Pandemic Regulatory Changes
Should They Stay or Should They Go?

Smart Regulation: A Continuing Imperative

Regulation can provide a number of societal benefits, such as improving food safety, ensuring safety and efficacy of pharmaceuticals, protecting consumers against fraud, promoting safety in transportation, protecting workers in the workplace, enforcing civil rights laws in areas such as fair housing, and ensuring that public policy priorities are implemented.

But regulation can also have real costs, both financial and strategic—costs to business, costs to consumers, and costs to US competitiveness in the world. Regulation can also limit or restrict new product development and creativity and limit access to new demographic entrants. Ironically, excessive or inappropriate regulation can actually lead to conditions of greater risk to public safety as resources are diverted from critical areas to meet the high-profile regulatory burden.

Resources that could be spent on new investment instead go toward regulatory compliance, and the impact on smaller businesses can be particularly profound. It is hard to measure the benefits and costs of regulation—even as the fundamental tool of regulation should be cost-benefit analysis.

The questions are whether a regulation is necessary, whether it achieves the purposes for which it was adopted, and whether the benefits outweigh the negatives. The Committee for Economic Development, the public policy center of The Conference Board (CED), has promoted “smart regulation”—the idea that regulation should achieve the purpose for which it was imposed at the lowest possible cost and with the maximum possible benefits. Smart regulations are well designed, using actual appropriate subject matter experts at the outset, and must be reviewed, revised, or sunsetted, particularly given the rapid pace of technological change. CED has previously described this process as “turning speed
bumps into guardrails.”1 The process of adopting these regulations requires strong input from all stakeholders who have expertise in how they would be implemented in practice, including from those who would be subject to the regulations, and the process of reviewing regulations likely requires data on how those regulations are implemented in practice over time.

CED recommends that US regulatory policy receive an energetic review. Today, the nation has a unique opportunity to do just that. The COVID-19 crisis required the waiver of many regulatory policies across the economy but perhaps most urgently and most importantly in health care, one of the most heavily regulated sectors. It also brought into effect new regulations in an attempt to meet the demands of the crisis.

This Solutions Brief examines three broad areas, each of which shows the power of regulation: two concerning waivers removing regulation—pandemic waivers from the Centers for Medicare and Medicaid Services (CMS) and efforts by the Food and Drug Administration (FDA) to speed authorization of new therapies—and the third concerning a new regulation—the Department of Labor’s and HHS’ regulations on vaccination of many employees. Two of these initiatives were broadly successful, while one tested—and the Supreme Court found that it exceeded—the limits of regulation.

Changes in Regulatory Policy During the Pandemic

It is no overstatement to say that decision-making and communication of US regulatory policy during the pandemic affected the health outcomes for many and the lives of all Americans. Regulatory policy decisions even touched billions of people around the world (through the acceleration of COVID-19 vaccine reviews and decisions to communicate and collaborate with global partners).

Health care is normally a highly regulated sector—for good reason. Only qualified and trained individuals should be allowed to practice medicine. Pharmaceuticals and medical devices are subject to strict review for safety and efficacy before approval. Hospitals receive enormous amounts of federal funding, and taxpayers have a strong interest in ensuring their money is well spent.

The COVID-19 pandemic tested whether many of those regulations, including some directly related to the practice of medicine, could be modified or waived without harm—and perhaps even with great benefits—to the public health. Some of these waivers allowed for health care to reach communities that are not easily accessible and led to breakthroughs in science and technology that spurred the development and distribution of vaccines at a pace and on a scale not even imagined at the outbreak of the pandemic. At the same time, the pandemic also tested the limits of regulation.

More broadly, our pandemic crisis procedures and processes need to be reviewed (and constantly updated) to identify with great clarity where the federal government is seen as having a role and where the states would be expected to take ownership. An important area where this clarity did not exist in 2020 was the acquisition and distribution of personal protective equipment (PPE), which was unnecessarily chaotic.

It may still be too early to determine what worked best and what did not in terms of understanding best practices and identifying the full costs and benefits of the regulatory
actions the government took in the health care sector during the pandemic. But we can draw strong preliminary conclusions: public-private sector collaboration on regulatory policy was essential for meeting the challenge of the pandemic, the deregulatory actions were largely positive and allowed for the provision of health care to more underserved communities, and the close cooperation between the private sector and FDA to bring new products to market at an unprecedented pace was vital. We also note an example where regulatory policy action was less successful: the government’s new regulation to require vaccination in companies with over 100 employees, however well intentioned for the safety of employees, lacked input from the private sector and failed on constitutional grounds because it exceeded the limits of the authority granted by Congress.

