KING & SPALDING

A SEA CHANGE

Biden Administration Healthcare

SUMMARY

As the Biden Administration takes the helm amid the apex of the most serious global pandemic in a century, the Healthcare industry remains front and center. Whether it is sweeping new legislation focused on delivering critical funding to providers on the front lines of administering COVID-19 testing, treatment and vaccines, or a series of new rules focused on delivering price transparency to healthcare consumers, healthcare providers must remain abreast of fast-moving developments. While vaccine priorities will continue to take center stage for much of 2021, we expect the Biden Administration to also continue to focus on developing the regulatory framework around digital health and price transparency, expanding access to care under the Affordable Care Act as well as focus on increasing healthcare fraud enforcement.

01 A Renewed Focus on Price Transparency

Centers for Medicaid and Medicare Services' ("CMS") hospital price transparency rule went into effect on January 1, 2021. The rule dramatically transforms hospitals' disclosure obligations requiring, for the first time, that hospitals publish detailed information regarding the specific rates for individual services they have negotiated with individual payors. We expect that the Biden Administration will use the price transparency rule as a key tool to advance an agenda that focuses on attempting to reduce prices for medical care. Indeed, in his Senate confirmation hearings, Secretary-designate Xavier Becerra pledged that he would pursue "robust enforcement" of the rule.

The hospital price transparency rule is only one component of the new legal regime. CMS has also expanded upon hospitals' price disclosure obligations in Medicare cost reporting rules that go into effect in 2021. Moreover, a new rule requiring similar pricing disclosures from payors will go into effect in the coming months, and both hospitals and payors will face additional price transparency obligations under the newly enacted federal No Surprises Act. This new regime presents a series of multi-faceted challenges for hospitals in their interactions not only with state and federal regulators but also with payors and the public.

We expect that the new Administration will use each of these tools in an effort to encourage or compel hospitals to disclose more pricing information. Although CMS has not yet publicly announced any enforcement activities under the hospital

price transparency rule, we anticipate that it will do so in the near future. Hospitals facing the possibility of enforcement actions will need to consider and weigh both the potential financial penalties that CMS could impose as well as the public relations considerations that would arise if the agency follows through on its threat to publicize hospitals' lack of compliance.

02 The No Surprises Act

The No Surprises Act, enacted on December 27, 2020, applies to protect patients who seek out-of-network emergency care or in-network, non-emergency care at a facility and then receive care from an out-of-network professional provider. When the No Surprises Act applies, providers are prohibited from billing patients more than the "in-network" cost-sharing, deductibles and out-of-pocket maximums. Providers are also prohibited from "balance billing" patients for more than in-network cost-sharing amounts. Payors, in turn, must issue payment directly to providers and are prohibited from issuing payments to patients.

Plans must disclose, on a public website and in applicable EOBs, the requirements and prohibitions against surprise billing, and the contact information for the appropriate state and federal agencies to notify when a provider or facility has violated such prohibitions.

The No Surprises Act applies to emergency services rendered through stabilization of the patient's medical emergency. Notably, the Act also applies to post-stabilization services that would be covered for in-network patients unless the patient is able to travel using non-medical transportation and informed consent is obtained from the patient. Under certain conditions, out-of-network providers of non-emergency care may request that a patient waive the protections of the Act.

To address provider/health disputes over appropriate reimbursement, the Act creates an independent dispute resolution ("IDR") process to resolve such disputes. By December 27, 2021, the Health and Human Services ("HHS") Secretary will establish a process to certify and recertify IDR entities to resolve these disputes in accordance with competency standards set forth in the Act.

Notably, when determining the appropriate rate of payment, IDR entities may consider many factors including the training and experience of the provider, the parties' respective market share and contracted rates between the parties. Perhaps more notable, IDR entities may not consider the hospital's charges or rates paid by public entities like Medicare and Medicaid. Because contract rates will be considered, we expect increased focus on managed care contract negotiations and rates.

The Biden Administration is expected to continue the policy of the No Surprises Act through the promulgation of a regulatory framework to support the law and the creation of the first federal payor-provider dispute resolution forum. If providers and payors participate in the IDR process, it could have a significant impact on out-of-network managed care disputes and reimbursement.

