



**Fraud, Waste,
and Abuse**
in the Context of
COVID-19



**HEALTHCARE
FRAUD
PREVENTION
PARTNERSHIP**

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The Healthcare Fraud Prevention Partnership would like to thank participating Partners for their contributions.

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EXECUTIVE SUMMARY

Since early 2020, coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has significantly shaped public life and healthcare delivery in the United States. The novel and devastating virus led to necessary and comprehensive changes in the nation's healthcare system. As in any rapidly developing healthcare situation, potential vulnerabilities for healthcare fraud, waste, and abuse arose for bad actors to capitalize upon. To mitigate these actions, stakeholders, including federal, state, and local agencies, private payers, law enforcement, and healthcare anti-fraud associations, responded and collaborated extensively.

This white paper outlines background information on COVID-19 and its impact on healthcare delivery, frequently observed, pandemic-related fraud, waste, and abuse schemes, and the methods used to prevent schemes. During this time, traditional fraud schemes were modified and appeared with new entry points to the system: COVID-19 testing, services, and treatments. Expedited due to the pandemic and social distancing measures, the transition to increased telemedicine services provided an avenue for bad actors to adapt previously existing fraud schemes to take advantage of patients. This evolution in healthcare delivery is a topic of growing concern, with action taken by the U.S. Department of Justice (DOJ) Criminal Division Fraud Section's Health Care Fraud Unit in September 2020 identifying \$4.5 billion in allegedly false and fraudulent claims related to telemedicine fraud.

Balancing the delivery of necessary healthcare services with the needed fraud, waste, and abuse controls is vital for the healthcare system to be resilient to the impact of the COVID-19 pandemic. Within this context, this paper will describe events relating to the Public Health Emergency (PHE), suspect and fraudulent schemes, and methods to address acts of fraud, waste, and abuse observed during 2020 and the beginning of 2021.



INTRODUCTION AND OBJECTIVES

HFPP and Fraud, Waste, and Abuse Prevention

The Healthcare Fraud Prevention Partnership (HFPP) is a voluntary, public-private partnership between the federal government, state and local government agencies, law enforcement, private health insurance plans, employer organizations, and anti-fraud organizations that seeks to identify and reduce fraud, waste, and abuse across the healthcare sector.¹ To advance this effort, HFPP Partners regularly collaborate, share information and data, and conduct studies using a unique cross-payer data set. Additionally, the HFPP's broad membership provides a platform to discuss emerging healthcare issues.

As a part of its mission, the HFPP publishes white papers focused on relevant and emerging fraud, waste, and abuse topics. These publications are a method of revealing fraud, waste, and abuse schemes, as well as highlighting important strategies and actions HFPP Partners and other healthcare stakeholders can take to counter them. Previous white papers have reviewed opioids, clinical laboratory testing, and genetic testing. For example, the white paper, *Genetic Testing Fraud, Waste, and Abuse*,² recently brought together new information for commonly observed fraud, waste, and abuse schemes and best practices involved in the expansion of genetic testing services.

Objectives

Coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has significantly impacted public life and healthcare delivery. Beginning in January 2020, the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) took note of the virus and the rapidly developing healthcare situation, and by the end of the month, both organizations declared a PHE.³ The virus and its impacts quickly spread – from the declaration of the PHE on January 31, 2020 through February 2021, there were over 27 million cases of COVID-19 in the United States, with over 500,000 deaths attributed to the virus.^{4,5} In response, numerous waivers and policy changes were implemented within the first months of the PHE to provide the flexibility needed for healthcare providers and payers to address the drastic shift in healthcare needs stemming from COVID-19.



As these necessary changes were implemented, bad actors repurposed and modified fraud, waste, and abuse schemes to adapt to the evolving healthcare landscape. For example, telemarketing schemes involving direct solicitation have evolved since the early 1990's and have historically been associated with laboratory testing, genetic testing, and the unnecessary sale of durable medical equipment and back braces, among others.^{2,6,7,8} To fit within the context of the PHE, fraudsters have now modified this scheme to include COVID-19 testing. As such, this paper outlines how fraud schemes have adapted to the changed healthcare environment.

In fiscal year 2020, the Department of Justice (DOJ) opened 1,148 new healthcare fraud investigations, consistent with the number of yearly investigations observed over the past decade.⁹ Although healthcare fraud schemes occurred prior to the PHE, fraudsters have adjusted to COVID-19, and therefore, efforts to prevent and mitigate healthcare fraud must also adapt. To address these concerns, this paper describes the vigorous response of federal, state, and local agencies, private payers, healthcare anti-fraud associations, and law enforcement, who worked together to combat this adapted fraud, waste, and abuse by collaborating extensively, anticipating vulnerabilities associated with various healthcare flexibilities and waivers, and working to actively mitigate those vulnerabilities.

The primary goal of this white paper is to provide an overview of fraud, waste, and abuse associated with COVID-19 testing, prevention, treatment, and care. Insights gained from HFPP Partners during interviews conducted in the fall of 2020, additional feedback provided through January 2021, as well as a review of available literature, contribute to meeting the following objectives:

- 1) Provide background information on the COVID-19 PHE and highlight areas of focus for healthcare payers
- 2) Describe fraud, waste, and abuse schemes related to the delivery of care for COVID-19, as well as schemes that capitalize upon the PHE
- 3) Identify methods used to detect, take enforcement action against, mitigate, and prevent fraud, waste, and abuse schemes in the context of the COVID-19 PHE



The following sections outline COVID-19 related fraud, waste, and abuse in the context of the COVID-19 PHE from a healthcare payer perspective. Robust anti-fraud practices related to COVID-19 (e.g., monitoring for fraudulent advertisements of medical products claiming inaccurate COVID-19 prevention and treatment abilities) occurred in addition to efforts described within the scope of this white paper.¹⁰ The fact that the PHE is ongoing at the time of this white paper's publication, as well as other limitations regarding collection of data (e.g., in many health plans, delays between when services are furnished and when claims may be submitted), creates certain constraints. Therefore, this paper is intended to provide a snapshot of HFPP Partners' experiences from early 2020 through January 2021, along with relevant events that occurred across approximately the same timeframe, to inform best practices to reduce fraud, waste, and abuse during both the COVID-19 pandemic and potential future healthcare emergencies.



COVID-19 AND ITS IMPACT ON HEALTHCARE

COVID-19, discussed in detail below, created several concerns in the healthcare domain, including for healthcare payers. As the virus spread, the need for testing, treatment, and personal protective equipment (PPE) increased. Additionally, changes to policies and practices addressing billing codes, telehealth, and prescriptions, among other areas, were swift and comprehensive. These developments triggered the concern that the changes could lead to modified healthcare fraud, waste, and abuse.

COVID-19 Introduction

COVID-19 is caused by SARS-CoV-2 (an RNA virus).¹¹ Symptoms, shown in Figure 1 below, can include one or more of the following: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and/or diarrhea. Symptoms may appear between 2 and 14 days after exposure to the virus, or infected individuals may remain asymptomatic.¹² There is a wide spectrum of clinical presentations in symptomatic patients, with some patients experiencing transient and self-limited cold-like symptoms and other patients passing away from sepsis, acute hypoxic respiratory failure, or other life-threatening conditions.^{12,13} Research indicates that various risk factors, including increased age and underlying medical conditions (e.g., cancer, chronic kidney disease, heart conditions, immunocompromised state, obesity, pregnancy, sickle cell disease, smoking, and Type 2 diabetes mellitus), can increase the risk for COVID-19 and shape disease severity.¹⁴ Evidence also suggests Hispanic, Black, and American Indian/Alaska Native patients bear a disproportionate burden of COVID-19 risk factors and are more susceptible to serious complications.^{15,16,17}