While the general vaccine mandate was controversial and eventually unsuccessful, the pandemic regulatory waivers, in the face of a national and global public health emergency, were broadly supported in a bipartisan manner as well as among the business community and the general public. They form a good case study of how the nation can move toward smart regulation and what to avoid. Now, the question is whether the country can keep the benefits that came with regulatory waivers—without losing sight of important safety concerns that prompt regulation in the first place—and in so doing, not only improve public health but also promote innovation in regulation, in private sector provision of health care, and in US technology to address public health challenges and spur research and development.²

**Insights for what’s ahead**

**RECOMMENDATIONS**

Public policy and business leaders should seize this opportunity to conduct a comprehensive review of overall regulatory policy during the pandemic to determine the scope of regulatory policy going forward. The objective of this CED Solutions Brief on the regulatory impact on health care policy during the pandemic is to provide insights and recommendations for leaders in the public and private sector to prioritize as we emerge from the pandemic:

- Close cooperation between the federal government, state governments, and the private sector for regulation is essential.
- Regulators should take account of the experience of those who would be subject to the regulations. This will promote innovation in regulation and spur US research and development.
- States should move toward reciprocal licensing of physicians and other health care professionals. As an interim step, however, states that are not part of interstate medical licensure compacts should move to join them, to provide greater uniformity to the licensing system for physicians and as a step toward reciprocal licensing.
The federal government should conduct a study of the use of telehealth and other waivers during the pandemic. Regulations should be considered for possible permanent modification (or not) based on an examination of how they were used during the pandemic and a study of the balancing of benefits and costs.

The Department of Health and Human Services (HHS), in conjunction with the private sector, should undertake a comprehensive review of the Food and Drug Administration’s exercise of regulatory flexibility during the pandemic to determine how effective it was and whether it can or should be applied more broadly without compromising safety and efficacy, potentially leading to faster approval of new therapies.

Congress should speak in clear language—as clear as possible—in stating the powers it chooses to delegate and not to delegate to agencies.

Agencies should ground their regulatory activities firmly and only within those delegations.

Safe harbors in regulation are appropriate in a number of circumstances, but particularly in areas of great uncertainty and in instances when conditions change rapidly.

Business leadership should participate actively and robustly in the regulatory process, particularly at the comment stage of notice-and-comment rulemaking.

CMS: Waivers as a Quick Response to a Public Health Emergency

The Social Security Act and the Public Health Service Act are complex statutes. The laws themselves are lengthy and have been amended repeatedly. Regulations promulgated under those acts occupy a thick volume in the Code of Federal Regulations. They also, however, give great discretionary powers to senior officials to waive the regulations in certain circumstances, notably a national emergency or public health emergency (PHE).

In particular, Section 319 of the Public Health Service Act allows the Secretary of Health and Human Services (HHS) to declare a PHE in response to outbreaks of infectious diseases. When combined with a separate presidential declaration of a PHE, the Secretary then has authority under Section 1135 of the Social Security Act to grant temporary waivers of regulations under a variety of federal programs, including Medicare and Medicaid as well as the Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA), for the period of the emergency. (A PHE declaration is valid for 90 days and may be renewed for 90-day periods thereafter; the HHS PHE declaration related to the COVID-19 pandemic was declared on January 27, 2020, and has been renewed constantly since then.)

As the pandemic took hold across the country in early 2020, CMS issued a number of blanket waivers, taking a broad approach to exercising waiver authority given the extreme pressures on the public health system during the early stages of the pandemic.
CMS further issued these rules as “interim final rules” without engaging in formal notice-and-comment rulemaking under the Administrative Procedure Act but also linked the applicability of the rules specifically to the COVID-19 PHE. In total, CMS issued more than 100 waivers over the course of the pandemic.

Under the federal government’s responsibility for Medicare and Medicaid, the CMS waivers were intended to allow CMS to reimburse hospitals, physicians, and other providers for services for which CMS ordinarily would not pay absent the waivers. The waivers did not force states to adopt any particular program, and many waivers were explicitly linked to the limits of state law—states regulate the practice of medicine, including licensure of medical professionals. Because virtually all health care facilities treat Medicare and/or Medicaid patients, the applicability of the waivers across the health system was very broad. In addition, many private insurers followed the CMS waivers for their own members, which expanded the positive effects of the waivers.

For many Americans who desperately needed care, these regulatory waivers were a bright spot in the pandemic, even if they did not realize it. The waivers increased access to health care and permitted facilities to focus more intensely on patient care instead of regulatory compliance.

Will the provisions of the regulatory waivers survive? Should they? Three particular areas—telehealth and the related issue of the practice of medicine, physician and hospital regulations, and post-acute care—make good case studies.

Telehealth

HHS defines “telehealth” as “the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, and public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and landline and wireless communications.” During the pandemic, and thanks to CMS waivers, telehealth grew rapidly and has proven remarkably popular and durable. In the first year of the pandemic, over 28 million of all Medicare beneficiaries—43 percent—used a telehealth service of some kind, an 88-fold increase over 2019; according to one study, 73 percent of telehealth users want to continue it after the pandemic waivers expire.

Beyond simply increasing access to telehealth, the waivers expanded the types of services permissible via telehealth, notably mental health and substance abuse treatment—a real boon given the psychological hardships to many people during the pandemic—as well as speech therapists, occupational therapists, and physical therapists.

