Dist. LEXIS 80160 *79; *Harden*, 938 So.2d at 495). In *Carrel*—a subsequent case from the same court that decided *Starks*—the 11th Circuit distinguished Starks because the payments "were made to non-employees in exchange for referrals not contemplated by a healthcare program", and confirmed that an employer may pay employees for referrals for covered services, at least where the federal program pays for such referral services. (898 F.3d at 1275).

Similarly, in *Borrasi*, the defendant was convicted of AKS violations based on compensation for referrals paid through both a sham employment arrangement as well as additional remuneration conferred outside the scope of the alleged employment relationship. (639 F.3d at 777). On appeal, the 7th Circuit upheld the jury instructions relevant to the AKS:

> To convict Borrasi, the instruction required the jury to find … that some amount was paid not pursuant to a bona fide employment relationship.… Because at least part of the payments to Borrasi was "intended to induce" him to refer patients to Rock Creek, "the statute was violated, even if the payments were also intended to compensate for professional services."

(639 F.3d at 781, quoting *United States v. Greber*, 760 F.2d 68, 71 (3d Cir.1985)). But

as in *Starks*, the facts in *Borrasi* were fairly egregious and confirmed there was no bona fide employment relationship and/or payments were made outside any bona fide relationship, thereby negating application of the employee safe harbor:

> In order to conceal these bribes, Borrasi and other Integrated employees were placed on the Rock Creek payroll, given false titles and faux job descriptions, and asked to submit false time sheets. Borrasi, for example, was named "Service Medical Director" and was allegedly required to be available at all times; Baig later testified that Borrasi was not expected to perform any of the duties listed in his job description. According to minutes of Rock Creek's various committee meetings, Borrasi and some Integrated physicians occasionally attended meetings and submitted reports of their work. But they attended only a very small percentage of the actual meetings, and multiple witnesses testified to rarely seeing them in the Rock Creek facility for meetings or other duties. Jonas, Jawich, and Roper each testified that the Integrated physicians did not perform their assigned administrative duties, their reports and time sheets notwithstanding. Baig testified that he, Borrasi, and Mamoon did not expect the Integrated physicians to perform any actual administrative duties.
>
> In addition, Rock Creek paid the salary for Integrated's secretary, as well as lease payments for one of Integrated's offices. This arrangement purportedly gave Rock Creek an outpatient clinic at Borrasi's building and certainly supplemented Borrasi's rent. Further, Baig was paid both to oversee the admission and stays of Integrated's referrals to Rock Creek and also to ensure the referred patients were returned to nursing homes and facilities that Borrasi could access and control. These methods enabled Rock Creek and Borrasi to maximize their Medicare reimbursement claims.

(639 F.3d at 777). Again, *Borrasi* did not address a situation in which referral-based compensation is paid solely within the parameters of a bona fide employment relationship that included the provision of legitimate services. As the *AIDS Healthcare Found.* court explained,

> Importantly though, like Starks, Borrasi was never a bona fide employee of the organization that paid him kickbacks. In fact, Borrasi actively faked his employment at that organization to conceal the bribes he received. (*Id.* at 777). The Court finds Borrasi inapplicable because there is no evidence that AHF fraudulently employed Rodriguez to hide the bonus payments at issue.

(262 F.Supp.3d at 1366).

In *Luis*, the defendant paid employed nurses to recruit patients for services. In considering the applicability of the employee safe harbor, the district court stated:

> The text of the safe-harbor provision upon which Luis relies states that "remuneration" does not include "any amount paid by an employer to an employee ... *in the furnishing* of any item or service for which payment may be made in whole or in part under Medicare." 42 C.F.R. § 1001.952 (emphasis added). Similarly, the safe harbor contained in § 1320a–7b states that it will apply

> to "any amount paid by an employer to an employee … *for employment in the provision of* covered items or services." § 1320a–7b(b)(3)(B) (emphasis added). The emphasized language in both of these provisions makes clear that the safe-harbor provisions will only apply when payments made to an employee compensate the employee for furnishing or providing covered items or services or items or services payable by Medicare, not simply for referring patients.

(966 F. Supp.2d at 1330–31, emphasis in original). Citing *Starks* and *Borrasi*, the district court concluded that because the nurses were paid in part for referrals, the compensation structure violated the AKS even if the patients received covered items or services. (*Id.* at 1331). The court went on to note, however, that even if the employee safe harbor permitted payment for referrals for covered services, the defendants in *Luis* fraudulently billed Medicare for services that were not medically necessary or never provided and, therefore, the safe harbor would not apply on that basis. (*Id.*). Thus, *Luis* is distinguishable from a situation in which compensation is paid for referrals for legitimate services that are properly billed to Medicare. (*AIDS Healthcare Found.*, 262 F.Supp.3d at 1370 n.13).

c. A Number of Courts Have Rejected the Analysis in *Stark*, *Borresi*, and/or Luis.

Aside from the factual differences, several courts have expressly rejected the analysis (or lack thereof) in *Starks*, *Borresi*, and/or *Luis*. For example, courts have repeatedly pointed out that *Starks* contains no substantive analysis of the relevant statutes to support is conclusions.[13] In *Vista Hospice*, for example, the court stated:

> *Starks* engaged in no substantive analysis of the exception, and commented on the "covered items or services" clause without relying on it—the defendants in that case clearly were not bona fide employees, clandestinely receiving checks or cash for their referrals in parking lots to avoid detection. *See United States v. Crinel*, 2015 U.S. Dist. LEXIS 77773, 2015 WL 3755896, at *5 (E.D. La. 2015) (disagreeing with *Starks* and stating that the *Starks* court engaged in no substantive analysis of the statute). Here, it is uncontested that the payments at issue were to bona fide employees.

(2016 U.S. Dist. LEXIS 80160 *79; *see also AIDS Healthcare Found.*, 262 F.Supp.3d at 1364–65; *Harden*, 938 So.2d at 495; *Hericks*, 2014 U.S. Dist. LEXIS 39706, *54 at n.17).

In *Crinel*, the court also provided a cogent critique of the *Borrasi* decision:

> In *United States v. Borrasi*, the Seventh Circuit undertook the in-depth analysis missing in *Starks* but, in this Court's opinion, focused on the wrong statutory provision. Specifically, the court focused on one of the substantive provisions of the anti-kickback statute—42 U.S.C. § 1320a-7b(b)(1)—as opposed to the safe-harbor provision in 42 U.S.C. § 1320a-7b(b)(3)(B). The Seventh Circuit held the substantive provision is violated "if part of [a] payment compensated past referrals or induced future referrals." The Court then applied this interpretation to the safe-harbor defense, finding the defense did not apply, because "at least part" of the payments to the defendant were intended to induce future referrals. In other words, the Seventh Circuit essentially held that if a particular payment violates a substantive provision of the

> anti-kickback statute, the safe harbor provision does not apply. This reading allows the rule to swallow the exception.

(2015 U.S. Dist. LEXIS 77773, *19; *accord Vista Hospice*, 2016 U.S. Dist. LEXIS 80160, *79; *see also AIDS Healthcare Found.*, 262 F.Supp.3d at 1365–66).

The analysis in *Luis*—which generally parallels the Thornton footnote—has been repeatedly rejected. In *AIDS Healthcare Found.*, for example, the court stated:

> [T]he *Luis* court's discussion seemingly narrow[s] what the text of the safe harbor actually protects. The [employment] exception's statutory text exempts "any amount paid by an employer to an employee … *for employment in the provision* of covered items or services." 42 U.S.C. § 1320a–7(b)(3)(B) (emphasis added). Although … *Luis* read this provision to exempt only the specific amounts paid by an employer to an employee for "providing" or "furnishing" covered services, other courts have rejected such a constrained reading. *See Hericks v. Lincare, Inc.*, No. 07-387, 2014 WL 1225660, at *14 n.17 (E.D. Penn. Mar. 25, 2014) (applying employee safe harbor because "the employees are employed by [the defendant] for more than simply referrals" and perform other covered services).

(262 F.Supp.3d at 1368). The court noted that *Luis's* interpretation "would read the exception out of the statute." (*Id.* at 1366).

The *Vista Hospice* court reached the same conclusion. In that case:

> Relator claims the bona fide employee exception does not apply, because Defendants have not shown that bonuses to employees were "for employment in the provision of covered items or services." Defendants, on the other hand, claim all of their employees were employed in the provision of covered services: hospice services eligible for reimbursement under [Medicare].
>
> The text of the statute supports Defendants' position. The statutory exception applies to payments for *employment in the provision of* covered services, not for providing covered services. 42 U.S.C. 1320a-7b(b)(3)(B).... On its face, therefore, the exception protects payments to employees of entities in the business of providing covered services of hospice care, not only for specific direct patient care for which bills can be submitted to Medicare.
>
> Further, the structure of the statute supports this reading of it. If the exception did not apply to payments intended to induce referrals or business for the program, it would be superfluous. The court in *U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center* rejected the argument that a bonus paid to employees to induce referrals was not protected by the safe harbor:
>
> [T]he Bona Fide Employment Exception provides that the normal prohibition on payments to induce referrals does not apply where the payments are made to a (for lack of a better word) legitimate employee. The Relator would change that to read that the prohibition on payments to induce referrals does not apply where the payments are made to a legitimate

> employee *unless they are payments to induce referrals*. The exceptions set forth in the Anti-Kickback Statute and accompanying regulations "provide immunity from prosecution for behavior that might have violated the Anti-Kickback Statute." . . . The Relator's interpretation of the Bona Fide Employment Exception would eviscerate it.

(2016 U.S. Dist. LEXIS 80160, *75–76 (quoting *Halifax Hosp.*, 2013 WL 6196562 at *8, emphasis in original).

