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New DOJ Guidance Formalizes Requirement that Corporate Defendants Must Provide Information about Individual Misconduct in Order to Obtain Credit for Cooperating with DOJ Investigation

By Precious Murchison Gittens

On September 9, 2015, Deputy Attorney General (DAG) Sally Quillian Yates (Yates) – the number two in command at the Department of Justice (DOJ) – issued new guidance to DOJ personnel and the Director of the Federal Bureau of Investigation concerning individual accountability for corporate wrongdoing.

The Yates memo sets forth six principles to guide DOJ prosecutions and enforcement actions:

1. To be eligible for any cooperation credit, corporations must provide to DOJ all relevant facts about the individuals involved in the corporate misconduct.

   As a practical matter, this new guideline will require corporate providers to investigate all facts relevant to individual misconduct, and then provide all such facts about individuals who engaged in the misconduct to the prosecutor as a "threshold requirement" to obtain cooperation credit under the U.S. Attorneys' Manual Guidelines, the U.S. Sentencing Guidelines, or the False Claims Act's "reduced damages" provision (31 U.S.C. § 3729(a)(2)). Expect this new "condition of cooperation" to impact the scope of a corporate provider's internal investigation and its related disclosure to the government. Defense counsel should guide the provider in its efforts to cooperate in any government fraud and abuse investigation while maintaining the attorney-client and work product privileges. Notwithstanding the former DAG's 2008 declaration that a "corporation does not need to produce, and a prosecutor may not request" privileged materials "as a condition for the corporation's eligibility to receive cooperation credit[,]" prosecutors may pressure providers to waive privilege without explicitly requesting a waiver (See Deputy Attorney General Mark Filip Memorandum, *Principles of Prosecution of Business Organizations*, August 28, 2008).

2. Both criminal and civil investigations should focus on individuals from the inception of the investigation.

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Yates instructs prosecutors to focus on building cases against individual corporate employees. This guideline will aid prosecutors in determining the facts of each case and the extent of any corporate misconduct, as well as increase the likelihood that employees with knowledge of the corporate misconduct will cooperate in the government's investigation and provide information against individuals higher in the corporate hierarchy, resulting in both civil and criminal charges against the corporation and all culpable individuals. As a result, defense counsel increasingly may face obstructionist employees during the course of an internal investigation, and experience dealing with government cooperating witnesses may be useful.

3. Criminal and civil attorneys handling corporate investigations should routinely communicate with one another.

   Here, the DAG directs criminal and civil prosecutors to communicate early on in parallel investigations. According to the memo, prosecutors should discuss potential civil referral of matters that the criminal prosecutor declines to prosecute; similarly, a civil prosecutor should involve the criminal prosecutor when she/he believes that an individual identified in a civil corporate investigation should be criminally prosecuted. Defense counsel should proactively communicate with prosecutors and ultimately make a good faith assurance that the corporate provider has provided all relevant information about culpable individuals that is reasonably within the provider's control.

4. Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.

   Generally, prosecutors may not enter into a corporate resolution that involves an agreement to dismiss charges against, or provide immunity for, individual officers, executives, senior managers, in-house counsel, or other employees. Defense counsel must demonstrate any extraordinary circumstances that may exist, providing evidentiary support for the same.

5. Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.

   Prosecutors are directed either to resolve matters against culpable individuals before the expiration of the limitations period, or to preserve the ability to charge individuals by tolling agreement or by Court order. If prosecutors ultimately decline to prosecute individuals, that decision must be memorialized and approved at the supervisory level, by the United States Attorney or the Assistant Attorney General whose office handled the investigation, or their respective designees. Accordingly, prosecutors may be less willing to decline prosecution of individual defendants. Defense counsel should be less willing to enter into tolling agreements without good cause and related benefit to the corporate provider.

6. Civil attorneys should continuously focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.

   A prosecutor's decision to pursue a civil enforcement action against an individual will not be controlled by the fact that the individual may not have sufficient resources to satisfy a significant civil judgment. In making charging decisions, civil prosecutors likely will focus on the traditional factors considered by criminal prosecutors, such as the nature and seriousness of the offense, and strength and admissibility of the evidence. Defense counsel should focus on individuals, evidence of intent and corrective action from the outset and during the course of the internal investigation.

In sum, DOJ's recently announced guidelines formalize the government's intent to focus on individual employees and senior management as part of broader investigations of corporate wrongdoing. The guidelines reinforce the expectations that corporate providers must carry out thorough investigations in the face of fraud and abuse allegations and disclose all relevant facts about potentially culpable individuals as a condition for corporate providers to obtain cooperation credit. DOJ will likely scrutinize the nature and scope of a corporate provider's internal investigation, as well as the persons who conduct and supervise it, in determining whether a provider has met the new "threshold requirement" for cooperation credit. Accordingly, providers should obtain the active

involvement of defense counsel who are not only experienced in criminal and civil fraud matters generally, but also are experienced in the complex regulatory matrix of the health care system more specifically.

