Wynne Health Group

Issue Brief

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COVID-19 VACCINE: STATE OF PLAY

I. INTRODUCTION

As the United States surpasses 200,000 COVID-19 deaths and hovers around 40,000 new COVID-19 cases per day, the Trump administration and pharmaceutical manufacturers have sought to develop, manufacture, and distribute a safe and effective COVID-19 vaccine at an unprecedented pace.[1] The likely limited supply of COVID-19 vaccines, at least initially, has also raised questions about who will receive the COVID-19 vaccine and when. In addition, a patchwork of existing policies and new federal requirements enacted in the various coronavirus relief bills govern COVID-19 vaccine coverage, subsequently influencing timely and affordable access to a vaccine.

With multiple COVID-19 vaccine candidates in development and potentially available – at least to a segment of the U.S. population – in the coming months, the Wynne Health Group developed this issue brief to provide a state of play on COVID-19 vaccine policy developments. Specifically, we discuss vaccine development, manufacturing, and distribution; prioritization of COVID-19 vaccine distribution; and coverage and costs. In light of the vast issues related to COVID-19 vaccines, this issue brief does not specifically touch on the community engagement and outreach efforts to address vaccine hesitancy, Democratic presidential nominee Joe Biden's plan to address COVID-19, and ongoing congressional oversight on COVID-19 vaccine development and distribution, among other issues.

II. VACCINE DEVELOPMENT, MANUFACTURING, AND DISTRIBUTION

Developing and distributing a vaccine against COVID-19 in an accelerated timeframe has been a top priority for the Trump administration and a focal point for President Donald Trump. This ambitious goal requires a coordinated effort across the Department of Health and Human Services (HHS), Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). The centerpiece of this initiative is HHS's Operation Warp Speed (OWS), a new public-private partnership aimed at delivering a COVID-19 vaccine by January 2021, years ahead of the typical multi-year vaccine development process.[2] Table 1 delineates the responsibilities of each agency in the development, manufacturing, approval, and distribution of a COVID-19 vaccine.

Table 1. Federal Agency Responsibilities

Agency	Responsibility
Operation Warp Speed	• Provides funding for the development of vaccine candidates through the support of vaccine research, clinical trials, and advanced manufacturing.

	• Coordinates distribution of approved vaccines and related supplies from the federal government to jurisdictions (including all 50 states) and authorized partners.
FDA	• Issues clinical trial requirements and guidance to assist vaccine sponsors in the development of vaccine candidates, including the establishment of safety and efficacy standards. • Approves licensure or emergency use authorization applications submitted by vaccine sponsors.
CDC	• Develops and issues recommendations on the use of vaccines, including how to prioritize the allocation of initial doses of COVID-19 vaccine among target groups, through the Advisory Committee on Immunization Practices (ACIP) • Provides technical and financial support for states in developing and implementing individual vaccine distribution plans. • Requires providers to enroll in the CDC COVID-19 Vaccination Program in order to receive and administer COVID-19 vaccines procured by the federal government.

While President Trump is optimistic that initial vaccine doses could be available before the election on November 3, Dr. Anthony Fauci, Director of the National Institute of Allergies and Infectious Diseases (NAID) at the National Institutes of Health (NIH), and Dr. Robert Redfield, Director of the CDC, are less certain of this timeline. During a Senate Committee on Health, Education, Labor, and Pensions (HELP) hearing, Dr. Fauci stated that Phase 3 clinical trial data could be completed and submitted to the FDA between October and November, but then the agency would still need time to review the submission and issue an approval or emergency use authorization (EUA).[3] Dr. Fauci and Dr. Redfield also stated that it may take until May or June 2021 to vaccinate the remaining populations that were not targeted during the initial distribution.[4]

A. FDA GUIDANCE

The FDA issued guidance in late June to assist pharmaceutical manufacturers with the development and licensure of a COVID-19 vaccine. The guidance provides recommendations to manufacturers to help ensure that a vaccine candidate meets the agency's safety and efficacy standards for licensure. Notably, the guidance does "not establish legally enforceable responsibilities" and manufacturers may pursue an "alternative approach" to satisfy regulatory or statutory requirements. The guidance contains recommendations on the conduct of clinical trials (e.g., inclusion of diverse populations in all phases of clinical trial), and post-licensure safety evaluation considerations, among other aspects of vaccine development.[5]