03 Biden Administration's COVID-19 Vaccine Priorities

On January 21, 2021, the Biden Administration released its National Strategy for the COVID-19 Response and Pandemic Preparedness, available here. The National Strategy is organized around seven goals, including to: (1) restore trust with the American people; (2) mount a safe, effective and comprehensive vaccination campaign; (3) mitigate spread through expanding masking, testing, data, treatments, healthcare workforce and clear public health standards; (4) immediately expand emergency relief and exercise the Defense Production Act; (5) safely reopen schools, businesses and travel while protecting workers; (6) protect those most at risk and advance equity, including across racial, ethnic and rural/urban lines; and (7) restore U.S. leadership globally and build better preparedness for future threats.

Orders and presidential appointments to date suggest that the President intends to follow through on many of these promises. In the first few months of his presidency, the Biden Administration has already taken many significant steps:

1. On February 17, 2021, the Biden Administration announced that it was increasing the weekly allocations of vaccine doses to states, tribes and territories from 11 million doses to 13.5 million doses. The Biden Administration is additionally doubling the weekly vaccine supply to local pharmacies from 1 million to 2 million doses.
2. On February 10, 2021, the Biden Administration announced members of the COVID-19 Health Equity Task Force. This task force will provide recommendations for addressing health inequities caused by the COVID-19 pandemic and for preventing such inequities in the future.
3. On February 2, 2021, the Biden Administration announced an increase in vaccine supply, the launch of the Federal Retail Pharmacy Program and the expansion of FEMA Reimbursement to the states.

4. On January 20, 2021, the Biden Administration issued an Executive Order on Organizing and Mobilizing the United States Government to Provide a Unified and Effective Response to Combat COVID-19 and to Provide United States Leadership on Global Health Security. The Executive Order establishes the position of a Coordinator of the COVID-19 Response to assist the President and coordinate activities of the Federal Government to combat COVID-19 and prepare for future biological and pandemic threats.

Vaccine guidance is rapidly changing and evolving. In the first town hall of his Presidency, on February 16, 2021, President Biden affirmed that COVID-19 vaccines would be widely available by the end of July. On March 3, 2021, the Biden Administration moved up the target by two months to May. We might expect additional executive orders and guidance on increasing supply and expanding eligibility categories in order to meet that goal.

04 Biden Administration Reopens Enrollment of Federal Exchanges and Announces Policies to Protect Medicaid, the ACA and Reproductive Health Care.

On January 28, 2021, President Biden signed an Executive Order on Strengthening Medicaid and the Affordable Care Act ("ACA") ordering the reopening of the Affordable Care Act's federal insurance marketplaces from February 15, 2021 – May 15, 2021, offering millions of Americans who need coverage during the COVID-19 pandemic an extended opportunity to purchase health plans on HealthCare.gov. President Biden also announced his policies to protect and strengthen Medicaid, the ACA, and access to reproductive health care. These actions signal a strong commitment by the Biden-Harris Administration to protect and build on the Affordable Care Act, meet the health care needs created by the pandemic, reduce health care costs, protect access to reproductive health care and increase efforts to make the health care system more equitable. A Fact Sheet regarding the Order was also published on January 28.

RE-EXAMINING MEDICAID AND THE ACA

The President will also direct federal agencies to reconsider rules and other policies that limit Americans' access to health care and consider actions that will protect and strengthen that access. As set forth in the Order, agencies are directed to re-examine:

1. Policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19;
2. Demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements;
3. Policies that undermine the Health Insurance Marketplace or other markets for health insurance;
4. Policies that make it more difficult to enroll in Medicaid and the ACA; and
5. Policies that reduce affordability of coverage or financial assistance, including for dependents.

As part of their reviews, agencies are required to consider whether to take additional actions to strengthen and protect access to health care.

05 CARES Act Provider Relief Fund Reporting and Preparing for Impending Audits

The Coronavirus Aid, Relief, and Economic Security ("CARES") Act and Paycheck Protection Act allocated $175 billion in grants to be distributed through the Provider Relief Fund ("PRF") to support healthcare providers affected by the COVID-19 pandemic. Throughout 2020, individual eligible healthcare providers received millions—in many cases *hundreds of millions*—of dollars through several rounds of PRF grant distributions. All eligible providers received funds simply because they certified that they treated actual or potential COVID-19 patients (General Distribution payments). Other providers received additional PRF payments that were targeted to address specific, challenging circumstances, such as hospital providers that were significantly impacted by large numbers of COVID-19 inpatients or rural providers who were struggling to meet a surge in cases with limited financial means to do so. In all cases, the CARES Act requires PRF recipients to use grant funds to cover expenses and lost revenues that are "attributable to" the coronavirus pandemic. All providers who receive funds are also required to certify that they will comply with a detailed set of Terms & Conditions that include prohibitions against balance billing "actual or presumptive" COVID-19 patients and using any PRF funds to pay salaries above the Federal Executive Level II salary limit ($197,300). Both the CARES Act and the Terms & Conditions prohibit providers from using PRF funds to cover expenses or lost revenues that were reimbursed by another source of funds, whether government or private.