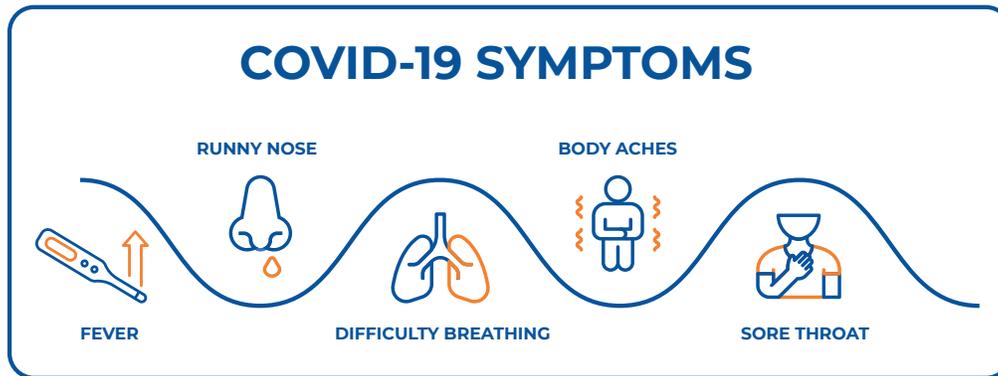


Figure 1: COVID-19 Symptoms

Mutations in the virus identified in late 2020 led to various new strains, including some with demonstrated increased transmission rates, also being a concern.¹⁸ After rapid increases of COVID-19 in certain geographic regions during late 2020, genomic surveillance unveiled several new variants of SARS-CoV-2. For example, the B.1.1.7 lineage, originating in the United Kingdom, has been shown to spread more easily and quickly than other variants. The B.1.351 lineage was originally detected in October 2020 in South Africa and was discovered in the United States in late January 2021 with initial evidence indicating one of the spike protein mutations may affect neutralization by some polyclonal and monoclonal antibodies. During the same timeframe, the P.1 lineage, originating in Brazil, was also detected in the United States and notably contains a set of additional mutations that may impede its ability to be recognized by antibodies, a consideration for potential for reinfection and further evaluation of vaccine efficacy.

Testing

Throughout the PHE, there has been a focus on COVID-19 testing in order to detect, treat, and limit the spread of the virus. During the early global spread of this virus, the lack of accessible testing hampered the possibility for healthcare professionals, policymakers, and citizens to mitigate community spread. Additionally, increased demand for testing led to the presence of fraudulent test kits for COVID-19 being sold online.¹⁹ Over the course of the PHE, testing has become more readily available and there have been several efforts to publicly track the testing results. For example, the Johns Hopkins Coronavirus Center captured daily figures including positive case and death rates across countries globally, as well as critical trends such as state hospitalization rates in the United States, which emerged as an important resource for HFPP Partners, physicians, and the public.²⁰



There are two main categories of laboratory tests available for COVID-19:

- 1) Diagnostic testing through detection of genetic or protein material for current infection including nucleic acid amplification tests (NAATs), such as reverse transcription polymerase chain reaction (RT-PCR), and antigen testing, a more rapid result test, which are both types of lab assays that detect the SARS-CoV-2 virus directly; and
- 2) Antibody testing, which uses a blood sample to identify antibodies made by the immune system in response to the virus SARS-CoV-2 typically measurable 7 to 14 days after illness onset, indicates a prior infection, and has been shown to have highly variable sensitivity and specificity.

Nasopharyngeal swab testing (Figure 2) was first evaluated for routine RT-PCR diagnostic testing,²¹ followed by the development of additional nasal and saliva swab specimen collections for diagnostic testing. Antigen tests are generally less sensitive than NAATs. For the detection of the SARS-CoV-2 virus, antigen testing performs better among symptomatic individuals within 5 to 7 days of symptom onset than asymptomatic individuals.^{22,23,24}

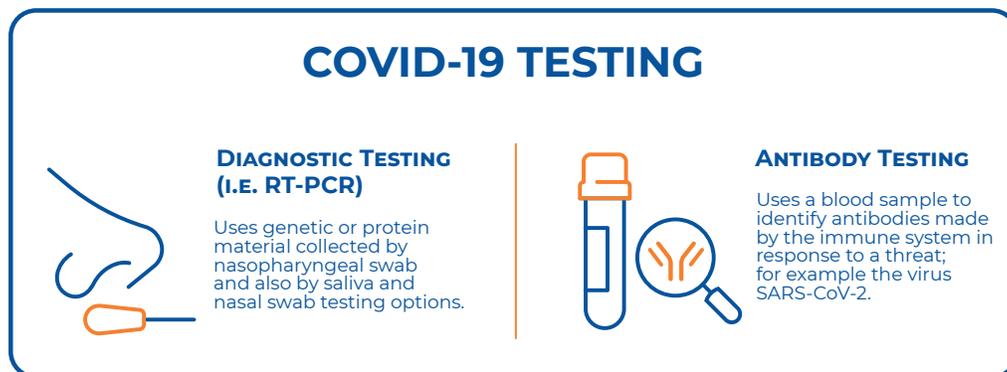


Figure 2: COVID-19 Testing

In this description, sensitivity represents the proportion of true positives that are correctly identified, while specificity measures the proportion of true negatives that are accurately identified. In the context of a COVID-19 diagnosis, a false negative could lead to further viral community spread, while a false positive could lead to unnecessary quarantine and additional testing and public health measures. The U.S. Food and Drug Administration (FDA) maintains a list of in vitro diagnostic tests that have been issued an Emergency Use Authorization (EUA).²⁵



The required volume of testing for patients, and rapid changes to healthcare policies during the PHE, generated concerns about the potential for fraud, waste, and abuse. Key policies and examples of testing fraud schemes are found in the Changes in Practices and Policies and the PHE Fraud, Waste, and Abuse Schemes sections of this paper.

Treatments and Vaccines

Numerous treatments for COVID-19 were investigated through clinical trials throughout 2020, and preventive vaccines were researched and tested for safety and efficacy. Several medications were issued EUAs by the FDA for patients hospitalized with COVID-19, including remdesivir (a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor) in May 2020 and baricitinib (selective inhibitor of Janus kinase [JAK] 1 and 2) in combination with remdesivir in November 2020. Notably, remdesivir received FDA approval for the treatment of COVID-19 in October 2020, and clinical trial data demonstrated shorter time to recovery in hospitalized patients with evidence of lower respiratory disease who received remdesivir compared to those who received a placebo.²⁶ National Institutes of Health (NIH) COVID-19 treatment guidelines also recommended dexamethasone (corticosteroids) in certain contexts.²⁷ For treatment of mild to moderate COVID-19, casirivimab and imdevimab (REGEN-COV) administered together showed effectiveness and reduction of viral load that supported FDA criteria for EUA in November 2020. Specifically, the REGEN-COV treatment has been granted an EUA by FDA for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.²⁸ Bamlanivimab and etesevimab administered together were also granted an EUA in February 2021 for the same use as REGEN-COV.^{29,*}

Additionally, two vaccines, using mRNA, showed promising data in Phase III clinical trials performed in 2020, demonstrating safety and efficacy in preventing symptomatic COVID-19 in adults.³⁰ In mid-December 2020, the FDA granted EUAs to allow two mRNA vaccines (developed by Pfizer-BioNTech and ModernaTX, Inc.) to be administered to individuals 16 years of age and older (Pfizer-BioNTech), and to individuals 18 years of age and older (ModernaTX, Inc.).[†]

* Bamlanivimab alone was revoked in April 2021 due to the sustained increase of viral variants in the US that were resistant to bamlanivimab alone treatment. Updates to FDA COVID-19 Emergency Use Authorizations can be found on the [FDA website](#).

† In May of 2021, FDA expanded the emergency use authorization for the Pfizer-BioNTech COVID-19 Vaccine for use in adolescents 12 to 15 years of age. Updates to FDA COVID-19 Emergency Use Authorizations can be found on the [FDA website](#).



