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The Great Pandemic Unwind: Five Healthcare Issues to Watch

In response to the COVID-19 pandemic, a wide range of new policies and flexibilities were put into place to reduce administrative burdens on overworked healthcare providers, accommodate patient needs for care to be delivered in different ways, and help clinicians and staff respond rapidly to the changing pandemic environment. While these policies were important for supporting the unique and dynamic demands of the pandemic, not all of these policies and flexibilities will remain in place indefinitely.

In fact, many of these policies will no longer be in effect when the Department of Health and Human Services (HHS) public health emergency (PHE) declaration expires, which is expected to occur as early as October 13, 2022.[i] While not all the new policies are tied explicitly to the PHE declaration, it is expected that the PHE expiration could result in an "unwinding" of federal pandemic changes beyond just those tied to the PHE. In this brief, we highlight five major issue topics for the healthcare industry, particularly providers, to watch as the pandemic policies begin to unwind:

1. Telehealth
2. Expanded coverage
3. Provider financial supports
4. Other provider waivers and flexibilities
5. Emergency use authorization (EUA) and other product access authorizations

Each of the five topics we highlight have their own complex set of policy and political considerations that will influence when and how pandemic changes will be lifted, modified, or made permanent. For example, some of the COVID-19 policy changes and flexibilities were specifically authorized by Congress, while others could be extended or amended through regulatory authority or related declarations from the Secretary of HHS.

In addition, the authorities and associated timelines enabling these policy changes do not all perfectly align, given that some are bound by the PHE declaration, some are driven by congressionally set timelines, and others are dictated by additional HHS authorities (e.g., FDA). This is likely to create a cascade of changes and confusing timelines over the coming months and year(s). While this could give providers additional time to prepare, it will also create additional complexity in understanding and tracking compliance timelines. As a result, providers must understand the implications of the changes and timelines and begin to develop strategies to adjust operations and patient care accordingly.

Why Does the PHE Declaration Matter?

The combination of the PHE[ii] and a National Emergencies Act (NEA) declaration by former President Trump empowered the HHS Secretary to utilize authority under section 1135 of the Social Security Act to waive or modify certain requirements of Medicare, Medicaid, and State Children's Health Insurance Programs (CHIP) and of the Health Insurance Portability and Accountability Act (HIPAA) through the duration of the pandemic emergency. Using this

[i] The Biden Administration has indicated that it will provide 60 days' notice prior to allowing the PHE to expire. Given that the Administration did not provide notice by May 16, 2022 that the PHE would end on July 15, 2022, we can expect the PHE to be extended by another 90 days through October 13, 2022.

[ii] On January 27, 2020, former Department of Health and Human Services (HHS) Secretary Alex Azar first declared that a public health emergency (PHE) existed "as a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic." The PHE determination, which must be redetermined every 90 days, has been renewed nine times since then, most recently by current HHS Secretary Xavier Becerra on April 12, 2022, effective April 16, 2022.

authority, CMS issued temporary blanket waivers and regulatory flexibilities for the duration of the PHE,[iii] which were intended to support healthcare providers and states in meeting the unique demands of the pandemic. These waivers and flexibilities would end when the PHE expires on October 13, 2022, or later if extended. The likelihood of further extension is far from certain, although a continuing increase in cases or significant surge in hospitalizations are certainly factors that will influence public health decisions.

In addition to PHE-related flexibilities, legislative changes made during the pandemic through the Coronavirus Aid, Relief, and Economic Security (CARES) Act;[1] Paycheck Protection Program and Health Care Enhancement Act;[2] Families First Coronavirus Response Act (FFCRA);[3] and American Rescue Plan[4] have also impacted the healthcare industry in various ways over the past two years. Importantly, the Provider Relief Fund was established to support providers financially in responding to the pandemic. Congress also passed legislation to, among other things:

- Require coverage of COVID-19 testing and therapeutics by insurance companies without patient cost sharing
- Reimburse healthcare providers and facilities for testing, treating, and administering vaccines to the uninsured
- Augment provider payment relative to existing law
- Increase the federal Medicaid match for states and ensure patients' access to continuous Medicaid enrollment; expand eligibility for subsidies through the ACA exchanges
- Increase funding across the federal government to respond to the pandemic, including for development, distribution, and administration of COVID-19 therapeutics
- Provide flexibilities on where and how patients could access telehealth services.

Many of these legislative changes are tied to the expiration of the PHE, while others expire or return to prepandemic policies at a time specified in the legislation.

