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Contact: CMS Media Relations (202) 690-6145 | <u>CMS Media Inquiries</u>

Trump Administration Champions Reporting of COVID-19 Clinical Trial Data through Quality Payment Program, Announces New Clinical Trials Improvement Activity

Improved availability of data key to driving improvement in patient care and development of innovative practices

The Centers for Medicare & Medicaid Services (CMS) is encouraging clinicians who participate in the Quality Payment Program (QPP), such as physicians, physician assistants, nurse practitioners, and others, to contribute to scientific research and evidence to fight the Coronavirus Disease 2019 (COVID-19) pandemic. Clinicians may now earn credit in the Merit-based Incentive Payment System (MIPS), a performance-based track of QPP that incentivizes quality and value, for participation in a clinical trial and reporting clinical information by attesting to the new *COVID-19 Clinical Trials* improvement activity. This action will provide vital data to help drive improvement in patient care and develop innovative best practices to manage the spread of COVID-19 within communities.

"The best scientific and medical minds in the world are working night and day to find treatments to combat Coronavirus," said CMS Administrator Seema Verma. "But without solid data, their efforts are liable to run up against a brick wall. At the direction of President Trump, CMS is supporting efforts of researchers to obtain solid, actionable data to accelerate the development of new treatments and our understanding of the coronavirus. Today's action encourages clinicians to report data that will help us monitor the spread of the virus, find innovative medical solutions, and unleash scientific discovery as we seek to overcome this terrible disease."

In order to receive credit for the new MIPS *COVID-19 Clinical Trials* improvement activity, clinicians must attest that they participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study.

The new improvement activity provides flexibility in the type of clinical trial, which could include the traditional double-blind placebo-controlled trial to an adaptive or pragmatic design that flexes to workflow and clinical practice. It also carries a high weight from a scoring perspective. This means that clinicians who report this activity will automatically earn half of the total credit needed to earn a maximum score in the MIPS improvement activities performance category, which counts as 15 percent of the MIPS final score.

For example, clinical trials could include those conducted by the National Institute of Health (NIH). Clinicians could also report through a clinical data repository, such as Oracle's COVID-19 Therapeutic Learning System. Oracle has developed and donated a system to the U.S. government that allows clinicians and patients at no cost to record the effectiveness of promising COVID-19 drug therapies. Having clinicians use an open source data tool to submit their findings will bring the results of their research to the forefront of healthcare much faster, leading to improvements in care delivery and the ability to treat COVID-19 patients.

This action, along with the unprecedented regulatory flexibilities recently introduced, is just one part of the agency's efforts to address the COVID-19 pandemic. CMS, in coordination with the White House Coronavirus Task Force, remains committed to reducing regulator burden and supporting clinicians, stakeholders, and the health care community to identify unique solutions that enhance care for patients and further mitigate the spread of the virus.

This action, and earlier CMS actions in response to the COVID-19 virus, are part of the ongoing White House Task Force efforts. To keep up with the important work the Task Force is doing in response to COVID-19 click here <u>www.coronavirus.gov</u>. For information specific to CMS, please visit the <u>Current Emergencies Website</u>.

To view a database of privately and publicly funded clinical studies currently being conducted on corona virus visit: <u>https://clinicaltrials.gov/</u>

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