In late February 2021, the FDA issued an EUA for a third vaccine for the prevention of COVID-19 caused by SARS-CoV-2. The vaccine, developed by Janssen Biotech, Inc. (Johnson & Johnson), uses an adenovirus mechanism and was shown to be safe and effective in preventing moderate to severe COVID-19 disease. The Johnson & Johnson vaccine is packaged as a one-dose vaccine (versus two spaced doses for the mRNA vaccines) and does not require the same ultra-low temperature storage as the mRNA vaccines.^{31,32,†,§}

Since vaccinations began in December 2020, the CDC has released ongoing recommendations with respect to the prioritization of vulnerable populations to help guide states and localities in the distribution of vaccines. One challenge of distribution for mRNA vaccines has been their initial ultra-low temperature storage requirements, which led to some vaccine distribution sites having thawed doses of vaccines at the end of the day that could not be restored for later distribution.

The vaccine distribution process may be vulnerable to fraud, waste, and abuse in particular from false offers of vaccines available at various vaccination sites. Daily complaints have appeared across the United States regarding potential vaccine-related scams. In Florida for example, there have been complaints of scammers taking money in exchange for COVID-19 vaccine reservations. Nationwide, there have been concerns that the older adult population that was prioritized for COVID-19 vaccinations may also be more susceptible to scam calls.³³

In light of potential vaccine scams, the Federal Bureau of Investigation (FBI), U.S. Department of Health and Human Services (HHS), and the Centers for Medicare & Medicaid Services (CMS) released a vaccine scam alert on December 21, 2020; these agencies also urged people to consult their state health departments website for up-to-date information about authorized vaccine distribution channels and only obtaining the vaccine through such channels.³⁴ This alert particularly highlighted the reports they have received of scammers using the public's interest in COVID-19 vaccines to obtain personally identifiable information and compensation through various schemes.

† On April 13, 2021, the CDC and FDA recommended a pause in the use of Johnson & Johnson's COVID-19 vaccine. Of the nearly 7 million doses administered by this date in the United States, a small number of reports of a rare and severe type of blood clot have been reported in people after receiving Johnson & Johnson's COVID-19 vaccine. Following a thorough safety review, the FDA and CDC determined that the recommended pause regarding the use of Johnson & Johnson's COVID-19 Vaccine in the U.S. should be lifted and use of the vaccine should resume. The FDA amended the EUA for the COVID-19 vaccine to include information about the very rare and serious type of blood clot in people who receive the vaccine. The most up to date information and frequently asked questions regarding the Johnson & Johnson COVID-19 vaccine can be found on the [FDA website](#).

§ Based on a review of data submitted by Pfizer Inc., in May of 2021, FDA authorized undiluted, thawed Pfizer-BioNTech COVID-19 Vaccine vials to be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month. Previously, thawed, undiluted vaccine vials could be stored in the refrigerator for up to 5 days.



The alert from the FBI National Press Office outlined the following indicators for fraudulent activity:³⁴

- Advertisements or offers for early access to a vaccine upon payment of a deposit or fee
- Requests asking you to pay out of pocket to obtain the vaccine or to put your name on a COVID-19 vaccine waiting list
- Offers to undergo additional medical testing or procedures when obtaining a vaccine
- Marketers offering to sell and/or ship doses of a vaccine, domestically or internationally, in exchange for payment of a deposit or fee
- Unsolicited emails, telephone calls, or personal contact from someone claiming to be from a medical office, insurance company, or COVID-19 vaccine center requesting personal and/or medical information to determine recipients' eligibility to participate in clinical vaccine trials or obtain the vaccine
- Claims of FDA approval for a vaccine that cannot be verified
- Advertisements for vaccines through social media platforms, email, telephone calls, online, or from unsolicited/unknown sources
- Individuals contacting you in person, by phone, or by email to tell you the government or government officials require you to receive a COVID-19 vaccine

Personal Protective Equipment (PPE)

In addition to limited testing availability, the lack of PPE supplies became a central problem of the pandemic and continues to be a challenge for healthcare systems and under-resourced healthcare settings. Surgical masks, N95 respirators, face shields, goggles, gloves, and contact isolation gowns are examples of PPE that have risen in demand to help mitigate the spread of the virus – mainly by protecting against contact, droplet, and airborne transmission.

During interviews for the preparation of this white paper, several HFPP Partners described PPE as a potential inroad for bad actors to obtain member or beneficiary information. Demand for PPE was high during the beginning of the pandemic, as suppliers were still ramping up production of masks and adequate



PPE for healthcare providers and the public; bad actors took advantage of the situation to market PPE and collect beneficiary information as a part of the sale. Additionally, counterfeit PPE is a particular concern for both the public and healthcare systems. CDC's [National Institute for Occupational Safety and Health \(NIOSH\)](#) maintains public information on counterfeit respirators that are falsely marketed and sold as being NIOSH-approved and may not be capable of providing appropriate respiratory protection to workers.³⁵ Counterfeit PPE was also noted in hotline complaints as described by certain Partners. Continued reports of PPE fraud have captured its persistence as a public health issue and resource challenge. For example, individuals in Texas have been associated with a large scheme attempting to sell 50 million nonexistent N95 respirators.³⁶

In addition, several investigations have led to charges in connection with PPE fraud schemes. One example involved a man in Philadelphia, Pennsylvania who was wired over \$700,000 that was spent on his personal expenses and funds to his brokerage accounts as part of his scheme that used Mask Medical, LLC to sell manufactured medical gowns that were never delivered to the City of New York.³⁷

Changes to Practices and Policies

Waivers and Policy Adjustments

To expand healthcare delivery at the frontline and to allow services and supplies to meet rapidly increasing demands, Congress enacted a number of laws, agencies promulgated a number of regulations, many policy waivers and flexibilities were established or implemented, and enforcement of a number of regulatory requirements and restrictions was temporarily relaxed or otherwise altered.

The list below and shown in Figure 3 highlights major events in the federal government's response to the rising cases of COVID-19 beginning in early 2020 and the legal and policy actions taken to best ensure the public received appropriate healthcare and financial assistance. Of note, this is not an exhaustive list, but highlights actions pertaining to topics addressed within this paper.

- **January 31, 2020 (Retroactive to January 27, 2020):** Secretary of the Department of Health and Human Services declares PHE under the Public Health Service Act, which enabled funds and grants to mobilize,



appropriate modifications and waivers to be instituted, and increased personnel available for response.

- **March 6, 2020:** CMS expanded the list of Medicare telehealth services payable during the PHE published and updated through 2021.³⁸
- **March 13, 2020:** President declares a National Emergency, which included the Stafford Act pledging \$50 billion in unspecified aid and the National Emergencies Act allowing the Secretary of HHS to exercise the authority under Section 1135 of the Social Security Act to enact the temporary waiver or modification of certain requirements of the Medicare, Medicaid, and State Children’s Health Insurance Program (CHIP) programs. The Secretary of HHS also exercised the authority under Section 1135 to issue a limited waiver of sanctions and penalties arising from noncompliance with certain provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule.
- **March 17, 2020:** The HHS Office for Civil Rights announced a Notification of Enforcement Discretion to not impose penalties for noncompliance with the regulatory requirements under the HIPAA Privacy, Security, and Breach Notification Rules in connection with the good faith provision of telehealth during the PHE.
- **March 18, 2020:** The Families First Coronavirus Response Act (FFCRA) was enacted. In part, it set forth requirements for health insurers to cover certain services related to COVID-19 without cost-sharing. It also required paid sick leave or expanded family and medical leave for specified reasons related to COVID-19.³⁵
- **March 27, 2020:** The Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted. Among other things, the act expanded upon the insurance coverage requirements set forth in the FFCRA³⁵ and provided economic assistance for American workers, families, and small businesses. The CARES Act also established the Pandemic Response Accountability Committee (PRAC) to support oversight independently of the funds provided and deliver reports to help inform spending. The PRAC oversees pandemic relief funding to help inform and monitor federal spending as well as to detect and combat fraud, waste, abuse, and mismanagement.
- **December 27, 2020:** The Consolidated Appropriations Act, 2021 was enacted, which included over \$900 billion for various COVID-19 relief programs and an extension and significant expansion of the original CARES Act.