1. Telehealth

Use of telehealth increased dramatically in the first year of the pandemic[iv] and has remained above prepandemic levels,[v] although utilization has declined in recent months. The major driver of this dramatic increase in telehealth utilization was legislation authorizing flexibilities put into place by CMS in early and mid-2020[5] to ensure that Medicare beneficiaries had access to the care they needed during the initial surge in COVID-19 cases. Most private insurers in the group and individual market followed suit by also expanding coverage of telehealth, including waiving cost sharing for such visits.[6]

To promote and incentivize telehealth visits for Medicare patients, CMS extended full Medicare payment for office, hospital, and other visits furnished via telehealth across the country, including in patient's places of residence, through the duration of the PHE. This authority was given to CMS through the *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020* and the *CARES Act*, permitting the agency to waive the statutory "originating site" and "geographic site" requirements, which generally only permitted reimbursement when telehealth services were provided at qualifying originating sites (e.g., practitioner office, hospital, rural health clinic) and patients were in rural areas. As a result of the waiver of these requirements, patients were generally permitted to receive telehealth services in their home, regardless of geography, and providers were incentivized to invest in telehealth technology.

Additionally, CMS established payment parity by setting evaluation and management (E/M) payment rates equal for telehealth and in-person visits and provided a broad range of other flexibilities to expand access to telehealth services (see box: *HHS Telehealth Flexibilities during the PHE*).

These Medicare flexibilities were set to expire with the PHE; however, the *Consolidated Appropriations Act, 2022,*[7] enacted on March 15, 2022 extended these telehealth waivers for 151 days beyond the expiration of the PHE. This extension would authorize these waivers to remain in place beyond the end of 2022.

[iii] On March 30, 2020 CMS announced new flexibility and a series of waivers to apply for the remainder of the PHE. A number of these flexibilities were included in an interim final rule with comment (IFC), Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. The flexibilities in the interim final rule and others announced by CMS since then have, among other things, "permit[ted] hospitals and healthcare systems to expand capacity by triaging patients to a variety of community-based locales... enable[d] and encourage[d] hospitals to hire local physicians and other providers to address potential surges… allow[ed] hospitals to support physician practices by transferring critical equipment, including items used for telehealth… and dramatically lessen[ed] administrative burdens."

[iv] HHS's Office of the Assistant Secretary for Planning and Evaluation reported that the share of Medicare visits conducted through telehealth in 2020 increased 63-fold, from approximately 840,000 in 2019 to 52.7 million in 2020, and that 92 percent of beneficiaries received telehealth visits from their homes, which was not permissible prepandemic.

[v] Although a Kaiser Family Foundation analysis found that telehealth accounted for 13 percent of outpatient visits from March 2020 to August 2020 and 8 percent of outpatient visits a year later (March 2021 to August 2021), utilization remained significantly elevated from prepandemic use (rounding to 0 percent of outpatient visits).

Patients' and providers' preferences suggest that telehealth will remain a significant component of healthcare moving forward.[vi]

However, the transition from pandemic flexibility to full integration into postpandemic practice may not be as straightforward as patients and providers would like.[8] While CMS could extend some telehealth flexibilities through future rulemaking (e.g., through annual Medicare payment rules, etc.), many policy changes would require an act of Congress to be made permanent.[9] For example, waiving the statutory "geographic requirement" and "originating site requirement" would require a change in statute to make the PHE-limited legislative authority permanent after the PHE ends.

HHS Telehealth Flexibilities during the PHE

- Expanded the list of healthcare providers permitted to furnish distant site telehealth services to include physical therapists, occupational therapists, and speech language pathologists.
- Expanded the list of telehealth services eligible for reimbursement, including certain emergency department visits, initial and subsequent observation, critical care, and home visits.
- In conjunction with the Office of Civil Rights (OCR), permitted use of audio-visual functionality on mobile phones by allowing good faith use of video chat applications such as FaceTime, Zoom, and Skype services; OCR also exercised enforcement discretion regarding HIPAA requirements that typically apply to remote communication technologies.
- Allowed reimbursement for certain audio-only E/M codes for new and established patients.
- Allowed the use of telehealth services across state lines (i.e., not requiring providers to be licensed in the state where they are providing services, based on meeting certain conditions).
- Lifted restriction on the number of times that certain services can be provided via telehealth.
- Permitted physicians to provide direct supervision through virtual presence.
- Expanded telehealth codes that rural health clinics (RHCs) and federally qualified health centers (FQHCs) may use for reimbursement and allowed them for new and established patients.
- Waived frequency restrictions and face-to-face requirements for several other provider types and visits, including home dialysis, hospice, rehabilitation, home health, inpatient visits, subsequent nursing facility visits, and critical care consultations.