Along the same lines, the *Crinel* court rejected the prosecutor's argument that "payment of Medicare referral fees never falls under the safe harbor, even if made to a bona fide employee":

> The Government's interpretation contravenes "the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative." The antikickback statute criminalizes the payment or receipt of Medicare referral fees. The safe-harbor provision expressly exempts certain payments of referral fees. If this exemption does not apply to Medicare referral fees under some circumstances, what purpose does it serve? In other words, if all Medicare referral fees were illegal, there would be no safe-harbor provision. Under the Government's strained interpretation, it is impossible to imagine any scenario in which a defendant could successfully invoke the safe harbor defense.

(2015 U.S. Dist. LEXIS 77773, *17; *see also Hericks*, 2014 U.S. LEXIS 39706, *54 at n.17, ("Because the safe harbor language applies to payment to individuals for employment in the provision of covered items and services, and because the Lincare employees are employed in the provision of covered items and services, the cash bonuses for referrals are not necessarily illegal remuneration in violation of the Anti-Kickback Statute.")).

d. Cases Involving Bona Fide Employees Have Generally Applied the Employee Safe Harbor.

As discussed above, the facts in *Starks, Borresi,* and *Luis* differ significantly from the situation in most referral-based compensation programs for employees. Courts that have considered the employee safe harbor in the context of bona fide employment relationships have consistently upheld referral-based compensation for employees, including the following:

- Bonuses paid to employed "Linkage Coordinators" to refer patients to employer for AIDS-related services. (*Carrel*, 898 F.3d 1267 and *AIDS Healthcare Found.*, 262 F.Supp.3d at 1368).
- Cash incentives (including a $15 per referral bonus) given to employed drivers and service representatives who generated business for the employer. (*Hericks*, 2014 U.S. LEXIS 39706 *43 and n.17).
- Incentive compensation pool offered to employed oncologists based on operating margin of oncology program. (*Halifax Hosp.*, 2013 WL 6196562).
- "Per head" payments to employees for soliciting and driving Medicaid-eligible children to employer for dental treatment. (*Harden*, 983 So.2d 480).
- Employed physicians allegedly required to make referrals to hospital and paid a percentage fee for referred patients. (*Obert–Hong*, 211 F.Supp.2d 1045).
- $1,000 commission paid to employed marketer for each long-term care facility she recruited to enter contracts for medical services from hospital. (*New Boston Gen. Hosp.*, 47 S.W.3d 34).

The *Vista Hospice* case provides a good example. In that case, Vista Hospice

> offered financial incentives to all classes of its employees to generate admissions and retain patients, by paying bonuses to employees for meeting admission and census goals. These programs most frequently rewarded salespeople, but sometimes rewarded all staff. For example, the 2004 "Growth Incentive Plan" provided cash incentives to all site employees if the site reached a "target goal" for new admissions. Site executive directors received $1,000 for hitting the admissions quota, and $75 for each additional admission, and admission coordinators would receive $500 for reaching the quota, and $50 for each additional admission. A "March Madness" plan awarded $500 weekend getaways to the top executive directors, area vice presidents, and regional vice presidents in each region who exceeded admissions goals for the month, while a "Spring Madness" promotion awarded the same to patient care managers and admissions coordinators at sites in each area achieving the highest average compared to the plan for achieving admissions goals over three months.

(2016 U.S. Dist. LEXIS 80160 *27–28). The *qui tam* relator argued that Vista Hospice "had a comprehensive, pervasive program to bonus employees, all of them, at times, but certainly and regularly the sales employees, for the purpose of obtaining patients and retaining them on census." (*Id*. at *75). After a thorough review of the cases and arguments discussed above (including the argument that the employee safe harbor did not apply to payments for referrals), the court concluded that the employee safe harbor protected the census-based incentive payments:

> Relator's interpretation reads the bona fide employee exception out of the statute and is inconsistent with the text, structure, and purpose of the exception. No binding case law supports such an interpretation, and the Court rejects it. Therefore, because Relator relies on bonuses paid to Defendants' bona fide employees for employment in the provision of hospice services, Relator cannot prevail on her AKS theory.

(2016 U.S. Dist. LEXIS 80160, *80–81).

e. Payments to Induce Fraudulent Conduct.

The foregoing analysis assumes that the compensation is paid to incentivize the provision of legitimate services. Some cases have distinguished payments to refer covered services from those in which payments are made to incentivize illegal conduct, *e.g.*, fraudulent billing practices, provision of medically unnecessary care, etc. (*See, e.g., Luis*, 966 F. Supp.2d at 1330–31 (employee safe harbor does not apply to compensation arrangements that promote fraudulent billing for services that were not medically necessary or never provided)). The *Crinel* court offered an interpretation of the employee safe harbor that factors in the difference between paying for referrals for legitimate service versus paying for fraudulent practices:

> The starting point is the text of the statute, which exempts payments made to employees "for employment in the provision of covered items or services." If an employee refers a patient who is actually eligible for Medicare and receives medically necessary services, the employer may provide appropriate compensation in the form of a referral fee. If, on the other hand … an employee receives a referral fee from its employer/co-conspirator

> as part of a scheme to provide benefits to individuals ineligible to receive them, the safe harbor provision is not applicable. The Court believes this interpretation best harmonizes all provisions of the anti-kickback statute and accords with Congressional intent.

(2015 U.S. Dist. LEXIS 77773, *23 (emphasis added)).

OIG commentary supports this distinction. For example, the OIG's Compliance Program Guidance for home health agencies warns against "[c]ompensation programs that offer incentives for number of visits performed and revenue generated", and explains:

> The current nature of the home health benefit (*i.e.*, no limits on reimbursable home health visits in a cost-reimbursed system) and customary business pressures create risks associated with incentives (*e.g.*, payments benefits, etc.) for productivity and volume of services. Such risks include over-utilization and billing for services not provided in order to meet internal goals and budget benchmarks imposed by home health agency management.

(63 FR at 42414 n.35).

> Clarifying and emphasizing these areas of concern through training and educational programs are particularly relevant to a home health agency's marketing and financial personnel, in that the pressure to meet business goals may render these employees vulnerable to engaging in prohibited practices.

(*Id.* at 42421). Among other things, the Guidance suggests that home health agency compliance programs should:

> Provide that the compensation for billing department personnel and billing consultants should not offer any financial incentive to submit claims regardless of whether they meet applicable coverage criteria for reimbursement or accurately represent the services rendered;

(*Id.* at 42415).

As with home health agencies, the OIG Compliance Program Guidance for Hospices warns that

> the compensation for hospice admission personnel, billing department personnel and billing consultants should not offer any financial incentive to bill for hospice care regardless of whether applicable eligibility criteria for reimbursement is met.

(64 FR at 54037).

Admittedly, it may be difficult to draw a line between programs that promote legitimate activities and those that promote abusive conduct, but as *Vista Hospice* demonstrates, employee incentive programs that promote legitimate services should receive employee safe harbor protection. Any employer implementing a referral-based compensation program should ensure that it is carefully structured and requires strict compliance with Medicare, Medicaid and other similar payer rules.

AKS in Summary

In summary, although there is some authority to suggest that paying employees for referrals violates the federal AKS, the majority of—and better reasoned—cases that have addressed the issue have concluded that the employee safe harbor applies to incentive-based compensation programs so long as: (1) the compensation is paid to a bona fide employee, and (2) the compensation relates to referrals or the generation of legitimate items or services,

not to induce fraudulent misconduct. These cases are consistent with the OIG's official commentary that the employee safe harbor "permit[s] an employer to pay an employee in whatever manner he or she cho[oses] for having that employee assist in the solicitation of program business ...." (56 FR 35953 (7/29/91)). (*See* OIG Adv. Op. 08-22).

Eliminating Kickbacks in Recovery Act

Although the federal AKS and Stark laws are most often cited, employers wishing to pay employees for healthcare referrals must beware of other potentially applicable laws, especially the Eliminating Kickbacks in Recovery Act (EKRA). EKRA is a relatively recent law passed in the wake of the opioid epidemic and provides:

> whoever, with respect to services covered by a health care benefit program,[14] in or affecting interstate or foreign commerce, knowingly and willfully—
>
> (1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
> (2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
> (A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
> (B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,
>
> shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.

(18 U.S.C. § 220(a)). Although similar to the AKS in that it prohibits remuneration in exchange for referrals, it is both narrower and broader than the AKS in certain respects. It is broader in that it applies to referrals for services that are payable by private payors in addition to federal healthcare programs. It is narrower in that it only applies to referrals to a recovery home, clinical treatment facility, or laboratory.

Laboratories, Recovery Homes, and Clinical Treatment Facilities

Relatively few healthcare employers operate recovery homes[15] and clinical treatment facilities[16] within the meaning of EKRA. Laboratories are another matter: EKRA is not limited to laboratories affiliated with opioid or substance abuse programs; instead, it extends to virtually any lab, *i.e.*, any

> facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(42 U.S.C. § 263a(a), as referenced in 18 U.S.C. § 220(e)(4)). Thus, any healthcare employer operating a laboratory must be concerned about EKRA.

Employee Exception

Like the AKS, EKRA does contain a limited exception for payments to employees, but like Stark, EKRA generally prohibits a compensation structure based on the volume or

value of most types of referrals. The exception applies to:

> a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—
>
> (A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
> (B) the number of tests or procedures performed; or
> (C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

(18 U.S.C. § 220(b)). It is difficult to imagine a referral-based compensation structure implicating labs that would satisfy the exception. And, unfortunately, we currently have few cases, no regulatory safe harbors, and little additional guidance discussing the parameters of the exception. Until we do, healthcare employers that operate laboratories should ensure that any referral-based compensation structures exclude laboratory referrals.