- **December 28, 2020:** CMS published the CY 2021 Final Rule (85 FR 84472), which added additional permanent services to the Medicare Telehealth List of Services.
- **February 15, 2021:** 2021 Special Enrollment Period for the Health Insurance Marketplace® opened in response to the COVID-19 National Emergency.

COVID-19 GOVERNMENT RESPONSE TIMELINE: MAJOR MILESTONES

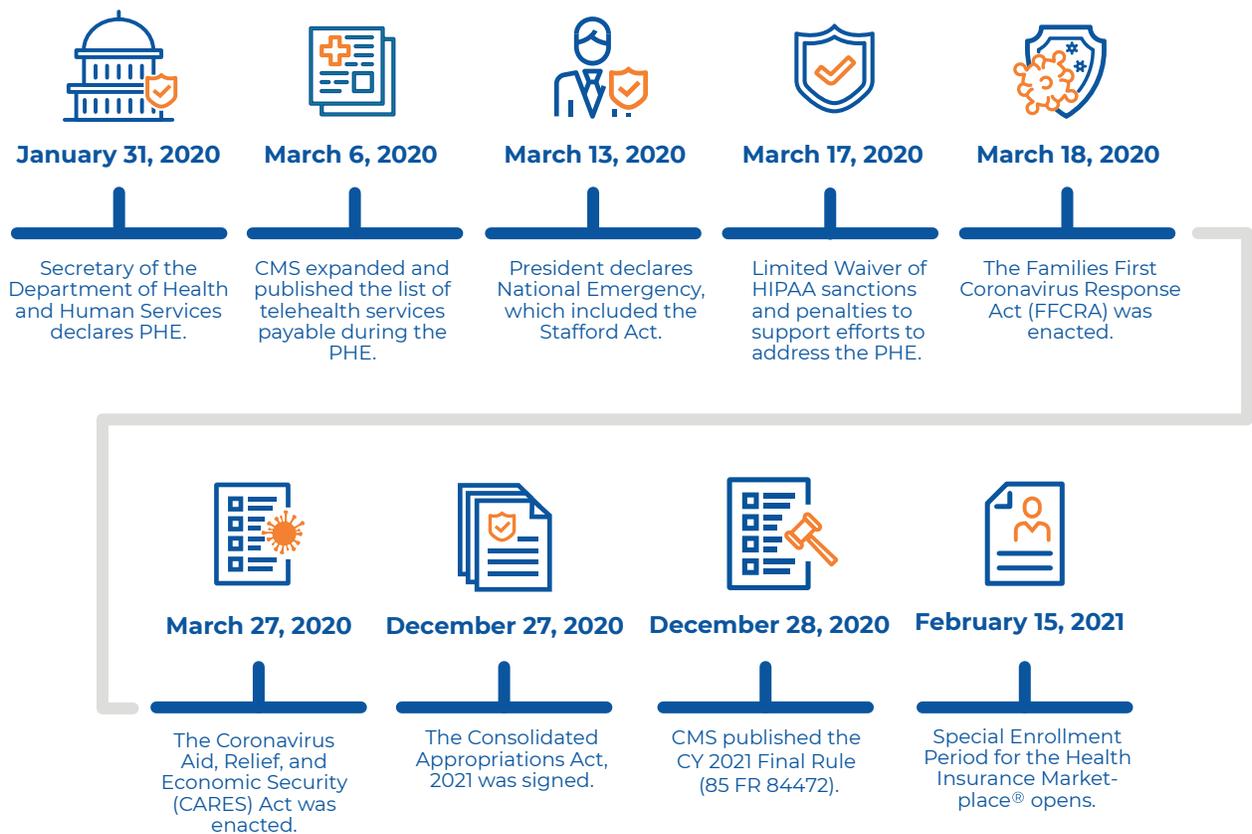


Figure 3: COVID-19 Government Response Timeline: Major Milestones

Public and private payers adjusted their policies in response to changes in laws and regulations and the needs created by the PHE. While the changes in practices vary by payer, some examples of changes stemming from waiver and policy adjustments include:

- Geographic and site of service restrictions for telehealth were relaxed



- Certain telehealth services that were not previously covered by some payers, such as telehealth services that use audio-only modalities (e.g., phone calls), were payable during the PHE
- Providers did not need an initial in-person visit to establish telemedicine care
- Out-of-state providers could deliver services via telemedicine
- Physical Therapy (PT), Occupational Therapy (OT), Speech Language Pathology (SLP), and some types of behavioral health services, such as Applied Behavior Analysis (ABA) and services offered by clinical social workers and clinical psychologists, could be provided via telemedicine
- Prescriptions for controlled substances could be provided via telemedicine through psychotherapy services and qualified providers
- Telehealth services covered at the same rates as in-person visits for all patients, using the same billing codes and Place of Service codes as in-person visits
- Established payment on an interim final basis for a longer brief virtual check-in

For more information about waivers, policy adjustments, and certain permanent changes related to telehealth services, as well as additional resources related to COVID-19, please see the “Useful Articles, Resources, and Sites” addendum at the end of this document.

Billing Codes

Of particular use and importance to payer Partners are the billing codes used in the delivery of care associated with COVID-19. A Current Procedural Terminology (CPT®)** code or Healthcare Common Procedure Coding System (HCPCS) code delineates the treatment or professional service delivered by a healthcare provider.

During the PHE, Partners and healthcare systems focused in particular on several codes to help analyze and detect fraud, waste, and abuse schemes such as those discussed in this paper. The codes listed below (Table 1) represent the most salient codes observed between the beginning of the PHE and January 2021, however, this should not be considered an exhaustive list.

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Key COVID-19 PHE Related CPT^{††} & HCPCS Codes

Type of Service	Description of Service	CPT ^{††} (& Proprietary Laboratory Analyses [PLA]) Code	HCPCS Code	Provider Relationship
COVID-19 Diagnostic Labs	<ul style="list-style-type: none"> • Infectious agent detection by nucleic acid (DNA or RNA) • Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), amplified probe technique • Combined respiratory virus multiplex testing for SARS-CoV-2 with Influenza A&B • Combined respiratory virus multiplex testing for SARS-CoV-2 with Influenza A&B and respiratory syncytial virus (RSV) • Antigen detection of SARS-CoV-2 by direct optical (i.e., visual) observation • Detection of SARS-CoV-2, Influenza A&B, detects RSV 	87426, 87631-87637, 87811 0202U, 0223U, 0225U, 0240U, 0241U	U0001-U0004	New or established patients
COVID-19 Antibody Labs	Report immunoassay for infectious agent antibodies	86318, 86328, 86408, 86409, 86413, 86769 0224U, 0226U		New or established patients
Provider Services	Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a PHE as defined by law, due to respiratory-transmitted infectious disease	99072		New or established patients
Medicare Telehealth Visits	A visit with a provider that uses telecommunication systems between a provider and a patient	99201-99215 (Office/Outpatient visits payable under Medicare Physician Fee Schedule when furnished via telehealth)	G0425-G0427 G0406-G0408 G2025 (Rural Health Clinics and Federally Qualified Health Centers)	New or established patients

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Type of Service	Description of Service	CPT ^{††} (& Proprietary Laboratory Analyses [PLA]) Code	HCPCS Code	Provider Relationship
Virtual Check-In	A brief check-in with your practitioner via telephone or other device to decide whether an office visit or other service is needed	98966-98968	G2012 G2010 G0071 (Rural Health Clinics and Federally Qualified Health Centers)	Established patients
E-Visits	A communication between a patient and their provider through an online patient portal	99421 99422 99423	G2061 G2062 G2063	Established patients

Table 1: Key COVID-19 PHE Related CPT^{††}/HCPCS Codes (Adapted from CMS Types of Telemedicine Visits)⁴⁰

To identify patients hospitalized due to COVID-19, CMS designated use of the following International Classification of Disease, Tenth Revision, Clinical Modification (ICD-10-CM) codes:

- B97.29 (Other coronavirus as the cause of diseases classified elsewhere) for discharges occurring on or after January 27, 2020, and on or before March 31, 2020.
- U07.1 (COVID-19) for discharges occurring on or after April 1, 2020, through the duration of the COVID-19 PHE time period.

