DAILY COVID-19 REGULATORY UPDATE

As we detail below, there have been several important updates since noon on Thursday, June 4.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

• HHS <u>released</u> new <u>guidance</u>, as directed by the CARES Act, specifying the additional data laboratories must report to HHS with COVID-19 test results. More information is available in the <u>FAQs</u> (WHG client <u>summary</u>).

CENTERS FOR MEDICARE AND MEDICAID SERVICES

• In follow up to its recently announced enforcement actions for nursing homes, CMS has announced its first set of COVID-19 nursing home data is now available online (WHG client summary).

FOOD AND DRUG ADMINISTRATION

• The FDA has <u>published</u> antibody test performance data from four serology tests kits from its independent performance validation study effort with the National Institutes of Health's (NIH) National Cancer Institute (NCI).