Chapter 4

Advancing the Quality and Efficiency of America's Healthcare System

In the face of the global COVID-19 pandemic, the Trump Administration has taken decisive action to address the strain the health and economic crisis placed on the healthcare sector and on working families. This response has been twofold: financial support for hospitals and workers, and deregulation within the healthcare sector to accelerate the availability of testing and the development of vaccines and advanced therapeutics.

In March 2020, President Trump signed the bipartisan CARES Act, which appropriated $100 billion for healthcare providers, and which has alleviated the financial burden hospitals are experiencing during the COVID-19 pandemic. This was supplemented by an additional $75 billion for the Provider Relief Fund as part of the Paycheck Protection Program and Health Care Enhancement Act, and also funding for testing provided by the Families First Coronavirus Relief Act, resulting in $175 billion in direct aid to the healthcare sector. As a result, the CEA finds that the healthcare system has been one of the most resilient industries during the COVID-19 pandemic. The Administration also established emergency paid family and sick leave through tax credits available to private employers with fewer than 500 employees for leave payments through December 31, 2020. This has served to protect public health by encouraging workers to stay home rather than working while ill, and has allowed employees to care for sick family members without trading off work hours. In addition, the Administration provided funds to offer COVID-19 testing and treatment at no cost to uninsured patients, removing cost barriers for low-income and high-risk

individuals—and, in turn, helped the United States identify positive COVID-19 cases and mitigate the effects of the COVID-19 pandemic.

When the United States needed to ramp up its testing capabilities for the virus at the onset of the COVID-19 pandemic, the Trump Administration, through the Food and Drug Administration (FDA), took action to issue Emergency Use Authorizations for COVID-19 diagnostic tests. As a result, the FDA permitted the use of over 20 diagnostic COVID-19 tests by the end of March 2020, helping public health officials track the spread of the coronavirus throughout the United States.

Similarly, the Centers for Medicare & Medicaid Services relaxed many of the regulations surrounding the use of telemedicine to allow patients seeking COVID-19 screening or advice on non-life-threatening conditions to do so from the safety of their homes. This reduced nonessential in-person healthcare visits, decreasing the strain on overburdened healthcare facilities and diminishing the potential transmission of COVID-19 throughout hospitals and healthcare facilities.

In one of the largest efforts during the pandemic, the Trump Administration mobilized the public and private sectors through Operation Warp Speed (OWS) in order to accelerate the development, production, and distribution of a safe and effective COVID-19 vaccine. OWS accomplishes this by identifying promising vaccines earlier in development, standardizing testing protocols, preparing manufacturing capacity, and funding infrastructure for vaccine distribution. Not only will the accelerated vaccine timeline provide an enormous benefit to public health, but the CEA estimates that OWS could provide an economic benefit of $155 billion if it pushes the arrival of the vaccine one month earlier, or $2.4 trillion if scientists were to deliver the vaccine by January 1, 2021. As of mid-November 2020, four vaccine candidates had entered Phase III clinical trials. The highly promising results of interim analyses of these candidates raise the possibility that researchers may develop a vaccine before the end of 2020 for widespread use among a set of targeted populations.

The deregulatory actions of the Trump Administration can continue to improve healthcare outcomes for the American people far beyond the scope of the COVID-19 pandemic. For example, the CEA estimates that more widespread adoption of telemedicine would allow rural Americans to save $130 per visit in travel-related opportunity costs while increasing their access to high-quality healthcare nationwide. In addition, the CEA estimates that a permanent reduction in FDA approval times by one, two, or three years for new drugs would provide trillions of dollars in social surplus. Moreover, the CEA calculates that expanding occupational licensing deregulation for nurse practitioners nationwide could result in $62 billion in cost savings annually. Also, this chapter explores the effects of several healthcare policy achievements beyond the response to the COVID-19 pandemic that will promote additional choice and competition in the market. Permanently deregulating aspects of the healthcare sector will provide better healthcare options and higher monetary savings for Americans as the Nation emerges from the COVID-19 pandemic.

The United States endured a major adverse health and economic shock in 2020 due to the arrival of the SARS-CoV-2 virus in the United States. The impact of this pandemic is likely to persist past 2020 as widespread mitigation takes hold. COVID-19—the disease stemming from the novel coronavirus—led to a global pandemic that, as of November 2020, has resulted in over 50 million confirmed cases worldwide and a global death toll of at least 1.25 million people. In the United States, there have been over 10 million confirmed cases and over 230,000 deaths. This disease has taken a toll on the American people that has been manifested not just as a tremendous mortality and morbidity burden, but also as a significant economic burden that affects the Nation at every level. In the first and second quarters of 2020, the U.S. economy contracted by 10.2 percent, and total employment declined by 14.5 percent between February and April 2020 after a record 20.8 million decrease in employment in April. At its peak, the unemployment rate was 14.7 percent in April. Initial claims for regular State unemployment insurance peaked in the week ending March 28, at 6.9 million, whereas insured unemployment in regular State programs peaked in the week ending May 9, at 24.9 million. This unprecedented level of economic disruption resulted in the highest levels of unemployment since the Great Depression, and had a direct impact on the economic well-being of millions of Americans.

COVID-19's dual effects on public health and the economy necessitated a response on two fronts. The first one, as discussed in the previous chapters of this *Report*, has consisted of efforts to address the economic effects of the crisis. The second front, which this chapter discusses, is the Trump Administration's efforts to address the underlying health crisis itself.

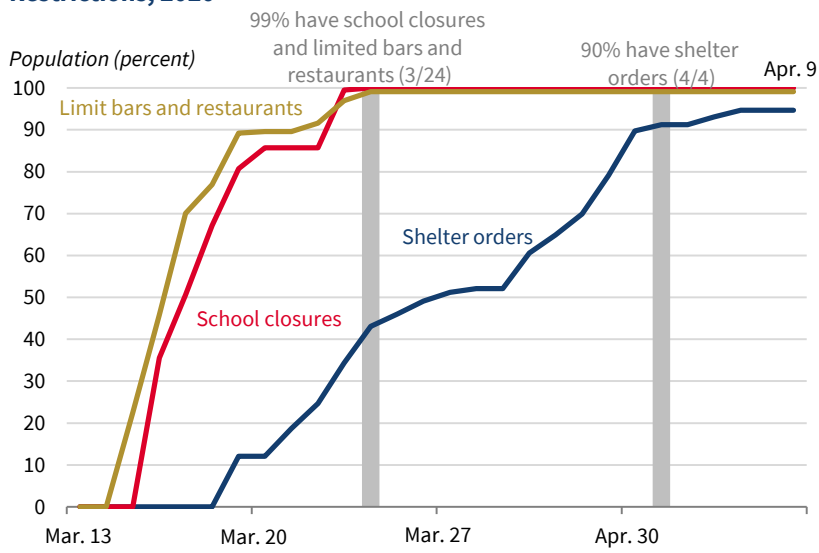
The resolution of any healthcare crisis relies largely on the efforts of three groups of people. First, it relies on the efforts of scientists to develop new treatments and tests for the disease. Second, it relies on the efforts of healthcare providers and healthcare systems to treat affected patients. And third, it relies on the efforts of the public to take appropriate actions during the crisis. These efforts require coordinated governance at the local, State, and Federal levels.

At the Federal level, the Trump Administration moved to eliminate regulatory barriers that could hinder the development of new treatments or the ability of healthcare providers to care for their patients. The CEA finds that these deregulatory efforts have had tremendous economic value. For example, the Centers for Medicare & Medicaid Services (CMS) relaxed many of the regulations surrounding the use of telemedicine and the share of telemedicine Medicare primary care visits increased dramatically, from 0.1 percent in February to 43.5 percent in April.

In addition, understanding that healthcare during a pandemic requires an economically strong healthcare system, the Administration moved to ensure the financial security of the healthcare system. Under the CARES Act and the Paycheck Protection Program and Health Care Enhancement Act (PPP/HCE Act), Congress made up to $175 billion available for healthcare providers to support their financial health and livelihood. As a result of this and other Administration actions, the CEA finds that the healthcare system has been one of the most resilient industries during the first three quarters of 2020 based on employment, and indeed appears to be one of the industries that recovered most quickly from the initial shock caused by COVID-19. A key threat to the healthcare system early during the pandemic was sudden surges in demand for healthcare services that overwhelmed locally available resources. To combat this risk and slow the spread of the virus more broadly, local and State governments began implementing lockdown orders and other restrictions to combat the spread at the cost of economic activity. As the pandemic spread throughout the country, lockdown measures expanded commensurately, with over 99 percent of the population residing in States that had closed schools and limited bar and restaurant activity by March 24, and with over 90 percent residing in States that had issued shelter-in-place orders by April 4 (figure 4-1).

