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# ***FAST BREAK:*** **ASERACARE**

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# Agenda

- Procedural Background
- The AseraCare Opinion – What Did the Court Decide?
- The Court's Explanation of the Medicare Hospice Benefit and Clinical Judgment
- What Does the Decision Mean for Healthcare Providers?

# Procedural Background

- AseraCare began as typical FCA *qui tam* matter
  - Relator brought claims on behalf of U.S. regarding clinical eligibility/medical necessity for hospice and aggressive marketing practices
  - Northern District of Alabama
- DOJ intervened, but atypically, the parties litigated all the way to trial
  - Trial evidence bifurcated – falsity first, then FCA “knowledge”
  - Trial was largely a “battle of the experts” on clinical appropriateness of certain patients

# Procedural Background

- In 2016, the trial court vacated a \$200 million jury verdict in favor of the government and invited renewed SJ motions
  - Determined that the jury instruction that false claims could be established by the opinion of one medical expert alone was wrong.
  - A mere difference of opinion among physicians alone is not enough to show falsity. The jury had found that 104 of 121 patients were not eligible for hospice services based on nothing more than expert disagreement.
- The government appealed to the 11<sup>th</sup> Circuit.

# What Did the AseraCare Court Decide?

- On appeal, the Eleventh Circuit held that the trial court was right in vacating the jury verdict and granting a new trial. Mere differences of reasonable opinion regarding a patient's prognosis is not sufficient evidence to show FCA liability.
- In an exhaustive review of the Medicare program and the False Claims Act, the court held that in hospice cases the government must show facts surrounding the physician's eligibility certification that are *inconsistent* with the proper exercise of physician judgment.
- The Court acknowledged that the Medicare hospice benefit was structured to consider *good-faith subjective clinical opinions* and two physicians may reasonably hold different opinions on prognosis and eligibility. At trial, this exact point was part of the testimony of the Medicare agency witnesses.

# What Did the AseraCare Court Decide? (Cont'd)

- The government's sample of 121 patients relied only on expert testimony to show falsity. The Court of Appeals held that the government should have the opportunity to present any other evidence of falsity related to the sample. It vacated the summary judgment in favor of the company for further proceedings consistent with the opinion. This means the case will proceed to a new trial governed with the legal precedent of the decision—a new and more level playing field.
- Both sides have declared “Victory” here – who is the real winner?
  - In any new trial, any other credible evidence of falsity must be linked to the government's sample claims and not general anecdotal evidence of alleged improper business or clinical practices.
  - In the prior trial proceeding, the government stated it did not have other evidence of falsity related to the sample so it remains to be seen how the new trial will proceed, if at all. Summary judgment could be granted again in favor of the company.

# Court's Explanation of Hospice Benefit

“To conclude that the supporting documentation must, standing alone, prove the validity of the physician’s initial clinical judgment would read more into the legal framework [of the Medicare statute] that its language allows. . . [t]hat is, the [certifying] physician’s clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records.”

# Court's Explanation of Hospice Benefit (Cont'd)

“Had Congress or CMS intended the patient’s medical records to objectively demonstrate terminal illness, it could have said so. Yet Congress said nothing to indicate that the medical documentation presented with a claim must prove the veracity of the clinical judgment on an after-the-fact review. And CMS’s own choice of the word ‘support’ – instead of, for example, ‘demonstrate’ or ‘prove’ – does not imply the level of certitude the Government wishes to attribute to it.”



# Court's Discussion of Clinical Judgment

- The Court also observes: “[m]ore broadly, CMS’s rulemaking commentary signals that well-founded clinical judgments should be granted deference.”
- “[W]hile there is no question that clinical judgments must be tethered to a patient’s valid medical records, it is equally clear that the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding.”

# What Does This Mean for Providers?

- Just a hospice decision?
  - Potentially broad applicability to all areas where practitioner judgment is scrutinized
- However, DOJ already attempting to minimize decision and/or make this a victory for the government
- Will DOJ, OIG, or CMS change its approach on judgmental issues?
  - Likely not immediately
  - Depending on amount of pressure applied, possible that CMS policy-makers could consider substantive changes as a result of the decision

## What Does This Mean for Providers? (Cont'd)

- What about CMS Contractors (MACs, UPICs, ZPICs, RAs, SMRCs, etc.)?
  - Likely not influenced by decision itself
  - Still likely to apply their nurse reviewers' judgment, even when unwarranted or inconsistent with that of the treating physician or practitioner
  - It will likely take several instances of ALJs applying and referencing the holding of the 11<sup>th</sup> Circuit's *AseraCare* decision before meaningful change in audit review protocol occurs

# What Does This Mean for Providers? (Cont'd)

- Two areas of application:
  - FCA context
    - Decision may change how healthcare defendants in medical necessity battles approach litigation and settlement
    - DOJ will (and already has) sought to minimize impact of *AseraCare*
  - Administrative appeals context
    - Unlikely that decision will have meaningful impact except perhaps at ALJ level (even then, ALJ not subject to judicial precedents so only discretionary application of *AseraCare* principles)
    - Nevertheless, worth including since the opinion is well-reasoned explanation of documentation of medical necessity determinations

# Thanks!



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# Thanks!



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A former Assistant US Attorney and US Department of Justice (DOJ) Healthcare Fraud Coordinator, Katie McDermott represents healthcare and life sciences clients throughout the United States in government investigations and litigation matters relating to criminal, civil, and administrative allegations, including violations of the False Claims Act and its whistleblower provisions. Katie also advises on corporate compliance matters relating to internal investigations, voluntary government disclosures, consent decrees, and corporate integrity agreements.

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