Other Laws

Importantly, many states have their own anti-kickback statute,[17] self-referral prohibition, or fee-splitting statutes.[18] The scope of such laws vary widely: some apply to only government healthcare programs; others apply to private payers, as well; still others apply to specific types of healthcare providers; *etc.* Healthcare employers need to be familiar with the laws applicable in their state and their specific situation. Interestingly, at least one state supreme court has held that the federal AKS employment exception preempts contrary state laws. (*Harden*, 938 So.2d 480).

Conclusion

Contrary to common belief, referral-based compensation formulas do not necessarily violate the federal Stark and AKS. Often such incentive-based programs for bona fide employees may be structured to comply with applicable laws, especially when not involving physicians or laboratories. On a federal level, the key is to ensure that the program is limited to bona fide employees, not independent contractors or other persons, and that the program does not incentivize referrals for laboratory services or that are otherwise inappropriate or not properly billable to federal programs. To that end, employers should work with their compliance officers and, if necessary, knowledgeable attorneys to structure the compensation programs to comply with the laws and minimize the risk of fraud and abuse.

Endnotes

1. Note that Stark applies to an employer's compensation arrangement with a referring physician's immediate family member in addition to a compensation arrangement with the physician; accordingly, compensation arrangements with family members of a DHS-referring physician must be analyzed for Stark compliance. For purposes of Stark,

   > *Immediate family member or member of a physician's immediate family* means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

   (42 C.F.R. § 411.351).
2. Currently, Stark law violations may result in civil fines of up to $27,750 per violation and up to $185,009 per circumvention scheme (which amounts are subject to annual adjustment) in addition to self-reporting and repayment of amounts received for services rendered per improper referrals. (42 U.S.C. § 1395nn(g); 42 C.F.R. §§ 1003.300 and 1003.310; 45

C.F.R. § 102.3). In addition, Stark law violations likely result in False Claims Act violations, thereby triggering additional penalties and the potential for *qui tam* lawsuits. (31 U.S.C. §§ 3729 and 3730; 42 U.S.C. §§ 1320a-7a and 1320a-7k(d); 28 C.F.R. §§ 85.5 and 1003.200(a) and (b)(k)).

3. "*Physician* has the meaning set forth in [42 U.S.C. 1395x(r)]" (42 C.F.R. § 411.351), *i.e.*, "(1) a doctor of medicine or osteopathy … (2) a doctor of dental surgery or dental medicine …, (3) a doctor of podiatric medicine …, (4) a doctor of optometry …, or (5) a chiropractor …" (42 U.S.C. 1395x(r)).
4. Under Stark, "referral" is generally defined as:

> the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare [or Medicaid], including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(42 C.F.R. § 411.351).

5. As defined by Stark, *designated health services* (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.)…

   (i) Clinical laboratory services.
   (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.
   (iii) Radiology and certain other imaging services.
   (iv) Radiation therapy services and supplies.
   (v) Durable medical equipment and supplies.
   (vi) Parenteral and enteral nutrients, equipment, and supplies.
   (vii) Prosthetics, orthotics, and prosthetic devices and supplies.
   (viii) Home health services.
   (ix) Outpatient prescription drugs.
   (x) Inpatient and outpatient hospital services.

   (42 C.F.R. § 411.351).
6. If certain conditions are satisfied, Stark also allows physician groups to compensate employed physicians based on the overall profits of the group (*see* 42 C.F.R. §§ 411.352(i) and 411.355(a)-(b)), which, of course, will be impacted by the employed physician's referrals. For more information about group practice compensation arrangements, see our article at *https://www.hollandhart.com/groupcompensation-arrangements-stark-requirements*.
7. For more information concerning paying physicians based on services they personally perform, see *https://www.hollandhart.com/directed-referrals-new-stark-rules.*
8. To qualify as a "group practice," the physician group must satisfy the requirements of 42 C.F.R. § 411.352.
9. "'Incident to' services or services 'incident to' means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, § 410.26 of this chapter, and Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4." (42 C.F.R. § 411.351).
10. An AKS violation is a felony punishable by up to 10 years in prison, a $100,000 criminal penalty, a $100,000+ civil penalty that is subject to annual inflation adjustments, treble damages, and exclusion from participating in the Medicare or Medicaid programs. (42 U.S.C. §§ 1320a-7 and 1320a-7b(b)(2)(B); 42 C.F.R. §§ 1003.300 and 1003.310; 45 C.F.R. § 102.3). An AKS violation is also a *per se* violation of the federal False Claims Act (42 U.S.C. § 1320a-7b(g); 31 U.S.C. § 3729), which exposes defendants to mandatory self-reports and repayments, additional civil penalties of $11,000+ to $22,000+ per claim, treble damages, private *qui tam* lawsuits, and costs of suit. (31 U.S.C. §§ 3729 and 3730; 42 U.S.C. §§ 1320a-7a and 1320a-7k(d); 28 C.F.R. §§ 85.5 and 1003.200(a) and (b)(k)).
11. For more information about such "carve out" programs, *see https://www.hollandhart.com/carving-out-federal-programs-does-not-preclude-anti-kick-back-liability*.
12. Although the OIG has had the opportunity to clarify or modify its position on referral-based employee compensation arrangements in several advisory opinions, it has so far declined to do so. For example:

    In Advisory Opinion 09-02, the OIG relied on the employee safe harbor to approve an employment agreement involving a mental health professional in which the professional was paid for administrative and clinical services. The opinion is a bit ambiguous in that the factual section states that the employer "would pay the Practitioner compensation based on revenues received for services delivered personally by her as well as total revenues of the Clinic," which may, of course, be impacted by the employee's referrals; however, the OIG's analysis states, "The compensation she received was based on professional services (including administrative services) she personally performed," and does not reference the overall revenues of the clinic. (OIG Adv. Op. 09-02 at 2, 4). The opinion does not contain any express discussion of referrals.

    In Advisory Opinion 08-22, the OIG approved a part-time employment agreement with two physicians in which they were paid based on the services they personally performed; there was no discussion of

pay for referrals. In Advisory Opinion 07-03, the OIG relied on the employee safe harbor to approve a hospital's plan to pass credit card rewards to employees based on the employee's performance. In that opinion, the requestor represented that it would not base the incentive on referrals; consequently, the OIG did not address referral-based compensation programs.

In Advisory Opinion 00-02, the OIG approved a program that would reward non-physician employees for submitting cost-saving suggestions that are subsequently implemented. In so doing, the OIG noted that "even if the anti-kickback statute were implicated, payments made to Hospital employees under the Proposed Arrangement may fit within the employee exception, depending on the specific suggestion." (OIG Adv. Op. 00-02 at n.4).

In Advisory Opinion 98-9, the OIG relied on the employee safe harbor to approve a collective bargaining agreement between a hospital and union that would give union nurses, health care aides, and certain other non-physician hospital service workers up to a 4% pay increase based on the number of admissions of union members. The requestors represented that those who were in a position to make referrals would not be allowed to participate in the program; accordingly, the OIG did not address referral-based employee compensation structures.

13. In two other cases, the courts suggested that the employee safe harbor does not apply if the payment was intended to induce referrals, but those statements appear in dicta, the context makes the statements ambiguous, and, like Starks, the statements were not accompanied by any analysis. (*See George*, 900 F.3d at 413–14 (no safe harbor protection where the defendant "was paid for referrals and not for the provision of items or services covered by Medicare, as required for that safe harbor provision to apply."); *Obert–Hong*, 211 F.Supp.2d at 1050 (employee compensation is exempt from the AKS "unless directly related to referrals.")). Accordingly, those cases are inapposite. (*See AIDS Healthcare Found.*, 262 F.Supp. at 1370 n.11).
14. "'Health care benefit program' means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." (18 U.S.C. § 24(b), as referenced in 18 U.S.C. § 220(e)(3)).
15. "'[R]ecovery home' means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders." (18 U.S.C. § 220(e)(5)).
16. "'[C]linical treatment facility' means a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law." (18 U.S.C. § 220(e)(4)).
17. For example, Idaho Code § 41-348 prohibits paying or receiving a payment in exchange for referrals for healthcare services or providing services with the knowledge that the patient was referred in exchange for a payment. The Idaho AKS is broader than the federal statute: it extends to payments to induce referrals for any healthcare services, not just those payable by federal programs.
18. Fee splitting statutes are common in state licensing statutes. For example, the Idaho Medical Practices Act prohibits "[d]ividing fees or gifts or agreeing to split or divide fees or gifts received for professional services with any person, institution or corporation in exchange for referral." (Idaho Code § 54-1814(8)). Depending on how broadly the relevant licensing board interprets the statute, it may prohibit certain remunerative relationships as well as investment interests in provider practices.

ROY SNELL

Gerry Zack Looks Back on the Challenges of the COVID-19 Pandemic and Discusses the Future of Compliance

Roy Snell is the ESG and Sustainability Officer for Osprey ESG Software. Roy is the co-founder of the Heath Care Compliance Association and the Society of Corporate Compliance. He is the author of Integrity Works and The Accidental Compliance Professional.

Gerry Zack is a compliance and antifraud expert and author, with more than 30 years of experience in the prevention, detection and investigation of fraud, noncompliance, and corruption. Gerry has been the CEO of SCCE & HCCA since 2018.

Snell: Before we get into the unbelievable challenges of the last couple years, why don't you share what has surprised you the most about the job of being a CEO of a professional association? What was the most surprising element of the job that you did not see coming?