Of the various waivers CMS issued, those concerning telehealth are likeliest to survive in some form—in part by becoming more firmly anchored in state law. In addition, certain services like physical and occupational therapy as well as behavioral health services via telehealth are now covered by federal law. The Consolidated Appropriations Act of 2022 provides that the CMS telehealth waivers for Medicare continue for 151 days following the end of the COVID PHE. Further, the law provides for a review of how Medicare beneficiaries have used telehealth during the pandemic—a move that should spur further reform—as well as a report by the HHS Office of Inspector General on ways to prevent fraud and abuse resulting from greater use of telehealth.
The issue is complex in part because the states regulate the practice of medicine. Thus, attempts to retain greater telehealth usage would require the approval of states, which license and discipline physicians and other practitioners.

The Federation of State Medical Boards has compiled a list of laws, regulations, state executive orders, and other documents about changes related to the pandemic. While the list specifically refers to telehealth, it also involves issues concerning practice by out-of-state physicians (without a waiver, they would face liability for the unlicensed practice of medicine in the state in which the telehealth service is received, unless they hold valid licenses in that state). Also waived during the pandemic was the requirement that patients who are Medicare beneficiaries must be under the care of a physician. This greatly increased the number of health care providers who could care for patients, in particular COVID-19 patients, and expanded opportunities for care during the height of the pandemic.

At the same time, however, that waiver struck at the heart of state regulation of the practice of medicine (an area of state competence) by expanding the category of people who could, in essence, qualify as physicians for certain purposes. State laws vary widely, for instance, on the powers granted to other health care professionals such as nurse practitioners or physicians’ assistants. As the time approaches when the PHE will end, so questions about the proper scope of practice—what uniquely should belong to physicians—will become more prominent in debates about the future of health care. Some, for instance, have raised concerns about the potential abuse of prescriptions, particularly regarding opioids and similar treatments, given over telehealth platforms.
Beyond the question of scope of practice is the more direct question of geography of practice. Licensing of medical professionals is the responsibility of the states, not CMS; telemedicine makes it easier for health care professionals to practice across state lines and provide more access to communities across the nation. CMS was very clear that interstate telehealth could qualify for reimbursement during the PHE, but as the concern over the pandemic receded, many states changed their laws and regulations. In the tradition of the states as “laboratories of democracy,” the states adopted a dizzying and sometimes confusing array of requirements relating to physician practice during the pandemic (for instance, some states permitted “infrequent” interstate telemedicine that was otherwise prohibited; others permitted telehealth for mental health providers but not for other practitioners). Some made perfect sense: smaller and more rural states often adopted more generous procedures for telehealth and temporarily granted practice rights to out-of-state physicians to ensure more opportunities for patient care. Other states more strictly guarded their prerogatives in regulating the practice of medicine and chose to end their states’ PHEs more quickly, even in some cases in mid-2020.

Even though interstate telehealth use was only a small proportion of overall telehealth use, the trend—and the associated movement to regulatory flexibility—is important.

As of August 16, 2022, only 11 states maintain waivers permitting interstate practice by physicians licensed in another state, including for telehealth. One state (Alabama) maintains a waiver but does not accept new applications, and 37 states and the District of Columbia no longer offer waivers, with most expiring with the end of the state’s declared PHE (as opposed to the continuing federal PHE) or a short period thereafter. However, 20 states and four territories (Guam, the Northern Mariana Islands, Puerto Rico, and the US Virgin Islands) have at least some permanent provision for interstate telemedicine. Most such provisions, though, reflect contingencies such as permitting telemedicine in contiguous states, with previously existing provider relationships, “infrequent” telemedicine consultations, or limited telemedicine on a pro bono basis only with registration with the state (e.g., Utah). Clearly, it would take significant reform to get back to the wide availability of telemedicine, including interstate telemedicine, during the height of the pandemic.

There are two ways for states to increase the availability of interstate medical licensing, which will be necessary for use of telehealth services to continue to expand. The first is the Interstate Medical Licensure Compact (IMLC), which currently covers 38 states. But that compact only helps physicians currently licensed in one state gain licenses covering multiple states, paying fees to each and requiring compliance with the regulations (for instance, continuing medical education) in each state in which a physician is licensed. The second solution would be to move toward reciprocal licensing, as the Nurse Licensure Compact provides, in which states accept licenses issued by another state as sufficient to practice in that state.
The IMLC is endorsed by the American Medical Association and the Federation of State Medical Boards. While it is useful for national telehealth providers who seek to have their physicians employed in as many states as possible, it has limitations, notably that physicians who wish to practice in more than one state must be separately licensed by each state.

In contrast, reciprocal licensing would permit physicians to practice in other states without having to obtain special licenses in those states (although notifying a state’s medical board would presumably be required). South Dakota’s law may provide a good model for reciprocal licensing. It permits reciprocity in cases in which “the applicant has completed a residency program in the United States or Canada; ii) has passed one of the following licensure examinations...; iii) has not had any allegations of misconduct or proceedings instituted for the cancellation, conditioning, suspension or revocation of the applicant’s license in any state; and completion of a state and federal criminal background investigation.”