Patients hospitalized due to COVID-19 may require more hospital resource utilization (e.g., increased purchasing of PPE, increased staff time to repeatedly put on and take off PPE, enhanced disinfection protocols, increased length of stay, case management or social work resources to find safe quarantine locations upon discharge, etc.); accordingly, the CARES Act increased the weighting factor of the assigned Medicare-Severity Diagnosis-Related Group (MS-DRG) by 20% for an individual diagnosed with COVID-19 discharged during the COVID-19 PHE time period. To address potential Medicare program integrity risks, effective with admissions occurring on or after September 1, 2020, discharges eligible for the 20% increase in the MS-DRG weighting factor also

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required a positive COVID-19 laboratory test documented in the patient's medical record.⁴¹ To ensure coding accuracy, appropriate use of the weighting factor, and compliance with federal requirements, the HHS Office of Inspector General (OIG) is conducting audits of payments made by Medicare for COVID-19 discharges.⁴¹ In addition, ICD-10-CM codes have evolved as needs of the pandemic demanded expanded diagnoses, for example “pneumonia due to COVID-19” (J12.82). Further new diagnosis codes, in particular the [2021 release of ICD-10-CM](#), are included in the “Useful Resources and Sites” addendum section of this white paper.

Telehealth

Telehealth, which includes telemedicine services (i.e., providers delivering medical services via technology rather than in-person) during the PHE, has increased and several waivers and policy flexibilities were put into place to help support those services. These waivers and flexibilities permitted HIPAA-covered healthcare providers to deliver telehealth services to patients using non-public facing remote communication technologies, such as FaceTime, Facebook Messenger, Google Hangouts, Zoom, or Skype, even if the application did not fully comply with HIPAA Rules, though they indicated that providers should not use public-facing applications (e.g., Facebook Live, Twitch, TikTok) to provide telehealth.⁴²

As evidenced by a cross-sectional analysis of the U.S. National Disease and Therapeutic Index audit, telehealth visit utilization for primary care during the PHE increased from 4.1% in Q1 2020 to 35.3% in Q2 2020.⁴³ Initial data from Medicaid and CHIP beneficiaries captured from March through June 2020 indicated that 2,632% more services were delivered via telehealth than during the same period in 2019.⁴⁴ Similarly, Medicare showed significant growth in services performed via telehealth. Between mid-March and mid-August 2020, more than 12.1 million Medicare Fee-For-Service beneficiaries received a telemedicine service.⁴⁵

As an example of how telehealth services may be categorized by a payer, Table 1 above summarizes some of the main types of telemedicine services that can be

Depending upon the HFPP Partner, telehealth and telemedicine may be used interchangeably or as unique terms and Partners may have different practical or legal definitions to consider. For the purposes of this white paper, the HFPP is using telehealth as it is associated with the delivery of both clinical and non-clinical services, whereas telemedicine is focused on the delivery of medical care.



provided to Medicare beneficiaries. From March 2020 to March 2021, CMS updated the list of telehealth services temporarily available. Notably, in December 2020, CMS published CY 2021 Final Rule (85 FR 84472), which added additional permanent services to the Medicare Telehealth List of Services.

In addition to increased utilization, many bad actors used telehealth as a way to reach out to patients to take advantage of vulnerabilities during the pandemic. This use of direct-to-consumer advertising of telehealth is often referred to as telehealth fraud, telefraud, or telemarketing fraud and is associated with beneficiary information being compromised or used to bill for additional care not delivered to the patient. Notably, the DOJ heavily investigated fraud, waste, and abuse throughout the PHE in 2020, leading to a takedown with the largest amount of alleged fraud loss (\$4.5 billion in allegedly false and fraudulent claims) connected to schemes involving telehealth.⁴⁶

HFPP Partners noted concerns about ensuring telehealth services were being delivered appropriately. In particular, they wanted to be sure that services such as PT, OT, behavioral health services, and substance use care could be provided virtually and in a HIPAA-compliant manner.

Delivery of care via telemedicine provides numerous benefits, including increased access to medically necessary services and for individuals in rural areas or with transportation constraints; however limitations also need to be considered when delivering care in this manner. For example, a physical exam, which provides information for a healthcare provider to consider in the context of the patient's illness narrative, can be limited in this virtual setting due to the lack of in-person physical exam objective data.⁴⁷ While the benefits of distancing are clear for provider and patient, and telemedicine provides an essential role during a pandemic, the protocol of those services needs to be adequately captured to inform future utilization goals for healthcare delivery.

Prescriptions

Psychotherapy and psychiatry specific waivers were initiated to facilitate the delivery of care for these services. For example, certain aspects of The Ryan Haight Act, which regulates the use of online prescriptions, were relaxed due to healthcare precautions during the PHE.

Requirements such as in-person initial and follow-up visits to prescribe controlled substances were temporarily waived.^{48,49} While such alterations were necessary for services and medications to be delivered safely, these changes



serve as potential entry points for fraud, waste, and abuse in healthcare system delivery during the COVID-19 PHE.

HFPP Partners also shared their concerns about an observed increase in early refills for prescriptions since the onset of the COVID-19 PHE, particularly for controlled substances. One HFPP Partner, for example, described how these observations led to an investigation of two providers who wrote fraudulent opioid prescriptions not indicated for proper patient care.



COVID-19 PUBLIC **HEALTH EMERGENCY**

Fraud, Waste, and Abuse Schemes

Adapting to the changing healthcare environment during the course of the COVID-19 PHE, opportunistic bad actors have repurposed and applied numerous fraud, waste, and abuse schemes. This section outlines major schemes as described by HFPP Partners during their interviews, including:

- Billing potentially unnecessary services
- Incorrect coding and billing
- Direct solicitation and identity theft

Billing Potentially Unnecessary Services

Testing and treatment for COVID-19 could create opportunities to conduct and bill services that may not be necessary. HFPP Partners described schemes of this nature relating to respiratory pathogen panels (RPPs), cardiac magnetic resonance imaging (MRI) testing, and others, described below.

Respiratory Pathogen Panels (RPPs)

RPPs are used to evaluate a specimen for viral or bacterial nucleic acids. While potentially useful for patients with significant respiratory symptoms who are being treated in a hospital or other appropriate settings, this panel is typically not indicated for the screening of asymptomatic patients or management of most symptomatic patients, particularly in the outpatient or community setting; thus, RPPs may be provided when they are not needed. In particular, multiple HFPP Partners expressed great concern about observing increases of the expensive and large RPP testing for many pathogens (CPT^{§§} code: 87633) being added to COVID-19 testing. For example, the charge to Medicare for COVID-19 testing with this panel resulted in charges greater than \$500 as opposed to a typical \$50 to \$100 charge for COVID-19 PCR diagnostic testing.⁵⁰

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Other Lab Testing

Similar concerns extend to other types of testing that may not typically be associated with COVID-19 testing and treatment, including genetic testing and sexually transmitted disease (STD) panels. Partners indicated receiving complaints from beneficiaries and members about extra tests being added to COVID-19 testing or seeing patterns of spikes in tests alongside COVID-19 tests when that practice would not normally be expected.