Zack: Other than having to react to the pandemic, which nobody saw coming, the thing that amazes me most is the degree to which members of SCCE & HCCA are willing to give of their time and expertise. I have sometimes referred to myself as the "Chief Matchmaker" because one of things that I enjoy the most is speaking with someone who wants to contribute their expertise and finding the best match for their skills as well as what they will find fulfilling. There are so many ways to contribute. Often, it's just a matter of walking through all the different ways of helping and one or two of them stand out and have tremendous appeal. So many people in this profession are interested in helping others.

Snell: You are certified in 5 different professions. You have a deeper commitment to professional development than most people. What advice would you give to people who are not as engaged with their own profession? What are the benefits of certification, networking, speaking, writing, etc.?

Zack: I'll address certification separately from the others. Becoming certified in a field, especially when it's a rigorous and challenging certification, demonstrates a commitment to and mastery of a body of knowledge that is relevant to a field one is involved in. Whether it's one or ten certifications, I always encourage people to become certified in fields that will help them in their careers.

As for writing and speaking, I've always found that sharing whatever knowledge I might have is incredibly rewarding when I see that is has helped someone else. Just like so many people have helped me along the way, it is very gratifying to do the same for others. But the process of writing or preparing and giving a presentation also sharpens my own skills. It reinforces certain aspects of my own knowledge, and also forces me to explain things in a logical manner. If there are any gaps in my expertise, this process usually exposes them. Writing and speaking often lead me to do further research when I see weaknesses in my own knowledge.

Last but not least is networking. The value of making and maintaining connections is tremendous. The networks that can be made through membership in SCCE & HCCA will benefit you for years to come.

Snell: You are working closely with the new publishing group set up by your predecessor. You have written books and been a student of professional writing before the publishing world changed significantly in the last few years. How is publishing different now than the recent past?

Zack: Unsurprisingly, the biggest shift we've seen is the increased consumption of digital content and a gradual decline in print. Digital content is more portable and can be read anywhere quite easily. At the same time, and partly related to the first point, readers want their content faster. Today, when compliance news hits, there will be 20 bloggers and other sites who have it covered within a couple of hours. We don't try to compete on this speed aspect of news reporting. Our focus is more on the analysis of developments and what things mean for the compliance practitioner.

Snell: Can you tell us a little about COSMOS?

Zack: COSMOS is the name for the digital platform on which we provide our books, magazines, and a lot of other content that is useful for compliance and ethics professionals. Whether a reader is on a laptop or using a portable device, the content on COSMOS can be accessed and read anywhere and anytime. Members automatically have access to certain content on COSMOS, and other content is available for purchase or subscription.

Snell: A few months after the previous CEO retired COVID-19 hit and all of your live conferences (about 100 a year) were canceled for about 2 years. Let's take them one at a time and start with the Basic Compliance Academies. That must have had an impact on the certification programs. What did you decide to do to try to offset the impact of COVID on certification, assuming there was something you could do?

Zack: Even though our Compliance Academies aren't exam review courses per se, they are commonly used by candidates as part of the process of preparing to take one of our certifications examinations. And the highly interactive aspect of academies, including case studies and group discussions, made them impossible to replicate once our only option was virtual. Fortunately, we were already planning to develop a virtual Compliance Essentials workshop, which we fast-tracked once the pandemic caused us

to stop doing academies. These virtual workshops cover the expectations for each of the required elements of a compliance program. They provide a solid base of information to build from. As we begin holding in-person academies once again, we'll continue offering the virtual compliance essentials workshops as well. Neither is a substitute for the other. In fact, some people have indicated that attending a compliance essentials virtual workshop first provides a solid knowledge base that enables the attendee to immerse themselves in and get more from the more interactive academy experience. So, while many of the topics covered are similar between the two, the approach and experience is quite different—something for everybody.

Snell: You just got back from your second live post COVID annual conference. What was the atmosphere like? People had not seen each other for 2 years. How did they respond? What did they say about the return to gathering live? Did they miss it?

Zack: It was some of the most fun I've ever had at a conference. While the in-person attendance was about half of what it had been prior to the pandemic, with the others tuning in virtually, the people who made the trek to the conference were very enthusiastic. Everyone was so happy to have in-person conversations again. That's a theme that I've noticed even in some of our other, smaller regional conferences that we've been holding in person—people who go just love it. The whole idea of a "regional" conference took on new meaning during the pandemic. We continued doing them virtually, and they were planned by, and usually featured speakers from, a particular region. But people anywhere in the world could attend. But the gradual return to in-person regional events is being met with a lot of enthusiasm. Much like with our other conferences and workshops, we'll continue doing a mix of in-person and virtual regional conferences. The pandemic has certainly changed many things permanently, and one of the things we see is that for some people, their preference may have shifted to virtual, while others can't wait for a return to in-person. So, we'll keep doing both.

Snell: When COVID first hit you had to cancel a live annual conference for HCCA that had typically a couple thousand attendees. You converted it to a virtual conference in a matter of a couple weeks. That must have been simply terrifying to go from very little experience in virtual conferences to doing your first one with your largest meeting. What was that experience like?

Zack: Maybe it's good that we didn't have any time to think about it, we might have talked ourselves out of trying to convert a conference from in-person to virtual in two weeks. But we knew that thousands of people count on that conference for their continuing education. So, when two weeks before the 2020 Compliance Institute it became apparent that we couldn't hold it in person, complete cancellation simply wasn't an option we ever entertained. We had an obligation to the thousands of people who were counting on that conference. So, we converted it to a virtual event. We had a few technical issues at the outset, but our conferences team did an amazing job at rolling with it and coming up with alternative approaches to problems with almost no notice. I've never been prouder of the collective efforts of our association as in those moments. It was remarkable.

Snell: Sadly, when a crisis hits everyone and their brother starts running around with their heads cut off telling everyone else what must be done. They all point in different directions and then light their

hair on fire. So not only did you have to deal with material issues like switching 100 live conferences to virtual overnight, but you had to deal with all the emotion brought on by the global crisis. What have you learned about helping a very large group of people (staff, members, speakers, employees, board members, vendors, etc.) all with strong opinions… deal with a crisis?

Zack: To me, the key to calmly dealing with things like that in a crisis, where you're bombarded with hundreds of opinions, is to always focus on what the goal is, what the priorities are. Our two goals were to serve the profession by continuing to offer the best education in any format we needed to utilize, while at the same time being mindful of the health and safety of members of the compliance profession and our own staff. Everything else was secondary. And the financial part of it was even further down the list of priorities—we lost money in some instances and actually outperformed expectations in others. Either way, we had to serve the profession whichever way we could.

Snell: Conversely you had people stay calm and help during the crisis. I am guessing some people you might not have expected to rise to the occasion, helped significantly. Some people had great ideas and others had ideas that, if implemented, might have exacerbated the problem. Going forward, do you think you will change the way you assign tasks to people based on their positive or negative response to what is probably the greatest crisis you will ever see in the organization?

Zack: Knowing when to dive in and insert yourself versus just letting people do their job is one of the most important decisions any CEO has to make, especially in times of crisis. I was fortunate that in some very important areas where I chose to keep myself in a high-level oversight role and resist any temptation to get in the weeds, the people I trusted proved why that trust was well-deserved. They responded and executed amazingly well.

Snell: What else will come out of all this that you would consider positive?

Zack: Several positives are emerging. First, we have gotten better at delivering valuable educational content to the compliance profession using a variety of methods—in-person, virtual, hybrid, digital publishing, etc. Some of it was planned and some was by trial and error as we quickly responded to the new environment. And this will help us going forward.

Another positive is that we've been able to experiment with a greater variety of conference themes in a virtual setting than we ever were able to do with in-person, due to the lower cost structure and risk associated with trying out a new virtual event. We've successfully launched virtual conferences dealing with different industries (defense, nonprofit, etc) as well as topics (ESG, technology, etc).

Snell: And while all this was all going on you needed to continue to help the organization evolve, grow and change. One great example of this is the new Environmental, Social and Governance (ESG) movement. You have done some virtual conferences on ESG and are working on an ESG column. What impact will ESG have on healthcare compliance professionals?

Zack: ESG is already having an impact in the healthcare sector. The ESG movement first became big in connection with publicly traded companies and their investors, but it has expanded rapidly to all sectors that have stakeholders who are interested in what an organization is doing in relation to the environment, social issues, or its governance practices. It's a huge area once you look at the issues underlying each of the three broad categories. And

the nature of interested stakeholders has grown to include employees, customers, the local community in which an organization operates, and segments of the general public.

And what makes ESG important for compliance professionals is that once an organization commits to certain ESG goals and begins reporting on the related metrics, the risk of not meeting these goals has numerous similarities to failing to meet a compliance requirement. Rather than being subject to fines and penalties imposed by a government agency, a wide variety of adverse consequences can be imposed by stakeholders. Treating these as compliance requirements and having the compliance team play an important role in managing these risks only makes sense.

Snell: Do you think that compliance professionals will have responsibility for ESG in their organization?

Zack: I think it can work in a variety of ways. Whether compliance takes responsibility or some other group does, compliance needs to play a role. Application of the same framework used to manage compliance risk is very effective in managing ESG risks. Much like individual business units often own compliance risks, and the compliance team provides expert assistance in managing these risks, compliance does not have to own ESG risks. That ownership can reside in one or more other departments. But compliance should play a similar role in applying the framework that can work so well in managing compliance risks to the management of ESG risks.

Snell: How big do you see ESG getting? Will it be as big a compliance?