To date, Congress has not made permanent changes in telehealth policy except in limited circumstances, such as with telemental health (see box: *Congressional Action to Extend Pandemic Telehealth Flexibilities*).

Congressional Action to Extend Pandemic Telehealth Flexibilities

Section 123 of the Consolidated Appropriations Act of 2021 required coverage of telemental health services in the patient's home. As a result, the 2022 Medicare Physician Fee Schedule finalized a policy for coverage of telehealth-based mental health services when a patient is located at home, if three conditions are met: (1) the practitioner conducts an in-person exam of the patient within the 6 months before the initial telehealth service; (2) the telehealth service is furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder (other than for treatment of a diagnosed substance use disorder (SUD) or co-occurring mental health disorder); and (3) the practitioner conducts at least one in-person service every 12 months of each follow-up telehealth service.

While there are legislative proposals being discussed to make more telehealth flexibilities permanent, the prospects of passage for a comprehensive stand-alone telehealth bill are challenged in this Congress by a congressional calendar with other legislative priorities before and immediately after the November 2022 elections.

[vi] Patients have generally viewed telehealth favorably; 83 percent of respondents to a COVID-19 Healthcare Coalition survey reported both good overall visit quality and strong communication with their provider. Physician views, however, are a bit more mixed. A McKinsey survey found only 36 percent of providers believe telehealth is more convenient for providers than in-person care and only 32 percent agree that telehealth can improve patient experience, while an Optum survey found that although 93 percent of providers plan to continue using telehealth after the pandemic, they express concerns about the quality of care they can provide, managing patient expectations, and technical challenges. Most recently, a Morning Consult survey found nearly 85 percent of providers support being able to practice telehealth across state lines after the pandemic ends.

Congress has yet to signal an intention to act quickly and decisively on long-term telehealth policies given the number of outstanding and the unanswered policy questions about value, cost, and patient benefits of telehealth.[10] For example:

- While telehealth appears to be a good alternative to a physician office visit during a pandemic (and, in some cases, a necessity) to reduce the chance of exposure to COVID-19, what should be the primary use case for telehealth after the PHE—vulnerable populations who remain most at risk for infection; patients in rural areas; patients with established relationships with providers receiving routine follow-up care for chronic conditions; individuals seeking the convenience of not having to travel to a provider's location; etc.?
- What is the justification for Congress and/or CMS creating broader parameters around which providers can be reimbursed for telehealth- and for which services?
- Are the incentives aligned to ensure the most judicious use of telehealth in Medicare or the best possible health outcomes for beneficiaries? For example, if telehealth results in fewer lab tests, images, and referrals to specialists ordered through telehealth, will these net savings come at the expense of the best possible health outcomes?
- Even with greater data on how telehealth was used during the pandemic and its impact on cost and quality of patient care, what conclusions can be reached on the true value of telehealth outside of a public health emergency?
- Is in-person care and care delivered via telehealth comparable for all patients, all conditions, and in all circumstances?
- Is payment parity between in-person and telehealth services in Medicare the best policy for driving the highest quality and value of care for beneficiaries or the program?
- Once the pandemic ends and in-person visits become more standard, what is the relative value of in-person versus telehealth care and does that justify continued payment parity?

Prior to a full policy embrace of telehealth, policymakers must resolve the tension between the public policy goals of appropriate use (or value) and equitable access. Managing these trade-offs between access and delivering only high-value care will be hard for CMS, especially outside of demonstration programs or fully capitated plans with the ability to tailor coverage to targeted populations and access to value-based payment funding. CMS and commercial payers must ensure that any flexibilities put in place are resulting in high-value care that is an appropriate substitution for in-person care and not leading to duplicative services. A recent *JAMA* study[11] of Blue Cross Blue Shield Association plan members' telehealth utilization during the pandemic (July 1, 2020 to December 31, 2020) suggests the relative value of telehealth services may differ by patient population—increased telehealth use did not generally lead to duplicative care for chronic conditions; however, telehealth visits for acute care were more likely to require follow-up care than in-person visits. Crafting telehealth policies that segment use and reimbursement according to patient characteristics (chronic versus acute care, health status, access to alternative care settings, location, social risk factors, etc.) may help to ensure that telehealth is used to maximize value; however, these policies must be defensible so as not to exacerbate existing inequities.

CMS and other payers must consider whether their telehealth policies are aligned with the growing emphasis on health equity and reducing racial and ethnic disparities. These issues are particularly important in the context of long-term policies on audio-only telehealth services, which are vital for many underserved and disadvantaged communities that may not have access to broadband connections necessary for real-time audio and video virtual visits.