One challenge to physician licensure reform is that state medical boards receive large revenues from state-only licensing systems; fees paid for licensing and renewal in California, for instance, amount to $56 million, or 91 percent of the state medical board’s revenues.

But here principles of smart regulation come into play. It seems reasonable to assume that the overall benefits to California’s own residents (and society at large) of permitting interstate telemedicine would likely amount to far more than the $56 million the California state medical board would lose. Reciprocal licensing would also likely smooth out disparities in access to physicians, including specialists, between underserved areas.
and areas with an abundant supply of physicians, helping to address one aspect of the current health care workforce shortage. As one telehealth expert noted, “[w]e have all the clinician resources we need. We just can’t mobilize them because of red tape.”

Moving to a reciprocal licensing system, therefore, would provide greater benefits to the economy and to society than the current system. As an interim step, however, states that are not part of the IMLC should move to join it to provide greater uniformity to the licensing system for physicians and as a step toward reciprocal licensing.

Reciprocal licensing would also make it easier for physicians to take their practices to other states, increasing labor mobility. As Vin Gupta, MD, argued in a July 9, 2022, tweet: “Just like driver’s licenses, valid, up-to-date medical licenses should be accepted in all 50 states.”

Given state regulation of the practice of medicine, in the absence of a PHE, the federal government’s powers here are limited, although some have suggested tying federal health funding to state adoption of licensing compacts. The Department of Veterans Affairs (VA) already permits a doctor licensed in any state to offer care to anyone in the VA system, wherever the patient is located, since enactment of the VA Mission Act of 2018. Beyond this, some bills have been introduced in Congress to expand use of telehealth and to study it further.

Given the looming shortage of physicians, as well as shortages in other aspects of the health care workforce, the states should move toward reciprocal licensing, with clear rules and obligations on physicians, including notifying all medical boards in states in which they actively practice of disciplinary proceedings against them in the state of their original licensure and accepting the possibility of liability in the states in which they practice. In the spirit of the unique nature of our federal system, one doctor wrote that “[p]erhaps the most promising strategy is one that uses federal authority to encourage reciprocity...Physicians could be permitted to provide telemedicine services to Medicare beneficiaries in any state, as long as they possess a valid medical license.” In essence, this would make the pandemic CMS waiver permanent, which would be an important advance in assuring broader access to health care services. CMS should work with Congress on this significant change.

Physicians

As the number of COVID-19 cases rose exponentially early in the pandemic, hospitals faced increasing needs for physicians. Here, too, regulatory waivers played a role. Separate from the question of interstate practice, CMS waivers permitted those with recently expired privileges to return to the workforce and new physicians to enter the workforce early. Physicians were also permitted greater leeway in issuing orders verbally rather than in writing, to save precious time.

But many of these waivers will likely end with the PHE, as the number of cases has stabilized to levels where questions of appropriate supervision of physicians’ responsibilities may take precedence. Similarly, states that broadened what is normally considered the “practice of medicine” by those other than physicians (for instance, nurse practitioners) may also consider restoring the definitions of professional boundaries that existed before the pandemic.
Hospitals

CMS also issued waivers regarding the number of providers who could treat patients and the sites where hospitals could offer services (for instance, off-site facilities), waiving limits on the size of doctor-owned hospitals, and offering personal benefits (such as free on-site meals) to hospital personnel. Without the waivers, each change would have required a time-consuming review by CMS. The changes were essential in adding space for patients to be treated, as hospitals reconfigured spaces to treat additional patients to keep up with volume and separate COVID-19 patients from those with other conditions. Some provisions on quality assurance programs were also waived to keep the focus exclusively on meeting patient care needs; however, these waivers will likely end as keeping them would mean the end of HHS’ quality assurance programs.\(^{26}\)

While some hospital groups generally favor extension of hospital-related waivers, including the ability to provide care at home,\(^ {27}\) in particular to help address hospital workforce shortages, others argue that care at home can cause greater risk to patients, in particular from reduced access to physicians and other specialists.

Long-term and post-acute care

As the pandemic’s early impact was felt particularly among the elderly, including those in long-term care facilities, HHS issued waivers relating to long-term and post-acute care.\(^ {28}\) Many have expired,\(^ {29}\) particularly those given to speed bureaucratic rules at the onset of the peak early pandemic demand, and waivers regarding hospice care have also ended,\(^ {30}\) as has the waiver regarding physicians’ ability to delegate tasks in certain health facilities.\(^ {31}\)

Overall, in the post-acute and long-term care context, many waivers are unlikely to be renewed. For instance, at least for now that the worst impacts of the pandemic have receded, requirements on giving patients rapid access to their medical records can be restored, and CMS will want to renew the practice of annual inspections, suspended earlier in the pandemic.\(^ {32}\) Perhaps the most significant waiver in this context was that of the required three-day hospital stay before a patient could be moved to subacute care. This waiver was adopted specifically to relieve hospital overcrowding at the height of the pandemic. But making that rule permanent would be very costly for Medicare and should be considered only in the context of notice-and-comment rulemaking\(^ {33}\)—or, of course through an Act of Congress, as one bill would provide.\(^ {34}\) Proponents argue that observation periods in hospitals should count toward the three-day stay, balancing benefit for beneficiaries against increased public spending on health care.