While current guidance is limited to the FDA licensure process for COVID-19 vaccines, manufacturers may also choose to pursue emergency use authorization (EUA) for their vaccine candidate. As with other COVID-19 medical countermeasures, such as diagnostics and treatments, the FDA Commissioner may allow unlicensed medical products to be used in emergency circumstances if the product meets the limited scope defined under the EUA.[6] FDA Commissioner Stephen Hahn detailed in his most recent Congressional

testimony that licensed vaccines would be approved for larger populations, while EUA vaccines would be intended for smaller, more targeted populations.[7]

The FDA released guidance on EUA for COVID-19 vaccines in early October, despite attempts by White House officials to block the more stringent standards.[8]. The FDA notes that while an EUA is a different standard than licensure, both pathways require submission of data on the vaccine's safety and effectiveness.[9] Additionally, the agency emphasizes that EUA determination will be made on a case-by-case basis considering the target population, characteristics of the product, the clinical study data, and the totality of the available scientific evidence and that sponsors would continue to work toward a biologic license application (BLA) as soon as possible.[10] Notably, manufacturers will be required to meet at least 50 percent efficacy (the same threshold for vaccine licensure) and monitor half of Phase 3 clinical trial participants for at least two months after completion of the full vaccination regime – which makes it unlikely that a vaccine will be authorized before the election. The guidance also establishes additional Phase 3 clinical trial data requirements, such as detailed information on adverse reactions.

To ensure transparency, the FDA details that the Vaccines and Related Biological Products Advisory Committee (VRBPAC) will convene an open session prior to any EUA issuance, with a general meeting slated for October 22 and other meetings potentially to follow.[11] VRBPAC is a panel of independent experts charged with reviewing and evaluating data on the safety, effectiveness, and appropriate use of vaccines and related biological products and providing recommendations to the FDA Commissioner.[12]

Amid concerns that the FDA may succumb to political pressure from the Trump administration and prematurely authorize a COVID-19 vaccine before it is proven safe and effective, the Chief Executive Officers of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck, Moderna, Novavax, Pfizer, and Sanofi signed a pledge to "uphold the integrity of the scientific process" as they seek approval for their COVID-19 vaccine candidates.[13] Each signatory committed to "only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA."[14] This pledge was signed prior to the issuance of the COVID-19 vaccine EUA guidance.

B. Operation Warp Speed

Operation Warp Speed aims to deliver 300 million doses of a safe and effective COVID-19 vaccine by January 2021.[15] To this end, HHS, the NIH, the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD) have collaborated to engage vaccine manufacturers and support the development and production of vaccines.

HHS has also made investments to support the distribution infrastructure, including the manufacturing of syringes and glass vials needed to administer the vaccine. McKesson Corporation will serve as the central distributor of future COVID-19 vaccines and related supplies.[16] This arrangement leverages an existing 2016 contract with McKesson to serve as the vaccine distributor during any pandemic. McKesson distributed H1N1 vaccines during the H1N1 pandemic.

In a Report to Congress, the Administration outlines how OWS plans to distribute a COVID-19 vaccine when one is available. The strategy consists of four key components: vaccine distribution; engaging with local governments and stakeholders; vaccine administration; and data monitoring.[17] In the same announcement, OWS released a playbook for states outlining steps for operationalizing a vaccination response to COVID-19 within their local jurisdictions, accounting for the need to prioritize distribution of a limited supply of doses in the earlier phases of the Vaccination Program.[18] Additionally, OWS intends on leveraging the existing 64 Vaccines for Children (VFC) Program recipients to coordinate distribution at the jurisdiction level – including all 50 states and the District of Columbia, eight territories, and five cities (Chicago, Houston, New York City, Philadelphia, and San Antonio). In a letter to governors, CDC Directors asked states to prepare their vaccine distribution programs to be fully operational by November 1.[19]

Table 2 details investments to date to support the development and manufacturing of vaccines among several manufacturers. Through supplemental funding, OWS has been appropriated almost $10 billion, which includes $6.5 billion for countermeasure development and $3 billion for NIH research, and additional flexible funding.[20] This funding will also be used to purchase and deliver the vaccines at the indicated cost per dose.[21] All manufacturers intend to deliver their COVID-19 immunization in two doses, with the exception of Janssen/Johnson & Johnson who plan to provide the immunization in a single dose. Vaccine candidates are either in Phase 2 of clinical trials, which further evaluates safety, or in Phase 3, which confirms and expands on the safety and effectiveness of the vaccine.[22]

