# Senate Judiciary Committee Advances False Claims Act Amendment to Full Senate

 On October 28, a majority of members on the Senate Judiciary Committee voted 15-7 to advance to the full Senate a bipartisan bill that would make a number of amendments to the False Claims Act ("FCA"), including one that would make significant changes to the FCA's definition of "materiality." Senator Chuck Grassley of Iowa, who serves as the ranking member of the Judiciary Committee, argued for the materiality amendment, stating that it is intended to correct the "misinterpretations" of the FCA "created by the *Escobar* court."

Under the FCA, only a material violation – one that has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property by the government" – can form the basis for liability. The Supreme Court in *Universal Health Services v. United States ex rel. Escobar* stated that the FCA's materiality standard is "rigorous" and "demanding," and held that a violation of a particular requirement would likely not be considered material if (for example) the government had actual knowledge of the violation and chose to pay the claim anyway.

The materiality amendment advanced to the full Senate would undo the protections offered by the *Escobar* ruling, and instead states that "in determining materiality, the decision of the government to forego a refund or pay a claim despite actual knowledge of fraud or falsity shall not be considered dispositive if other reasons exist for the decision of the government with respect to such refund or payment."

The number of suits filed under the *qui tam* provisions of the FCA are steadily increasing over the years, with **672 *qui tam* actions filed in 2020** alone. Should this FCA amendment be enacted, its lowered materiality standard will make it significantly more difficult for defendants in *qui tam* actions to win motions to dismiss on materiality grounds, or to obtain summary judgment; as a result, many more of these cases will move forward to more expensive and time-consuming stages of litigation.

Health care providers and other health care companies who are the potential defendants in FCA cases already often spend significant resources defending against these claims. While the proposed amendment advanced by the Judiciary Committee last week is intended to reduce fraud and abuse – for example, the amended materiality standard would be particularly important in situations in which the government is aware of fraudulent claims but is unable or unwilling to stop paying for the provision of critical healthcare services***; but, it may also have an effect on the overall costs of defending a claim, whether or not meritorious. We will continue to monitor updates with respect to the FCA and related legislation.***

# HHS, Labor, and Treasury Departments Defer Enforcement of Transparency in Coverage and No Surprises Act Requirements

 The No Surprises Act and Transparency in Coverage final rules go into effect January 1, 2022. Implemented as Titles I and II of Division BB of the Consolidated Appropriations Act, these rules are intended to protect patients from surprise medical bills and increase transparency by requiring certain health care facilities and insurers to disclose certain information. The U.S. Departments of Health & Human Services, Labor, and Treasury are jointly charged with implementing specific sections of the **No Surprises Act** and **Transparency in Coverage** final rules. On August 20, 2021, however, these agencies jointly announced through an **FAQ** published on HHS's website that they are deferring enforcement of certain requirements from the final rules.

One of the No Surprises Act's final rule's requirements is that certain health care providers and facilities must provide a good faith estimate of an individual's expected charges for health care items or services, if the individual is enrolled in a health plan and seeks to submit a claim to the plan. The government, recognizing that providers and facilities must develop complex technical infrastructure to comply with this provision, has decided to defer enforcement of this portion of the final rules until it can issue further rules on implementing these requirements. For nearly identical reasons, the government also decided to defer enforcement of requirements that plans and health insurance issuers provide individuals an advanced explanation of benefits pending further rulemaking.

The government further stated its plan to streamline some of the overlapping requirements in the No Surprises Act and the Transparency in Coverage final rules. For example, the Transparency in Coverage rule requires certain group health plans and health insurance providers to publicly disclose specified information about their in-network provider rates, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for prescription drugs in separate, machine-readable files for plan years beginning on or after January 1, 2022. ("Grandfathered" health plans and health insurance providers, however, are exempt from these rules if they were in place prior to the March 2010 enactment of the Affordable Care Act.)

The government has decided to defer enforcement of the Transparency in Coverage rules that require plans and health insurance issuers to publish machine-readable files related to prescription drug pricing pending further rulemaking, given overlap with similar requirements in the No Surprises Act. The government also indicated it will defer enforcement of all other machine-readable file publication requirements of the Transparency in Coverage final rule until July 1, 2022.

The requirements of the No Surprises and Transparency in Coverage final rules are complex and will require significant effort from health plans, healthcare facilities, and others to implement. Despite

the government’s decision to defer enforcement of certain requirements, health care facilities and health insurance providers should begin preparing to meet as many of these requirements as possible – and should do so as soon as possible.  This starts with understanding which of the myriad remaining No Surprises Act and Transparency in Coverage requirements still apply to which health plans or healthcare facilities.

Partnering with trusted legal counsel early on can help ensure health care providers and insurers are prepared when the full requirements of the No Surprises Act and Transparency in Coverage rules begin being enforced by the government.