Additionally, as more data and evidence are assembled on the telehealth-related outcomes, reimbursement policies must align to reward the appropriate use of telehealth (i.e., the patients and conditions most likely to benefit from remote services). Absent specific direction from Congress, CMS will have to justify continued payment parity between in-person and telehealth services for all telehealth services. While increased reimbursement may have been necessary to accelerate the investments in and use of telehealth by providers that lacked existing access to or resources for virtual care platforms, continuing to pay the same rate for telehealth when in-person care is once again safe and widely available to patients will be hard for CMS and commercial payers to justify. In fact, based on a CBO score of the policy extending flexibilities for 151 days post-PHE, the Committee for a Responsible Federal Budget estimated that a permanent extension of telehealth flexibilities could cost Medicare $25 billion over 10 years, even without expanded use.[12] The continued cost of payment parity to CMS and other payers would likely be unsustainable, absent clear data that telehealth is resulting in true substitution for in-person care and creating more efficient, high-value care and better outcomes.

These considerations will become magnified as Congress considers what, if anything, should be done after the 151-day extension expires. Policymakers are likely to look to reports from MedPAC and the HHS OIG, required by the *Consolidated Appropriations Act* and due by June 15, 2023,[13] for guidance on how telehealth has been used during the pandemic, including its impact on cost and quality of patient care and the incidence of fraud, waste, and abuse. Some industry experts believe Congress is likely to extend the pandemic-related waivers until these reports are issued and policymakers have better data to drive policy.[14] Indeed, MedPAC recommended in March 2021[15] that policymakers temporarily continue certain telehealth expansions for one to two years after the PHE to gather more evidence on access, quality, and cost to inform any permanent changes, while also implementing safeguards to protect Medicare and its beneficiaries from unnecessary spending and potential fraud.

Regardless of which telehealth flexibilities and policy changes are made in the short versus longer term, providers may have to plan for alternative patient care scenarios, especially for individuals who are unable or unwilling to return to in-person visits.

2. Expanded Coverage

As part of the *Families First Coronavirus Response Act (FFCRA*), states were given a 6.2 percent Federal Medical Assistance Percentage (FMAP) increase, conditional on meeting four requirements:[16] (1) maintaining eligibility standards, methodologies, or procedures that are no more restrictive than those the state had in place as of January 1, 2020; (2) not charging premiums that exceed those that were in place as of January 1, 2020; (3) covering, without the imposition of cost sharing, testing services and treatments for COVID-19, including vaccines, specialized equipment, and therapies; and (4) not terminating individuals from Medicaid if such individuals were enrolled in the program as of the date of the beginning of the emergency period, or become enrolled during the emergency period, unless the individual voluntarily terminates eligibility or is no longer a resident of the state.

The "continuous coverage" requirement in Section 6008(b)(3) of FFCRA generally prevents states from terminating coverage for individuals enrolled as of or after March 18, 2020, through the end of the month in which the COVID-19 PHE ends. As a result of this change, Medicaid and CHIP enrollment has reached a record nearly 87 million individuals,[17] up approximately 20 percent since the start of the pandemic.

If the PHE declaration expires on October 13, 2022, the 6.2 percent FMAP increase would continue until the end of the quarter (December 31, 2022); however, the continuous enrollment requirement would end on October 31, 2022. States would initiate eligibility redeterminations beginning on November 1, 2022. The end of the PHE could have a profound impact on Medicaid enrollment. Analysts estimate that up to 15 million adults and children[18] could lose Medicaid coverage once states begin to unwind continuous enrollment requirements. This significant shakeup in coverage could have serious negative impacts on low-income individuals who are already disadvantaged.

Medicaid Guidance on Redeterminations and the Role of MCOs

CMS has tried to partially ease the burden of Medicare redeterminations by providing states with two additional months (14 total) to complete the redetermination process; states must still initiate all redeterminations during the first 12 months, providing a relatively quick turnaround time to conduct extensive administrative work. Additionally, Medicare is allowing managed care plans to support the redetermination process, which could add needed administrative capacity to states, and HHS has asked the Federal Communications Commission to allow federal, state, and local workers, including managed care plans to communicate with enrollees through text messages and automated phone calls about redeterminations without running afoul of the Telephone Consumer Protection Act.

A KFF survey of state officials[19] found many states are taking steps to promote continuity of coverage (e.g., updating enrollees' mailing addresses, following up with enrollees when action is required to maintain coverage, and boosting eligibility-staff capacity); however, just 27 states have plans in place for how they will prioritize outstanding eligibility and renewal actions. Regardless of when these changes take effect, the unprecedented volume of Medicaid redeterminations and changes in individuals' circumstances will pose significant challenges for states in validating correct information for beneficiaries, particularly those who may have housing instability and be unable to easily reach for validation of income.