Evaluation of Cardiac MRI for COVID-19 Patients

Another service that drew the attention of HFPP Partners was cardiac MRI, as its utility for COVID-19 patients is still being evaluated. Cardiac MRI tests became a point of discussion after a German study highlighted subclinical myocarditis in patients with mild or moderate COVID-19.⁵¹ This test may be clinically appropriate in some circumstances, but spikes in cardiac MRI testing may indicate clinically unnecessary use of the test. In an open letter, experts across major institutions highlighted that the utility of cardiac MRI is unknown, and discretion should be used for cardiac MRI in COVID-19 positive patients.⁵² While this test may be important in understanding the long-term impact of COVID-19, the utility of cardiac MRI testing, in both the general population and for sports medicine, is still being evaluated. As more data are investigated regarding the utility of cardiac MRI, it is important to use individual discretion with COVID-19 patients.

Non-Evidence-Based Treatments

On March 28, 2020, based on the totality of scientific and clinical evidence available at the time, the FDA granted an EUA for hydroxychloroquine and chloroquine to treat adults and adolescents who weigh 50 kg or more and are hospitalized with COVID-19 when participation in a clinical trial was not available, or participation was not feasible. Based on new data, including data from a large randomized clinical trial, the FDA later, on June 15, 2020, revoked that authorization, as further studies revealed that among patients hospitalized with COVID-19, those who received hydroxychloroquine did not have a lower incidence of death than those who received usual care, and previously demonstrated, long-standing evidence has shown that taking hydroxychloroquine poses cardiac and other toxicity risks.^{53,54} During interviews in the fall of 2020, HFPP Partners described situations where providers, despite this evidence and revocation, prescribed hydroxychloroquine to patients as well as themselves and their family members. These actions contributed to



shortages of this drug for patients who used it in accordance with FDA approved indications for specific diseases (e.g., malaria, systemic lupus erythematosus). As a result, professional societies such as the American Medical Association (AMA) developed relevant guidelines in line with the evidence from clinical studies evaluating the risks and benefits of hydroxychloroquine.⁵⁵

Another example highlighted by HFPP Partners was the investigation into intravenous (IV) vitamin infusions, touted as a COVID-19 “cure all.” Studies have researched the relationship between levels of vitamin D and COVID-19 infectivity and mortality. One study showed that patients with likely deficient vitamin D status were more likely (1.77 greater odds) to test positive for COVID-19 compared to patients with likely sufficient vitamin D status.⁵⁶ While sufficient vitamin D status might provide some protective effects (research is still ongoing), the type of expensive IV vitamin infusions being offered were claiming more extreme benefits than those highlighted in the study, and regular, appropriately dosed vitamin D supplementation from over-the-counter vitamins should generally be adequate to address potential vitamin D deficiencies.

Incorrect Coding and Billing

HFPP Partners expressed the importance of maintaining vigilance to ensure services were correctly coded. Before, during, and after the PHE there may be instances of up-coding, such as billing codes for full evaluation and management (E&M) visits that were in actuality check-in calls or billing codes that reflect a more complex visit than actually occurred. In addition to different levels of services, use of certain modifiers, such as the CS (cost sharing) modifier allowing services related to COVID-19 testing to be billed without any cost sharing requirements or prior authorizations, have increased during the PHE. HFPP Partners noted that these modifiers would need to be monitored to confirm that they were being used appropriately.

Beyond whether services are correctly coded, HFPP Partners were also paying attention to whether or not services were being billed appropriately. In a scheme identified by multiple HFPP Partners, several laboratories were double-billing for COVID-19 testing, directly billing the patient for COVID-19 testing as well as the patient’s insurance. These labs had recorded higher levels of COVID-19 diagnoses in relation to the typical trends of positive diagnoses in the geographical area; this brought about an additional concern of which test results were being shared with patients. HFPP Partners were concerned that, in



a possible attempt to minimize the likelihood of billing being flagged, labs were using more COVID-19 diagnosis codes (rather than codes for suspected exposure, contact, or screening) than matched positive rates in the geographical area.

Several Partners also described instances in which billing occurred for services not provided, such as no contact being made with a previous patient who then was billed for a check-in visit or adding billing for an e-visit check-in call and then elevating that service to a regular E&M visit. In addition, one HFPP Partner voiced initial concerns and started surveillance of claims for vaccination office visits outside of larger sponsored vaccination sites and any potential fraudulent services added on during a COVID-19 vaccination visit, including possibly inappropriately charging an E&M code.

Direct Solicitation and Identity Theft

COVID-19-related services may serve as a conduit for bad actors engaging in telemarketing or direct solicitation of health plan members and beneficiaries. While concerns with potential telemarketing fraud have previously existed, the nature of the global pandemic led to heightened fear and susceptibility on the part of members and patients to respond to these solicitations. HFPP Partners reported in interviews that aggressive solicitation of members and beneficiaries for COVID-19 diagnostic testing was rampant early in the pandemic. Individuals perpetrating these schemes used a wide range of approaches to collect medical and insurance information including emails, telephone calls, social media, and in-person events – such as drive-through and parking-lot pop-up testing centers, tables or booths at shopping malls, and visiting assisted care homes. This solicitation of information was gathered largely using incentives of COVID-19 testing and PPE. In return, these patients often ended up having unnecessary tests performed in addition to COVID-19 testing and, in many cases, services were rendered by providers with whom they had no prior relationship.

With the use of social media to advertise COVID-19 testing, several HFPP Partners identified the improper distribution of home kits for COVID-19 diagnosis early in the PHE. Additionally, during the same time frame, multiple HFPP Partners identified, via hotline complaints, an increased volume of calls by fraud perpetrators attempting to engage patients and providers in their schemes. Investigations ultimately uncovered compromised lists of member and beneficiary information and increased identity theft.



These circumstances heightened existing concerns with direct solicitation schemes involving Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS). The schemes, illustrated in Figure 4 below, involved several key fraudulent actors, including international call centers, DMEPOS suppliers, telemedicine companies, and medical professionals, that solicit beneficiaries, obtain their personal information, and bill insurance for medically unnecessary orthotics. Previous kickback schemes with providers receiving compensation for working with DMEPOS suppliers, coupled with more providers being able to prescribe orthotics, have led to past spikes of potentially fraudulent reimbursement for orthotics. During the PHE, several screening requirements for Medicare DMEPOS supplier applications, including the application fee, criminal background check, and site visits, were waived, and CMS did not require accreditation for newly enrolling DMEPOS suppliers. These necessary changes created the potential for increased referral and billing of medically unnecessary DMEPOS items. Of note, CMS reinstated site visits in August 2020. HFPP Partners, though concerned by the spike in billing of DMEPOS items during this period of waivers, commented that the guidelines and strategies revealed by “Operation Brace Yourself,” a DOJ-coordinated takedown of a large Medicare fraud scheme involving DMEPOS and telemedicine companies in 2019, helped inform their efforts to address these schemes during the PHE.⁵⁷