Finally, the Trump Administration's efforts focused on protecting Americans from the costs of care related to COVID-19 and on providing incentives for Americans to engage in appropriate behaviors during the crisis. For example, the Administration established emergency paid family and sick leave for COVID-19 patients to encourage these patients to stay at home instead of

Figure 4-1. Percentage of U.S. Population under Statewide Restrictions, 2020



Sources: *New York Times*; State policy announcements; CEA calculations.

working while ill. This also allowed family members to take leave so they could look after those affected by COVID-19. Similarly, though much has been written on the Administration's effort to increase testing capacity, from an economic perspective, other important—and overlooked—parts of its approach were its efforts to decrease the barriers for Americans to receive testing. In the absence of treatment, testing may be of limited value to the individual, because a positive test will have little impact on disease management. However, testing does provide social value from a public health perspective, because it enables public health approaches that can limit the spread of the disease such as quarantining and contact tracing for infected individuals. Because individuals do not face the full social incentives for testing, making COVID-19 testing free at point-of-care by requiring that it be covered by insurers and reimbursing providers for the cost of testing for the uninsured are an important way to align the individual and social incentives for testing. The Kaiser Family Foundation found that, in July 2020, data from 78 hospitals revealed that COVID-19 diagnostic test prices ranged from $20 to $850 per diagnostic test, with a median cost of $127. The Administration's subsidies probably increased the likelihood of COVID-19 testing, especially for lower-income Americans.

The President's response to the unique dual health and economic crises caused by COVID-19 include an agenda for healthcare reform and deregulation. Although regulation is intended to benefit the public, whether it actually does so in practice is an empirical question, one that has been partly answered by

the Administration's efforts to suspend and relax many regulations to address COVID-19. The benefits of deregulation to bolster the pandemic response are clear. For example, effective treatments and vaccines for COVID-19 have been and will be introduced at an extremely fast pace, and healthcare providers face fewer restrictions in providing care. If the absence of many regulations has improved social welfare, a natural question is why these regulations need to be reimposed when the pandemic subsides. Indeed, the CEA finds substantial benefits from extending many of the existing deregulatory efforts. For example, the CEA finds that expanding occupational licensing deregulation nationwide could result in $62 billion in cost savings annually.

This chapter begins with an overview of the Administration's efforts to promote research and development for COVID treatments and vaccines, followed by a discussion of the Administration's efforts to support the healthcare system. Next, we discuss the Administration's effort to protect the broader American public by subsidizing appropriate behaviors and the cost of COVID care. Finally, we conclude with an analysis of how healthcare can be improved by extending COVID-19 related reforms.

Expediting Research and Development for Novel Therapies and Tests for COVID-19

One important aspect of research and development for COVID-19 treatments and vaccines is the issuance of Emergency Use Authorizations to facilitate availability of pharmaceutical products in the event of an emergency. In addition, to accelerate the availability of effective COVID-19 therapeutics and vaccines, the Administration launched Operation Warp Speed, a public-private partnership to support the development, production, and distribution of treatments, diagnostics, and vaccines.

Emergency Use Authorizations

Ultimately, the solution to any healthcare crisis is to find a treatment for the underlying disease, and the Trump Administration moved aggressively to field treatments as quickly and in as widespread a manner as possible. A key roadblock in the development of treatments is the heavily regulated drug and vaccine development processes. On average, it takes 10 years to bring a new drug or vaccine to market, with just the preclinical phase of vaccine development taking six months to three years (André 2002; CEA 2019; DiMasi, Grabowski, and Hansen 2016; Grady et al. 2020; Mullard 2020; Plotkin et al. 2017; Pronker et al. 2013). These timelines are not tenable in the face of a global pandemic.

Early returns from these efforts appear promising. For example, Remdesivir, an antiviral, received an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) on May 1—within 3.5 months of the first reported case of COVID-19 in the United States. By October 22, Remdesivir

had been approved by the FDA for treatment of COVID-19. Similarly, the Trump Administration quickly solved early COVID-19 testing capacity problems. Pre-pandemic FDA rules required that the FDA provide premarket clearance, approval, or EUA review for COVID-19 diagnostic tests before their use in clinical labs, which led to significant delays in adequate testing capacity at the onset of the COVID-19 pandemic. Indeed, in February, only CDC's COVID-19 diagnostic test had been authorized by the FDA for emergency use in labs across the nation. While it can take years for the FDA to ultimately approve new diagnostic tests, by the end of March 2020, the FDA had issued EUAs permitting the emergency use of over 20 diagnostic tests for COVID-19 (FDA 2020; Ivanov 2013). This rapid access to numerous COVID-19 tests was made possible by FDA granting unprecedented flexibility to manufacturers and labs, including allowing labs to begin developing and using their own tests before FDA review of their validation data. And finally, as of September 2020, four vaccine candidates had entered Phase III clinical trials, raising the possibility that a vaccine may be developed before the end of 2020 (Milken Institute 2020).

Emergency Use Authorization is an authority granted to the FDA by the Federal Food Drug and Cosmetic Act, and it allows the FDA to permit the production and distribution of an unapproved product or temporarily allow an unapproved use of an approved product during a state of emergency. This does not constitute approval of the new product or use and can be revoked by the FDA once the emergency has ended or evidence arises that suggests that the EUA is not in accordance with public health. EUAs have been employed in previous pandemics, including for the development of influenza testing and treatment as well as the test for the Novel Coronavirus 2012, more commonly known as Middle East Respiratory Syndrome (MERS).

Operation Warp Speed

The Trump Administration also worked to expedite the development and large-scale production of new vaccine treatments. Operation Warp Speed (OWS) is a public-private partnership that encompasses most of these Administration efforts to expedite the availability of vaccines. OWS accelerated vaccine deployment by identifying promising vaccines earlier in development, standardizing safety and efficacy protocols, preparing manufacturing capacity, and funding infrastructure for vaccine distribution.

Under a traditional timeline, a COVID-19 vaccine would likely not be ready until September 2021. But under OWS, initial doses of the vaccine could become available as early as the end of December 2020 or beginning of January 2021. If OWS accelerates initial vaccine deployment by these 8 months, the CEA estimates that OWS would save $2.4 trillion in economic and health costs. Even if OWS only accelerates a vaccine by one month, OWS still provides an expected benefit of $155 billion.

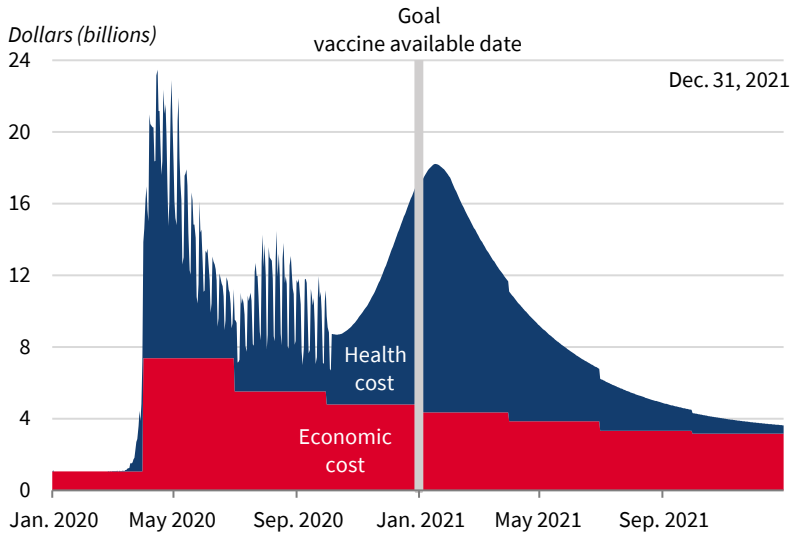
Traditionally, vaccine candidates are developed individually by different firms and are not compared with each other until after they are approved and commercialized. However, under OWS, animal studies of candidate vaccines were compared with each other (before additional testing in humans) to ensure that resources were directed toward the most promising candidates. As of August 31, the Federal government financially supported and approved additional testing for seven vaccine candidates. Notably, OWS does not change the number or types of trials required for vaccines, nor their safety and efficacy tests, but it does change when they can occur.

Moreover, manufacturing and distribution infrastructure are typically not established until a vaccine has demonstrated safety and efficacy in clinical trials, leading to additional delays in vaccine deployment. But under OWS, the Federal government invested in manufacturing capacity for the promising vaccine candidates while they were still being tested, rather than waiting until they were approved. Manufacturing capacity that is developed will be used for whatever vaccine is eventually successful, if possible given the nature of the successful product, regardless of which firms have developed the capacity. OWS also preemptively expands the supplies of materials that are necessary to scale up production of any vaccine, such as glass vials. On October 16, the President announced that the department of Health and Human Services (HHS) and the Department of Defense will form a partnership with CVS and Walgreens to deliver the vaccine once it is available to vulnerable Americans in long-term-care facilities, free of charge.