Table 2. COVID-19 Vaccine Candidates Supported by Operation Warp Speed

Manufacturer	Contract Amount	Doses	Clinical Trial	Expected Timeline	Cost
AstraZeneca	$1.2 billion	300 million doses guaranteed to the U.S.	Phase 3	October 2020	$3 per dose (two doses required)
Pfizer	$1.95 billion	100 million doses guaranteed to the U.S. upon approval, and 500 million more after	Phase 3	End of 2020	$19.50 per dose (two doses required)
Moderna	$955 million	100 million doses guaranteed to the U.S.	Phase 3	Early 2021	$15 per dose (two doses required)
Janssen/ Johnson & Johnson	$1.5 billion	100 million doses guaranteed to the U.S.	Phase 3	Early 2021	$10 per dose
Novavax	$1.6 billion	100 million doses guaranteed to the U.S.	Phase 2	N/A	$16 per dose (two doses required)
Sanofi and GlaxoSmithKline	$2 billion	100 million doses guaranteed to the U.S.	Phase 2	N/A	$10.50 per dose (two doses required)

In consideration of the potential impact of a COVID-19 vaccine, some manufacturers have signaled that they are not seeking to make a profit on their approved vaccines. At a Congressional hearing before the House Energy & Commerce Subcommittee on Oversight and Investigations in July, Johnson & Johnson and AstraZeneca stated that they will sell their vaccines at a "not-for-profit price," while Pfizer and Moderna acknowledge that they seek to make a "marginal profit."[23] Mr. John Young, Chief Business Officer for Pfizer, explained that while the vaccine will be priced for profit, the price will reflect the "extraordinary circumstances" of developing a vaccine in an accelerated timeframe.[24] Novavax and Sanofi are still working through their pricing structure, but have committed to equitable access through affordable pricing and fair distribution.[25]

C. CDC COVID-19 VACCINATION PROVIDER PROGRAM

In the "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations (Interim Playbook)," the CDC stipulates that health care providers must enroll in the CDC COVID-19 Vaccination Program in order to receive and administer COVID-19 vaccines. Enrolled providers must adhere to requirements regarding vaccine administration (such as compliance with ACIP recommendations and FDA requirements), recordkeeping and reporting, and storage and handling, among other conditions.[26] Health care providers licensed or credentialed to possess and administer vaccines are eligible to enroll in the CDC COVID-19 Vaccination Provider Program.

The Interim Playbook also outlines how Operation Warp Speed will determine the number of COVID-19 vaccines to be allotted for each jurisdiction, which takes factors such as ACIP recommendations and vaccine provider site vaccine storage into consideration.[27] The CDC details that through the centralized distribution contractor, McKesson, vaccines and ancillary supplies will be procured and distributed by the federal government, at no cost, directly to the enrolled COVID-19 vaccination provider sites.[28] Later in this issue brief, we discuss additional costs that may potentially fall on vaccine providers.

Of note, HHS issued guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) to expands authorization for certain pharmacists to order and administer COVID-19 vaccines. [29] Specifically, the guidance authorizes state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of a qualified pharmacist to administer, COVID-19 vaccines to individuals ages 3 and older in accordance with federal requirements.[30]

III. VACCINE PRIORITIZATION

Given the limited amount of vaccine doses that will initially be available, the Trump administration is also developing a prioritization plan to determine who will receive a COVID-19 vaccine and when. This effort is coordinated by two expert panels: (1) the CDC's Advisory Committee on Immunization Practices (ACIP), and (2) the National Academies for Sciences, Engineering, and Medicine (NASEM) ad hoc Committee on Equitable Allocation of Vaccine for the Novel Coronavirus. While ACIP is typically tasked with establishing the prioritization list for vaccines, the NIH and CDC requested NASEM to provide a framework that can inform ACIP's decisions.[31] Both entities have committed to equitable prioritization,

with special considerations for vulnerable groups such as communities of color that have been disproportionately impacted by COVD-19.

ACIP intends on reviewing NASEM's framework for equitable allocation to make final decisions on distribution prioritization. The expert panel will make individual prioritization recommendations for each vaccine candidate once it is licensed or authorized by the FDA. Their discussions, thus far, indicate initial vaccine doses will go to health care workers, followed by other frontline workers and individuals with preexisting conditions.[32]

On October 2, NASEM released its final framework for equitable COVID-19 vaccine allocation. The framework outlines a four-phase vaccine allocation framework that first prioritizes front line health care workers, first responders, people with severe comorbid conditions, and older adults in congregate living conditions. These groups were prioritized based on risk-based criteria for allocation of vaccine under a limited vaccine supply scenario. As vaccine supplies increase, the Committee notes that it is important have an equitable framework in place to determine who will receive a vaccine first, second, and so forth. Table 3 reflects the application of the allocation criteria to specific population groups.