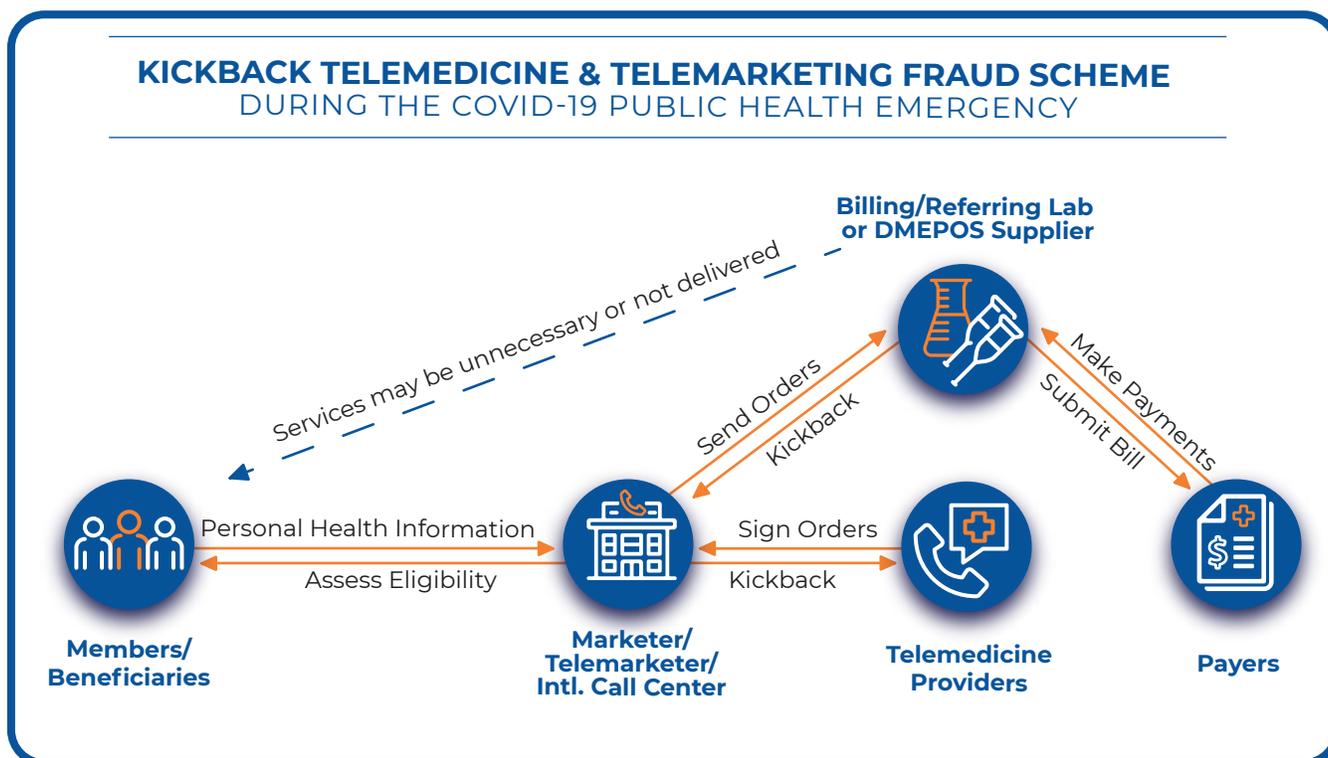


Figure 4: Kickback Telemedicine & Telemarketing Fraud Scheme During the COVID-19 Public Health Emergency



FRAUD, WASTE, AND **ABUSE DETECTION**

Enforcement, Prevention, and Mitigation Methods

Healthcare payers and law enforcement agencies applied numerous strategies to address the fraud, waste, and abuse schemes and concerns described in the previous section. Methods surrounding detection, resulting enforcement, prevention, and mitigation are outlined below.

Detection

For a majority of HFPP Partners involved in combating fraud, waste, and abuse during the PHE, in-depth analysis of waivers and regulations, robust data collection, and routine monitoring for fraud began in February or early March 2020. Since that time, payers have applied many strategies to detect fraud, waste, and abuse, including increased collaboration, using data identified through patient-reported complaints of fraud, waste, and abuse, and data analytics.

Collaborative Efforts

At the start of this PHE, HFPP Partners undertook comprehensive collaborative efforts, quickly working to convene meetings across agencies and departments. As one HFPP Partner described, the response was the greatest collaborative effort across states and law enforcement they had seen in many years to combat fraud, waste, and abuse. The Partner also commented that they had never before seen a community prepare itself with preventive measures to such a degree. Multiple HFPP Partners, speaking about their experiences, highlighted the increased frequency of team meetings and data sharing and analysis.

HFPP Partners stressed the importance of the camaraderie between teams across institutions as communication became more prolific during this time of crisis, which ultimately created more robust relationships between organizations. In addition to increased meetings and video calls, one example included the development of online case status boards with debriefs about current and anticipated schemes. This type of information sharing led to increased awareness of evolving fraud, waste, and abuse schemes and the potential for improved mitigation.



Data Analysis

HFPP Partners commented repeatedly on data analysis efforts, highlighting the increased use of algorithms and monitoring during the PHE. Data analysis teams used both supervised models that use training data to guide detection and unsupervised models that work with unlabeled data and allow the algorithm to find features or patterns to identify trends. In particular, these teams tracked COVID-19 modifiers and telehealth modifiers closely. Specific indicators of interest are listed below:

- **No Prior Relationship:** These are instances where COVID-19 tests or full outpatient E&M visits were billed to patients without a previous relationship with that provider, which could indicate compromised patient information. A related concern identified during interviews with HFPP Partners was foreign-based doctors improperly using or appropriating HIPAA-standard National Provider Identifier (NPI) numbers.
- **Impossible or Improbable Days:** This data analysis method detects the sudden use of telemedicine visits to bill “impossible days” (i.e., billing over the maximum or feasible hours in a day). In particular, Partners highlighted psychotherapy and psychiatry as potential areas of focus as analysis demonstrated increased daily hours as well as amplified weekly trends for visits during the PHE. One HFPP Partner indicated that, prior to the COVID-19 PHE, 99.3% of mental health visits occurred in-person, while after its onset only 56.0% occurred in-person. Given this shift to telehealth, several HFPP Partners described an increase in detection and investigations of impossible days. Of note, while some investigations found providers billing inappropriately, other supplemental investigations into given medical practices displayed an appropriate spike of impossible days attributed to advanced practitioner providers (APP), such as a Physician Assistant or Nurse Practitioner, billing under a physician name in Medicare via “incident-to” services.⁵⁸ From these examples, both data driven analyses and supplemental investigations are helpful to evaluate impossible or improbable days.
- **No Expected Decrease in Services or Testing:** This trend describes sustained billing patterns where it would be anticipated that the PHE would cause disruptions, such as a provider that continued billing in-person visits while locally-based peers experienced decreased in-person visits when restrictions were in effect. HFPP Partners at the



beginning of the PHE noticed dentists, podiatrists, or other providers that would typically provide in-person services continuing to bill at consistent rates or even for improbable telemedicine visits for these services. An HFPP Partner identified a particular trend by using 2019 data to inform its analysis of cardiac genetic testing. Working with numbers from before and during the pandemic, this HFPP Partner was able to track expected targets for this type of genetic testing and identify areas of concern during the pandemic where additional billing may be happening. Creating these models helped identify the statistical likelihood of certain trends and patterns and enabled models to be trained on baseline structured data related to fraud, waste, and abuse. Primary data analyses related to testing and treatment, as well as secondary analyses considering payer policies, were used to help identify potential COVID-19-related fraud, waste, and abuse.

One such example of the HFPP applying data analytics to detect potential fraud, waste, and abuse came from HFPP Partners expressing concerns with billing of additional, unnecessary, and/or unordered RPPs, genetic tests, and other unrelated tests in conjunction with COVID-19 tests. The HFPP conducted a study using its unique, cross-payer dataset focusing on laboratory billing of additional testing beyond the COVID-19 diagnostic tests. In order to identify suspicious or potentially unnecessary add-on laboratory services, the Trusted Third Party (TTP) for the HFPP first established the presence of a COVID-19 diagnostic test for a given member and laboratory biller. While not the focus of the study, the diagnostic test itself is the encounter that creates an opportunity for a laboratory biller to inappropriately maximize reimbursement over and above the relatively low-paying COVID-19 test. The study then identifies additional services billed by the same laboratory, for the same patient, on the same day and looks at total volume and reimbursement for these situations, as well as measures of the frequency with which this behavior occurred. Typically, the identified billing represents only a fraction of a given laboratory's total COVID-19 diagnostic encounters. However, laboratory billers with many instances of add-on laboratory tests, high levels of payment, and high frequencies of this type of billing within their entire COVID-19 testing population may warrant further Partner review.