The CEA estimates that OWS has the potential to bring tremendous economic benefits, given COVID-19's unprecedented costs. Figure 4-2 provides an estimate of the daily cost to the United States of not having a vaccine, separated into the costs due to COVID-19 deaths (health costs) and the costs due to lower economic activity (economic costs). As is common for many infectious diseases, the economic costs of preventing a disease are often of comparable magnitudes to the direct mortality and health costs induced by the disease. Daily costs were highest in early April due to the peak of COVID-19 deaths at that time. However, one prominent model, that of the Institute for Health Metrics and Evaluation (IHME), projects a second wave in 2021, which suggests the possibility of additional high future costs. Though IHME is just one among several COVID-19 forecasting models currently used by public health authorities, it is the only one that has released 2021 projections.

Figure 4-2 demonstrates why even small delays in vaccine deployment can be costly. Consider a vaccine that has initial doses deployed on January 1, 2021, which is shown by the gray vertical line. In this case, the value of the vaccine is equal to the sum of the daily health costs for all days January 2, 2021, or later, plus the sum of the daily gross domestic product costs through April 1, 2021, or later—assuming that it will take 90 days for the economy to return to normal. However, the vaccine cannot reverse damage that has already

Figure 4-2. Daily Health and Economic Costs of COVID-19 to the United States If No Vaccine Is Found



Sources: Institute for Health Metrics and Evaluation; Centers for Disease Control and Prevention; Congressional Budget Office; CEA calculations.

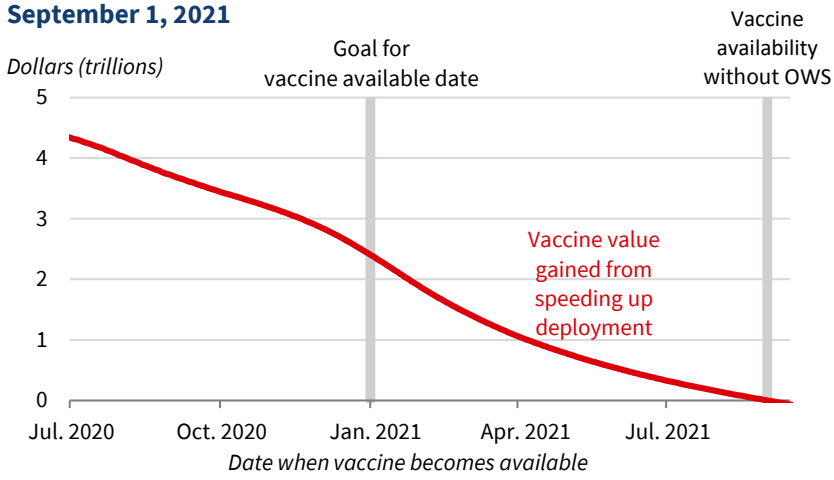
occurred, so the costs to the left of the gray line cannot be recovered, even with the introduction of a vaccine in January 2021.

Figure 4-3 demonstrates the value of faster vaccine development. We assume that without OWS, a vaccine would be available in September 2021, based on internal HHS projections. However, this should be viewed as a lower-bound estimate of the benefits of OWS, given that vaccines traditionally take 10 years to develop. The vertical axis gives the dollar value of an earlier vaccine, depending on the date at which it becomes initially available (horizontal axis). If OWS could accelerate vaccine deployment by 8 months (from September 1, 2021, to January 1, 2021), then the CEA estimates that the benefits would be $2.4 trillion above traditional deployment (the intersection of the red line and the left vertical gray line in figure 4-3).

The full value of the vaccine on January 1, 2021, would be $3.8 trillion. Some estimates suggest that traditional vaccine development processes would not result in a COVID-19 vaccine until September 2021, at which point it would provide benefits of $1.4 trillion. The benefit of the eight-month acceleration from OWS ($2.4 trillion) is the difference between the $3.8 trillion value in January and the $1.4 trillion value in September.

The CEA's methodology to create figures 4-2 and 4-3 has two aspects. First, for the value of lives lost (the health cost), the CEA used a widely cited model developed by the IHME. The model's most recent update reports the actual number of COVID-19 deaths in the United States for each day between

Figure 4-3. Value of Speeding Up a COVID-19 Vaccine Starting September 1, 2021



Sources: Institute for Health Metrics and Evaluation; Centers for Disease Control and Prevention; Congressional Budget Office; CEA calculations.
Note: OWS = Operation Warp Speed.

February 4 and October 19, 2020, and then projects the daily number of deaths for each day through February 1, 2021. The CEA lacks information on what will happen after February 1, and thus assumes, for this exercise (absent a vaccine), a 1 percent daily decline in deaths after February 1, 2021, recognizing that costs would be greater or less if the future path of pandemic mortality were more or less severe. The CEA then converted the number of deaths for each day to an economic cost by using the age-adjusted value of a statistical life, which is the standard way of evaluating economic costs of mortality (CEA 2019). The CEA assumes that as soon as the vaccine becomes available, it will immediately eliminate the health costs of COVID-19. However, because the vaccine will take time to deploy, only critical populations will get access to it first, and many will not take the vaccine at all, the CEA notes that this is a very optimistic scenario.

Second, to estimate the value of forgone gross domestic product (the economic cost), the CEA used the Congressional Budget Office's forecasts (CBO 2020) through 2022 to calculate the output losses between the current and pre-COVID baseline (January 2020) projections. These projections only take into account current law, meaning that the projections do not take any additional fiscal relief packages into account. Once a vaccine is available, for the sake of simplicity, the CEA optimistically assumes that the economy will return to pre-COVID conditions after 90 days, although it is likely that COVID-19 may have inflicted some permanent scarring on the economy.

Although the CEA makes these optimistic assumptions for simplicity, they do not significantly bias the estimate of the value of OWS. This is because they apply equally to both the case that a vaccine is developed by January

2021 and the counterfactual comparison without OWS that it is not developed until September. The CEA's analysis likely underestimates the true value of a COVID-19 vaccine because it does not include harder-to-measure factors such as loss of human capital and non-COVID negative health effects or the value of a vaccine to countries other than the United States.

Supporting the Healthcare System

Along with the Administration's efforts directly related to the COVID-19 pandemic, it is undertaking deregulatory initiatives to support the healthcare system more broadly. In addition, providing financial support to healthcare providers is critical to avoid exacerbating health risks for Americans.

Deregulation

Beyond working toward a vaccine, the Trump Administration has expanded short-term supply of healthcare services to meet the needs of the pandemic by enacting a variety of deregulatory actions across Federal agencies. Some of the larger changes, such as granting nurse practitioners more autonomy by loosening scope-of-practice regulations and removing restrictions on the provision of telemedicine, are dealt with more thoroughly later in this chapter because they represent significant opportunities for long-term improvements in the regulatory space. In addition to these major actions, regulators at various agencies within HHS took a number of less quantifiable but significant actions that increased the capacity of healthcare providers to meet the needs of their communities.

One of the primary public health concerns at the onset of the pandemic was the dearth of testing capabilities. To quickly expand diagnostic capacity, the FDA utilized EUA procedures and allowed for the production of tests earlier in their life cycle. To supplement these actions on the production side, the Trump Administration increased consumers' ability to access COVID-19 diagnostic testing by relaxing scope-of-practice regulations with regard to which healthcare providers were able to administer testing and by reducing or eliminating the out-of-pocket cost of testing through the CARES Act. The National Institutes of Health expanded on diagnostic efforts by investing in improvements in rapid testing technology.

As some localities began to be hit hard by COVID-19 outbreaks, one of the key public health risks was the limited supply of healthcare providers. To address this concern, CMS relaxed a plethora of occupational licensing restrictions to increase the number of providers. The supply of doctors and nurses was increased by allowing those with licenses that had expired or were still under review to practice. CMS also used deregulatory action to increase the supply of other healthcare workers by waiving certain licensing requirements for positions like nurse aides and paid feeding assistants. Such actions were

particularly beneficial for hard-hit long-term-care facilities, whose patients are disproportionately at risk from COVID-19. CMS also encouraged out-of-State practitioners to assist in harder-hit areas by removing Federal restrictions on their ability to provide care to Medicare beneficiaries outside their State of licensure.

The Administration also helped to mitigate dangerous shortages of personal protective equipment (PPE). During the early months of the pandemic, a key risk to healthcare workers was the limited supply of PPE and stringent Federal regulations on how it must be used. To provide a temporary increase in the supply of PPE and protect healthcare providers working in settings that put them at high risk of contracting COVID-19, the FDA's EUA and the Families First Coronavirus Relief Act (FFCRA) allowed for highly protective facemasks initially designed for use in industrial settings to also be used in medical settings. Furthermore, CMS removed regulations that limited the ability of healthcare providers to store and reuse masks, which gave hospitals increased autonomy in determining what PPE policies they wanted to implement and substantially decreased demand for new masks in facilities that chose to capitalize on the deregulation.