Zack: For starters, ESG is becoming more and more of a leading indicator of future laws and regulations. Europe has led the way in enacting laws that mirror what many organizations have already been doing voluntarily from an ESG perspective. This trend will only gain further momentum. As for whether ESG becomes as "big" as compliance, that's hard to say and depends on a lot of different factors. But it sure seems that the punishment that can be imposed by upset stakeholders can be every bit as severe, if not more so, than that imposed by government regulators. So, it's a risk that has to be taken very seriously.

Snell: Are there any other new changes coming up for the compliance profession? What can people expect to see in the near future from a professional development standpoint?

Zack: Professional development will continue to mirror the profession itself. First, more than ever, people are entering the profession right out of college or law school. It used to be that people transferred into compliance or took on compliance responsibilities after serving in some other capacity. So, the need for extensive basic training is stronger than ever. By the same token, people are staying in compliance for many years and want to stay highly engaged, learning from their peers. So, what we are doing is aiming to develop more ways for the highly experienced compliance professional to learn and share with other experienced professionals. Lastly, people are specializing in various aspects of compliance more than ever. So, our professional development offerings have been expanding to provide more intensive experiences in specific parts of compliance, such as performing risk assessments, conducting investigations, auditing and monitoring, etc.

Snell: What advice would you give someone who wants to write or speak for HCCA? In particular what advice would

you give people who feel that they may not have enough experience? How do people get started so they can start learning about contributing to their profession?

Zack: A big misconception is that there is some minimum number of years of experience required before someone can write or speak on a subject. Great knowledge comes from people with experience in any aspect of compliance. Some of that comes from spending time in the profession. But much of it comes simply from being exposed to a particular issue, and some of the best advice and guidance comes from peers. Someone with just a year or two of experience, but who has dealt with a particular issue, is likely to be able to provide valuable guidance to peers, and also provide unique perspectives to those professionals who have been at it for many more years. If anyone is unsure where to start, but they know they'd like to contribute, just give me a call!

Snell: Do you have any tips for getting selected as a speaker for HCCA? How can people increase their chances of getting selected?

Zack: I think the keys to being selected as a speaker are to submit something very specific that compliance professionals can benefit from or utilize immediately. A common mistake I see is that a speaker's submission is too broad, trying to cover all possibilities. And in the end, it doesn't address anything deeply enough to provide any value. The session's title should be clear. But, also develop the description, or the learning objectives, so that the individuals deciding on whether to select the session have sufficient information on which to evaluate the session.

Snell: Thank you for taking your time to do this Gerry and it is my hope that you don't have to deal with another crisis like COVID for a few months. But if something does come up sir remember… better you than me. Muhahahaha. Seriously sir, you have done an amazing job! We all really appreciate you leading us through this nightmare scenario with so much class.

Gerry Blass

Extended Downtime: Why You Need to Update Your Business Continuity Plan

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Steps to Consider for Implementing a Solid Business Continuity Plan

The headline in a June 2021 article in Health IT Security stated that, "The University of Vermont (UVM) Health Network Continues to Feel Effects of Ransomware Attack—Eight months after a ransomware attack that incurred costs upwards of $63 million, UVM Health continues to experience setbacks and financial losses."[1] Since that article was published one year ago, motivation for attacks has grown due to a number of factors, including the War in Ukraine. The U.S. sanctions against Russia have resulted in additional cyber threats, especially against U.S. healthcare organizations, which have been a prime target for several years.

Small, medium, and large healthcare organizations are all at risk for an incident that causes a breach of protected health information (PHI) and impacts patient safety and lives. It is crucial for healthcare leadership to assume that it is not a question of if but when. Many factors are responsible for this, including merger and acquisition activity, increase in networks and applications, and interoperability.

In addition, while the effects of COVID appear to be taking less of a toll on our day-to-day lives, they are still being felt. Among those impacted are CISOs, CIOs, and other technology professionals in the healthcare space. In a survey of 250 technology leaders, 86% reported increased workload during the COVID-19 pandemic.[2] Additionally, 77% reported feeling work-related stress during this time.

As discouraging as these numbers are, they shouldn't be surprising. After nearly 30+ years in the profession, 20 of which were spent consulting clients, I have seen firsthand the pressure that many of our industry leaders on the frontline are facing when it comes to showing up at work every day and doing their job well. Of

those pressures, disaster recovery and business continuity remain at the forefront of concern.

In the last year alone, 45% of organizations faced a third-party security incident.[3] While there are more tools and products in place in 2022 to help organizations deal with these threats, 45% are still using outdated spreadsheets to do vendor risk assessments, and 32% face more than a month of downtime. Having a **business continuity (BC) plan** is essential for many reasons, the biggest of which is ensuring your organization and patients are protected. This article outlines some steps to consider for a solid BC plan.

Step 1: Prepare Before the Incident Occurs

Some healthcare organizations may assume a cybersecurity incident will not happen to them. Unfortunately, this is a dangerous way of thinking. As we have seen with the SolarWinds and Colonial Pipeline incidents, even the world's biggest companies can fall victim to attack.

Here are some important figures to consider—according to IT Governance, in March 2022, 88 cybersecurity incidents were publicly disclosed.[4] That equates to 3,987,593 breached records for March. If these are the numbers for incidents reported, think about all that were *not* reported. Furthermore, the all-in number for breached records in Q1 of this year is 75,099,482.

What is the moral of the story? Well, it doesn't matter if your organization is public, private, large, small, or somewhere in between—you need to plan for the worst-case scenario and know what to do when it occurs.

Step 2: Business Continuity vs. Disaster Recovery (and Knowing the Difference)

It is essential to know the difference between business continuity (BC) and disaster recovery (DR). The best way to differentiate the two is as follows: DR plans focus on steps needed to restore systems to fully recover normal business operations. In contrast, BC plans allow an organization to continue functioning when systems are not available during a disaster.

It's best to think of DR as how IT supports operations during a disaster, and BC as focusing primarily on contingency processes. To link the two, companies will often start by completing/updating their Business Impact Analysis (BIA) to determine which applications or systems are considered mission critical. Each department within the organization must participate in this exercise to create a cohesive list. The end product will outline the risk level (low, medium, or high) of each of the respective systems/applications. Strategies and tactics are then determined to address each.

There are many outcomes, none of them positive, resulting from not conducting a proper BIA and, in turn, developing an ineffective BC plan. It's also important to note that BC plans are never a finished product. They require periodic updates for change management. We'll dive into that more in later sections of this article.

Step 3: The Cybersecurity Threat Landscape Continues to Expand

Life has changed dramatically for all of us since COVID-19 flipped the world upside down in March of 2020. Contrary to the wheels of healthcare technological innovation that tend to move slow, healthcare cybersecurity has to move fast. We live in a different world than we did two years ago, much less ten years ago, and the stakes are too high to be reactive. Organization leaders must work together to review, update, test, train, and invest in a BC plan. That's why practices like completing a BIA and offering ongoing organizational education opportunities are crucial components in mitigating risk at the highest level.

Furthermore, it is essential that healthcare leadership teams actively participate in governance oversight meetings and tabletop exercises, approve adequate internal and external resources and implement controls that reduce the risk of threats of a successful cyberattack. Curious to see this in action? Check out my company's Web site to learn about available critical resources.[5]

Step 4: The Risk Outweighs the Cost

It is important to know that the risk most definitely outweighs the cost your organization will invest in creating a cohesive BC plan. I assure you that whatever that cost looks like for you (time, money, staffing, or a combination of all three) pales compared to the devastation of having an extended period of downtime.

Here are some considerations for your BC plan:

- Payment of a ransom (can it legally be paid?)
- Reduction of cash flow and hospital revenue
- Compensation of employees and critical vendors
- Ability to provide elective procedures
- Diversion of ICU, chemo, dialysis, and other patients for urgent care
- Potential for a complete shutdown

The list outlined above is a snapshot of what healthcare organizations should include in their BC plan. There is increased vulnerability and opportunity for the worst to happen with so much at play. Don't let it happen to you.

In Closing

Ready to push play on your BC plan, so you are more prepared when disaster strikes? Here are some takeaways to keep in mind:

- **Review the standards.** Standards that come into play include HIPAA Security, NIST CSF, CMS, Joint Commission, state authority regulations for contingency planning/emergency preparedness, and compliance requirements with cybersecurity policies.
- **Refer to this excellent resource.** The Healthcare and Public Health Sector Coordinating Council (HSCC) Cybersecurity Working Group (CWG) released a checklist to help healthcare staff and executives preserve operational continuity while recovering from a serious cyberattack.[6] Healthcare organizations can use the Operational Continuity-Cyber Incident (OCCI) checklist to maintain business continuity even amid an extended enterprise outage.
- **Know the risk factors.** In partnership with the Department of Health and Human Services (HHS), the Health Industry Cybersecurity Practices (HICP) was developed to help organizations pinpoint the top 5 risks that could threaten their business.
- **Don't go it alone.** Align yourself with a trusted partner and subject matter expert to help navigate the complexities of an extended BC plan, including long-term contingency strategies, ensuring plan maintenance, conducting a comprehensive BIA, tabletop exercises, and more.

Endnotes

1. Available at *https://healthitsecurity.com/news/uvm-health-continues-to-feel-effects-of-ransomware-attack*.
2. Forbes, "77% of Tech Leaders Have Work-Related Stress Because of Covid-19, New Survey Shows" (June 7, 2021), available *at https://www.forbes.com/sites/edwardsegal/2021/06/07/77-of-tech-leaders-have-work-related-stress-because-of-covid-new-survey/?sh=26f3f8cd1c8a*.
3. PR Newswire, "New Prevalent Study Reveals Organizations Are Not Equipped to Handle Increasing Third-Party Security Incidents" (May 5, 2022), available at *https://www.prnewswire.com/news-releases/new-prevalent-study-reveals-organizations-are-not-equipped-to-handle-increasing-third-party-security-incidents-301540146.html*.

