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Welcome to the first issue of *Three Key Things in Health Care*. To be published weekly by the Hunton Andrews Kurth Health Care Practice Group, *Three Key Things* offers short summaries of three significant issues in health care that we believe merit your attention. Depending on the week, *Three Key Things* might address compliance items, risks to be avoided or novel ideas for transactions. Our goal is not to repeat what is already in the trade press, but to provide actionable ideas that will benefit your organization. Let us know what you think!

- **Regulators are moving at breakneck speed** to distribute funds from the Paycheck Protection Program (PPP), healthcare Provider Relief Fund and other financial assistance programs funded by the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the PPP and Health Care Enhancement Act. Getting relief to those who need it is vital, but the pandemic seems to have pushed us fully into the age of rulemaking via the internet. Requirements appear, disappear and reappear on agency websites. FAQs are issued, augmented and revised. Often, these missives pop up after the federal funds to which they relate have been distributed or even expended. Many pronouncements are undated, leaving the beneficiaries of these programs unsure of what happened when. At least the Small Business Administration material is making its way into the Federal Register. The Department of Health and Human Services thus far has been using only its website. **Key takeaway:** Providers must pay careful attention to an evolving regulatory terrain with respect to requirements around the receipt and use of relief funds. Those that do not are walking a False Claims Act minefield.

- **Provider Relief Fund monies** have been flowing for the past month, divided among at least seven buckets:

    - General Allocation (First $30 billion)
    - General Allocation (Follow-on $20 billion)
    - Targeted Allocation – Treatment of the Uninsured (amount not announced)
    - Targeted Allocation – COVID-19 High-Impact Areas ($12 billion)
    - Targeted Allocation – Rural Providers ($10 billion)
    - Targeted Allocation – Indian Health Service ($400 million)
    - Additional Allocations – future separate allocations to skilled nursing facilities, dentists and providers that solely take Medicaid

    Each bucket is tied to legal requirements (enacted by Congress) and agency-issued Terms and Conditions (T&Cs). Payment recipients must deliver attestations confirming receipt and agreeing to the T&Cs and must submit reports and maintain documentation. Getting any of this wrong opens up the potential for significant liability under the False Claims Act (think recently laid-off employee whistleblowers, treble damages, per-claim civil penalties and attorney's fees). **Key takeaway:** As to each bucket, providers must document their eligibility case now, implement systems to capture the data that must be tracked and reported, monitor those systems and submit what is required by the applicable deadline. Documentation should be kept for 10 years, and providers should assume someone not currently involved in the process will have to dust it off and explain it to skeptical investigators.

- **The Stark Law, as applied to "designated health services,"** has been with us for almost 30 years now, and its basic prohibitions are well known—no referrals and no billing if an unexcepted financial relationship exists. So too are the perils of violating it. Legions of plaintiffs' attorneys now focus on converting Stark Law violations into False Claims Act mega recoveries. No doubt the Stark Law presents some thorny issues, particularly when it comes to structuring novel transactions, but a fair bit of Stark compliance amounts to basic blocking and tackling. A pair of FCA settlements announced recently confirm that some providers keep missing the basics. We understand the financial pressures that lead some hospitals and health systems to bring this important work in-house (assuming there is an in-house legal department). But it is imperative that the work gets done. **Key takeaway:** Having knowledgeable counsel run the traps on financial arrangements with physicians is a bit like buying fire insurance. People don't like paying for it every year given the low odds of having to use it, but no one wants to take the risk of going bare or having a cut-rate policy that doesn't really cover the potential loss.[1] With Stark Law compliance, appropriately documented legal advice can help put the fire out before it consumes the entire structure.

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[1] The risk of a health system incurring a Stark Law FCA settlement loss is also significantly greater than the risk of a homeowner incurring a fire insurance loss. Only one in 360 homeowners incurs a fire/lightning loss in a given year with an average loss of approximately $68,000. In contrast, health systems have about a one in 77 chance of incurring a Stark Law settlement, and the average loss is over ***$26 million***.