Enforcement

HFPP Partners emphasized collaborative efforts as a means to conduct fraud, waste, and abuse enforcement amidst the COVID-19 PHE. A DOJ-coordinated takedown in September 2020 highlights the benefits of conducting collaborative investigations and the significant financial impact fraudsters have on the delivery of care.⁴⁶ Telemedicine claims alone accounted for over \$4.5 billion of the more than \$6 billion allegedly false and fraudulent claims identified. In conjunction with the takedown, the DOJ created the National Rapid Response Strike Force, with a mission to investigate and prosecute fraud cases involving major healthcare providers that operate in multiple jurisdictions.

As a result of these collaborative efforts, the DOJ charged 345 defendants responsible for more than \$6 billion in alleged fraud losses. As the largest takedown in healthcare fraud history, this effort represented the culmination of identifying vulnerabilities and immense collaboration while also managing the ongoing challenge of balancing risk with necessary waivers during a PHE. The Health Care Fraud Strike Force program's response to these bad actors serves as an important mitigation step in the evolution of the COVID-19 PHE. Additionally, these actions will help to inform future strategies for waivers and healthcare fraud early prevention, similar to how the 2019 "Operation Brace Yourself" takedown highlighted schemes that informed Partners' efforts to address DMEPOS-related schemes during the PHE.

The September 2020 investigation also identified more than \$800 million in allegedly false and fraudulent claims to Medicare, Medicaid, TRICARE, and private insurance companies for medically unnecessary and, often, never provided treatments.⁴⁶ This included the distribution of controlled substances, which has trended upward during the pandemic, with the resulting September takedown evidencing the distribution of more than 30 million doses of opioids and other prescription narcotics.

Prevention and Mitigation

Preventing fraud, waste, and abuse during the PHE has included both education and early mitigation strategies. A key prevention strategy that a majority of HFPP Partners emphasized was specifically educating providers on new waivers and proper billing codes in the form of calls, letters, or online guidance. In addition to provider education, HFPP Partners have pursued a variety of communication approaches, from newsletters to regular website



updates, which helped to keep members, beneficiaries, and patients informed and aware of fraud, waste, and abuse prevention best practices.

Additionally, an important strategy for many HFPP Partners has been creating robust data alert systems. This approach allowed HFPP Partners to focus on specific codes and areas of concern, including COVID-19 and telehealth modifiers or particular lab testing, and to use algorithms to uncover discrepancies in either geographical or timeline analyses.

While it is difficult to quantify the mitigation value of these educational, analytical, and collaborative strategies, it is clear that prevention of future fraud, waste, and abuse relies heavily on these approaches. All of these examples highlight prevention strategies as a key takeaway from the COVID-19 PHE, as well as the importance of early collaboration and communication as a crucial pillar to fraud, waste, and abuse prevention.



CONCLUSIONS AND **FUTURE DIRECTIONS**

Developed with direct HFPP Partner input and a review of available literature, this white paper describes fraud, waste, and abuse related to the delivery of care for COVID-19, as well as schemes that capitalize upon the PHE, which occurred in the United States from the onset of the PHE through early 2021. One purpose of the white paper is to provide a foundational background on the devastating impact of COVID-19 on individuals' general health, which includes an overview of the SARS-CoV-2 virus, efforts to test for and treat COVID-19, and the changes to practices and policies implemented to improve the delivery of healthcare during the PHE.

In addition, this paper speaks to fraud, waste, and abuse schemes that occurred between early 2020 and January 2021. HFPP Partners rapidly began to observe and worked to counter repurposed and modified fraud, waste, and abuse schemes in the delivery of COVID-19 care. The observations in this paper are important to consider as the trajectory of fraud, waste, and abuse associated with COVID-19 continues to evolve and future analyses are conducted. For instance, delayed billing and medical record review conducted in the future may reveal increased evidence of fraud, waste, and abuse related to COVID-19 (e.g., regarding in-patient services) and can be informed by the fraud scheme and data analysis descriptions in this paper.

With COVID-19 vaccinations beginning in December 2020, fraud, waste, and abuse related to the delivery of care for COVID-19 will continue to surface, as evidenced by the advertising of fake vaccines or providers obtaining vaccine doses and unnecessarily and illegally charging for them, even though the federal government is providing the vaccine free of charge to all people living in the United States.⁵⁹ As HFPP Partners and healthcare delivery systems in the United States work to ensure patient safety, privacy, and equity of vaccine distribution, the future examination of direct solicitation and incorrect billing for COVID-19 vaccine administration may largely parallel or leverage some of the robust processes built during the PHE to investigate COVID-19 testing, services, and treatment related fraud, waste, and abuse.



More broadly, as healthcare fraud continues to evolve and adapt, this paper outlines important steps that federal and state agencies, private payers, and law enforcement have taken and can continue to take to respond. The scope of the PHE required a large-scale response that included dynamic changes in healthcare delivery regulations and policies and rapid increases in funding and resources. Lessons learned from HFPP Partners identification and mitigation of issues during the COVID-19 PHE can inform future efforts, including if similar changes and resources should be needed to respond to future emergent health challenges.

Numerous HFPP Partners stressed the importance of early communication and close collaboration, whether through online status boards, regional task force meetings, or individual meetings across departments within their organizations or with peers in other organizations. A key component in understanding and adapting to the changes during the course of the PHE was connecting even more regularly than before the PHE. The rapid onset of a challenge of unknown magnitude drove HFPP Partners to quickly identify and monitor key metrics, which allowed them to respond swiftly, and find possible solutions when problems arose. The sudden demand for telehealth services offered important examples about delivery of care via telemedicine and how to monitor for fraud, waste, and abuse. These and other practices described in this paper, which HFPP Partners have found beneficial in addressing fraud, waste, and abuse associated with the delivery of care for COVID-19, can also be carried forward when considering how to address and be more prepared for future changes and challenges.



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58. [“PART 410 - SUPPLEMENTARY MEDICAL INSURANCE \(SMI\) BENEFITS.”](#) *Code of Federal Regulations*.
59. [“Key Things to Know about COVID-19 Vaccines.”](#) CDC, CDC.



ADDENDUM

Useful Articles, Resources, and Sites

Source	Resource
American Medical Association (AMA)	Boards of pharmacy and other actions relating to COVID-19 prescribing
CDC	COVID-19
CDC	2021 Release of ICD-10-CM
Cigna	Cigna's response to COVID-19
CMS	COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers
CMS	Coronavirus waivers & flexibilities
CMS	Approved 1135 Waivers
CMS	Approved Telehealth Waivers
CMS	1135 Waiver Request Information
CMS	Blanket Waivers – Claims Submission
CMS	Medicare Fee-For-Service: Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With a § 1135 Waiver
CMS	Medicare Fee-For-Service: Emergency-Related Policies and Procedures That May Be Implemented Without § 1135 Waivers
CMS	COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing
CMS	List of Telehealth Services That May Be Furnished Under Medicare Physician Fee Schedule
CMS	New Waivers for Inpatient Prospective Payment System (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) Due to Provisions of the CARES Act
CMS	State Medicaid & CHIP Telehealth Toolkit



Source	Resource
CMS	Permanent Expansion of Medicare Telehealth Services (12/01/2020)
DOJ	Coronavirus Response
DOJ	Federal Court Issues Temporary Restraining Order Against Website Offering Fraudulent Coronavirus Vaccine
FDA	Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments
FDA	FDA EUA Drugs and Biological Therapeutics
FDA	Fraudulent Coronavirus Disease 2019 (COVID-19) Products
HHS OIG	COVID-19 Portal
The New York Times (NYT)	Coronavirus Drug and Treatment Tracker
NYT	How the Johnson & Johnson Vaccine Works
NYT	How Moderna's Vaccine Works
NYT	How the Pfizer-BioNTech Vaccine Works
USA.Gov	Government Response to Coronavirus, COVID-19
State of Washington Office of the Attorney General	AG Ferguson wins refunds for victims of COVID-19 "vaccine" scam