

Managing the Attorney/Consultant Relationship in the Landscape of Self-Disclosure and FCA Investigations

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Attorney-Client Privilege

The attorney-client privilege is a legal privilege that works to keep communications between an attorney and his or her client confidential.

As a general matter, disclosing attorney-client communications to a third party waives the privilege.

There are well-established exceptions in the case law for certain third parties who are **employed to assist the attorney in rendering legal advice**, including secretaries, paralegals and clerks, as well as for **consultants** who “have a close nexus to the attorney’s role in advocating the client’s cause before a court or other decision-making body.”

The applicability of the privilege to **non-attorney consultants** is still uncertain and not uniformly applied across jurisdictions. It is important to review your particular jurisdiction’s law on the subject.

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Attorney-Client Privilege:

Consultant must be retained for purposes of rendering legal advice

An attorney who consults with a non-attorney professional/consultant, such as an accountant, must establish, from the beginning of the engagement, that the professional's advice will facilitate legal advice from the attorney.

If the attorney consults with the non-attorney professional/consultant simply to obtain the consultant's advice itself, the communications would not be protected.

If a client communicates with the non-attorney professional/consultant *before* consulting with the lawyer, the discussion is most likely not privileged.

- The attorney should be consulted first, should formally retain the consultant, and should direct and control the flow of communications between the client and the consultant.
- The consultant should bill the attorney, not the client.

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Application of Work Product Doctrine:

In Anticipation of Litigation

Courts apply different tests to determine whether documents were prepared in "anticipation of litigation," as follows:

Some courts have indicated that the document must be prepared because of the prospect of litigation when the preparer faces an actual or potential claim following an actual event or series of events that reasonably could result in litigation. Thus, materials prepared in the ordinary course of business or pursuant to regulatory requirements or for other non-litigation purposes are not documents prepared in "anticipation of litigation."

Other courts have adopted a "function of the document" test. Under this theory, if the reason the adverse party seeks the documents is to help the adverse party understand the legal arguments of the party that prepared the documents, then the doctrine will protect the documents even if the party did not prepare them in anticipation of a specific or potential claim.

Finally, under the "primary motivation" test, a document is protected by the work-product doctrine if the primary motivation of the party preparing the document is to assist in possible future litigation, or because of the prospect of future litigation.

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Work Product Doctrine

A party seeking attorney work product immunity must establish that the materials it seeks to protect are documents “prepared in anticipation of litigation” by a party or the party’s representative. FED. R. Civ. P. 26(b)(3).

- An opposing party can overcome the work product immunity if it can show that it has a “substantial need” for the documents and that it is “unable without undue hardship to obtain the substantial equivalent of the materials by other means.”

Shields the attorney’s own observations, strategies, reflections and plans.

Application of the doctrine is more complicated where documents were prepared for both litigation **and** business purposes.

- However, documents prepared to assist a business decision **might still be protected** if they were created at least in part because of the **prospect of litigation**.

Documents prepared in anticipation of litigation do not need to be prepared at the request of an attorney, but may be prepared by client or a non-attorney consultant in anticipation of litigation.

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Application of Work Product Doctrine: *Routine Business Audits*

Routine business audit reports and work papers are generally not protected by the attorney-client privilege or work product doctrine.

A company’s internal audits are likely to be considered business activities unless the audit is conducted at least in part in anticipation of litigation.

Therefore, internal auditors should notify legal counsel in the event any impropriety is identified, who may then direct a privileged internal investigation into the alleged misconduct and focus on providing the company with legal, rather than business, advice.

Merely sending documents related to an audit to an attorney or copying an attorney on emails or other communications does not make such communications privileged if not seeking legal advice, or at least that being a significant purpose.

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Application of Work Product Doctrine: *Internal Investigations*

When internal audits are conducted for the purpose of investigating alleged misconduct, such audits are more likely to be considered privileged because they are being conducted as a result of the initial misconduct and that there is a reasonable, subjective belief such conduct could lead to litigation or criminal prosecution.