4. IT Governance, "List of Data Breaches and Cyber Attacks in March 2022 – 3.99 Million Records Breached" (March 31, 2022), available at *https://www.itgovernance.co.uk/blog/list-of-data-breaches-and-cyber-attacks-in-march-2022-3-99-million-records-breached*.
5. *https://www.complyassistant.com*.
6. Healthcare & Public Health Sector Coordinating Councils, "Operational Continuity – Cyber Incident (OCCI) Checklist (version 1.1, May 2022), available at *https://healthsectorcouncil.org/occi/*.

Jenny O'Brien

Walk Before You Run

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Environmental, Social, and Governance (ESG) continues to be the hot-button topic for Boards of Directors and senior leaders as organizations determine what type of focus or program is appropriate for them. As a compliance professional, if you are not at the table for these discussions with your organization, get there. As highlighted in my last article, your skillset and leadership will be key in helping assess the right type of response for your organization as you define a strategy and develop processes around assessing and addressing ESG risks.

Much of the information around ESG centers on publicly traded companies and the increasing focus shareholders and investors are putting on ESG issues. Included, is scrutiny on related metrics being developed to measure the progress and drive to commitments being made on outcomes. An example of this you may be hearing about is carbon dioxide measures and reducing emissions to effectuate climate change, which may lead you to ask … *do I need the same type of program if I'm a non-profit and in healthcare?*

The answer is … there is no one better in your organization than you and your compliance team to figure it out and facilitate the risk assessment process as you would any other emerging risk area. Per my article title, ESG is an area where your leadership can help your organization walk before they run as they look to make commitments to their board of directors on the scale and metrics that may be included in their ESG program.

Consider three simple steps as you look to build out your work plan around ESG:

- **Highlight ESG on your Annual Risk Assessment:** Calling out ESG as an emerging risk will demonstrate to your senior leadership and your Board of Directors that this is top of mind for your organization and on your radar.
- **Create an ESG Oversight Team to Assess the Risk:** As you think about accountable business leaders over the various areas, consider who your key stakeholders are for your organization as you review the environmental, social and governance buckets. Some suggestions include your facilities management, environmental

services, supply chain, human resources, treasury, technology, communications, legal, and compliance. This list will continue to mature as the discussions evolve and as your organization grows.

- **Provide Recommendations/Timeline:** Provide a timeline for leadership and your Audit and Compliance Committee (ACC) to review and include steps such as: 1) conduct your risk assessment; 2) assess the current state and make recommendations for a desired state; 3) consider which key measures are most important to develop and measure; 4) provide a date the ACC can expect to see your progress and approve a plan for the Board to review.
- **ESG Report:** Continue to work on your plan which will culminate with an ESG report for the organization by year-end, similar to other reports your team develops. And remember, this report can be as simple or complex as your ESG Oversight team wants to make it. Consider erring on the simple approach as you manage this process for the first time and continue to build out the program and reporting as driven by the risks identified.

We are all familiar with the saying—"what gets measured gets managed." By instilling discipline and rigor around the ESG assessment process, the compliance team will once again show their value to the organization and help prevent unnecessary speed and activity around a program that may benefit from walking at this stage until it assesses with its business partners where warp speed may ultimately be needed.

Margo Wilkinson Smith

Provision of Support Services by Pharmaceutical Manufacturers under the Federal Anti-Kickback Statute

Federal Court Sheds Light on When Support Services Constitute "Remuneration"

Margo Wilkinson Smith is a managing associate in Denton's Health Care group and a resident of the Kansas City office. Margo's practice focuses on helping clients navigate federal and state regulatory issues, including Medicare and Medicaid compliance and reimbursement issues. Margo also provides guidance on fraud and abuse prevention and remediation. She represents a variety of health care providers and entities, including hospitals, clinics, and physician groups.

On May 5, 2022, the U.S. District Court for the Southern District of New York dismissed a complaint brought by a relator against pharmaceutical manufacturer McKesson Corporation and its affiliates (collectively "McKesson") under the federal False Claims Act (FCA).[1] The relator alleged that the business management tools McKesson provided to its customers violated the federal health care program anti-kickback statute (AKS). The provision of such "support services" to customers is commonplace in the pharmaceutical industry, in part due to the complexity and expense of many pharmaceutical products. Existing guidance from the federal government, however, does not provide a clear standard for determining when such services constitute "remuneration" for purposes of the AKS. The court's opinion in *United States ex rel. Hart v. McKesson Corp.* provides a valuable example of how courts may apply existing guidance on support services arrangements. This article briefly summarizes the AKS legal framework and relevant agency guidance, discusses the court's opinion in *Hart*, and highlights key takeaways for pharmaceutical manufacturers.

Anti-Kickback Statute

Statutory Framework

In general, the AKS prohibits a person or entity from "knowingly and willfully" giving or offering to give remuneration to another person or entity if the payment is intended to "induce" the recipient to:

- "refer" an individual for the furnishing of any item or service for which payment may be made under a

Federal health care program (a "covered item or service");
- "purchase" or "order" any covered item or service;
- "arrange for" the purchase or order of any covered item or service; or
- "recommend" the purchase or order of any covered item or service.[2]

Where the AKS has been violated, the government may proceed criminally or civilly. AKS violations also can serve as the basis for claims under the FCA, which creates civil liability for any person who "knowingly" presents, or causes to be presented, a "false or fraudulent claim" for payment or approval to the federal government.[3] Pursuant to the FCA's *qui tam* provision, FCA cases may be brought by private citizens (known as "relators") on behalf of the government.[4]

AKS Analytical Framework

Because the AKS is so expansive, it potentially is implicated by a wide variety of common, and often appropriate, arrangements. Recognizing this, Congress and the U.S. Department of Health & Human Services, Office of Inspector General (HHS-OIG) have created a number of statutory exceptions and regulatory safe harbors (collectively, "safe harbors"). An arrangement that precisely meets all of the conditions of a safe harbor is immune from prosecution under the AKS. Safe harbors, however, do not exist for every type of arrangement that implicates the AKS, and it can be difficult to meet each and every condition of a particular safe harbor. Importantly, HHS-OIG recognizes that there are many arrangements that implicate the AKS and are not covered by a safe harbor, but do not pose a material risk of program abuse or warrant the imposition of sanctions because they do not implicate any of the AKS's principal policy objectives.[5]

Accordingly, determining whether an arrangement implicates or violates the AKS requires analyzing the following four questions:

1. Does the arrangement provide for an exchange of "remuneration"?
2. If so, is the remuneration intended to induce the recipient to engage in conduct that is prohibited by the AKS?
3. If so, does the remuneration qualify for protection under an AKS safe harbor?
4. If not, does the arrangement pose a material risk of program abuse?

This article focuses on the first question in this analytical framework.

Remuneration Under the AKS

HHS-OIG has defined remuneration broadly to include "anything of value in any form . . . whatsoever."[6] Due to the breadth of this definition, the agency has been asked numerous times over the years to weigh in on whether a particular arrangement involves remuneration. One recurring question posed to HHS-OIG involves "product support service" arrangements, which arise when a seller provides a buyer with items and/or services that supplement or closely relate to the seller's products.

In its 2003 Compliance Program Guidance for Pharmaceutical Manufacturers (Compliance Program Guidance), HHS-OIG explained that the AKS is not implicated when product support services offered by pharmaceutical manufacturers have no "substantial independent value."[7] The AKS would be implicated, however, where a "manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks)."[8]

HHS-OIG has applied this general framework in a number of advisory opinions addressing product support services. For example, in an advisory opinion issued in 2000 (2000 Advisory Opinion), the agency considered an arrangement pursuant to which a pharmaceutical

manufacturer of a physician-administered drug provided to its physician-customers (i) support services, including verifying the patient's insurance covered the drug, and (ii) financial services, including physician credits for denied claims, discounts, and extended payment terms.[9] Recognizing that "[d]rug manufacturers often offer free assistance to physicians and other providers" through insurance and coverage verification, HHS-OIG determined that the support services had "no independent value to providers apart from the [manufacturer's] products," and, therefore, the services "are properly considered part of the products purchased and their cost [] already included in the products' price."[10] In other words, "standing alone," the support services "do not implicate the Federal anti-kickback statute."[11] In contrast, the financial services "confer an independent financial benefit upon referring physicians by shifting the financial risk of unanticipated delays and denials associated with obtaining third party payor reimbursement from the prescribing physicians to the [manufacturer]."[12] Because the support services and financial services were offered together, HHS-OIG concluded that the proposed arrangement implicated the AKS.[13]

United States ex rel. Hart v. McKesson Corp.