Table 3. NASEM Framework for Equitable COVID-19 Vaccine Allocation

Phase	Population Groups
Phase 1A	• High risk workers in health care facilities; and • First responders
Phase 1B	• People with significant comorbid conditions; and • Older adults in congregate and overcrowded conditions
Phase 2	• Critical workers at increased risk of exposure; • Teachers and school workers; • People with moderate comorbid conditions; • All older adults not included in Phase 1; • People in homeless shelters or group homes; and • Incarcerated people and staff.
Phase 3	• Young adults; • Children; and • Critical workers not at risk for exposure
Phase 4	• Remaining U.S. residents who did not receive a vaccine in the previous phases.

The Committee notes that equity implications were considered when defining each priority group. The Committee acknowledges that the data demonstrates that people of color, specifically Black, Hispanic, and American Indian and Alaskan Native individuals, have been disproportionately impacted by the pandemic and have higher rates of morbidity, mortality, and transmission. The Committee therefore asserts that vaccines should be distributed to areas of high social vulnerability and be delivered at locations accessible to the populations living in those areas.

The final framework also includes recommendations for the application of the framework for HHS and state, tribal, local, and territorial (STLT) governments, including considerations for administering and

implementing an effective and equitable national COVID-19 vaccination program; coordination and cost; communication and engagement strategies; vaccine acceptance, and global equitable allocation.

IV. Vaccine Coverage and Costs

Congress and the Trump administration have taken actions to mitigate some cost barriers and help facilitate timely access to an eventual COVID-19 vaccine upon approval by the FDA (either through licensure or EUA). These new reforms attempt to reduce disparities in COVID-19 vaccine coverage among the various payers as well as accelerate access to a COVID-19 vaccine. Vaccine-related provisions in the CARES Act (P.L. 116-136) and the Families First Coronavirus Response Act (FFCRA) (P.L. 116-127) expanded consumer protections by requiring individual and group plans to provide first-dollar coverage for federally recommended COVID-19 vaccines within 15 days of an ACIP recommendation. The CARES Act also stipulates that Medicare beneficiaries have coverage for COVID-19 under Medicare Part B without incurring any deductible or coinsurance. However, CMS would not cover administration costs of an EUA-authorized vaccine and the Administration is investigating potential workarounds.[33]

A. Immunization Coverage Requirements

The nation's patchwork of public and private health insurance coverage contains gaps that pose challenges to achieving universal COVID-19 vaccination. These gaps are largely attributed to disparate coverage of vaccines that predate the pandemic. For example, exemptions to consumer protections for plans not regulated by the ACA, such as short-term health plans and grandfathered health plans, and limitations to coverage for traditional Medicaid programs (in states that did not expand Medicaid) create vaccine coverage loopholes.

In the following subsection, we discuss current federal programs intended to serve as a safety net for uninsured individuals who might otherwise note be vaccinated.

Table 4. COVID-19 Immunization Coverage Requirements

Coverage	Federal Requirements that Predate the Pandemic	New Reforms & Application to COVID-19 Vaccine
Private Health Insurance Plans Exemptions include grandfathered health plans; short-term, limited	Plans must cover vaccines recommended by ACIP with no cost-sharing when furnished by an in-network provider.[34] Insurers have a "minimum interval" of at least one year to implement the coverage recommendation.	CARES Act forgoes the "minimum interval" and requires plans to cover an ACIP-recommended COVID-19 immunization with no cost-sharing when furnished by an in-network provider within 15 business days following issuance of the recommendation.[35] *ACIP may recommend a specific COVID-19 immunization for a targeted population rather than the general*

