Policy and Practice: A CMS Update

ICE Annual Conference

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This publication is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference

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Objectives

- Discuss current CMS priorities
- Provide an overview of Medicare policy changes for 2022 related to the expansion or continuation of telehealth/telemedicine
- Review key elements of the CMS COVID-19 Pandemic Response including Acute Hospital Care at Home and the new vaccine requirements for participating facilities
- Highlight details of the recent regulations related to Surprise Billing
- Questions/discussion

CMS Priorities

- Advance health equity by addressing the health disparities that underlie our health system
- Build on the Affordable Care Act and expand access to quality, affordable health coverage, and care
- Engage our partners and the communities we serve throughout the policymaking and implementation process
- Drive innovation to tackle our health system challenges and promote value-based, person-centered care
- Protect our programs' sustainability for future generations by serving as a responsible steward of public funds
- Foster a positive and inclusive workplace and workforce, and promote excellence in all aspects of CMS's operations

https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms

CY 2022 Physician Fee Schedule (PFS) Final Rule

Telehealth Provisions

https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2022-medicare-physician-fee-schedule-final-rule

Current Telehealth Flexibilities Under the Public Health Emergency

- **Eligible Practitioners**
  - All health care practitioners who are authorized to bill Medicare for their professional services may also furnish and bill for telehealth services
  - Healthcare professionals who were not previously authorized under the statute to furnish and bill for Medicare telehealth services—including physical therapists, occupational therapists, speech language pathologists, and others—may receive payment for Medicare telehealth services.

- **Audio-only Telehealth for Certain Services**
  - Beginning on March 1, 2020, telephone evaluation and management and certain behavioral health care and educational services may be furnished via telehealth using audio-only telephones.

PFS 2022: Telehealth and Other Services Involving Communications Technology

- **Mental Health (Consolidated Appropriations Act)**
  - Section 123 of the CAA **removed the geographic restrictions and added the home of the beneficiary as a permissible originating site for telehealth services when used for the purposes of diagnosis, evaluation, or treatment of a mental health disorder**
    - Also requires that there be an in-person, non-telehealth service with the physician or practitioner within six months prior to the initial telehealth service, and thereafter, at intervals as specified by the Secretary.

  - We are implementing these statutory amendments, and finalizing that **an in-person, non-telehealth visit must be furnished at least every 12 months for these services**, that exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that more frequent visits are also allowed under our policy, as driven by clinical needs on a case-by-case basis.

PFS 2022: Telehealth and Other Services Involving Communications Technology (2)

- **CMS is amending the current definition of interactive telecommunications** system for telehealth services – which is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner – **to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients in their homes** under certain circumstances.

- CMS is **limiting the use of an audio-only interactive telecommunications system to mental health services furnished by practitioners who have the capability to furnish two-way, audio/video communications, but where the beneficiary is not capable of, or does not consent to, the use of two-way, audio/video technology**.

- CMS also **finalized a requirement for the use of a new modifier for services furnished using audio-only communications**, which would serve to verify that the practitioner had the capability to provide two-way, audio/video technology, but instead, used audio-only technology due to beneficiary choice or limitations. We are also clarifying that mental health services can include services for treatment of substance use disorders (SUDs).

PFS 2022: Telehealth and Other Services Involving Communications Technology (3)

- CMS finalized that certain **services added to the Medicare telehealth services list will remain on the list through December 31, 2023**, allowing additional time for us to evaluate whether the services should be permanently added to the Medicare telehealth services list.

- We finalized that **we will extend, through the end of CY 2023, the inclusion on the Medicare telehealth services list of certain services added temporarily to the telehealth services list that would otherwise have been removed from the list as of the later of the end of the COVID-19 PHE** or December 31, 2021.

