

Q1 2021 Compliance Update

Pfizer-BioNTech COVID-19 Vaccine

Status: On December 11, 2020, the [U.S. Food and Drug Administration](#) issued the first [emergency use authorization](#) (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The EUA allows the [Pfizer-BioNTech COVID-19 vaccine](#) to be distributed in the U.S.

What it is: The Pfizer-BioNTech COVID-19 vaccine is authorized for the prevention of COVID-19 for individuals that are of 16 years of age or older.

What you need to know:

- The [Advisory Committee on Immunization Practices](#) (ACIP) advised that the following be offered COVID-19 vaccines in the initial phase of the vaccination program:
 - 1). health care personnel; and
 - 2). residents of long-term care facilities.
- Section 3203 of the [Coronavirus Aid, Relief, and Economic Security \(CARES\) Act](#) generally requires issuers offering non-grandfathered group or individual health insurance coverage to cover any qualifying coronavirus preventive service, including a COVID-19 vaccine, without imposing any cost sharing requirements, such as copays, coinsurance, or deductibles.
- On November 5, 2020, the [Centers for Medicare & Medicaid Services \(CMS\)](#) released a set of toolkits for providers, states, and issuers to help the healthcare system prepare for administering the COVID-19 vaccine.
- Additional guidance is expected as more COVID-19 vaccines become available.

For the most up-to-date information on COVID-19 vaccine(s), visit the CDC website at: <https://www.cdc.gov/vaccines/covid-19/index.html> or the U.S.

Food & Drug Administration website at: <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

The use of telehealth solidified in 2021 Medicare Physician Fee Schedule Rule

Status: On December 2, 2020, the [CMS](#) issued a [final rule](#) that includes updates on policy changes for Medicare payments under the [Physician Fee Schedule \(PFS\)](#), and other Medicare Part B issues, on or after January 1, 2021.

What it is: The calendar year ([CY 2021 PFS final rule](#)) is one of several rules that reflect a broader Administration-wide strategy to create a healthcare system that results in better accessibility, quality, affordability, empowerment, and innovation.

What you need to know:

- Since 1992, Medicare has paid for the services of physicians and other billing professionals under the PFS.
- Physicians' services paid under the PFS include a variety of settings such as physician offices, hospitals, ambulatory surgical centers, skilled nursing facilities, and more.
- For CY 2021:
 - The CMS is adding the following list of services to the Medicare telehealth list on a Category 1 basis:
 - Group Psychotherapy
 - Psychological and Neuropsychological Testing
 - Domiciliary, Rest Home, or Custodial Care services for established patients
 - Home Visits for established patients
 - Cognitive Assessment and Care Planning Services
 - Visit Complexity Inherent to Certain Office/Outpatient Evaluation and Management (E/M)
 - Prolonged Services
 - The CMS is also creating a third category that will be temporary and includes adding services to the list of Medicare telehealth services, such as:
 - Domiciliary, Rest Home, or Custodial Care services for established patients
 - Home Visits for established patients
 - Emergency Department Visits, Levels 1-5
 - Nursing facilities discharge day management
 - Psychological and Neuropsychological Testing
 - Therapy Services, Physical and Occupational Therapy, All levels
 - Hospital discharge day management
 - Inpatient Neonatal and Pediatric Critical Care, Subsequent
 - Continuing Neonatal Intensive Care Services
 - Critical Care Services
 - End-Stage Renal Disease Monthly Capitation Payment codes
 - Subsequent Observation and Observation Discharge Day Management

For more information on the CY 2021 PFS Final Rule, visit: <https://www.federalregister.gov/public-inspection/2020-26815/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part>

[HHS proposes changing HIPAA privacy rules](#)

Status: On December 10, 2020, the [HHS proposed modifications](#) to the Health Insurance Portability and Accountability Act of 1966 ([HIPAA](#)) rules to help improve care coordination, while giving patients more access to their health information.

What it is: According to the HHS Secretary, Alex Azar, the *“proposed changes to the HIPAA Privacy Rule will break down barriers that have stood in the way of commonsense care coordination and value-based arrangements for far too long.”* The proposed changes will aim to reduce burdens on providers and empower patients and their families to “secure better health.”

What you need to know:

- The proposed changes to the HIPAA Privacy Rule include:
 - strengthening individual's rights to access their own health information, including electronic information;
 - improving information sharing for care coordination and case management for individuals;
 - facilitating greater family and caregiver involvement in the care of individuals experiencing emergencies or health crises;
 - enhancing flexibilities for disclosures in emergency or threatening circumstances, such as the Opioid and COVID-19 public health emergencies; and
 - reducing administrative burdens on HIPAA covered health care providers and health plans, while continuing to protect individuals' health information privacy interests.
- Public comments on the Notice of Proposed Rulemaking (NPRM) will be due in sixty (60) days after the publication of the NPRM. The NPRM can be viewed and downloaded from the HHS's website at: <https://www.hhs.gov/sites/default/files/hhs-ocr-hipaa-nprm.pdf>