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Clinical research billing and the law: Tips for compliance

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Almost 500 years! "The first clinical trial of a novel therapy was conducted accidentally by the famous surgeon Ambroise Pare in 1537" while serving in the battlefield treating wounded soldiers.[1] From modernizations in clinical trial design to advancements in countless ethical and legal considerations, clinical research has made significant strides in five centuries. Fast forward to the year 2020, when there was a total of 362,511 research studies registered on ClinicalTrials.gov![2]

Even though there has clearly been exponential growth in the medical field these past 500 years, the COVID-19 pandemic has had a sudden and significant impact on the US healthcare system. The COVID-19 pandemic has also shifted the development and implementation paradigms for clinical trials. Many institutions and investigators found themselves pumping the proverbial breaks in the clinical trial arena. Due to the abrupt and widespread impact of the pandemic, sites have found it increasingly difficult to activate new studies, enroll subjects, and monitor regulatory risks, among many other distinct challenges.[3]

Despite the countless changes and roadblocks encountered, do you know what remains constant? The law!

> 'Even in the face of a nationwide pandemic, the department's dedicated employees continued to investigate and litigate cases involving fraud against the government and to ensure that citizens' tax dollars are protected from abuse and are used for their intended purposes,' said Acting Assistant Attorney General Clark. 'The continued success of the department's False Claims Act enforcement efforts are a testament to the dedication of the civil servants who pursue these important cases as well as to the fortitude of whistleblowers who report fraud.'[4]

Granted, many governmental regulatory and enforcement authorities have responded to the pandemic with increased flexibility and guidance in order to overcome the unique challenges clinical trials have faced; however, the pandemic has not given institutions, investigators, or sponsors a free pass from abiding by the laws and regulations enacted for healthcare and clinical trials.

In 2007, the Centers for Medicare & Medicaid Services (CMS) released the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (NCD 310.1) to provide guidance on Medicare coverage of research services.[5] For any items or services to be potentially billable to Medicare, a study must meet CMS's "qualifying" criteria. If the study is then determined to be a qualifying clinical trial, then Medicare will pay for certain "routine costs." NCD 310.1 includes three exceptions to the "routine costs" for Medicare coverage; while they

may seem basic and easy to follow, the associated risks and penalties of getting it wrong are anything but.