For additional information, please contact Precious Murchison Gittens in Washington, D.C. at 202.580.7700; Patric Hooper in Los Angeles at 310.551.8111, or Joe LaMagna in San Diego at 619.744.7300.

Privileging for Novel Procedures or Treatments

By Katherine M. Dru, Esq. and Jennifer A. Hansen, Esq.

Practitioners often assume that because they are privileged to do X, they automatically also should be privileged to do Y, and are frustrated when they encounter new or different privileging requirements for Y, arguing that it is just an extension of what they already are authorized to do. This can come up in many different situations (collectively referred to as "new services"), including:

- Novel surgical procedures or techniques
- Novel treatments
- Procedures or treatments new to particular practitioners
- Research or experimental treatments (including drugs/devices not FDA-approved for marketing)
- Newly-FDA approved devices or drugs
- New uses for FDA approved devices or drugs.

For example, many hospitals have spent millions of dollars on Da Vinci technologies for robotic surgeries in the past few years although the training and experience required of physicians who perform such surgeries may vary among medical staffs of different hospitals. In August, the Food and Drug Administration (FDA) approved Addyi (the pink pill) as a novel drug to treat female hypoactive sexual desire disorder, but practitioners are required to complete a training course before prescribing the new drug.

While there may be differences of opinion regarding the effectiveness of new services, hospitals rightly are concerned about liability and risks they may face if they offer procedures or treatments that may be unfamiliar. At the same time, hospitals, medical staffs, and practitioners want to keep current with medical advances. How should they balance these considerations and when should a medical staff grant practitioner requests for privileges for new services?

Regulatory and Accrediting Requirements

The Centers for Medicare and Medicaid Services' (CMS) Medicare Conditions of Participation require that a hospital's medical staff ensure that practitioners meet approved criteria for both medical staff membership and privileges, including character, competence, training, experience and judgment (*See* 42 C.F.R. § 482.22(a)(6)). This applies both to initial membership and to privilege requests, as well as to requests for new privileges. Likewise, accrediting bodies like The Joint Commission set forth criteria to determine a practitioner's ability to provide a service. These criteria must be consistently evaluated across all practitioners, since all patients are entitled to receive the same standard of care, regardless of which type of practitioner provides the service (*See* Joint Commission Standards MS.06.01.01 and MS.06.01.05).

Thus, when a practitioner wants to perform a new service — whether new in general or simply new to that practitioner — the medical staff must ask if the procedure or treatment is part of the privileges the practitioner already has, or if it is something different. In doing this, the medical staff should evaluate if the new procedure or treatment involves different training, skills, judgment, techniques, equipment, or infrastructure, among other questions.

Determining Whether to Consider Privileging for a New Procedure or Treatment

The medical staff may consider adopting policies and procedures addressing when to consider a new service, what steps will be followed to develop criteria for the new service, how the new service will be operationalized, what steps will be followed to assure that practitioners meet the new criteria, and what steps will be followed for Board approval. The medical staff may wish to create a subcommittee or task force specifically for this purpose.

As a first step, the medical staff may begin by gathering information from the practitioner(s) seeking to perform the new procedure or treatment. This includes descriptions of the procedure or treatment, new equipment or other resources that will be required, results, complications, and other pertinent information in scientific literature, and background and training required, as well as a proposed monitoring and quality review plan

to assess overall experience and a proposed proctoring requirements to verify competence.

The medical staff's primary consideration then would become whether to offer the new service. To this end, the medical staff may wish to set up an ad hoc committee to evaluate the risks and benefits of offering the new service. For example, if it is a drug or device, has it been approved by the FDA, and is the proposed use consistent with that approval? Is there supportive scientific literature? Does it involve "research," as defined by state and federal laws, and if so, does the hospital have an Institutional Review Board? Does the hospital have space, staffing, and financial resources to perform the service? Is taking the steps to perform the service a good investment? Will practitioners be able to perform a sufficient number to retain competency? Is offering the service consistent with the hospital's mission and vision? Do similar organizations offer the service? What is the quality data like where the service is performed? Will the new service affect other practitioners or the call pool? Only if the anticipated benefits outweigh the risks and possible disadvantages would the medical staff likely want to recommend offering the service and creating new privileges.

Developing Criteria for and Operationalizing New Services

Once a value analysis has been completed and it has been determined that the hospital may want to offer the new service, the logical next step is to develop criteria for privileges for the new service. It is important to remember that physicians who trained at different times may have learned different techniques, but all physicians must provide services within the standard of care. Resources that may be consulted in developing these criteria include Credentialing Resource Center white papers, organizations of similar size to the hospital, training facilities and organizations with more experience, specialty societies, academic training programs, experienced clinicians, industry representatives, and regulatory requirements.

