Healthcare False Claims Act (FCA) cases trigger the specter of significant damages and penalties, and these cases are expensive to litigate. This financial reality, in conjunction with the upward trend in volume of FCA cases being filed, has created increased interest by parties on all sides in asking whether mediation is a useful tool to facilitate efficient resolution of these cases. FCA litigation, however, presents a number of unique features that make mediation more complex than in a typical commercial dispute. This paper discusses select issues unique to FCA cases that parties should consider in mediation.

I. Pre-Mediation Consideration

A. Attendees—Recognize that FCA cases present in many different forms with many entities whose interests can converge or diverge on different issues—and which alignment may change over the course of a mediation. One of the first issues to consider is who should attend the mediation (or at a minimum be available by phone) to reach a complete resolution.

   o **DOJ**—In an FCA case, the United States is the real party in interest.
   
   o **State Medicaid Fraud Control Unit/State Attorney General’s Office**—If there is a parallel claim under a state false claims act, one may need a state representative present or at least a clear indication from the State that DOJ has its proxy in the negotiation.
   
   o **Relator**—Should relator be present or just relator’s counsel? Are there separate claims that will be mediated in addition to the substantive FCA allegations? E.g., retaliation under 31 U.S.C. § 3730(h) or counterclaims.
   
   o **Co-Defendants**—Will DOJ’s need to resolve the matter with co-defendants impede or slow down the resolution?
   
   o **U.S. Department of Health & Human Services Office of Inspector General (OIG)**—Has there been discussion with OIG about whether/how it plans to exercise its Civil Monetary Penalty and exclusion authority? E.g. CIA with release, cold comfort letter without release, or no release and no cold comfort. Is this a material term for the resolution?
   
   o **Other Payors**—Do the potential damages materially implicate payors beyond CMS (typical Medicare and Medicaid), such as Tricare and FEHBP?
B. Prepare Clients for the FCA Settlement Agreement—For those practitioners who regularly negotiate FCA settlements, it is well-known that the standard DOJ settlement agreement contains some negotiable provisions, and many more that will not be changed. It is important to educate clients about those provisions that can be negotiated and those that cannot. Several potentially unfamiliar provisions worth discussing before the mediation include, among others:

- Unallowable cost treatment;
- Scope of release/dismissal with prejudice (including release—or not—of individuals);
- Reservation of rights (criminal, tax, individual, administrative); and
- Agreement not to resubmit previously denied claims and to withdraw claims on appeal.

II. Key Terms/Negotiation Points

A. Financial Resolution

- Recognize Total Cost to Settle—It is important to appreciate that the total cost to resolve an FCA case includes funds beyond the bottom line paid to DOJ for a release of the core substantive allegations. Defendants in particular should have a plan at the outset of mediation regarding whether the settlement must resolve all liability, including individual relator claims such as retaliation and attorney’s fees. On the other hand, some litigants agree to carve out these issues from the resolution and continue to litigate them with the Realtor after reaching a resolution of the substantive FCA liability with DOJ.

- Payment Terms/Ability to Pay—FCA defendants in financial distress are wise to raise with the mediator, and potentially DOJ directly, that they have concerns about the ability to fund a settlement beyond a certain point. DOJ has a robust “ability to pay” process that requires comprehensive financial disclosures to put the government in a position to evaluate a defendant’s claims in this regard. Having done this front-end work may be necessary to an effective mediation if these issues are present. Also, if the potential for payment terms over time is present, this too should be discussed proactively before mediation.

B. Non-Monetary Terms

- Covered Conduct—In addition to the amount paid, the most important term in the settlement agreement is how “covered conduct” is defined, because in an FCA settlement the scope of the release keys off of the definition of covered conduct. Time should be devoted at mediation to carefully negotiating the covered conduct provision.
o **OIG Release/CIA**—Will the settlement agreement reflect the parties entering into a CIA with a release from OIG? Often the parties will leave this to be decided by making the settlement contingent on “mutually acceptable resolution” of OIG’s review of the matter.

o **Cold Comfort Letter**—Will DOJ provide a cold comfort letter on conduct beyond the scope of the “Covered Conduct” reflecting that there is no present intention to pursue the other claims?

o **Individual Treatment**—After promulgation of the Yates Memorandum in September 2015, it is worth discussing with DOJ how it plans to address exposure of individuals. If individuals are to be pursued, has the corporation considered the real cost to it of any state law, contractual, or corporate bylaw obligations to advance fees and/or indemnify officers, directors, and employees? This could be a material cost to a corporate defendant worth raising at mediation.

o **Handshake interest/rate**—It is common to agree to pay interest from the day of the agreement in principle, known as “handshake interest.” Consider being clear whether interest will run and the current rate.

o **Express Denial**—Will the settlement agreement include an express denial of the allegations in the covered conduct and the complaint?

o **Master Agreement(s)**—Will there be one agreement with all entities (DOJ, states, Relator on fees), or will there be several agreements?

o **Press Release**—Although it is DOJ practice not to negotiate press release language, consider discussing whether the parties can agree on the timing of press releases to avoid surprises.

o **Proposed Timeline for Signatures**—It often takes time to negotiate the final agreement and to secure approvals, so it can be helpful to discuss a proposed settlement timeline at mediation to keep the parties focused on finalization of the settlement agreement by a target date.

**C. Separate Settlement with Realtor**—A gating issue to be determined is whether the mediation will be a global resolution of all issues with the Relator and his or her counsel, or whether Relator-specific issues will be carved out?

  o **Scope of Release**—Regardless of the scope of the release negotiated with DOJ, it is standard practice to secure a comprehensive release of all claims the Relator has against the defendant of any sort.

  o **Retaliation Claim**—If the Relator has a separate retaliation claim, will this be included within the mediation with DOJ or mediated separately? At a minimum, it is wise to have a demand for the retaliation claim at mediation to be able to evaluate the potential all-in amount required to resolve the case.
Attorneys’ Fees and Costs—Recognize that a settlement entitles the Relator under the FCA to reasonable attorneys’ fees and costs, so defendants should consider requesting a fee demand before mediation for the time expended by Relator’s counsel to that point.

Confidentiality—The master settlement agreement with DOJ will not be confidential, so consider whether there are any terms with the Relator that a defendant would prefer to be kept confidential, e.g., amount paid in attorneys’ fees and/or to resolve a retaliation claims. If these concerns are present, negotiate at mediation with Relator a separate confidential agreement.

Non-Disparagement—Will the settlement agreement with Relator contain a one-way or mutual non-disparagement clauses?

Document return—If the Relator took any documents or data, consider negotiating for the return or destruction of the material by a specific date.

D. Collateral Issues

Express Reservation of Approval—Recognize that both sides composing a term sheet at mediation typically make the resolution contingent on approval of relevant entities—DOJ/State chain of approval and governing body of the defendant, e.g. board of directors.

Unsealing Logistics—If the case has been partially unsealed and shared with the defendant and counsel, but remains under seal as to the outside world, there may be a need to share the details with additional entities to complete the settlement.

i. Insurance—The amount of the funds available for settlement may in part be linked to the presence of insurance coverage, but the seal may have prevented disclosure of the FCA case to the insurer. Defendants should discuss with DOJ going to the court to seek an expansion of the seal lift to permit such disclosure as necessary.

ii. Financial Institution Approval—Defendants may have bond or other debt covenants that require approval or a waiver from a financial institution before significant funds can be expended.