In addition to the Medicaid continuous enrollment change, the *American Rescue Plan Act (ARPA)* included provisions to expand access to insurance coverage through the ACA during the pandemic.[vii] As a result of this expanded eligibility for financial assistance, CMS reported that a record 14.5 million individuals signed up for or were automatically reenrolled in 2022 individual marketplace coverage.[20] Although this expanded access is only effective for 2021 and 2022, Congressional Democrats are attempting to extend the "enhanced" ACA marketplace subsidies through 2025.[21] Without extension, millions of individuals who gained affordable coverage because of the ARPA provisions would lose subsidized coverage and have to pay more to continue marketplace coverage.

Families USA recently projected that 18 million Americans could lose insurance coverage in the next 12 months due to Medicaid eligibility redeterminations and the expiration of enhanced ACA subsidies.[22] Furthermore, the end of the PHE will pull back required coverage without cost-sharing of COVID-19 testing and therapeutics by insurance companies and those types of claims for the uninsured claims are no longer being covered by HRSA. These disruptions in coverage will impact individual patients and providers in both predictable and unpredictable ways. As a result, each state must begin preparations for these coverage expansions to end so that millions of beneficiaries do not abruptly lose their healthcare coverage.

3. Provider Financial Supports

Provider Relief Fund (PRF)[viii] payments have been distributed in four phases[23] through a combination of general distributions, which all providers meeting criteria are eligible to receive, and targeted distributions for those that meet additional criteria, such as having a high number of COVID-19 inpatients or being a skilled nursing facility, safety net hospital, children's hospital, or rural provider. Although providers are generally not required to repay the amounts received through the PRF,[ix] they must attest to certain terms and conditions associated with the distribution and report on the use of funds, if receiving more than $10,000. Failure to comply with these reporting requirements could result in HHS requiring providers to repay the funding.

Additionally, HHS Office of the Inspector General (OIG) has already indicated it will perform its own audits of the PRF program to determine whether payments were calculated and paid appropriately by HHS[24] and whether hospitals fully complied with PRF terms and conditions,[25] including not balance billing out-of-network patients. Audits could result in hospitals and providers being required to repay PRF funds.

In addition to the PRF, Section 3710 of the *CARES Act* directed HHS to provide a 20 percent add-on payment to hospitals for services provided to COVID-19 patients.[x] The PRF and other financial supports have played an important role in supporting hospitals as they experienced steep declines in revenue early in the pandemic during 2020. MedPAC concluded in December 2021[26] that these financial supports provided to hospitals during the pandemic may have contributed to a significant decline in hospital closures; increased hospitals' all-payer margins, including near record margins for rural hospitals; and kept Medicare's margin at inpatient hospitals relatively steady. In aggregate, despite declines in patient volume during the PHE, financial supports from the federal government have helped hospitals maintain, if not improve, financial performance.

The American Hospital Association (AHA) reports a slightly less optimistic financial outlook for hospitals during the pandemic. AHA recently reported that per-patient hospital costs increased 20.1 percent during the pandemic (2019 to 2021), including a 36.9 percent increase in drug costs. More broadly, total hospital costs increased 11 percent from 2019 to 2021, while 33 percent of hospitals are currently operating on negative margins.[27] Although both the PRF and hospital add-on payments may have provided some essential financial stability during the pandemic, hospitals and other providers must be prepared to return to "normal"

[vii] Section 9661 modified the affordability percentages used for 2021 and 2022 ACA premium tax credits by reducing the maximum percentage of income an individual must contribute to premiums for a benchmark plan from 9.8 to 8.5 percent as well as decreasing the minimum percentage to 0 percent for the lowest income individuals. In effect, the lowest income individual not eligible for Medicaid (150 percent of the federal poverty line (FPL)) could enroll in a benchmark plan with no premiums. Additionally, *ARPA* allowed individuals with incomes above 400 percent of FPL, previously ineligible for coverage, to enroll in coverage with premiums totaling no more than 8.5 percent of household income.

[viii] *The CARES* Act appropriated $100 billion through a newly established Public Health and Social Services Emergency Fund, later renamed the Provider Relief Fund (PRF), "*to reimburse, through grants or other mechanisms, eligible healthcare providers for healthcare-related expenses or lost revenues that are attributable to coronavirus.*" The fund was subsequently increased by $78 billion, with $75 billion added in the *Paycheck Protection Program and Health Care Enhancement Act and $3 billion in the Consolidated Appropriations Act, 2021*. In addition, Section 9911 of the American Rescue Plan Act appropriated $8.5 billion for rural providers that bill Medicare and Medicaid.