In addition to using deregulation to increase the number of healthcare providers and the supply of PPE, the Trump Administration loosened regulations of hospital classifications and facilities. To reduce the spread of COVID-19 within hospitals, HHS allowed hospitals to screen potential patients offsite to prevent the spread of COVID-19. As hotspots arose in large cities, CMS allowed for the expansion of patient care areas to respond to sudden increases in demand for medical services. CMS also waived eligibility requirements for several classifications of rural hospitals to allow them to expand their capacity and serve their communities during the pandemic. Many of CMS's deregulatory actions for facilities benefited long-term-care facilities, including waiving resident group requirements for in-person meetings, statutory limitations on transfers and discharges, and requirements to honor resident roommate requests. All these actions were undertaken to decrease the risk of COVID-19 spreading among both the patient and provider populations.

Finally, CMS temporarily waived a number of paperwork and bureaucratic requirements during the pandemic to allow healthcare providers to make informed decisions about how to prioritize their time and best meet their patients' needs. These included regulations of the time frame for reporting requirements, the necessity of verbal orders, discharge planning, emergency preparedness plans, patient privacy, utilization reviews, and food plans.

Financial Support for Healthcare Providers

The COVID-19 pandemic represented a threat to the financial solvency of healthcare providers across the country, restricting their ability to ensure high-quality

care for patients in their communities. In response, the Administration worked with Congress to pass the CARES Act, which established the Provider Relief Fund to help healthcare providers in the midst of the pandemic. The CARES Act, through HHS, made up to $100 billion available to eligible hospitals and other healthcare providers, which constituted about 4.5 percent of spending from the bill. The PPP/HCE Act provided an additional $75 billion for the Provider Relief Fund to reimburse healthcare providers for expenses related to healthcare and lost revenues that are attributable to COVID-19. In addition, the PPP/HCE Act provided $25 billion to help increase COVID-19 testing. This includes up to $1 billion to reimburse the cost of testing uninsured individuals, in addition to the $1 billion previously appropriated for this purpose by the FFCRA.

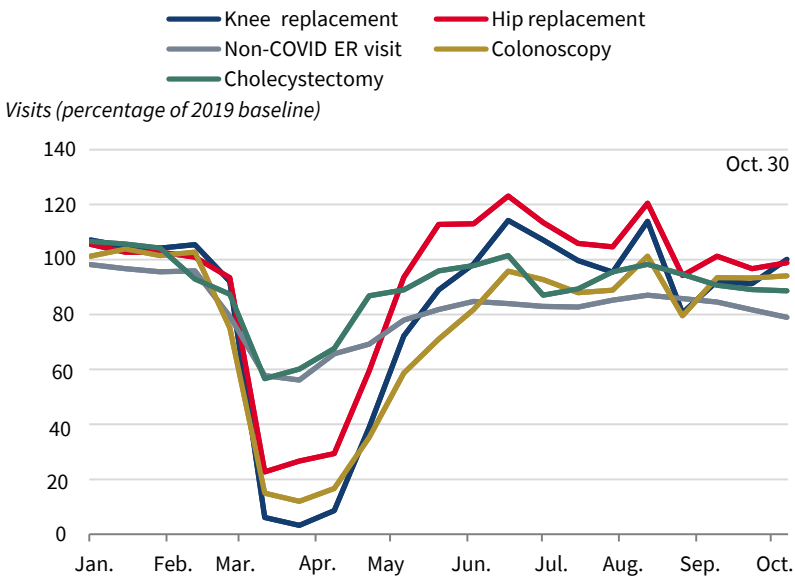
The FFCRA also, as amended by the CARES Act, requires Medicare Part B, State Medicaid, Children's Health Insurance Programs (CHIP), and group health plans and health insurance issuers to cover COVID-19 diagnostic testing without cost sharing for patients. Uninsured individuals may also obtain COVID-19 diagnostic testing free of charge under the State Medicaid programs, if the State offers this option. CMS has developed an accessible, easy-to-use toolkit for States to amend their Medicaid programs so they can offer this service. The CARES Act also appropriated $150 billion for the Coronavirus Relief Fund, which is administered by the Department of the Treasury, to reimburse expenses incurred by State, local, and Tribal governments as part of their response to the COVID-19 pandemic.

With funding allocated by the CARES Act and the PPP/HCE Act, HHS can allocate up to $175 billion of aid to eligible hospitals and other healthcare providers to offset these costs. Over $100 billion had been paid to hospitals and other providers by early October. This includes relief to hospitals that serve the most vulnerable segment of the population as well as rural hospitals and those in small metropolitan areas.

Canceling elective surgeries played a major role in declining revenue for many providers. Following the advice of both State-level policymakers and the surgeon general, in mid-March, elective surgeries were canceled or postponed as part of the effort to curb the spread of COVID-19 and prevent the potential straining of healthcare infrastructure and resources during the pandemic. Figure 4-4 shows the decline and subsequent recovery of five types of visits of Medicare patients relative to the comparable week in 2019, with total knee arthroplasties reaching as low as 3.2 percent of their baseline volume in mid-April. As restrictions were lifted throughout the summer, elective surgery volumes rebounded, with most at or near their baseline figures by early July. This likely represents a temporary surge in volume for those who rescheduled surgeries immediately after the end of restrictions but an overall lower demand for elective surgeries in the Medicare population.

However, due in part to the financial support that was provided to providers, healthcare has proven to be one of the most resilient labor markets

Figure 4-4. National Medicare Utilization, Jan. 10–Oct. 30, 2020

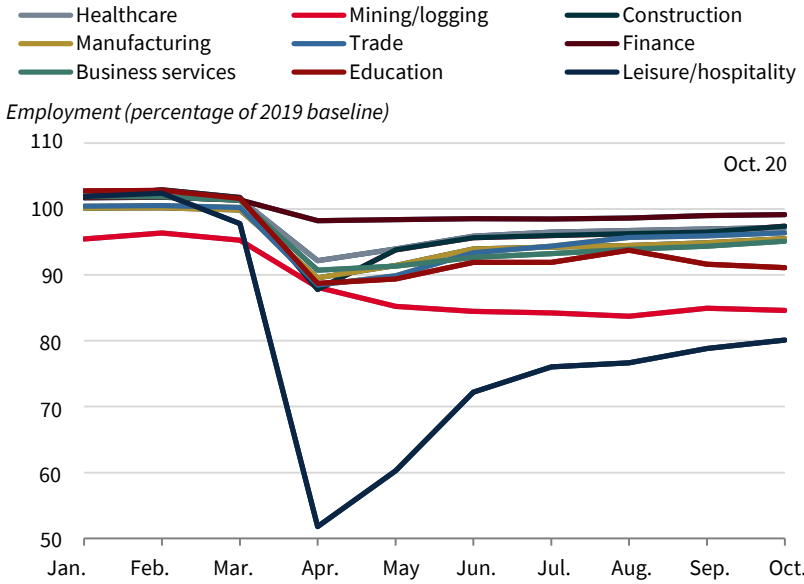


Sources: Department of Health and Human Services; CEA calculations.
Note: ER = emergency room.

during the pandemic. Figure 4-5 shows employment by sector for each month of 2020 as a percentage of the 2019 baseline using data from the Bureau of Labor Statistics (BLS). Healthcare employment fell to 92.2 percent of its 2019 level in April, the second-smallest decline of any sector. In contrast, average employment in all sectors in April was 86.6 percent and employment in leisure and hospitality was particularly volatile, falling to 51.8 percent. Healthcare has so far remained the second-most-resilient sector, after financial services, for the duration of the recovery and has steadily regained employment, rising to 97.2 percent of its 2019 level in October.

One major concern from the rapid job losses in March and April due to COVID-19 was the loss of health insurance for those obtaining benefits through employment. As of May 2, the Kaiser Family Foundation estimated that 47.5 million people who were covered by employer-sponsored insurance (ESI) were part of a family in which someone had lost a job (CBO 2020; Garfield et al. 2020). Of this group, about 26.8 million could potentially lose their health insurance, with the remaining 20.8 million retaining ESI though another worker in their family or another source of coverage. Given this consideration, all but 5.7 million would then be eligible for publicly subsidized coverage via Medicaid or marketplace subsidies, significantly reducing the share of job losses that result in a lack of health insurance.

Figure 4-5. Monthly Employment by Sector, 2020



Sources: Bureau of Labor Statistics; CEA calculations.

However, these projections have not been borne out in the data thus far. Data from Americans in the Household Pulse Survey from the Census Bureau showed minimal changes in ESI coverage between the end of April and the end of September, as Americans reported being both insured and uninsured at slightly lower rates, with a substantial increase in those who did not report or reported "don't know." In fact, between the end of April and the end of August, Pulse results showed that uninsurance rates had actually declined by 0.6 percentage point. The disparity between the observed changes in ESI coverage and initial projections may in part be due to the PPP/HCE Act allowing forgivable loans to employers to cover payroll costs, including employer contributions to health insurance coverage. Ultimately, although microsimulation modeling can be used to approximate the decline in health insurance coverage due to COVID-19, survey data to quantify the effect remains inconclusive at this time.