However, to preserve the work product privilege for such audits, counsel should ensure that auditors understand:

- That their work is being conducted at the direction of counsel as part of the investigation and in order for counsel to provide legal representation to the company;
- That the auditors should mark all documents created as part of the audit as being done at the direction of counsel and protected by the attorney work-product doctrine; and
- That the auditor should not disclose any confidential information relating to the audit without the consent of counsel.

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"60 Day Rule"

The Affordable Care Act of 2010 imposed a requirement on providers who submit claims to the Medicare and Medicaid programs to report and return identified overpayments within 60 days ("60-Day Rule").

Failure to report identified overpayments within 60 days carries liability under the United States False Claims Act (31 U.S.C. § 3729 *et. al*).

- Issues arose as to what constituted an "identified overpayment" and what kind of event would trigger the 60-day clock.

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Final Rule Provides Clarity

The Final Rule Addresses the following questions:

- When is an overpayment "identified" for purposes of the reporting requirement?
- What steps constitute "reasonable diligence" to determine if an overpayment has been made?
- What is the lookback period for identifying overpayments?
- What are a provider's options for repayment?

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Definition of an "Identified" Overpayment

Providers are responsible for overpayments that they **know or should have known** about through the exercise of "reasonable diligence."

Providers that deliberately choose not to investigate when they are made aware of the existence of potential overpayments, would be held liable under the False Claims Act.

The scope of a provider's obligation.

- A provider will be held responsible for overpayments that the provider causes as well as those that were not caused by the provider (e.g., an error by CMS or a Medicare Administrative Contractor (MAC)).

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Exercising "Reasonable Diligence"

Providers exercise reasonable diligence in identifying overpayments when they:

- (1) implement proactive compliance activities to monitor for the receipt of overpayments
- (2) undertake investigations "in a timely manner" in response to obtaining "credible information" of a potential overpayment.
 - CMS considers a "timely" investigation to be at the most 6 months from receipt of the credible information, except in extraordinary circumstances.

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Exercising "Reasonable Diligence" (cont'd)

CMS commented on additional steps a provider should take if a single overpayment is identified.

- Further inquiry would be advisable because "it is not appropriate for a provider or supplier to only return a subset of claims identified as overpayments and not extrapolate the full amount of overpayment."
- Exercising reasonable diligence, may require a provider to use statistical sampling in order to appropriately quantify the overpayment.
- A provider's compliance and audit activities should be adept at detecting potential overpayments in the timeliest manner.

The 60-Day period does not begin until provider has had opportunity to undertake follow-up activities and quantify the amount of the full overpayment.

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Lookback Period

The 60-Day Rule applies to overpayments identified within six years after they were received.

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Options for Repayment

Providers may use several options when returning overpayments to CMS.

- Providers may use claims adjustment, credit balance, OIG's Self-Disclosure protocol, or other appropriate processes to report or return overpayments.
- CMS reserves the right to modify or create new processes in the future.

Regardless of the process used, the refund should include an explanation or the statistical sampling methodology used if the overpayment was extrapolated.

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Action Items for Compliance

Promptly evaluate any evidence of potential overpayments to determine whether the report is credible.

Document the process of validating the potential of an overpayment and any follow up investigation.

If the evidence is reliable, promptly investigate with reasonable diligence whether additional overpayments exist and how they should be quantified.

Ensure the overpayment period encompasses 6 years.

Once the overpayment is quantified, ensure that it is submitted within 60 days through one of the methods deemed acceptable by CMS.

Implement policies, procedures and training regarding compliance with the 60-day rule.

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If providers are supposed to proactively identify potential overpayments, and they are, what do you look at?

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Potential Areas of Focus

Levels of E&M service

Ancillary services

- IPPE/AWV
- Orders for diagnostics, infusion, therapy
- Staff credentials

Separate reports (tests, procedures)

Can you tell who provided the service?

- Is it billed under that provider?

Any incident-to issues?

Medical necessity

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Potential Areas of Focus

Modifiers?

Unbundling?

ICD-10 code supported by documentation and is linked to the appropriate CPT/HCPCS code?

Billing for noncovered services as covered?