How should regulators proceed?

How should regulators and other stakeholders in the public and private sector think about the question of which regulatory waivers should be preserved?\(^ {35}\) While each regulation is different, some—like telehealth—have proven their worth in a broader context. Others should simply be considered for possible permanent modification (or not) based on an examination of how they were used during the pandemic and a study of the balancing of benefits and costs. The distinction between the two categories lies in those flexibilities that have proven themselves useful in expanding access to care—such
as telehealth—and those more directly related to HHS’ statutory oversight responsibilities, which should be subject to further review. At the same time, after over two years of experience under the PHE, it will take some time for the system to adjust to its previous “normal.” Sixty days’ notice of the expiration of the PHE—which the administration has promised—is a short time for a system to readjust.

FDA: Waivers in a Context of Safety and Public-Private Collaboration

FDA also applied significant regulatory flexibility during the pandemic, again operating under regulatory authorities from Congress that permitted this flexibility. But unlike CMS, given the nature of its mission to approve new drugs, it could not issue blanket waivers but instead had to make decisions specifically with regard to the drugs presented to it for approval.

Early in the pandemic, FDA provided guidance to drug sponsors (companies seeking approval of drugs); these companies would apply for Emergency Use Authorization (EUA) for the drugs, including therapeutics and vaccines, as an initial step before full approval of the products.

Emergency Use Authorization, as the name implies, is directly connected to use in emergencies. Congress first established this policy regarding emergencies connected with public health threats related to CBRN (chemical, biological, radiological, and nuclear) events that pose a threat to national security. The possibility of an EUA is based on a determination by the Secretary of HHS in conjunction with an emergency declared by the Secretary of Homeland Security or Secretary of Defense. EUA is limited to “products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by” the event that gave rise to the emergency when “there are no adequate, approved, and available alternatives.” Separate from the designation of COVID-19 as a PHE, the HHS Secretary made the relevant determination permitting EUA for certain products on February 4, 2020, based on the threat the pandemic posed to national security. Even though no such products currently existed, HHS’ hope was to spur the private sector to quickly research and develop vaccines, antivirals, and other therapies.

Broadly, HHS permitted working on different stages of clinical trials in parallel rather than sequentially. This meant that “later clinical trial phases can begin immediately upon successful completion of the Phase 1 clinical trial currently underway. Working in parallel instead of taking the traditional sequential approach to vaccine development potentially shaves months off the timeline for vaccine development.” That is exactly what happened: Phase 1 and 2 trials were combined in both the US and Europe, human clinical trials were successful, and EUAs for COVID-19 vaccines were approved on December 11, 2020, (Pfizer-BioNTech) and December 18, 2020 (Moderna). FDA later authorized use of the Novavax vaccine under the same EUA procedures.

The time was shortened considerably, saving lives. The Moderna and Pfizer vaccines later received full FDA approval on August 23, 2021 (Pfizer-BioNTech) and January 31, 2022 (Moderna). The global record on the use of these vaccines proves that the EUA procedures worked and the regulatory flexibility Congress granted for emergency use was justified.
FDA rapid review of COVID-19 vaccines

Vaccine Timeline, February 2020-June 2022

February 4, 2020
- FDA exercises enforcement discretion
  - FDA authorizes EUA to enable emergency use of the CDC’s 2019-nCoV Real-Time RT-PCR Diagnostic Panel

May 5, 2020
- Pfizer dose first participants in US as part of vaccine development program

July 2020 - Aug. 2020
- Production Agreement
  - Pfizer: Pfizer and BioNTech announce agreement with US Government for up to 60 million doses of vaccine (July 22, 2020)
  - Johnson & Johnson: J&J announces agreement with US Government for 100 million doses of vaccine (August 5, 2020)
  - Moderna: Moderna announces Supply Agreement with US Government for initial 100 million doses of vaccine (August 11, 2020)

Nov. 2020 - Feb 2021
- Applications for EUA Submitted
  - Pfizer (November 20, 2020)
  - Moderna (November 30, 2020)
  - Johnson & Johnson (February 4, 2021)

Dec. 2020 - Feb. 2021
- FDA announces Emergency Use Authorization
  - Pfizer (December 11, 2020)
  - Moderna (December 18, 2020)
  - Johnson & Johnson (February 27, 2021)

Dec. 2020 - Nov. 2021
- Administration of vaccines begins
  - First deliveries of COVID-19 vaccine began (December 14, 2020)
  - All people aged 16 and over eligible for vaccine (April 19, 2021)
  - All adults eligible for Booster (November 21, 2021)

Aug. 2021 - Jan. 2022
- FDA full approval
  - Pfizer (August 23, 2021)
  - Moderna (January 31, 2022)