Background

McKesson Corporation and its affiliates sell pharmaceuticals, medical supplies, and related services to health care providers.[14] Among its products are specialty drugs used in cancer treatment that are "more expensive than other drugs" because they are "complex to manufacture [and] require special handling."[15] On February 6, 2015, Adam Hart (Relator)—a former Business Development Executive at McKesson—filed a *qui tam* action alleging that the business management tools McKesson offered almost exclusively to specialty oncology practices that "committed to purchasing a significant portion of their drugs from McKesson" violated the AKS and resulted in the submission of false claims to the government.[16] The complaint focused on two business management tools—the Margin Analyzer and the Regimen Profiler (collectively, the "McKesson Tools")—intended to be used together "to understand a practice's overall profitability and/or potential profitability."[17]

The Margin Analyzer "allowed oncology practices to compare the reimbursement rates of interchangeable drugs" for "ten categories of drugs commonly used by oncology practices" and gave forward-looking recommendations that McKesson employees used to "aid the practices in choosing" a profitable "drug distribution."[18] The Regimen Profiler worked similarly, calculating the costs for the entire cancer treatment regimen (not just the costs of the cancer drug) on a provider-by-provider basis.[19] McKesson allegedly used these Tools to "acquire new customers and/or retain existing customers; to provide consultation and financial advice to existing customers at in-person 'Quarterly Business Reviews'; and to encourage the purchase of new drugs (or drugs with new pricing)."[20]

Following the government's decision not to intervene, McKesson filed a motion to dismiss the Relator's complaint, arguing that the complaint failed to (i) plausibly allege that the Margin Analyzer and Regimen Profiler constituted "remuneration" under the AKS, (ii) show McKesson acted with the required scienter, and (iii) plead the fraudulent scheme with particularity.[21] The court ultimately granted McKesson's motion to dismiss for failing to adequately plead that McKesson "knew the conduct was unlawful and proceeded with the business practice regardless."[22] The court rejected McKesson's other arguments, however, finding at this stage of litigation that the McKesson Tools constituted "remuneration" and that the

complaint adequately plead the fraudulent scheme with particularity.[23]

Remuneration

As noted above, McKesson argued that the complaint failed to adequately plead that the Margin Analyzer and Regimen Profiler constituted remuneration under the AKS. According to McKesson, HHS-OIG guidance requires the Relator to plead "at a minimum that a tool has (1) *substantial* and (2) *independent* value."[24] The Relator objected to this standard, claiming that reliance on Advisory Opinions and HHS-OIG guidance documents created an "implicit, uncodified safe harbor."[25] Without deciding the appropriate standard, the court used the standard proposed by McKesson, analyzing whether the McKesson Tools had "substantial and independent value" to the oncology practices.[26]

McKesson argued that the complaint failed to meet this standard because: (i) the underlying data was available for free, and thus lacked substantial value; (ii) the McKesson Tools lacked independent value because they only provided potential cost-savings; and (iii) the Tools were not independent of McKesson's products, and thus had no value to non-McKesson customers.[27] The court rejected these arguments, holding instead that the Relator "plausibly alleged that the Margin Analyzer and Regimen Profiler have substantial value apart from the products offered by McKesson."[28]

With respect to McKesson's first argument regarding the availability of the underlying data, the court found that the "overall value of the tools and consultations was greater than the value of the underlying data itself."[29] In coming to this conclusion, the court considered the resources McKesson employed to develop these tools, including the time and energy required to access, integrate, and synthesize data across multiple sources, and update that data on a quarterly basis.[30] The court also considered allegations in the complaint that McKesson employees discussed the data during quarterly reviews with customers, essentially providing practices "consulting" services that they would otherwise pay for.[31] The fact that a physician practice could have created a similar tool on its own did not sway the court, as the practices in the complaint "chose to have McKesson perform these services for them," and allegedly chose McKesson over lower-cost alternatives at least in part because of the McKesson Tools.[32]

Likewise, the court found unconvincing McKesson's argument that the Margin Analyzer and Regimen Profiler themselves lacked inherent value because they only offered speculative cost-savings to customers.[33] Agreeing "that the monetary value of the tools cannot be measured by the amount of cost-savings they offered customers," the court pointed to two pieces of evidence in the complaint that demonstrated the value of the McKesson Tools. First, one McKesson division provided the Tools "in a package of business-management tools in exchange for a percentage of a practice's overall revenue."[34] That a separate division provided the Tools for free to customers who made a purchase commitment suggested that the Tools had inherent value. Second, and similarly, McKesson's internal documentation allegedly stated that customers stayed with McKesson over lower-cost alternatives because of the McKesson Tools.[35]

McKesson's last argument—regarding whether the tools had "independent value"—was a "somewhat closer question," according to the court.[36] McKesson argued in its motion that the relevant question was whether the use of a support service is "tied to the product purchased."[37] Relying on HHS-OIG's 2000 Advisory Opinion, the court imposed a more stringent standard, explaining that the "critical distinction" in determining the independent value is "not whether the service is merely connected with, or 'tied to,' the product, but rather

whether the service is 'part of' the product itself, such that it cannot be considered to be something of value in its own right."[38]

The tools here did "enhance[] customers' experiences in purchasing drugs from McKesson," but that did not mean, the court explained, that they were "'virtually meaningless' to customers who did not purchase drugs from McKesson."[39] Indeed, as the court noted, one practice allegedly "requested continued access to the tools after ending its" purchase commitment.[40] The court also found the Margin Analyzer and Regimen Profiler "distinguishable from the types of typical product support services" HHS-OIG described in its Program Compliance Guidance and Advisory Opinions—such as billing assistance tailored to specific products and "software that aids physicians in reordering and accessing records of their patients' prescription medication"—in that the McKesson Tools had no "intrinsic connection to the drug purchases" and could be of use "to oncology practices that did not buy drugs from McKesson."[41] Based on the allegations in the complaint and HHS-OIG's previous guidance, the court determined that the Margin Analyzer and Regimen Profiler were "not so related to McKesson's drug offerings that they can be said to be integral to the products themselves or without 'independent value.'"[42]

Conclusion

As HHS-OIG itself has recognized, it is not uncommon for pharmaceutical manufacturers to provide support services to their customers. The provision of such services may implicate the AKS but only if the services are considered "remuneration." HHS-OIG guidance provides that such services will constitute remuneration if they have "substantial independent value" to the customers. Aside from providing this general framework, and analyzing specific arrangements in its advisory opinions, HHS-OIG has not given pharmaceutical manufacturers clear guidelines establishing when support services have substantial independent value, such that they constitute remuneration under the AKS. The court's opinion in *Hart* provides some insight into how a court may apply HHS-OIG's existing guidance to determine whether support services have substantial and independent value.

Specifically, the opinion makes clear that a court may look beyond the provision of the actual support service or tool itself to consider the cost of such tool to the manufacturer, the benefit provided to the customer, and any wrap-around services. In *Hart*, for example, the court looked at the time and effort it took McKesson to compile and analyze the data in the Margin Analyzer and Regimen Profiler, the effort it would take for physician practices to undertake the same activities and analysis, and the additional consulting services McKesson allegedly provided to practices in connection with the McKesson Tools.

In addition, this case demonstrates how a court may interpret HHS-OIG guidance on whether a support service is "independent." Rather than analyzing whether the McKesson Tools were "tied to" McKesson's products—the standard proposed by McKesson—the *Hart* court analyzed whether the McKesson Tools were "'part of' the product itself." This standard arguably makes it more difficult to establish that a support service is independent from the product, and, consequently, harder to establish that a support service is not remuneration under the AKS.

Given that HHS-OIG has not given explicit guidelines on the provision of support services, it is not clear how other courts would respond to similar allegations. Nor is it clear whether the Relator in *Hart* would succeed in establishing a potential AKS violation outside of the motion to dismiss stage, which requires courts to accept all allegations in the complaint as true and draw all inferences in favor of the non-moving party. As explained above, even where support

services constitute remuneration, such services must be intended to induce conduct prohibited by the AKS and fail to qualify for protection under a safe harbor, and the parties must be acting with the requisite state of mind. Nevertheless, pharmaceutical manufacturers should consider reviewing any existing support services arrangements in light of *Hart* and continue to closely monitor this changing landscape.

Endnotes

1. *United States ex rel. Hart v. McKesson Corp.*, No. 15-CV-0903, 2022 WL 1423476 (S.D.N.Y. May 5, 2022).
2. 42 U.S.C. § 1320a-7b(b).
3. 31 U.S.C. § 3729(a)(1)(A).
4. *Id.* § 3730(b).
5. Briefly, these policy objectives are to (i) prevent the overutilization of health care items and services and any related increase in Federal health care program costs, (ii) prevent improper patient steering, and (iii) prevent unfair competition.
6. 56 Fed. Reg. 35952, 35958 (Jul. 29, 1991).
7. 68 Fed. Reg. 23731, 23735 (May 5, 2003).
8. *Id*.
9. HHS-OIG Advisory Op. No. 00-10 (Dec. 15, 2000), *https://oig.hhs.gov/documents/advisory-opinions/418/AO-00-10.pdf*. Other product support services offered by the manufacturer included monitoring (i) shipment of the drug to the physician, (ii) the patient's drug treatment schedules, and (iii) status of insurance claims filed by physicians. *Id*.
10. *Id*.
11. *Id*.
12. *Id*.
13. *Id*.
14. *United States ex rel. Hart v. McKesson Corp.*, 2022 WL 1423476, at *1 (S.D.N.Y. May 5, 2022).
15. *Id*. at *2.
16. *Id*. at *1-2, 4.
17. *Id.* at *3.
18. *Id.* at *2-3.
19. *Id*. at *3.
20. *Id*.
21. *Id*. at *1, 5.
22. *Id.* at *5, 11–15.
23. *Id.* at *7–10, 15–16. The court granted the Relator leave to file a second complaint. *Id.* at *16.
24. Memorandum of Law in Support of Defendants' Motion to Dismiss at 7, *Hart*, 2022 WL 1423476 (S.D.N.Y. Sept. 30, 2020) (No. 52) (emphasis in original).
25. Relator's Opposition to Defendants' Motion to Dismiss the Complaint at 9, *Hart*, 2022 WL 1423476 (S.D.N.Y. Nov. 6, 2020) (No. 56). The relator did not appear to propose an alternative standard for assessing support services.
26. *Hart*, 2022 WL 1423476 at *7.
27. *Id*. at *7.
28. *Id*.
29. *Id*. at *8.
30. *Id*. at *7.
31. *Id*. at *8.
32. *Id*. at *7.
33. *Id.* at *8.
34. *Id*.
35. *Id*.
36. *Id*.
37. *Id*.
38. *Id*.
39. *Id.* at *9.
40. *Id*.
41. *Id*. The court also compared the Margin Analyzer and Regimen Profiler to the staffing services at issue in *U.S. ex rel. Forney v. Medtronic, Inc*., No. CV 15-6264, 2017 WL 2653568, at *2 (E.D. Pa. June 19, 2017). In contrast to free staff who "check the status of heart implants," which is "of no value to a physician who has not purchased any heart implants," the spreadsheets "help[ing] oncology practices track which drugs will generate the greatest profits . . . is not so integral to the product itself and thus not akin to the" free staffing in *Forney. Id.*
42. *Id.*

Shannon Sumner

Response to Detected Deficiencies: Developing an Effective Investigation Process

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Why Is an Investigation Process Important?