HHS has issued more than 60 pages of Frequently Asked Questions ("FAQs") that address how HHS intends to enforce the obligations described above as well as other CARES Act requirements. The FAQs are notorious for their frequent changes and confusing (and sometimes contradictory) guidance. They cover such issues as how to determine when a

provider has been reimbursed for COVID-19-related expenses through increased payments for care, how to apply the $197,300 limit on salaries, under what circumstances large healthcare organizations with many PRF recipient subsidiaries can share funds among subsidiaries and the circumstances under which PRF recipients are obligated to return funds. In many cases, the guidance is sparse and open to legal interpretation.

All PRF recipients must report how they have used their PRF grants to cover their COVID-19-related expenses and lost revenues. HHS has pushed back the reporting deadline many times, and there are no detailed instructions or templates that explain how these reports must be prepared. Nonetheless, eligible healthcare providers—particularly those who received large amounts of PRF dollars—can anticipate that their reports will be the subject of audit and review. The HHS Office of Inspector General ("OIG") has already announced a focus on PRF audits in its Work Plan. We anticipate these audits will focus on the prohibitions and obligations described above.

Healthcare providers must be aware that there are no appeals from these audits. An adverse finding from the HHS OIG could lead to the provider forfeiting a portion or all of its PRF grant payments. In order to avoid this result, we have worked with clients to provide an assessment and legal review of their use of CARES Act funds as they prepare to defend these audits.

06 Enforcement Priorities.

The year 2020 undoubtedly brought about changes in the enforcement and compliance risk landscape for healthcare industry stakeholders. With the epochal government regulatory changes, programs and provider relief funding brought new frontiers in investigation and enforcement. There were seismic shifts in the ways healthcare industry stakeholders operationalized services to ensure continued delivery of care, products and services during the public health crisis brought about by COVID-19—all in the wake of rapidly evolving legislative actions, agency regulations, sub-regulatory guidance and enforcement activities at both the federal and state levels. And, significantly, there was quick Congressional action to provide financial support through the CARES Act and the Paycheck Protection Program and Health Care Enhancement Act (the "Paycheck Protection Act"), among other legislative actions.

The U.S. Department of Justice ("DOJ") swiftly prioritized detecting, deterring and punishing wrongdoing related to the pandemic and announced that as early as mid-March 2020, it was already learning of allegedly fraudulent schemes to exploit the national emergency caused by the pandemic that warranted a coordinated, nationwide response. All the while, ongoing enforcement actions and activities related to the pre-pandemic world continued. While specific areas of focus and new enforcement priorities will emerge as the Biden administration takes shape, certain areas appear ripe for enforcement activity moving forward – whether through False Claims Act ("FCA") enforcement or another type of enforcement action:

A. **Provider Relief Fund payments**. While CARES Act Provider Relief Fund payments undoubtedly have provided critical financial assistance for many recipients, tied to those funds are a number of terms and conditions, including requirements on eligibility, permitted and non-permitted uses of funds, balance billing, accuracy of provided information, reporting, records and audits and public disclosure of payments. Moreover, recipients of PRF payments must attest to acceptance of the Terms and Conditions and acknowledge as part of that attestation that full compliance with all the terms and conditions is material to the Secretary's decision to disburse funds. Not only are providers subject to recoupment during an audit, but failure to comply could subject the provider to False Claims Act liability.

B. **Telehealth services**. The use of telehealth services expanded exponentially in 2020 due to rapid regulatory and payment policy developments in the face of the public health emergency to facilitate care delivery in a virtual environment. Between mid-March and mid-October 2020, over one-third (24.5 million out of 63 million) of beneficiaries and enrollees received a Medicare telemedicine service. There has been significant enforcement activity involving telehealth services in recent years, including the national fraud takedown announced in September 2020 involving an alleged $4.5 billion of false and fraudulent claims submitted by more than 86 criminal defendants in 19 judicial districts related to schemes involving telemedicine. While there may be continued criminal enforcement activity rooting out bad actors and fraudulent schemes involving non-reputable providers, the avalanche of regulatory and payment policy changes on a compressed timeline, coupled with the exponential increase in virtual care delivery, sets the stage for focused attention on the civil enforcement side as well.