Subsidizing Beneficial Behaviors and the Cost of COVID-19 Care

Testing is essential to identifying positive COVID-19 cases, quarantining and treating sick patients, and implementing contact tracing protocols. Test costs may be a barrier to some members of the public, which could thwart efforts to contain a pandemic. Passage of the FFCRA on March 18, 2020, reduced this

potential cost barrier for American families. Nearly all public and private insurance plans are required by this legislation to cover FDA-approved COVID-19 tests and any costs associated with diagnostic testing with no cost sharing, as long as the test is deemed medically appropriate by an attending health care provider and the federally declared public health emergency is in effect. The CARES Act, which was enacted on March 27, 2020, further mandated that private plans reimburse out-of-network COVID-19 tests up to a publicly reported cash price. The FFCRA Relief Fund includes up to $2 billion ($1 billion appropriated through the FFCRA, and up to $1 billion appropriated through the PPP/HCE Act) to reimburse healthcare providers who conduct COVID-19 testing for uninsured individuals, which could raise the likelihood that these individuals seek testing when they feel ill and therefore contribute to the nation's public health objective of mitigating the COVID-19 pandemic. As of September 22, 2020, the CDC has awarded over $12 billion to States, Tribes, localities, and territories. This total includes $10.25 billion for critical support to enhance COVID-19 testing and related activities at the State and local levels. All these Federal protections have reduced the cost barriers of COVID-19 testing—which, in turn, has helped the United States identify positive COVID-19 cases and deliver care to individuals who have contracted COVID-19.

Emergency Paid Sick and Medical Leave

To slow the spread and contain the COVID-19 pandemic, the Administration has encouraged members of the public to stay home when they are sick or caring for a family member who is sick. At the same time, the Administration has firmly acted to prevent American workers from trading off work hours for their own or a family member's health and the broader public's health protection. As provided by the FFCRA, on April 1, 2020, the U.S. Department of Labor announced that private employers with fewer than 500 employees are eligible for tax credits for costs associated with providing paid leave for COVID-19 until December 31, 2020. These dollar-for-dollar reimbursements through tax credits enable employers to keep their workers on the payroll when their employees become sick or are caring for someone with COVID-19 and are unable to work, which promotes public health and maintains the flow of financial support to both employers and employees. For employers that could not cover the cost of paid leave with funds they would otherwise pay to the Internal Revenue Service in payroll taxes, the FFCRA enabled employers to seek an expedited advance from the Internal Revenue Service through streamlined reimbursement claims.

Subsidizing the Cost of COVID-19 Care

In addition to financing the detection of COVID-19 in order to implement containment and mitigation procedures, the Administration has also provided Federal support to reduce the cost of COVID-19 treatment. The Administration has responded in several ways to ensure that individuals seek the care that they need.

Many private Medicare health plans, known as Medicare Advantage plans, have expanded coverage to meet the unique needs of Medicare beneficiaries during a pandemic, including telehealth and medical transportation benefits. These types of support are especially important for lower-income individuals in the elderly population who would otherwise face cost or mobility constraints that would make obtaining medical care for COVID-19 difficult.

In addition, through the use of "1135 waivers," the Administration has created greater flexibility for Medicaid, Medicare, and CHIP requirements that can sometimes pose challenges for healthcare providers to provide medical care and for States to manage their Medicaid and CHIP programs during a national emergency such as the COVID-19 pandemic. The reduced administrative burden facilitated by these waivers has helped providers deliver medical care in these high-risk medical populations. When granted, the ultimate goal of these is to improve the ability of States and the healthcare sector to meet the needs of Medicare, Medicaid, and CHIP beneficiaries and expand access to medical services for these beneficiaries during the COVID-19 pandemic.

Finally, the Administration has taken actions to address the significant out-of-pocket medical cost burden faced by uninsured individuals when they become ill. Life during a pandemic is especially daunting for the uninsured because they do not have an insurance buffer in the event that they are exposed to COVID-19 and end up suffering from it. As noted above, a total of up to $2 billion in Federal funds appropriated by the FFCRA and the PPP/HCE Act reduce testing cost barriers among the uninsured population. However, the Administration has also acted to address treatment cost barriers for these Americans. HHS is providing claims reimbursement to healthcare providers that treat uninsured patients with COVID-19. As of November 9, $1.76 billion had been distributed to providers to reimburse the cost of testing and treating uninsured COVID-19 patients. Of this amount, representing almost 25,000 claims, $677 million was for testing and $1.1 billion was for treatment. The CARES Act established and appropriated a total of $100 billion to the Provider Relief Fund, and the PPP/HCE Act appropriated an additional $75 billion in relief funds. A portion of the Provider Relief Fund was used to reimburse providers that are treating uninsured individuals with COVID-19. In April 2020, the Administration began requiring providers to certify that, as a condition for supplemental COVID-19 funding, they would not seek to collect out-of-pocket expenses from a patient in an amount greater than what the patient would have otherwise been required to pay for in-network care.

COVID-19 and Future Healthcare Reform

Several other key initiatives are related to COVID-19 and the future of healthcare reform. These include reform of the FDA drug approval process, the

expansion of telemedicine, and the deregulation of scope-of-practice requirements for nurse practitioners.

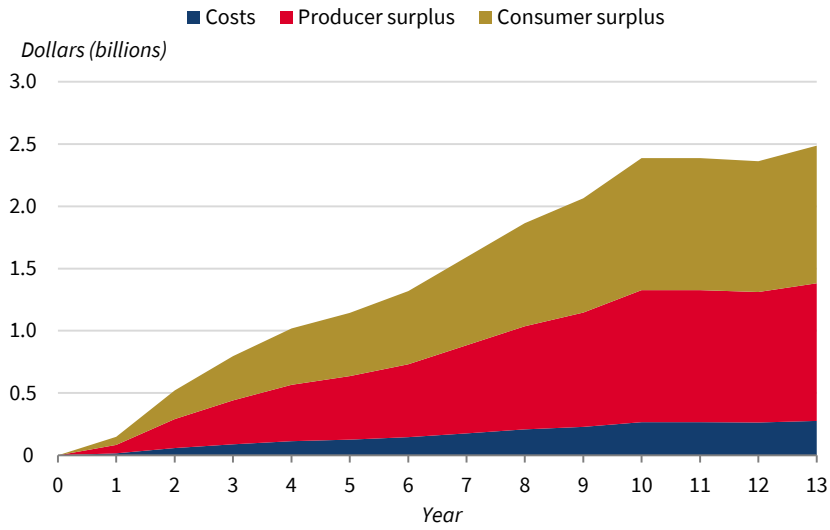
FDA Reform

The pandemic has also shown the value of speed in the development of new medical breakthroughs and the key role that deregulation can play in such efforts. At the onset of COVID-19, one of the reasons that testing was limited was extensive Federal regulations, including the long FDA approval process. To combat this, the Trump Administration took action through the FDA to issue EUAs for COVID-19 diagnostic tests. Such decisive actions played a key role in quickly ramping up testing capacity after initial delays, and they demonstrate the value of expedited the approval of medical breakthroughs. Currently, the United States has some of the most stringent regulations of new drugs in the world, with some approvals taking roughly 12 years from FDA application to market entry. As with COVID-19 testing and treatment, other new drugs have the potential to save lives and substantially improve well-being, which creates high opportunity costs for a long approval process. The CEA estimates that the net present value of the social surplus gained by decreasing FDA drug approval times by one, two, or three years would be $1.9 trillion, $3.9 trillion, and $5.9 trillion, respectively. Experience with the Prescription Drug User Fee Act (PDUFA) in the 1990s suggests that changes in policy can reduce approval times on this scale.

To estimate the value of shorter approval times, the CEA first estimates the annual social surplus generated by a drug for each year it is under patent protection. Because the FDA's approval time does not directly affect the patent expiration date of the average drug, the utility gained after postpatent expiration is assumed to be unchanged. Furthermore, the CEA's estimates of the value produced by such a policy change likely understates the true value because the number of new drugs introduced is treated as exogenous. In reality, shorter approval times increase the profitability of new entrants and would lead to further advances in medical technology, providing additional value for both consumers and pharmaceutical companies. (All dollar amounts are 2019 dollars.)

Figure 4-6 shows an average drug's life cycle, broken down into costs, producer surplus, and consumer surplus. The model updates the average drug revenue profile described by Philipson and others (2008)—using data from the FDA, BLS, and the Saint Louis Federal Reserve on the change in the number and prices of new drug approvals. Using this updated drug revenue profile, the CEA applies further calculations (described below) to estimate the producer and consumer surplus generated by the average drug. Of course, in reality most drugs will have very different revenue profiles, but the constructed average drug in the model uses data on average total revenue over the course

Figure 4-6. Average Drug Life Cycle during the Patent Period



Sources: Philipson et al. (2008); Food and Drug Administration; Bureau of Labor Statistics; Saint Louis Federal Reserve Bank; CEA calculations.

of the patent period and average share of revenue in each year to construct a representative example.