One of the seven elements of an effective compliance program relates to processes and controls over responding appropriately to detected deficiencies. A key factor to achieving this expectation is having an effective investigation process. As articulated in the US Attorneys' Manual's "Principles of Federal Prosecution of Business Organizations," the Department of Justice (DOJ) considers several factors when determining whether to bring charges, the severity of penalties and/or negotiating a settlement agreement. One of these factors is the extent to which an organization actively engages in investigating and responding to suspected wrongdoing. An effective investigations process will mitigate legal liability and risk, demonstrate to the public the desire to do the right thing, solidify a culture of compliance and will result in key process improvements. A thorough investigation process will also enable the corporation to demonstrate its willingness to cooperate, as outlined in the Yates Memorandum, by identifying any individuals accountable for the misconduct.

What Are the Key Elements of an Investigation Process?

Strong policies and procedures are key to an effective investigation process and carefully considers the nature of the allegations, internal documentation, and communication requirements, who performs the investigation including whether to invoke attorney client privilege, the development of corrective action plans, and the potential for self-disclosure of findings to regulatory bodies and other public reporting requirements. Many organizations may have an investigations philosophy or singular policy, however a strong process will include a variety of interconnected processes and policies. These may include:

- Investigations Policy—This policy should address the key individuals who will authorize an investigation as well as those individuals or areas of expertise who will be directly involved in the investigation. This also will include the process to invoke privilege and general counsel's oversight of the investigation, witness interviews, prohibition against retaliation (or reference a separate policy), how the investigation will be managed and by whom. The person or persons who authorize an investigation may be dependent upon the nature of the issue identified. Significant matters may be overseen by a governance committee (Audit or Compliance) or Legal Counsel. Generally, due to conflicts of interest, investigations involving leadership should be conducted by outside counsel engaged by the Board of Directors.
- Data Preservation and Legal Hold Policy—Thorough documentation is paramount to conducting an effective investigation. A data preservation/legal hold policy will outline the various types of documentation to maintain, where and how the data collected will be stored during and after an investigation, preservation of data to include detailed records (*e.g.*, date collected, location, summary of content) and who may have access to the information.
- Communications Policy—A communications policy, typically owned by the marketing department, will address when to contact a public relations firm regarding public comments, and potential reputation mitigation and who is authorized to make statements on the company's behalf.
- Search and Seizure Policy—this policy will apply when a government entity executes a search warrant, the company has been issued a Civil Investigative Demand (CID) or other type of notice such as a subpoena. It outlines the expectations for document retention (may also be covered in a legal hold policy), communications with government officials, who to contact immediately in these situations and finally, the protocols for appropriate and timely response to such events.
- Disciplinary Process—Every organization likely has a disciplinary process policy and procedure which addresses the protocols to follow when an employee violates company policies. This policy should also include the company's disciplinary activities if an employee fails to cooperate with an internal investigation.
- Overpayments Policy—An investigation may identify overpayments by federal programs and accordingly an overpayments policy will direct the organization regarding when and how to promptly return the overpayment (*e.g.*, within 60 days of discovery).
- Recoupment Policy—This policy will communicate to the workforce that any bonuses or incentives paid to an employee later found to have commitment fraud and/or violated company policy, will be recouped.
- Notices from Regulatory Agencies—Notices from regulatory agencies may inadvertently be sent to the wrong department or location. This policy outlines the company's expectations for timely forwarding of any such notices to the individual or department named in the policy. For many organizations, this may be Compliance or Legal.
- Hotline/Reportable Events—A hotline or reportable events policy (these may be combined or separated) will not only communicate to the workforce the purpose of the hotline, but may also communicate what is considered a reportable event. For example, a reportable event may be identified via the hotline or on-line reporting system. The criteria for a reportable event should also be addressed in a policy to include a materiality threshold for reporting.

- Corrective Action Plans—A corrective action plan (CAP) policy will address specific measures to address the misconduct which is a result of the facts and circumstances identified during the investigation. A CAP will identify the deficient policies, processes and internal controls and activities to correct such deficiencies, including accountable parties and implementation timeframes. Remediation efforts may include discussions with counsel, internal audit or compliance so that further follow-up of CAP implementation can be added to a compliance or internal audit work plan.

Who Is Involved in the Investigation Process?

An organization may include a variety of individuals and subject matter experts in an investigation. As noted previously, an investigation may be overseen by the Board or Board Subcommittee charged with such oversight. Depending on the nature of the issue identified, outside consultants with subject matter expertise may be engaged. These individuals may include Certified Fraud Examiners, forensic accountants, information technology experts, statisticians, and Certified Public Accountants (for financial statement fraud). Internally, compliance and internal audit are typically involved in the investigation process to ensure that proper controls are implemented to prevent future issues and that CAPs have been designed appropriately and implemented accordingly.

How Will an Investigation Process Be Implemented?

The key to an effective implementation process is thorough, timely and relevant education to all members of the workforce, governance, leadership and independent contractors, where appropriate. This education should be provided annually and will need to be tailored for each group of individuals involved in the process. For example, governance education should include their responsibilities for oversight of the investigations process, their ability to independently engage outside counsel, subject matter experts and responding to inquiries from the press or other outside bodies. General workforce training should include a reminder of the company's non-retaliation policy, yet outline responsibilities for cooperation with internal or external investigations and a reminder of the organization's culture of compliance.

Considerations for Self-Disclosure

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and generally follows a policy of imposing a multiplier of damages of 2.0 or greater.

General Guidelines for Self-Disclosure Decision-Making

A general guideline for options for self-disclosure may be based on the nature of the matter:

- In an overpayment matter where the evidence, on balance, suggests billing errors as the result of "mistakes"—disclose to the entity that processes the claims and issues payment for a particular health care program (*i.e.*, administrative contractor for Medicare and/or Medicaid programs);
- In an overpayment matter where the evidence suggests noncompliant conduct which may form the basis for liability under the Civil FCA—disclose to the Department of Justice and/or the OIG-HHS; and
- In a matter where the evidence suggests noncompliant conduct forming the basis for criminal liability — disclose to the Department of Justice and/or OIG-HHS.

Comment: There are pros and cons to each option and "one size definitely does not fit all" situations and an assessment of the risk of non-disclosure is always necessarily involved. The decision to make a self-disclosure and where, when, and how to make it can be a complex undertaking. These decisions should be made with the assistance of competent and experienced counsel to ensure that the important considerations can be taken into account and that navigation with the agency receiving the self-disclosure will be properly completed.

Endnotes

1. 18 U.S.C. § 1519.
2. *See* Office of Inspector General Self-Disclosure Protocol (updated November 8, 2021), available at *https://oig.hhs.gov/compliance/self-disclosure-info/files/provider-self-disclosure-protocol.pdf* (hereinafter "OIG-SDP").
3. *See* 42 U.S.C. § 1320a-7b(a)(3).
4. *But see* OIG-SDP.
5. *See* 31 U.S.C. § 3729(b)(3): *See also* 81 Fed. Reg. No. 29, Pgs. 7654–84, (Feb. 12, 2016); 42 C.F.R. Part 401–405 (Medicare Program; Reporting and Returning Overpayments).
6. *See* OIG-SDP.
7. *Id*.
8. 42 U.S.C. § 1320a-7b(b).
9. *See* 42 U.S.C. § 1320a-7b (h). *See also* 31 U.S.C. 3729 (b)(1).
10. *See* 37 U.S.C. § 3729 at seq.
11. *See* OIG-SDP; *see* also 42 U.S.C. § 1320a-7a(a)(7).
12. *See* OIG-SDP.
13. *Id*.
14. *See* Section 1128(d)(2) of the Social Security Act, 42 U.S.C. § 1320a-7k(d)(2). *See also* 31 U.S.C. 3729(b)(3) and Medicare Program: Reporting and Returning Overpayments, 42 C.F.R. Part 401–405.
15. 31 U.S.C. § 3729(a)(7)(A)–(C).
16. *See* OIG-SDP.
17. *Id.*
18. *Id*.
19. *See* OIG-SDP and CMS Voluntary Self-Referral Disclosure Protocol (revised Mar. 27, 2017), available at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf* (hereinafter SRDP).
20. *See* 42 U.S.C. § 1395nn(c); 42 C.F.R. § 411.350 et seq.
21. 64 Fed. Reg. 63518, 63520 (Nov.19, 1999).
22. *See* SRDP.
23. *See* Section 1128 (d)(2) of the Social Security Act; 42 U.S.C. § 1320a-7k(d)(2). See also 31 U.S.C. § 3729 (b)(3) and 42 C.F.R. Part 401–405.
24. *See* SRDP.
25. *See* SRDP.
26. 31 U.S.C. § 3729(a)(1)(G).
27. Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. 111-21 (*i.e.*, known overpayment).

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