The medical staff may want to consider implementing a policy and procedure for passing the proposed criteria for new privileges by department chairs, medical directors, and practitioners seeking to perform the service for comment. In particular, the stakeholders may want to verify and assess requirements for licensure, training, certification, eligible specialties, capacity, liability history, minimum threshold volume, professional references, and focused and ongoing professional practice evaluation for competence.

Once stakeholders have had their say, the medical staff should submit the proposed privileging criteria to the Credentialing Committee, the Medical Executive Committee, and, following any proposed modifications by each committee, the Governing Body. Each level of review should constitute an independent assessment, and be wary of rubber stamping.

Following approval of privileging criteria, the new procedure or treatment is ready to be operationalized. This includes training and support of nursing staff for the new procedure or treatment, ensuring that proper supply chain support (e.g., inventory and vendors) is in place, dealing with political issues such as exclusive contracts and call coverage, and ensuring that competence evaluation is ongoing.

Privileging for new procedures or technologies should be done in a thoughtful, thorough, and ongoing way to ensure that the hospital and medical staff have considered all angles, understand the risks associated with the new services, and are fully prepared to operationalize the new service.

For additional information about updating your policies for privileging for new services, please contact Katherine Dru in Los Angeles at (310) 551-8111, Jennifer Hansen in San Diego at (619) 744-7300, or Harry Shulman in San Francisco at (415) 875-8500.

CALENDAR

September 8	**California Alliance of Child and Family Services Fall Executive Conference, Palm Desert** Linda Randlett Kollar & Amy Joseph presented *Minors' Health Information: Navigating the Complex Web of State and Federal Laws.*
Sept 14-18	**Fall Trial Advocacy Workshop at Harvard , Law School, Boston, MA** Precious Murchison Gittens was a faculty member for this event.
September 15	**25th Annual HFMA Southern California & San Diego-Imperial Chapters Fall Conference, Long Beach, CA** Jordan Keville & Tracy Jessner Hale presented *Medicare Litigation Update.*
September 17	**HFMA Northern California Fall Conference, Concord, CA** Felicia Sze co-presented *Challenging Medi-Cal Managed Care Authorization/Payment Denials.*
Sept 28, 29	**AHLA Fraud and Compliance Program, Baltimore, MD** Robert Roth co-presents *Overpayments and the 60-Day Rule: A Need for Speed.*
October 1	**LACBA 12th Annual Healthcare Law Compliance Symposium, Los Angeles, CA** Amy Joseph co-presents *Responding toData Breaches;* Ben Durie co-presents *Self-Disclosure and the 60-day Repayment Rule.*
October 22, 23	**Baker Healthcare Consulting 2015 Conference on Health Reform, Daytona Beach, FL** John Hellow presents *IPPS and OPPS Update;* Precious Murchison Gittens co-presents *Overpayments—The 60-Day VultureComes Home to Roost;* Charles Oppenheim co-presents *Tax Matters;* Robert Roth co-presents *Litigation & Appeals Update;* Charles Oppenheim co-presents *The Purpose Driven Deal.*
November 6	**2015 CSHA Fall Program, San Francisco, CA** Charles Oppenheim presents *New Alliances.*

CHA Announces New Edition of Hospital Compliance Manual

The California Hospital Association (CHA) has just released the 2015, 6th Edition of the California Hospital Compliance Manual.

New to the 2015 edition are detailed explanations of state law regarding hospital financial assistance policies required by SB 1276 and IRS regulations that impact not-for-profit hospitals released on Dec. 31, 2014.

CHA's compliance manual is the only publication written for hospital compliance officers that integrates California with federal law regarding high-risk compliance areas.

Written by Hooper, Lundy & Bookman, PC, attorneys and CHA, the manual focuses on key components of an effective compliance program. The manual features nearly 700 pages of content including 16 chapters, a model hospital compliance plan, numerous compliance forms and appendixes, and an index.

The Manual includes the following Chapters:

- Hospital Compliance Plans
- Governing Boards
- Federal and State False Claims Acts
- Submission of Accurate Claims Information
- Proper Cost Reporting Practices
- Physician Self-Referral Laws
- Federal and State Anti-Kickback Laws
- Financial Assistance Policies — NEW chapter includes federal regulations
- Issues for Tax-Exempt Hospitals
- Fundamentals of Hospital Licensing and Certification
- Screening for Excluded Providers and Suppliers
- Hospital Signage Requirements
- Patient Safety Organizations
- Other Laws
- Repayment and Self-Disclosure
- Responding to Government Audits and Investigations

To order the new manual or for more information, see www.calhospital.org/compliance.

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