Although overall revenue profiles can be easily estimated using publicly available data on consumer expenditures, it is more difficult to calculate precise measures of producer and consumer surpluses, in large part due to the wide variation of producers and products in the pharmaceutical industry. The CEA estimates that the producer surplus in each year of the patent period is 80 percent of revenues, based on the finding that marginal costs are roughly 20 percent of revenue (Berndt, Cockburn, and Griliches 1996; Caves, Whinston, and Hurwitz 1991; Grabowski and Vernon 1992; Philipson et al. 2012). Of course, pharmaceutical companies also face high fixed costs early on in the life cycle of a drug in the form of research-and-development costs for both successful and unsuccessful products, approval application fees, and marketing expenditures (Kennedy 2018). A reduction in approval time may result in lower costs associated with the approval process if the preapproval time frame has nonnegligible marginal costs over time. However, to ensure that the result represents a true lower bound, the CEA does not include any reduction of fixed costs in the total benefit estimate.

To arrive at an estimate of total social surplus, the CEA conservatively assumes that consumer surplus is equal to producer surplus. It is well documented that consumers enjoy greater benefits from the development of new drugs than the profits made by their producers (CBO 2006; Lichtenberg 2014; Philipson and Jena 2006; Philipson et al. 2012; Roebuck et al. 2011). In fact, the

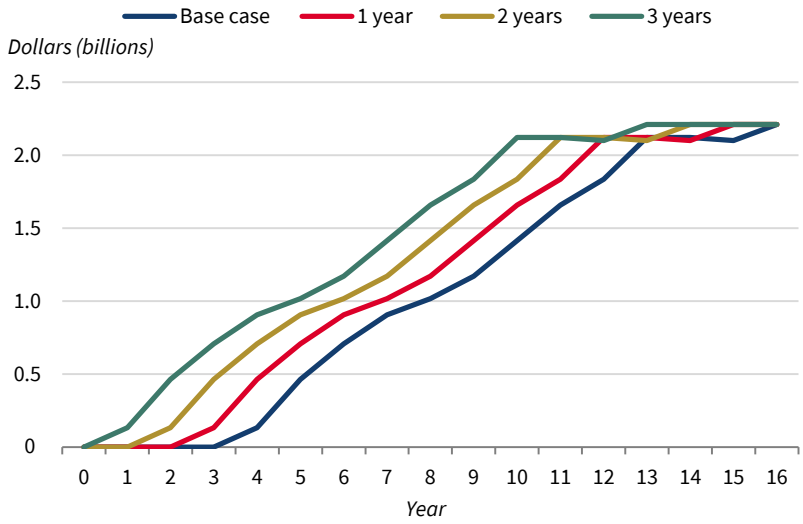
literature suggests that consumers capture the vast majority of the social surplus generated by new drugs, meaning that the CEA may substantially underestimate the total value to consumers of reducing drug approval times. Under these assumptions, the CEA finds that once an average drug has reached maturity in the market, it will generate about $2.1 billion in social surplus annually.

Figure 4-7 demonstrates how decreasing drug approval time by one, two, or three years would affect this annual social surplus. The figure also accounts for the time value of money by using an annual discount rate of 3 percent. That is, $1 in year one is worth 97 cents in year zero. Using a discount factor accounts for the fact that both the consumers and producers of a product would rather have it sooner rather than later. By allowing earlier entry into the market, drugs reach maturity in the market and provide maximum social surplus earlier than in the status quo. The maximum social surplus is reached earlier and attains a higher value due to the discounting of future periods, which represents the increased value for both consumers and producers.

Some critics of FDA reform suggest that decreased approval times would result in more unsafe products being brought to market and therefore an increase in approval withdrawals. However, approval times decreased by over one year under PDUFA, and Phillipson and others (2008) found no evidence of an increase in withdrawals after the reduction in approval times, but did not account for potential adverse effects on safety that do not result in withdrawal. Qureshi and others (2011) found that safety-related withdrawals accounted for less than a quarter of all withdrawals between 1980 and 2009. The CEA's analysis using an expanded data set of safety-related withdrawals also did not find an increase in withdrawals after the decreased approval times of PDUFA. Given the absence of data on the distribution of withdrawals by drug revenue, the CEA applies the overall drug withdrawal rate of 15.9 percent as a reduction to the potential increase in social surplus. This likely overstates the extent to which withdrawals would decrease potential benefit due to the skewed distribution of revenue by different drugs. Although the FDA's approval is withdrawn for a small share of drugs for safety reasons, almost 80 percent are voluntarily withdrawn by their producers for commercial reasons. In reality, the more successful drugs that generate larger surpluses for both producers and consumers are less likely to be withdrawn, resulting in a conservative estimate of the overall benefit.

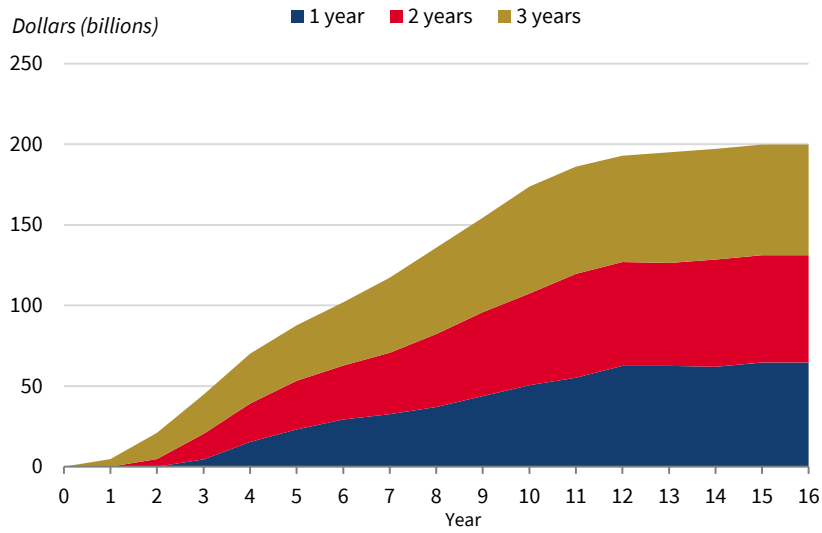
Using the estimate of the net present value of a drug's life cycle shown in figure 4-7, the CEA calculates the marginal cumulative net present value of social surplus generated by reducing FDA approval times, as shown in figure 4-8. The model uses the five-year average from 2015 to 2019 of 44 new drugs per year by the FDA. As noted above, by increasing the returns on investment in research, reducing FDA approval times would likely increase the number of new applicants, and hence approvals. Therefore, the static model that holds new drugs constant at 44 a year results in a conservative estimate of the value

Figure 4-7. Average Annual Social Surplus by Approval Time Decrease



Sources: Philipson et al. (2008); Food and Drug Administration; Bureau of Labor Statistics; Saint Louis Federal Reserve Bank; CEA calculations.

Figure 4-8. Cumulative Aggregate Net Present Value of Increased Social Welfare by Approval Time Decrease



Sources: Phillipson et al. (2008); Food and Drug Administration; Bureau of Labor Statistics; Saint Louis Federal Reserve; CEA calculations.

Table 4-1. Estimated Social Surplus by FDA Approval Time Reduction, 2025–40 (billions of real 2019 dollars)

Year	Approval Time Reduction		
	1 Year	2 Years	3 Years
Net present value	1,905.8	3,870.5	5,896.0
2025	0.0	0.0	4.9
2026	0.0	4.9	22.1
2027	4.9	22.1	48.3
2028	17.2	43.4	76.9
2029	26.2	59.7	97.3
2030	33.5	71.2	114.5
2031	37.6	81.0	133.3
2032	43.4	95.7	157.0
2033	52.3	113.7	181.6
2034	61.3	129.2	207.8
2035	67.9	146.4	224.9
2036	78.5	157.0	234.8
2037	78.5	156.2	238.0
2038	77.7	159.5	241.3
2039	81.8	163.6	245.4
2040	81.8	163.6	245.4

Sources: Philipson, et al. (2008); Food and Drug Administration; Bureau of Labor Statistics; Saint Louis Federal Reserve Bank; CEA calculations.

of deregulation, especially considering the fact that new approvals have been trending upward since 2005. The results, given in figure 4-8, represent the increase in social surplus for one year of drug approvals depending on whether the approval time for the drugs is reduced by one, two, or three years.

To calculate aggregate gain in social surplus, it is necessary to sum the gains in social surplus associated with quicker drug approvals over time. Because policies to reduce approval time may be difficult to implement immediately, the CEA assumes that the reductions in approval time would begin applying to drugs that would otherwise be approved in 2028. Under these assumptions, table 4-1 displays the nondiscounted gain in social surplus from a one-, two-, or three-year reduction in approval times for each year from 2025 to 2040, as well as the net present value in 2020 of such a policy change. The CEA estimates that the net present value of the increase in social surplus from a permanent reduction in approval times by one, two, or three years for new drugs would be $1.9 trillion, $3.9 trillion, or $5.9 trillion, respectively.