May 2021
- FDA EUA for first pediatric use (12+)
  - Pfizer for adolescents aged 12 to 15 (May 10, 2021)

June 17, 2022
- FDA EUA for third pediatric use (6 mo+) and Moderna authorization for pediatric use
  - Moderna EUA amended to include individuals six months through 17 years; Pfizer EUA amended to include individuals six months through four years (the vaccine had been authorized for use in individuals 5 years of age and older). (June 17, 2022)

Source: Food and Drug Administration, Pfizer, Moderna, Johnson & Johnson, The Conference Board, 2022
In 2013, Congress also gave FDA authority in the Pandemic and All-Hazards Preparedness Reauthorization Act in a new Section 564A(b) of the Federal Food, Drug, and Cosmetic Act to extend expiration dates of certain medical products, particularly those related to the Strategic National Stockpile of medicines and medical supplies for use in designated PHEs.

Using similar authorities to EUA under this provision, FDA has also provided regulatory flexibility on the expiration dates of certain medical products, where “testing has shown that certain properly stored medical products can be used beyond their labeled expiration date if they retain their stability 

40 FDA has used its authorities here to extend expiration dates on a variety of products: COVID-19 vaccines, therapeutics including monoclonal antibodies (sotrovimab; tixagevimab copackaged with cilgavimab; casirivimab and imdevimab; and bebtelovimab), oral therapies (nirmatrelvir and ritonavir), in vitro diagnostics, antivirals (including Tamiflu and Relenza), doxycycline held in stockpiles (some had been purchased for anthrax emergency preparedness and response purposes), and nerve agent auto-injectors—all products directly related to treatment of COVID-19 or for essential use in the national stockpile against other public health threats.

In each case, FDA acted only after receiving rigorous scientific data provided by the manufacturer. Such work is only possible with extensive public-private collaboration.

Here, FDA is using its regulatory expertise wisely: given the potential product safety implications of using a medical product beyond its expiration date, only with testing can the agency perform its role to ensure patient safety, balancing this against the need to maintain stockpiles of critical medicines at a reasonable cost. But this type of regulatory flexibility can only work with close public-private cooperation, in this case the presentation of rigorous data by the manufacturer and rapid review of the data by FDA. Regulatory cooperation is not always wise; opponents have suggested that it can sometimes lead to “regulatory capture” of agencies, but in this case the needs for the therapies were great, and the risks minimal or nonexistent.

It would take an Act of Congress to expand EUA beyond its current limitations and connection with a national security event. Whether that is wise is up to Congress. At a minimum, however, HHS, in conjunction with the private sector, should undertake a comprehensive review of how effective FDA’s use of regulatory flexibility was during the pandemic to determine whether this flexibility can be applied more broadly without compromising safety and efficacy, potentially leading to faster approval of new therapies.

In the meantime, it is also worth noting that FDA, in the context of oncology and Alzheimer’s disease, has established an Accelerated Approval Program, under congressional authorization, which has led to the accelerated approval of 282 drugs as of June 2022.41 The rationale for the program is that it can lead to the earlier use in patients, beyond the limited number enrolled in clinical trials, of potentially life-saving or life-prolonging therapies, in situations such as oncology where delay in approval could cost lives.

Accelerated approval is conditional approval of a drug based on evidence the manufacturer has provided to FDA based on clinical trials and specifically requires rigorous “Phase 4” post-marketing studies to determine safety and efficacy before full approval is granted; conditional approval may be withdrawn at any time based on new data, and
the manufacturer retains the right to withdraw the drug as well. Studying the Accelerated Approval Program to consider its potential further broadening could lead to more rapid general use of potential life-saving or life-prolonging therapies and provide a significant boost to domestic pharmaceutical research on conditions that might otherwise find it difficult to attract capital because of the high expense and protracted timeline involved in research and the uncertain possibility of success.

**Vaccine Mandate Regulations: A Cautionary Tale**

It is a basic principle of administrative law, and thus of regulation, that an agency can exercise only those powers that Congress has explicitly delegated to it. Article I of the Constitution grants Congress the right to enact all measures “Necessary and Proper” for the execution of its legislative powers, and this includes granting explicit powers to agencies in the executive branch. In the 20th century, what has come to be known as the nondelegation doctrine arose from the 1928 decision in *J.W. Hampton Jr. & Co., v. U.S.*, in which Chief Justice William Howard Taft wrote that Congress must “lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform.”

While the principle is flexible and broad, it also has clear limits. Some of those limits were established when the Court overturned several laws of President Franklin D. Roosevelt’s New Deal; others have arisen more recently. Even in the context of an emergency such as the pandemic, the nondelegation doctrine applies, and the Court did not hesitate to state that an agency could only act within the limits of the powers Congress had given.

Following the successful release and administration of COVID-19 vaccines under EUA, the question arose as to whether government could require not only its employees but employees in other industries to receive vaccines.