duration insurance		*population. Therefore, coverage requirements for plan enrollees may go into effect at various times.*
Medicare	Medicare Part B must cover the vaccine and administration of certain routine immunizations (e.g., influenza) with no cost-sharing.[36] Medicare Part D plan sponsors must cover the vaccine and administration of all vaccines licensed by the FDA through formularies, as long as they are not covered under Part B and are "reasonable and necessary."[37] Covered Part D immunizations may be subject to cost-sharing attributed to the vaccine and administration. Medicare Part D does not cover drugs approved under an EUA.	CARES Act requires Medicare Part B and Medicare Advantage to cover the vaccine and administration of a COVID-19 immunization with no cost-sharing immediately following FDA licensure.[38] *These coverage requirements do not apply to a COVID-19 vaccine approved under an EUA.*
Medicaid	<u>*Adults*</u> States that expanded Medicaid must cover all ACIP-recommended vaccines with no cost-sharing.[39] This requirement does not apply to traditional Medicaid. States that elect to cover all USPSTF Grade "A" or "B" recommended preventive services and ACIP-recommended vaccines and their administration with no cost-sharing will receive a one percentage point increase in the federal medical assistance percentage (FMAP) for those services.[40] This enhanced match is available to all states regardless of whether they expanded Medicaid, but a recent review found that only 22 state Medicaid programs cover all 13 ACIP-recommended vaccines for adults.[41] <u>*Children*</u> The Vaccines for Children (VFC) Program covers ACIP-recommended vaccines for Medicaid-eligible individuals	FFCRA requires state Medicaid programs to cover a COVID-19 vaccine with no cost-sharing, as well as comply with other requirements, in order to receive the temporary 6.2 percentage increase in the FMAP.[43] *This coverage incentive presumably applies to a COVID-19 vaccine recommended by ACIP.* *Per existing federal requirements, VFC and Medicaid programs in expansion states will be required to cover an ACIP-recommended COVID-19 vaccine with no cost-sharing.*

	and other qualifying individuals (discussed below).[42] VFC-covered vaccines may be subject to cost-sharing attributed to the administration and office visit.	

B. IMMUNIZATION SAFETY NET PROGRAMS

The federal government has a number of programs that play a key role in filling immunization coverage gaps among adults and children. Limited congressional funding, however, restricts the reach of these essential programs.

1. VACCINES FOR CHILDREN PROGRAM

The Vaccines for Children (VFC) Program, operational since 1994, is an entitlement program that provides ACIP-recommended vaccines to individuals younger than 19 years of age and is one of the following: Medicaid-eligible, uninsured, underinsured, or American Indian or Alaska Native. CDC defines underinsured as having health insurance that "doesn't cover vaccines, or doesn't cover certain vaccines, or covers vaccines but has a fixed dollar limit or cap for vaccines. Once that fixed dollar amount is reached, a child is then eligible." The CDC distributes vaccines, purchased at a substantially discounted price negotiated with vaccine manufacturers, to 64 grantees – all 50 states and the District of Columbia, eight territories, and five cities (Chicago, Houston, New York City, Philadelphia, and San Antonio).[44] Grantees then supply health care providers enrolled in the VFC program with the vaccines at no charge to the VFC providers. As an added benefit, VFC providers are allowed to charge an administrative fee to offset their costs. Nationwide, over 44,000 providers are enrolled in the VFC program.[45]

The VFC Program is funded through the Centers for Medicare and Medicaid Services (CMS).[46] The VFC Program will continue to operate at the fiscal year (FY) 2020 funding level at approximately $4.8 billion until regular FY 2021 appropriations are enacted or December 11, 2020, the expiration of the continuing resolution.[47] In the case of a government shutdown, the continuing resolution allows mandatory programs and appropriated entitlements, to maintain operations for additional 30 days beyond the December expiration date.

2. SECTION 317 IMMUNIZATION PROGRAM

The Section 317 Immunization Program, established in 1962, is a discretionary grant program (subject to annual congressional appropriations) that supports immunization program operations at the local, state and federal levels and provides states with federally-purchased vaccines for uninsured or underinsured adults, fully insured adults during public health response activities, and incarcerated individuals.[48] These vaccines are purchased at a price negotiated with manufacturers that is significantly lower than commercial rates. Grantees of the VFC Program are also Section 317 grantees.

The Section 317 Immunization Program will continue to operate at the FY 2020 funding level of $615.9 million until regular FY 2021 appropriations are enacted.[49] Historically, a majority of Section 317 grants – nearly 78 percent in FY 2019 – have been allocated towards immunization program operations rather than vaccine purchase.[50] The ability of the Section 317 Immunization Program to strengthen the immunization safety net for uninsured individuals, while supporting states and localities that are continuously grasping for resources amid the coronavirus pandemic, will hinge on adequate congressional funding.