Telemedicine Deregulation

One of the most substantial deregulatory opportunities for long-term healthcare improvement that has been highlighted during the pandemic is telemedicine.

Early during the pandemic, HHS took four key deregulatory actions to increase the availability of telemedicine opportunities. First, the Office for Civil Rights (OCR) announced that it would relax enforcement of HIPAA regulations to allow health professionals to communicate with patients and provide telehealth services via remote communication technologies that may not fully comply with HIPAA privacy rules. Though the laws remain unchanged, OCR used its enforcement discretion to allow any covered health professionals to use a wide array of commercially available communication technology (e.g., Zoom or Skype) as part of a good faith effort to provide telehealth services during the pandemic, regardless of whether the services are directly related to the diagnosis or treatment of COVID-19.

Second, President Trump's emergency declaration allows HHS to relax Federal licensing restrictions so many health professionals can provide care virtually to patients in other States. This has created a large pool of potential health professionals available to any given patient who is seeking telehealth services, increasing access to medical services in the States with the greatest need. Finally, CMS took two significant deregulatory actions to promote telehealth by temporarily expanding the scope of Medicare telehealth to allow Medicare beneficiaries across the country—not just in rural areas—to receive telehealth services from any location, including their homes, as well as adding over 135 allowable services, more than doubling the number of services that beneficiaries could receive via telehealth (Verma 2020). The CMS temporarily waived statutory and regulatory provisions that restrict reimbursement for telemedicine services to those furnished in certain healthcare facilities, allowing healthcare professionals to be paid for providing telehealth services regardless of location. CMS also allowed for a broader range of services to be provided via video or audio call, including emergency department visits, therapy services, and initial nursing facility and discharge visits. These measures are designed to promote the use of telemedicine and ensure that patients have access to healthcare while remaining safely at home.

During the beginning stages of the pandemic, quick deregulatory action mitigated disruptions in care for patients in hotspot areas and those in the greatest need. Mann and others (2020) found that telemedicine visits increased almost sevenfold during the period of maximal COVID-19 active cases in New York City. Many of these online visits were directly related to COVID-19, which advanced three key public health goals. First, telemedicine allows for comparatively inexpensive and efficient screening for patients before they arrive in the emergency room. This lowers costs and prevents unnecessary healthcare visits, which decrease the strain on already-overburdened healthcare providers and the potential transmission of COVID-19 to other patients and healthcare workers. Second, expanding access to telemedicine provides useful data to public health officials who are trying to track the spread of the disease and predict future hotspots, an approach that has been shown in the past to provide a

useful picture of the spread of influenza (Chauhan et al. 2020). Third, provision of telehealth services that is not directly related to COVID-19 is particularly necessary for patients who are actively quarantining and require healthcare, because in-person visits with such patients increase the risk of exposure for healthcare workers and their patients.

Telemedicine visits have also been useful in maintaining access to essential care services when physical access to medical services has been limited. For seniors who are at a heightened risk of serious illness from COVID-19, telemedicine has offered an appealing substitute due to the deregulatory actions of CMS. Telehealth visits constituted 43.5 percent of Medicare primary care visits in April, compared with just 0.1 percent of such visits before the pandemic in February. Urban areas that have had higher levels of COVID-19 hospitalizations have utilized telehealth services at a higher rate, suggesting that this uptake has been at least partly driven by concerns over COVID-19. With uncertainty and unemployment rising during the pandemic, telehealth services have also provided a safe and efficient method to meet rising demand for mental health services among patients of all ages. During the February-to-April period, increases in Medicare telehealth utilization for primary care visits were dramatic in every State; for example, visits went from 0.20 percent to 43.9 percent in Texas and from 0.03 percent to 69.7 percent in Massachusetts.

According to survey data from McKinsey & Company, 11 percent of U.S. consumers used telehealth services in 2019 (Bestsennyy et al. 2020). As of April 2020, 46 percent of U.S. consumers reported that they had already used telehealth to replace canceled in-person healthcare visits in 2020. Though telehealth has helped expand access to care at a time when COVID-19 has restricted patients' ability to see their doctors, there has been strong interest in making telehealth services a permanent option; 76 percent of U.S. consumers report being interested in using telehealth in the future. The enthusiasm for telehealth on the demand side is matched by favorable reviews of telehealth on the supply side; 57 percent of providers view telehealth more favorably than they did before COVID-19, and 64 percent are more comfortable using it. The positive reaction to exercising telehealth options is likely to increase over time as awareness and experience with virtual healthcare services grow and existing challenges (e.g., lower mobile and computer capabilities in lower-income communities and security concerns) are resolved.

The immediate and pressing nature of the COVID-19 pandemic has demanded that the healthcare system embrace telemedicine on a greatly accelerated timeline. Though the availability of telehealth services has been increasing consistently over time, the additional infrastructure built and deregulatory actions taken provide an opportunity to more strongly embrace telehealth as a key part of the future of healthcare. In 2019, the American Hospital Association identified Medicare reimbursement differentials and regulatory barriers as two key barriers to wider adoption of telemedicine in

the United States. Many of these regulatory burdens have been temporarily removed, and healthcare systems have already implemented telemedicine programs in response to the pandemic, so they can use them beyond COVID-19 without incurring additional setup costs if HHS's deregulatory actions become permanent. Although the benefits to individuals in quarantine and those at a high risk of contracting COVID-19 will decrease once the threat of the pandemic has passed, other benefits will remain. Studies of telemedicine programs have found that they increase patient satisfaction, decrease the loss of work time (which decreases the opportunity costs for patients to seek care they need), and decrease the unnecessary use of the emergency department due to prescreening arrivals, which lowers costs and improves the quality of care for patients who need it most.

In addition, though the greatest beneficiaries of increased availability of telemedicine during the pandemic have been patients in urban areas, the long-term benefits of normalizing telemedicine will be highest among rural Americans who do not reside near major medical centers. The Department of Veterans Affairs found that 45 percent of its telemedicine utilization came from rural veterans. Telemedicine would allow greater access to specialists with knowledge in a particular area of medicine, even when doctors are not at the same hospital or region of the country. Furthermore, rural populations are particularly subject to high opportunity costs for medical care, including lost wages, transportation costs, and childcare expenses. On the basis of a study of this phenomenon by Bynum and others (2003), the CEA estimates that rural Americans would on average save $130 per visit in opportunity costs such as fuel, wages, and other family expenses if their visits could be replaced by telemedicine. Rural patients who would otherwise make the national average 2.8 physician's office visits a year would therefore save up to $362 annually. Though rural patients may empirically make fewer physician visits per year (Spoont et al. 2011), the increased access provided by telemedicine may reduce the geographic disparity between rural and urban Americans.

Given both consumers' and providers' interest in continued access to telemedicine, it is a potentially significant source of future economic value. McKinsey & Company estimates that before the COVID-19, the total annual revenue of U.S. telehealth players was about $3 billion, with the largest vendors being focused on virtual urgent care (Bestsennyy et al. 2020). They estimate that going beyond this segment of virtual healthcare may allow up to $250 billion, or $1 in $5 current healthcare dollars, to be virtualized.

Scope-of-Practice Deregulation

During the COVID pandemic, relaxing stringent scope-of-practice (SOP) requirements allowed hospitals and other health providers to increase the amount of care that they could provide for their communities. Before the outbreak of COVID-19, 22 States and 2 territories allowed full practice for

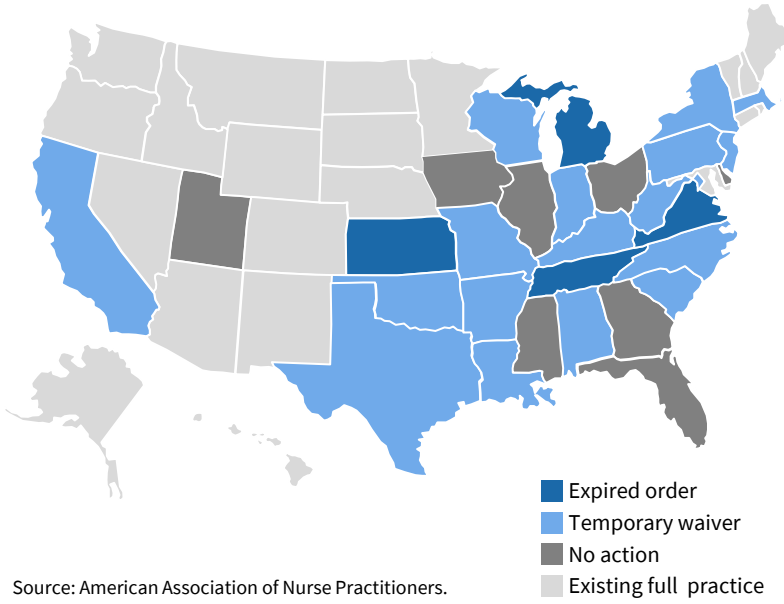
nurse practitioners (NPs), meaning that NPs in those States and territories are authorized by their boards of nursing to evaluate and diagnose patients, order and interpret diagnostic tests, and manage treatments (including prescribing medication) without a physician. Increased demand from virus patients combined with decreased supply due to practitioners being out sick threatened to overwhelm hospital systems across the country. In contrast, States with more restrictive SOP guidelines place restrictions on NPs in one or more of these areas, generally in the form of prohibitions or physician supervision requirements. In response, State governments and Federal agencies relaxed SOP guidelines that prevented nurse practitioners from performing certain routine tasks without the supervision of a licensed physician. By April 24, 2020, another 22 States had temporarily relaxed their SOP requirements. In addition, CMS temporarily relaxed its SOP guidelines in March 2020. Medicare and Medicaid reimbursement payments are critical for the survival of many hospitals, and State regulations are always binding. Because of this, hospitals tend to operate under the more rigid regulations when their State and CMS regulations are in conflict. This has enabled providers in areas that have been hit hardest by COVID-19 to respond with increased labor flexibility in meeting the needs of their communities.