C. **COVID-19 Vaccines**. Healthcare providers and pharmacies across the nation are engaged in an unprecedented effort to vaccinate hundreds of millions of Americans against the coronavirus while dealing with immense logistical challenges associated with a nationwide vaccine program that is unfolding at striking speed and scale. However, providers should be mindful of the potential for liability under the FCA and federal Anti-Kickback Statute ("AKS") in connection with these efforts. In return for free doses of the vaccine and the right to bill the government for the cost of

administering the vaccine, providers sign an agreement with the CDC promising to comply with a host of federal rules, which contains an express statement warning providers that non-compliance with agreement terms may result in criminal and civil penalties under federal law, including the FCA. For example, participating providers must navigate an ever-changing labyrinth of allocation rules at various levels of government. Giving the vaccine to people outside these rules, and then billing the government for the cost of administering the vaccine, could potentially lead to a False Claims Act inquiry. And in a world where there is immense demand for the vaccine, it is not far-fetched to think of potential scenarios under which one could allege a violation of the AKS, such as, for example, an alleged scheme to provide "remuneration" to physicians and other referral sources in the form of early access to vaccination doses for family members to induce (or reward) referrals of items or services reimbursed by federal health care programs.

07 Digital Health

As a general matter, support to advance digital health technologies is relatively bipartisan, and we expect that the Biden Administration, like the Trump Administration, will continue to focus on digital health products. Democrats and Republicans alike have sought to ensure that innovation in this space is not stymied by over-regulation.

Toward that end, last September, the Food & Drug Administration ("FDA") launched the Digital Health Center of Excellence within FDA's Device Center to help digital health products realize their full potential to empower more informed decision making by patients and physicians and to ensure comprehensive and consistent oversight. The FDA, under the Trump Administration, also issued a number of guidance documents announcing that it would not actively regulate certain low risk digital health devices. This guidance includes: (1) FDA's Guidance for Clinical Decision Support Software; (2) FDA's Guidance for Mobile Medical Apps; (3) FDA's Guidance on General Wellness Products; and (4) FDA's Guidance on Medical Device Data Systems, Medical Image Storage Devices and Medical Image Communication Devices.

The policies underlying these guidance documents, however, were not new and many were developed during the Obama Administration. The first iteration of the Guidance for Mobile Medical Apps, for example, was issued in 2013; and the statutory provisions that gave rise to the FDA's Guidance for Clinical Decision Support Software were enacted in 2016. Significantly, Bakul Patel, who was appointed the Director of the Digital Health Center of Excellence in September 2020, has been a thought leader at FDA in the digital health space since 2010. Therefore, we do not expect dramatic changes in the Biden Administration's approach to digital health regulation.

We expect that FDA's new Digital Health Center of Excellence will continue to focus on:

ENABLING DIGITAL HEALTH TOOLS THAT IMPROVE ACCESS TO CARE

Even before COVID-19, disruptive digital health technologies and platforms were beginning to enter the market in a way that better enabled access to care. For example, the FDA recently authorized a device that uses artificial intelligence (AI) to diagnose diabetic retinopathy. The device has an algorithm that analyzes images taken with a retinal camera and uploaded to a cloud server. Within minutes, the software can provide primary care doctors with a binary result indicating that the screening is negative or positive and that the patient should be referred to an eye care professional. Given that only 50% of diabetic patients see an eye doctor regularly, use of this type of diagnostic by primary care doctors could help millions access better care.

The pandemic, of course, has accelerated the use of digital technologies that enable access to care. For example, many clinical trial sponsors have adopted telehealth and remote patient monitoring technologies; mobile medical apps have been used to support public health surveillance, to disseminate educational materials and to keep patients and health care professionals connected. Regulatory relief from CMS also enabled many health care professionals to shift to virtual visits to reduce the risk of spreading COVID-19.

Since the pandemic began, the FDA has also issued a number of guidance documents with temporary policies aimed at increasing the use of helpful technologies, such as contact-free digital thermometers. Although many of these polices are intended to last only for the duration of the pandemic, the FDA is likely to build upon inroads that have been made in this space. For example, the FDA intends to work toward continued and greater utilization of digital technologies in clinical trials and toward utilizing real-world data regarding the benefits and risks of digital health products used during the pandemic to expedite regulatory decisions on those products when the pandemic is over.