Notably, on September 23, 2020, the CDC distributed $200 million in funds made available under the CARES Act to the 64 awardees of the VFC and Section 317 grant program to support the planning and implementation of COVID-19 vaccination services.[51] Grants were divided using a population-based formula.[52]

3. COVID-19 UNINSURED PROGRAM

The Health Resources and Services Administration (HRSA), using a portion of the Provider Relief Fund dollars made available under the CARES Act, established the COVID-19 Uninsured Program to reimburse providers for furnishing qualifying COVID-19 testing and treatment services, including an FDA-approved vaccine, furnished after February 4, 2020. Health care providers will have to submit claims for reimbursement, which "will be reimbursed generally at Medicare rates, subject to available funding."[53] The design of the program poses several limitations that may leave uninsured individuals without affordable access to an eventual COVID-19 vaccine as well as health care providers with uncompensated care costs.

The COVID-19 Uninsured Program relies on a finite, yet continuously shrinking, amount of funding. Approximately $31 billion of the $175 billion appropriated to the Provider Relief Fund is available, as of this writing.[54] HHS has signaled that an unspecified amount will be allocated in future distributions to health care providers. The amount of funding that will be available to reimburse health care providers for COVID-19 immunizations remains to be seen. Congress has failed to replenish the Provider Relief Fund, despite renewed attempts by both parties to pass another coronavirus relief package. Though the CARES Act stipulates that the federal government must purchase vaccines in accordance with federal guidance on "fair and reasonable pricing," the cost of the vaccines to the federal government (delineated in Table 2) may also limit the reach of the COVID-19 Uninsured Program.[55]

In addition, health care providers are not required to participate in the COVID-19 Uninsured Program and may choose to directly bill uninsured patients for the COVID-19 vaccine, potentially at its higher list price. Furthermore, HRSA does not publish a list of providers participating in the COVID-19 Uninsured Program, placing the onus on uninsured individuals to identify participants.

Lastly, HRSA has not specified whether an eligible "FDA-approved vaccine" encompasses both a COVID-19 vaccine licensed by the FDA as well as a COVID-19 vaccine approved under an EUA. Restricting reimbursements to COVID-19 vaccines licensed by the FDA could significantly curtail the impact of the COVID-19 Uninsured Program.

C. ADMINISTRATION FEES AND ASSOCIATED COSTS

While federal requirements shield most patients from out-of-pocket costs attributed to the COVID-19 vaccine itself, questions remain on who will bear administration fees and associated costs. In the Interim Playbook, the CDC states it "will share more information about reimbursement claims for administration fees as it becomes available."[56]

Typically, the total cost to vaccinate entails vaccine product and administration expenses. Specific administration expenses captured in Current Procedural Terminology (CPT) codes include the following:

- Physician work, including vaccine injection and related counseling;
- Practice expense, including clinical staff time (vaccine registry input, refrigerator/freezer temperature monitoring/documentation of temperatures and alarms), medical supplies (gloves, exam table paper, syringe with needle, alcohol swabs, band-aid), and medical equipment (e.g., exam table, commercial grade vaccine refrigerator with alarm/lock, and refrigerator/freezer vaccine temperature monitor/alarm); and
- Professional liability insurance expense.[57]

Notably, the CPT codes do not reflect additional overhead costs to providers, including personnel costs for ordering and maintaining an inventory of vaccines, certain storage costs (e.g., generators), and insurance against vaccine loss.

In the Interim Playbook, the CDC confirms that the federal government will cover the costs of COVID-19 vaccines and "ancillary supplies" for enrolled COVID-19 vaccination providers. Ancillary supplies include "needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE)" as well as supplies to reconstitute the vaccine, if necessary. The Interim Playbook further notes that "sharps containers, gloves, bandages, and other supplies" will not be included in the ancillary supply kits.

V. CONCLUSION

The COVID-19 vaccine, though not a magic bullet, will play a critical role in ending the pandemic. Leading members of the White House Coronavirus Task Force state that a safe and effective COVID-19 vaccine "will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks."[58]

The policy landscape surrounding COVID-19 vaccines will continue to evolve, as we await FDA approval of prospective vaccines, recommendations on vaccine use and prioritized groups, and the distribution of COVID-19 vaccines across the country.

We hope this is a helpful overview of the regulation, decision-making, and policies regarding COVID-19 vaccines. Please do not hesitate to reach out to Wynne Health Group with any questions on this issue.

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