Existing SOP restrictions on NPs display a strong geographic correlation (figure 4-9). This is likely due to the greater benefits associated with broadening SOP in rural areas relative to urban communities, given that full practice was primarily allowed in New England, the northern Great Plains, the Mountain West, and the Pacific Northwest. Rural areas rely more heavily on NPs and grant them greater autonomy than urban areas because they tend to have fewer physicians to oversee the NPs (Rosenblatt and Hart 2000). This shortage of physicians can prevent the opening of community health centers (CHCs). The opening of new CHCs in rural areas was associated with relaxed SOP requirements. Furthermore, CHCs in States with relaxed SOP guidelines have more NPs relative to physicians than CHCs in States with rigid SOP guidelines (Shi and Samuels 1997). More CHCs mean better access to care in rural areas. And because relaxing SOP allows more CHCs to open and more CHCs mean better access to care, deregulating SOP would improve the ability for rural populations to access healthcare.

In addition to expanding access, relaxing SOP regulations drives down healthcare costs. Such restrictions increase the cost of healthcare, because NPs are unable to perform certain tasks without the supervision of a physician and physicians' time is expensive. Rigid regulations requiring physicians to perform some tasks increased the cost of well-child medical exams by 3-16 percent (Kleiner et al. 2016) Another analysis found that costs were lower in States with reduced and full SOP than in States with restrictive SOP (Spetz et al. 2013).

To estimate the economic benefit of relaxing SOP guidelines for NPs nationwide, the CEA uses interstate cost comparisons from Poghosyan and

Figure 4-9. State Scope-of-Practice Deregulation



Source: American Association of Nurse Practitioners.

others (2019), who estimate the difference in outpatient and prescription drug costs for Medicaid patients between States that allow for full, reduced, and restricted practice for NPs. Using these figures, along with data from BLS and the Kaiser Family Foundation, the CEA estimates that allowing full practice nationwide would reduce outpatient costs by $33.96 billion a year and prescription drug costs by $27.73 billion a year across patients enrolled in employer health plans, nongroup plans, or Medicaid. This would lead to a reduction in national prescription drug spending of 5.3 percent and, combined, represent a reduction in national healthcare expenditures of 1.7 percent. Due to the limited supply of NPs, this number represents the potential long-run benefit once the labor market for NPs has expanded to match the increased demand. However, the supply of NPs has been flexible, more than doubling the past 15 years as States have removed SOP restrictions.

The CEA's estimate likely understates the total benefit in two ways. First, Medicaid spending per capita is lower than the privately insured population, so the savings for the general population in dollar terms may be larger than for Medicaid enrollees. Second, the CEA's analysis only accounts for individuals who are members of employer health plans, nongroup plans, or Medicaid. It is likely that relaxing SOP for NPs would also reduce costs for other groups, including those insured by military plans or Medicare, as well as the uninsured population.

The impact of relaxing SOP on health outcomes could go one of three ways. If relaxing SOP restrictions causes NPs to provide lower-quality care in the absence of physician supervision, then relaxing SOP would have a negative effect on health outcomes. If, instead, NPs performed just as well as doctors, then there would be no effect on health outcomes. In addition, if NPs could now perform more critical health actions, which previously could not have been performed due to a shortage of physicians to provide supervision, then one would expect health outcomes to improve when SOP restrictions are relaxed.

Empirical evidence suggests that allowing nurse practitioners full practice nationwide would not compromise the quality of patient care. State-level SOP restrictions had no effect on infant mortality or malpractice insurance premiums (Kleiner et al. 2016). Taking a broader approach, another study found that

> the considerable variation in the results for the measures included in each of the domains of primary care quality indicators we assessed—chronic disease management, cancer screening, ambulatory care–sensitive hospital admissions, and adverse outcomes—did not reveal a consistent pattern or relationship with state-level SOP. (Perloff et al. 2017)

In rural areas, the results of one analysis suggested a positive relationship between health outcomes and relaxed SOP guidelines (Ortiz et al. 2018). A wealth of literature analyzing the difference in patient outcomes between NPs and physicians has consistently found that, for most patients, NPs provide equivalent or better care at a lower cost (Lenz et al. 2004; Martin-Misener et al. 2015; Mundinger et al. 2000; Oliver et al. 2014; Stanik-Hutt et al. 2013). The States and Federal agencies that have temporarily relaxed their SOP guidelines during the COVID-19 pandemic could seize this opportunity to improve the access and affordability of healthcare for their citizens.

Additional Changes to Promote Choice and Competition

Beyond the response to the COVID-19 health crisis, the Trump Administration has championed several healthcare reforms to promote additional choice and competition in the market. These policies will provide tangible reform to Americans and play a critical part in the swift comeback for the U.S. economy.

First, CMS introduced site-neutral payment in 2019 for clinic services delivered by hospitals. Site-neutral payments were part of the 2019 Hospital Outpatient Prospective Payment System final rule and address unnecessary increases in utilization of clinic visits in off-campus, hospital-based departments. Medicare and beneficiaries often pay more for the same type of clinic visit in the hospital outpatient setting than in the physician office setting. The rule was challenged by a coalition of hospitals led by the American Hospital

Association in Federal court. In September 2019, the U.S. District Court for the District of Columbia ruled that CMS had overstepped its statutory authority in making the changes. However, a July 2020 decision issued by the U.S. Court of Appeals for the District of Columbia Circuit overturned the lower court's ruling, clearing the path for implementation. Site-neutral payments are estimated to generate healthcare savings that have a direct and positive impact on beneficiaries, the Medicare program, employers, and American taxpayers. An evaluation by CMS that has been extrapolated by the CEA shows that site-neutral payments for evaluation and management services are projected to save the Medicare program an estimated $330 million and lower patient copayments by $88 million in 2021.

Second, prescription drugs saw their largest annual price decrease in nearly half a century in 2019. For three consecutive years, the FDA has approved a record number of generic drugs. The CEA estimates that these approvals saved patients $26 billion in 2017 and 2018. The 2020 Creating and Restoring Equal Access to Equivalent Samples Act will also create opportunities for greater savings from generic drugs by increasing access to samples for testing. The CEA estimates that the projected savings to American taxpayers will be $3.5 billion from 2020 to 2030.

Also, in July 2019, the Trump Administration issued an Executive Order aimed at improving the care of patients with chronic kidney disease. In 2020, the Department of Health and Human Services published multiple rules that attempted to streamline the renal care system by removing regulatory barriers, increasing oversight of Organ Procurement Organizations, and encouraging living kidney donors. HHS estimates that its changes to the system of these organizations alone could generate up to 4,500 additional kidney transplants by 2026. The CEA estimates that these initiatives could have substantial health and economic benefits. Because each kidney transplant reduces lifetime medical spending by an estimated $136,000 and creates health benefits, such as increased longevity, that are worth an estimated $1.8 million, the net present value of these kidney transplants would be roughly $8.8 billion a year. Moreover, efforts to promote peritoneal dialysis could result in savings of $130 million to $450 million annually. When combined with the value of health gains and savings from kidney transplants, the CEA finds that the Administration's initiatives could provide societal benefits with a net present value of nearly $9.3 billion.

Conclusion

Although COVID-19 has imposed significant health and economic costs throughout 2020, the Trump Administration has been able to take decisive actions to mitigate its effects. Expediting the development of testing and treatment capabilities has played a key role in curbing the human cost of the

virus, while the removal of burdensome regulation and provision of financial support have helped the healthcare sector adjust to the adverse shock. The Nation's experience with COVID-19 provides opportunities for extending the suspension of harmful regulations, which will further encourage economic recovery and provide long-term health and financial benefits. In particular, the CEA finds that reforming the FDA drug approval process to reduce approval times, encouraging the widespread continuation of telemedicine, and removing harmful scope-of-practice regulations would generate significant savings and improve the health of Americans in the future.