The administration, citing the risks of COVID-19 to workers, took a broad, expansive view of its powers in this area. On November 5, 2021, the Occupational Safety and Health Administration (OSHA) published an Emergency Temporary Standard (ETS) mandating that employers with more than 100 employees require either vaccination of their workers, with exemptions for religious and medical reasons, or the alternative of wearing a face mask at work and agreeing to weekly testing for COVID-19. OSHA acted under the “General Duty” clause of the statute, giving it authority to impose requirements on employers, and specifically cited a statutory reason (“grave danger” to workers) when imposing a broad rule requiring vaccination, as well as its belief that employers with over 100 workers would be able to handle the requirement administratively.

Reaction, including litigation, was swift. While many employers adopted some form of vaccination requirements for employees on their own initiative, opposition from some employers and from segments of the public was strong. Litigation against the ETS began almost immediately. While the Court of Appeals for the Sixth Circuit initially permitted the rule to take effect, litigation continued, culminating in an appeal to the Supreme Court seeking emergency relief from the ETS. The Supreme Court agreed that OSHA had far exceeded its powers.

The Supreme Court, in *National Federation of Independent Businesses v. OSHA*, overturned the ETS. In strong language, the court wrote that “[t]he Secretary has ordered
84 million Americans to either obtain a COVID–19 vaccine or undergo weekly medical testing at their own expense. This is no ‘everyday exercise of federal power.’ ...We expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance.”45 In response, OSHA withdrew the ETS,46 although it continued its request for comment on its proposed rule issued at the same time.

Very different, however, was the fate of another vaccine mandate, this one issued by HHS regarding mandatory COVID-19 vaccinations for most health workers (except those with medical or religious exemptions) in facilities that receive Medicare and Medicaid funding.47 In another per curiam opinion issued the same day as the OSHA ETS case, the court held in Becerra v. Louisiana (decided together with Biden v. Missouri)48 that issuance of the vaccine mandate was within the authority of the HHS Secretary.

In particular, the court found that the Secretary had exercised statutory authority appropriately.49 Citing evidence that the vaccine mandate was “necessary for the health and safety of individuals to whom care and services are furnished” and figures showing that 35 percent or more of workers at some health care facilities remained unvaccinated, the Court also relied on data showing the ease with which the virus could spread from health care workers to patients—thus tying the rule directly to an occupational hazard, unlike the broader proposed ETS covering all employers with more than 100 employees. Therefore, the court agreed that “the Secretary’s rule falls within the authorities that Congress has conferred upon him. ...The rule thus fits neatly within the language of the statute.”50

In response to the ruling, OSHA published a proposed rule on “Occupational Exposure to COVID-19 in Healthcare Settings.”51 Importantly, despite the Supreme Court’s decision in Becerra v. Louisiana that permitted HHS to require vaccination against COVID-19 for workers in facilities receiving Medicare and Medicaid funding, “OSHA is not considering at this time requiring mandatory vaccination for employees covered by this standard” (their emphasis), but also noted that “[t]he majority of healthcare employees...are subject to [vaccination requirements].”52 OSHA further wrote that it was considering “providing a ‘safe harbor’ enforcement policy for employers who are in compliance with [applicable] CDC guidance.”

What differences made one regulation enforceable while the other was not? Most importantly, in the health care workers regulation, there was a clear link to direct statutory authority. Second, the process of how the rule was adopted for enforcement was also clearly linked to delegated powers. Third, the substance of the rule was narrowly tailored in one case and overly broad in another.

The Supreme Court’s decision overturning the broader ETS should not have been surprising given the long history of the nondelegation doctrine. A very recent case reaffirms that doctrine explicitly and points the way to similar decisions in the future.

In West Virginia v. EPA, the Supreme Court issued a major decision on the extent of agencies’ powers, in particular what it saw as an agency’s attempt to exercise powers that were not only not directly expressed in the underlying statute but that Congress had declined to adopt. The court criticized the Environmental Protection Agency for its attempt at exercising an “unheralded power representing a transformative expansion of
its regulatory authority in the vague language of a long-extant, but rarely used, statute designed as a gap filler. That discovery allowed it to adopt a regulatory program that Congress had explicitly declined to enact itself,” noting that the agency “conveniently enabled it to enact a program, namely, cap-and-trade for carbon, that Congress had already considered and rejected numerous times.”

This decision has three basic implications for the future of regulation—implications that are not new but that should receive greater attention in the future. First, Congress needs to be clear—as clear as possible—in stating what powers it has (and has not) delegated to agencies. Second, agencies need to ground their regulatory activities firmly within those delegations or risk defeat in litigation, thus upending the very regulatory goals they seek while undermining their credibility as regulators. Third, the business community should not fear robust participation in the regulatory process, particularly at the comment stage of notice-and-comment rulemaking. It is the way they can formally express their opinion to government, publicly and on the record. And agencies need to understand business’ expertise and perspective to adopt wise and smart regulation that will address the needs for which regulation is adopted without distorting economic incentives, discouraging investment in the US, or engaging in constant attempts at changing regulation in the face of new technologies or new developments.