[ix] In addition to the PRF, on March 28, 2020, CMS expanded the existing Accelerated and Advance Payments Program to a broader group of Medicare Part A providers and Part B suppliers to "to provide necessary funds when there is a disruption in claims submission and/or claims processing." This program does require repayment, which began on March 30, 2021.

[x] Specifically, the weighting factor that would otherwise apply to the diagnosis-related group (DRG) under the Inpatient Prospective Payment System (IPPS) was increased by 20 percent for Medicare beneficiaries diagnosed with COVID-19 who are discharged from the hospital during the PHE. In subsequent guidance, CMS indicated that a discharge with COVID-19 would be identified by the presence of one of two ICD-10-CM codes associated with COVID-19.

financial operations without these federal supports and contend with likely long-term changes in patient volume, costs, and revenue. Additionally, hospitals must be prepared for potential audits by HHS OIG and/or Medicare contractors to ensure that COVID-19 diagnosis codes were properly included on claims. Failure to properly assign and document diagnoses could expose providers to False Claims Act liability.

4. Other Provider Waivers and Flexibilities

Although the telehealth flexibilities may be the most discussed care delivery changes made during the pandemic, CMS established numerous other emergency blanket waivers[28] for healthcare providers that remain in effect for the duration of the PHE. For example, CMS modified care management policies, created alternate care sites, expanded provider capacity and workforce, modified reporting and appeals requirements, and modified conditions of participation (See appendix: *CMS Waivers Announced During PHE* for a subset of waivers and other flexibilities announced by CMS over the course of the pandemic, some of which were later withdrawn).

While some flexibilities could be extended beyond the PHE through rulemaking (subject to authority), such as annual Medicare payment rules, hospitals, and other providers will need to begin preparing for rollback of waivers that have been in place for the last two years. In anticipation of these changes, providers may be required to take several actions, including changes in protocols for care of COVID-19 patients; changes in staffing and licensing; changes in services that can be provided in alternative care settings and at home; reconfiguration of care spaces; changes in how certain services are billed; resumption of audit and reporting requirements; resumption of DME prior authorization requirements; and resumption of certain reporting requirements for MIPS, MSSP, and Center for Medicare and Medicaid Innovation (CMMI) models.

Although providers will be required to make operational changes to ensure compliance with all applicable CMS regulations and requirements, there may be lessons learned from operating under these waivers that can be carried forward to ongoing patient care.

For example, subject to regulatory restrictions, this could include reconsidering the roles of different members of the care team, closer collaboration with patients and caretakers to meet their care needs in different care settings, or further integration of services across the care continuum. In any case, providers must prepare for a new "normal" in which they are equipped to quickly respond to future pandemics at the same time as they continue innovative approaches for traditional patient care.

5. EUA and Other Product Access Authorizations

In response to the pandemic, HHS and FDA took several steps to expedite access to vaccines, therapeutics, tests, and other medical products useful to prevent and treat infections, including EUA, changes in enforcement policies, and liability immunity for makers of those products.

— On February 4, 2020,[29] former HHS Secretary Alex Azar determined that the PHE was significant enough to affect national security or the health and security of citizens abroad, thus setting the stage for possible support of EUAs.[xi] Through a series of declarations in February and March of 2020, the HHS Secretary determined that circumstances existed to justify emergency use of *in vitro* diagnostics for detection and/or diagnosis of the virus that causes COVID-19, personal respiratory protective devices during the COVID-19 outbreak,

[xi] Under section 564 of the *Federal Food, Drug, and Cosmetic Act*, the Food and Drug Administration may authorize an emergency use (EUA) of unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, and nuclear (CBRN) threat agents when the HHS Secretary declares that an emergency use authorization is appropriate and certain criteria are met, including that there are no adequate, approved, and available alternatives. The HHS declaration must be based on four types of determinations of threats or potential threats (a domestic emergency, a military emergency, a public health emergency, or one affecting national security or the health and security of US citizens abroad) by the Secretary of HHS, Homeland Security, or Defense. On February 4, 2020, HHS Secretary Alex Azar determined that the PHE was significant enough to affect national security or the health and security of citizens abroad, thus setting the stage for possible support of EUAs.

