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Dash to Digital Health? How the Regulatory Sprint to Coordinated Care Could Expand Access to Care

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Certain long-standing laws, such as the civil monetary penalty provision prohibiting patient inducements, have hampered providers' ability to fully leverage remote patient monitoring and other telehealth tools. Many stakeholders are hoping that developments in the Regulatory Sprint to Coordinated Care will begin the rulemaking process to enable greater access to digital health and virtual care products.

The US Department of Health and Human Services (HHS) launched the Regulatory Sprint to Coordinated Care in 2018 with the goal of reducing regulatory burden and incentivizing coordinated care. As part of this initiative, the Centers for Medicare and Medicaid Services and other agencies are scrutinizing a variety of long-standing regulatory requirements and prohibitions to determine whether they unnecessarily hinder the innovative arrangements policy-makers are otherwise hoping to see develop. While regulations such as the civil monetary penalty prohibition on patient inducements have significant benefits for reducing fraud and abuse, they can also make it difficult for health systems to deploy digital tools that help patients track, monitor and share health data with their providers.

For example, Medicare reimbursement of digital health and virtual care products, while <u>expanded in 2018</u>, is still limited. This means that if a provider wants to use un-reimbursed technology, the provider must either charge the patient separately for the non-reimbursable service or provide the service to the patient for free. The former option is tricky—it can result in surprise charges for patients, and digital health services can be part of a care service plan and difficult to break out separately as a standalone billable service. As a result, many providers would prefer to offer virtual care services to the patient for free, but doing so immediately implicates the civil monetary penalties prohibition. Substantial time, effort and cost is required to evaluate the facts and circumstances, understand the available regulatory guidance and case law, and determine whether the provision of the service—which results in no increase in revenue—could result in governmental scrutiny

This is just one example of how certain long-standing regulations have become a barrier to broad adoption of digital health. If HHS chooses to update these regulations or <u>issue additional guidance</u>, the Regulatory Sprint to Coordinated Care could bring digital health technologies such as telehealth



and virtual care products off the sidelines and into the race.

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