The Need for Regulatory Review

While much of this Solutions Brief has considered some of the largest agencies in the federal government—HHS and Labor—it is instructive to look at a recent example of a smart regulatory approach from one of the government’s smaller agencies, the Farm Credit Administration.

In July 2022, the Farm Credit Administration launched a public notice-and-comment rulemaking on a regulatory review process designed to eliminate “consistent with law and the safety and soundness of the [Farm Credit] System, all regulations that are unnecessary, unduly burdensome or costly, or not based on the law.” The agency defined “unduly burdensome regulations” quite simply as those that “impose burdens that are greater than the benefits received.” Importantly, the agency is also concerned about the differential impact of regulation: “how does [a Farm Credit] association’s district location, size compared to other associations in the district, or complexity of operations impact the burden of specific regulations?”

The agency was explicitly commanded to undertake this review periodically by statute (Section 212 of the Farm Credit System Reform Act of 1996). Confirming a continuous look at the effectiveness of regulation is a wise part of congressional legislation and helps mark a middle ground between a strict view on nondelegation of congressional powers and agencies exercising powers beyond those specifically granted them.

Not all agencies can undertake such a comprehensive regulatory review (for agencies such as HHS, Labor, or Transportation, the effort would take years), but many agencies should think more deeply about how they can take analogous steps to reduce unnecessary regulatory burdens consistent with enforcing laws enacted by Congress and performing the agency’s mission. For instance, in the Infrastructure Investment and Jobs Act (the Bipartisan Infrastructure Law), Congress included a provision requiring...
the Secretary of Transportation to examine waivers that have been in effect for six years to determine whether they should be adopted through a formal regulation, to provide predictability and certainty. That type of regulatory cleanup activity is important to the smooth functioning of the regulatory system and pushes the system in the direction of smart regulation.

Conclusion

The pandemic has shown that smart regulation is both thoughtful and flexible. In the fog of war that is endemic to almost every crisis, timely decision-making, involving appropriate subject matter experts and clear, candid, credible, consistent communications make regulatory practice as pragmatic as possible—and most important, ensure the greatest community support and adherence. The pandemic showed that well-planned regulatory waivers, considered by Congress in advance, offered the American people relief during the pandemic and a quicker exit from many of its impacts. They also offered US businesses a lifeline to expand beyond the limits of normal operations, both in research and development and in the provision of care. Now, the government should take these lessons, work with business leadership to plan now for the next public health or other emergency, and consider other areas in which similar planning for regulatory flexibility may be warranted.
Endnotes


16. Federation of State Medical Boards, *US States Modifying Requirements for Telehealth*.

17. Federation of State Medical Boards, *The Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, April 2022.

18. Federation of State Medical Boards, *US States and Territories Modifying Requirements for Telehealth in Response to COVID-19* (South Dakota).


27 American Hospital Association, Fact Sheet: COVID-19 Waivers that should be Extended, Made Permanent or Enacted in Order to Improve Patient Care; Stacey Hughes, Executive Vice President, Government Relations and Public Policy, Letter to The Honorable Chiquita Brooks-LaSure, Administrator, CMS, July 29, 2021.
29 CMS, Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers, April 7, 2022.
30 CMS Announces End of 1135 Waivers for Inpatient Hospices on June 6, 2022.
31 CMS, Physician Delegation of Tasks in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), March 8, 2013.
40 FDA, Expiration Dating Extension.
41 FDA, CDER Accelerated Approvals Based on a Surrogate Endpoint, June 30, 2022.
45 US Supreme Court, National Federation of Independent Businesses v. Department of Labor 595 U. S. ___ (2022) at 5, 6 (internal citations and quotations omitted).


50 *Becerra v. Louisiana*, citing to 86 Federal Register 61583, at 61586.


52 Specifically, the CMS vaccination rule (86 FR 61555).


54 US Supreme Court, *West Virginia v. EPA* at 6.

55 Farm Credit Administration, *Statement on Regulatory Burden*, 87 Federal Register 43227 (July 20 2022).

56 *Infrastructure Investment and Jobs Act*, Public Law 117-58 (November 15, 2021), Section 22411.
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Achieving prosperity for all Americans could not be more urgent. Although the United States remains the most prosperous nation on earth, millions of our citizens are losing faith in the American dream of upward mobility, and in American-style capitalism itself. This crisis of confidence has widened the divide afflicting American politics and cries out for reasoned solutions in the nation’s interest to provide prosperity for all Americans and make capitalism sustainable for generations to come. In 1942, the founders of the Committee for Economic Development (CED), our nation’s leading CEOs, took on the immense challenge of creating a rules-based postwar economic order. Their leadership and selfless efforts helped give the United States and the world the Marshall Plan, the Bretton Woods Agreement, and the Employment Act of 1946. The challenges to our economic principles and democratic institutions now are equally important. So, in the spirit of its founding, CED, the public policy center of The Conference Board, releases a series of CED Solutions Briefs throughout the year. These briefs address today’s critical issues, including health care, the future of work, education, technology and innovation, regulation, US global competitiveness, trade, infrastructure, inequality, climate, energy & the environment, and taxation.