[xii] On February 4, March 2, and March 24, 2020 the HHS Secretary determined that circumstances existed to justify emergency use, respectively, of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19, personal respiratory protective devices during the COVID-19 outbreak, and alternative products used as medical devices due to shortages from the COVID-19 outbreak. Over 500 EUAs have been granted for diagnostic tests and medical devices in the first two years of the pandemic. On March 27, 2020, the HHS Secretary further determined that circumstances existed to justify emergency use of drug and biologic products during the pandemic. Over the past two years, FDA has granted EUAs to three vaccine products from Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) and 15 drugs and non-vaccine biological products, including Gilead's Remdesivir, COVID-19 convalescent plasma, monoclonal antibody therapies from Regeneron, Eli Lilly, GlaxoSmithKline-Vir Biotechnology, and AstraZeneca, and antiviral pills from Pfizer and Merck. Although some of the products, most notably the vaccines from Pfizer-BioNTech and Moderna, have already been granted approval from the FDA, most of these products will not be assured approval (i.e., authorized use or marketing) when the underlying EUA declaration expire, the timing of which is still uncertain

alternative products used as medical devices due to shortages from the COVID-19 outbreak, and drug and biologic products during the pandemic.[xii]

— FDA has issued a series of enforcement policies that allowed the marketing of devices that would otherwise be in shortage, such as personal protective equipment (e.g., masks, gowns, face shields, and surgical gloves),[30] ventilators and other respiratory devices,[31] imaging systems,[32] infusion pumps and accessories,[33] and clinical electronic thermometers.[34]

In a declaration on February 4, 2020,35 the HHS Secretary invoked the Public Readiness and Emergency Preparedness (PREP) Act (with subsequent amendments) and declared COVID-19 a public health emergency warranting "liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures."xiii

In effect, product sponsors that have benefited from the flexibilities in use of COVID-19 products during the pandemic are faced with a series of overlapping authorities (EUAs, enforcement policies, and liability protections) that are related, but not necessarily dependent upon each other. These different authorities will impact if and how long products can remain on the market and what steps product sponsors must take to ensure continued authorization and/or approval.

One signal from FDA on what to expect came on December 22, 2021 when the agency released draft guidance documents on transitioning medical devices brought to the market during the pandemic through EUAs[36] and enforcement policies[37] once the pandemic policies are no longer in place. FDA noted that most enforcement policies would no longer be effective once the PHE declaration expires and proposed a 180-day phased approach (from date of issuance of final guidance or the end of the PHE) for manufacturers to seek marketing authorization or clearance for medical devices after the PHE. Similarly, the guidance on device EUA clarifies that advance notice of termination of each EUA will be published in the Federal Register 180 days before termination of the EUA declaration. The EUA guidance also made clear that an EUA for a medical device is "distinct from, and is not dependent on," expiration of the PHE. Both documents provide guidance on the steps that medical device sponsors must take to continue marketing and distribution of their products. FDA has not yet issued transition plan guidance for vaccines and therapeutics granted an EUA, creating additional uncertainty for the sponsors of those products on how long they may have to transition from EUA to approval after the pandemic.

Even though FDA has advised medical device sponsors to begin submitting applications to convert their EUAs to full approval to prevent a disruption when that 180-day period begins, some device makers have already expressed concerns that 180 days may not be enough time to gather and submit all appropriate data. To support this, the Director of FDA's Center for Drug Evaluation and Research recently told the House Energy and Commerce Committee during a hearing on the medical device user fee amendment that FDA will consider any data submitted by sponsors as part of the EUA request when making a determination about approval and that products would not come off the market during the review period.[38]

Just as product sponsors must prepare for some uncertainty over the coming months, providers that have relied on vaccines, therapeutics, medical devices, and other products to prevent and/or treat COVID-19 will need to pay close attention to which products continue to be available for use and for how long. Although it is highly unlikely that an effective, consistently used vaccine or therapeutic would be abruptly pulled from the market, changes impacting medical devices, including tests, could require short- or long-term reconfigurations in care delivery and processes.

Given this uncertainty, providers and product sponsors will need answers to a range of questions as the pandemic begins to wind down. For example:

— Will FDA postpandemic policies move in concert with CMS policies (i.e., tied to expiration of the PHE)?

— Will liability protections be extended beyond expiration of EUAs? If so, for how long?

— If, and how, will transition timelines for vaccines and therapeutics differ from medical devices (i.e., 180 days)?

[xiii] Countermeasures are defined as "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19. Courts have generally interpreted PREP Act immunity to be rather sweeping and to preempt state tort laws and, in certain contexts, other state and federal laws. In effect, manufacturers and distributors of authorized COVID-19 products are generally immunized from liability, absent "willful misconduct." The existing PREP Act declaration provides immunity through the final day of the emergency declaration or October 1, 2024, whichever comes first. Although the PREP Act declaration is unlikely to extend into 2024, there has been no signal to-date on if the timeline for such liability protections would align with the broader PHE declaration or EUAs. For a more detailed analysis of challenges and questions posed by these liability protections, see Flexible Administration Of COVID-19 Vaccines and Therapeutics—Clarifying Legality, Liability, And Compensation".