- Annual screening stress test

Use of ABNs and routine use

Denials

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Case Example

“Let’s have someone look at a few of each of our records to see how we’re doing with our coding. A couple of us are wondering how Stan has so many level 4 and 5 visits – he sees more patients than any of us.”

Great idea not to single out Dr. Stan!

Audit vs. chart review

Prospective v. retrospective review

Limit the scope to E&M only?

Was there data behind the question?

- Should that impact the approach?

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Case Example

No attorney involved at the onset – prospective review

Stan has a 40% error rate for new patient encounters

- 4:10 99204s have documentation issues
- His exam and medical decision making documentation consistently support 99204.
- Documentation does not support he reviewed any family history
- His review of systems does not meet the E&M DG’s requirement of 10 or more systems for a comprehensive history.

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Case Example Discussion

Are there potential overpayments or documentation issues, or both?

Time to call counsel?

Written or verbal report

Next steps to consider

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Issues to Consider

Type of audit – Compliance vs. Investigation

Attorney/Client Privilege

Standards – Authoritative vs. Guidance

Code Description vs. "Guidance"

Escobar Standard – Material to payment of claim but that is False

Claims Act standard vs. overpayment

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Authority vs. Guidance

Criteria to be used at the front end.

The Nature of Authoritative Standards

Segregating "musts/shalls" from "shoulds" within the standard.

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Authority vs. Guidance

Types of Authority –

- Case Law – It depends.
- Social Security Act (Medicare Statute)
- HHS Regulations, unless determined:
 - to conflict with statute
 - to be unconstitutional
- CMS Interpretive Guidance
 - Internet Only Manuals – These do not have the force of law and are therefore not technically binding
- Local Contractor Rules
 - LCDs – These do not have the force of law and are therefore not binding. Expressly not binding on QICs or ALJs.

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Authority vs. Guidance

Guidance

- Provide guidance in the absence of statutory, regulatory or contractual provisions.
- Not all are of equal value or validity. The quality of the source and the basis for the opinion will determine its value.
- Coding Decisions
 - Persuasive standards can be used by providers to explain why a particular code was used but only in the absence of a binding standard to the contrary.
- Audit Determinations:
 - **Guidance cannot be imposed as a basis for error but can be used to identify potential risk**

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Understanding Standard's Significance

Identifying the Significance of the Authoritative Standard

- Condition of Participation?
- Condition of Payment?

What is the difference?

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Condition of Participation or Payment?

Conditions of Participation:

- A condition or performance standard that must be met in order to be a participating provider.

Conditions of Payment

Medicare

- Conditions of payment are usually found in statute or regulation
- In many cases, documentation guidance is written as a condition of participation but applied as a condition of payment.

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Condition of Participation or Payment?

Does non conformance with interpretive guidance mean that you are not entitled to payment?

- FCA Case law:
 - *Universal Health Services v. United States ex rel. Escobar* – US Supreme Court held:
 - The precise label that the government affixes to the relevant law or contract such as, compliance is a "condition of payment"-is not determinative of whether the claim is "false or fraudulent"
 - Instead, it ruled that an implied certification theory can be a basis for FCA liability only if two conditions are satisfied:
 - (1) "the claim does not merely request payment, *but also makes specific representations about the goods and services provided*"; **and**
 - (2) the defendant must fail to disclose its noncompliance with a provision that is "material" to the government's decision to pay.

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Example – Resolving a Coding Dispute – Who is Right and How do you Prove It?

Most disputes result from the application of unincorporated standards by one side of the dispute or the other.

- Reliance on the "everyone knows" standard
- Reliance on published guidance that is not incorporated by the applicable statute, regulation or medical policy
- Failing to differentiate between coding rules and reimbursement rules.
- Some disputes are the result of legitimate ambiguity in a binding standard.

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Audit Reporting

Selected Code vs. Correct Code

Identify Standard – Authoritative vs. Guidance

Identify Risk Concerns

Recommend Corrective Action

No legal conclusions such as "overpayment"

Verbal vs. Written

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Recommendations

Education before audit

Review current compliance – not past deficit

Audit still required for effective compliance program

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Questions?

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