ARTIFICIAL INTELLIGENCE/MACHINE LEARNING

On January 12, 2021, the FDA issued an action plan titled "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device ("SaMD") Action Plan," which describes a multi-pronged approach to advancing FDA's oversight of AI/ML-based software. The plan responds to a discussion paper on AI/ML that FDA circulated in 2019, and it indicates that FDA will:

(1) issue draft guidance on a predetermined change control plans (for software's learning over time); (2) support the development of good machine learning practices to evaluate and improve machine learning algorithms; (3) foster a patient-centered approach, including device transparency to users; (4) develop methods to evaluate and improve ML algorithms; and (5) advance real-world performance monitoring goals.

PRE-CERTIFICATION PROGRAM

For the last several years, the FDA has been operating a pre-certification pilot program to help inform the development of a regulatory framework for more streamlined and efficient regulatory authorizations for SaMD. The program envisions moving from episodic oversight to more continuous oversight, and it would ideally allow for less stringent oversight of products that are developed by companies that implement certain principles of excellence. The pilot program has been criticized as being susceptible to bias, and there have been questions as to whether the program will actually be faster and less burdensome. The program has also been criticized as lacking appropriate authority. We expect the FDA to push for legislation expressly giving the Agency authority for the program, as part of the user fee reauthorization legislation in September 2022, and the industry will want to monitor the development of the legislation closely.

CYBERSECURITY

Currently, there is no statutory requirement (pre- or post-market) that expressly compels medical device manufacturers to address cybersecurity (although there is FDA guidance that addresses cybersecurity issues). FDA's FY 2021 Budget includes a legislative proposal that would, among other things, require: (1) devices have the capability to be updated and patched in a timely manner; (2) premarket submissions to FDA include evidence demonstrating the capability from a design and architectural perspective for device updating and patching; and (3) device firms publicly disclose when they learn of a cybersecurity vulnerability. Although the FY 2022 Budget document has not yet been released (as of March 17, 2021), we expect FDA to continue to pursue this new authority, perhaps with the user fee reauthorization legislation in September 2022.

REGULATION AND REIMBURSEMENT

On March 2, 2021, the Subcommittee on Health of the Committee on Energy and Commerce ("Subcommittee") held a hearing entitled, "The Future of Telehealth: How COVID-19 is Changing the Delivery of Virtual Care." The Subcommittee first detailed the expansion of telehealth services which occurred during the COVID-19 pandemic. During COVID-19, the HHS secretary waived certain Medicare, Medicaid and CHIP requirements, such as the originating site and rural health professional shortage area ("HPSA") requirements, permitting additional types of healthcare providers, such as physical and occupational therapists, to bill for telehealth services and for certain services to be provided by telephone. These waivers will remain in place throughout the public health emergency ("PHE").

The Subcommittee stressed that utilization of telehealth services increased markedly during the COVID-19 pandemic. Prior to the COVID-19 PHE, only 15,000 FFS Medicare beneficiaries received telemedicine services each week. Preliminary data indicates that between March and October 2020, more than 24.5 million Medicare beneficiaries received a telemedicine service during the public health emergency.

While public and private sector have expressed interest in expanding access to telehealth services after the pandemic resolves, the Subcommittee emphasized that additional data must be obtained to help prevent overutilization of low-value care. Legislation proposed during 2020 additionally suggested that various entities should conduct studies to improve telehealth services. While pending legislation from the last Congress will have to be reintroduced, additional studies will likely be conducted to determine how to improve these virtual services while expanding them.

Access to telehealth services will likely continue to expand throughout 2021. For example, the CARES Act provided $200 million for the FCC to advance telehealth. The FCC approved a COVID -19 Telehealth Program to use the $200 million to assist healthcare providers that purchase telecommunications services, broadband internet access and technological devices necessary for providing telehealth services in response to COVID-19. In addition, additional geographic restrictions may be removed permitting telehealth services to be administered to additional beneficiaries in their homes after the public health emergency. For example, the Consolidated Appropriations Act, which became effective in December 2020, waived the geographic and originating site requirements for mental health services delivered via telehealth.

The Biden Administration will also likely examine potential fraud associated with telehealth services. The Subcommittee noted that recent HHS OIG work has uncovered approximately $4.5 billion in telehealth related fraud. The HHS OIG has announced plans to examine the impact of the rapid adoption of telehealth services during the pandemic, particularly with respect to Medicare program integrity. As the legal and regulatory landscape is continuously evolving, providers should consult with legal counsel to ensure that their telehealth services comply with both state and federal laws during and after the public health emergency.