[xiv] Though we have not discussed state or local emergency declarations or other policies in this brief, these changes could also have profound impacts.

— Will FDA prioritize review or consideration of certain products for approval over others (e.g., therapeutics versus medical devices)?

Next Steps and Implications

The five issue topics outlined above demonstrate the complexity of unwinding federal pandemic-related policies and raise concerns about the impact that the end of flexibilities could have on the healthcare system, providers, and patients as we approach the end of the federal pandemic response.[xiv]

As PHE expiration draws closer, we can anticipate continued pressure from stakeholders for federal policymakers (Congress and federal agencies) to provide additional notice and support before policies revert to prepandemic status. Decisions on which policies should be extended, or which products should remain on the market, after the pandemic ends will be difficult to forecast and timing remains uncertain.

Ultimately, however, these pandemic-related policies and changes will not all take effect at the same time. We will not likely see a "flip of the switch," but rather a transition over time as various authorities expire and the federal government provides guidance on transition timelines. Regardless of timing, providers should be planning for a reversion to prepandemic policies and standards to determine how to manage possible impacts on their operations and the care they provide to patients. There will likely be transition challenges and providers must be prepared for possible disruptions that could accompany the return to the prepandemic normal.

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Appendix: CMS Waivers Announced During PHE

- Temporarily permits nonhospital buildings and spaces to be used for patient care and quarantine sites; for example, a hotel could be used to care for patients needing less intensive care.
- Allows communities to take advantage of local ambulatory surgery centers that have canceled elective surgeries, permitting the centers to provide contracted hospital services, such as cancer procedures, trauma surgeries, and other essential surgeries.
- Allows hospitals, laboratories, and other entities to perform tests for COVID-19 on people at home and in other community-based settings outside of the hospital. Lab technicians will be paid to travel to a beneficiary's home to collect a specimen for COVID-19 testing.
- Allows hospital emergency departments to test and screen patients for COVID-19 at drive-through and off-campus test sites.
- Allows ambulances to transport patients to a wider range of locations (including community mental health centers, federally qualified health centers, physician's offices, urgent care centers, ambulatory surgical centers, and dialysis service locations) when other transportation is not medically appropriate.
- Permits physician-owned hospitals to temporarily increase the number of licensed beds, operating rooms, and procedure rooms.
- Waives the requirements that critical access hospitals limit the number of beds to 25 and that the length of stay be limited to 96 hours under the Medicare conditions of participation.
- Waives the requirement for a three-day prior hospitalization for coverage of a SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay for those people who experience dislocations or are otherwise affected by COVID-19.
- Allows hospitals to bill for services outside their four walls, including to allow for more timely and effective screening of patients at off-site locations to prevent the spread of COVID-19.
- Allows hospitals and healthcare systems to increase their workforce capacity by removing barriers for physicians, nurses, and other clinicians to be readily hired from the local community as well as those licensed from other states without violating Medicare rules.
- Permits hospitals to use other practitioners, such as physician assistants and nurse practitioners, to the fullest extent possible so that they can perform services such as ordering tests and medications that may have previously required a physician's order.
- Allows licensed providers to render services outside of their state of enrollment.
- Allows healthcare providers (clinicians, hospitals and other institutional providers, and suppliers) to enroll in Medicare temporarily to provide care during the public health emergency.
- Waives the requirements that hospitals designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures.
- Waives the requirement for hospitals to have written policies on processes and visitation of patients who are in COVID-19 isolation.
- Provides hospitals with more time to provide patients a copy of their medical record.
- Provides temporary relief from many audit and reporting requirements so that providers, healthcare facilities, Medicare Advantage health plans, Medicare Part D prescription drug plans, and states can focus on providing needed care to beneficiaries affected by COVID-19 by extending reporting deadlines and suspending certain reporting requirements.
- Allows physicians to supervise their clinical staff using virtual technologies when appropriate, instead of requiring in-person presence.
- Considers any Medicare beneficiary who is determined to be unable to leave home because of a medical condition or suspected or confirmed case of COVID-19 to be homebound and qualify for the Medicare Home Health Benefit.
- Allows DME Medicare Administrative Contractors (MACs) to waive certain replacement requirements when Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) are lost, destroyed, irreparably damaged, or otherwise rendered unusable.
- Relaxes reporting requirements under the Medicare Shared Savings Program (MSSP) and Merit-based Incentive Payment System (MIPS).
- Modifies the calculation of the 2021and 2022 Part C and D Star Ratings to address the expected disruption to data collection and measures scores posed by the COVID-19 pandemic.

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