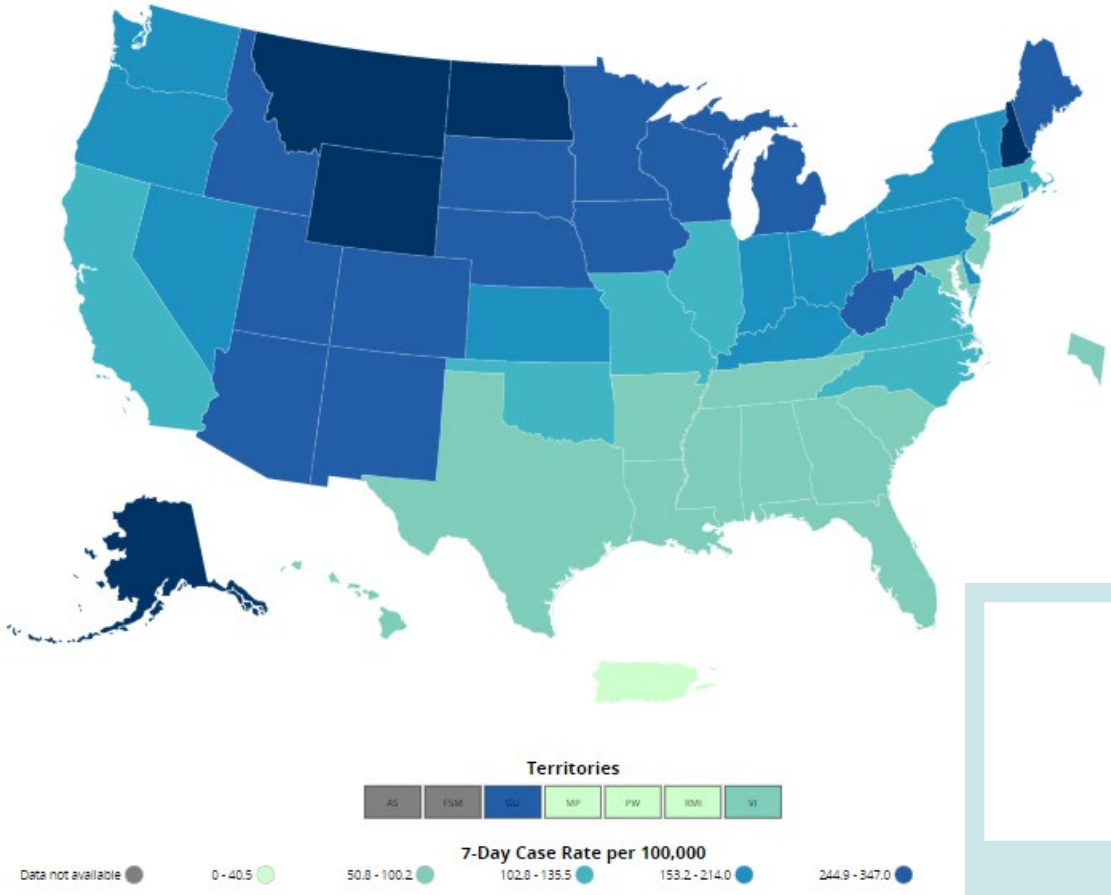
- We also have extended inclusion of certain cardiac and intensive cardiac rehabilitation codes through the end of CY 2023.

- Additionally, we are adopting coding and payment for a longer virtual check-in service on a permanent basis.

Current Data on Epidemic

As of 11/5/21

https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days



TOTAL CASES

46,268,465

+88,029 New Cases

7 DAY CASE RATE PER 100,000

150.2

TOTAL DEATHS

749,876

+1,208 New Deaths

CDC | Data as of: November 5, 2021 2:35 PM ET. Posted: November 5, 2021 3:41 PM ET

United States

At a Glance

Cases Total 46,268,465

Last 30 Days

Deaths Total 749,876

Last 30 Days

78.5% of People 12+ with At Least

One Vaccination

The CMS COVID-19 Response

Care by Phone

Patients can consult with a doctor, nurse practitioner, psychologist, and others and

Medicare will cover it.

Telehealth

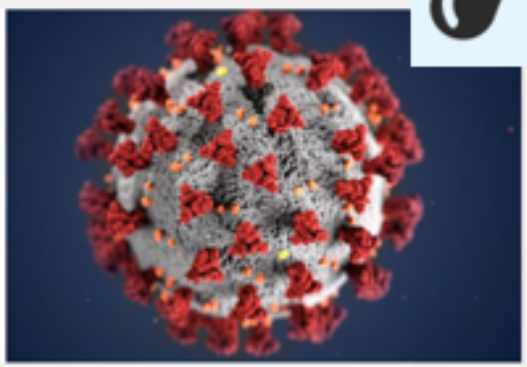
People with Medicare can now get telehealth services from their home, increasing their access to care.

Expanding Hospital Capacity

Community resources like hotels, convention centers and surgery centers can be converted for hospital care.

COVID-19 Vaccine Policies & Guidance

We're giving you the information you need to provide the COVID-19 vaccine. We have many resources about coverage and billing for providers, state Medicaid plans, and private health plans.



COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf

https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

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Acute Hospital Care at Home

Overview | Reporting Measures | Resources | Webinars

Acute Hospital Care at Home Individual Waiver Only (not a blanket waiver)

CMS is accepting waiver requests to waive **§482.23(b)** and **(b)(1)** of the Hospital Conditions of Participation, which require nursing services to be provided on premises 24 hours a day, 7 days a week and the immediate availability of a registered nurse for care of any patient.

Waiver requests will be divided into two categories based on a hospital's prior experience. Hospitals must submit the waiver request for individual CMS Certification Numbers (CCNs), not entire systems. For those hospitals which have provided at home acute hospital services to at least 25 patients previously, an expedited process will be conducted and include hospital attestation to specific existing beneficiary protections and reporting requirements. The immediate goal with this group is to allow experienced hospitals to rapidly expand care to Medicare beneficiaries. These hospitals will be required to submit monitoring data on monthly basis.

Key Actions

Request a Waiver

Submit Reporting Measures

Participation

View the Measures

https://qualitynet.cms.gov/acute-hospital-care-at-home

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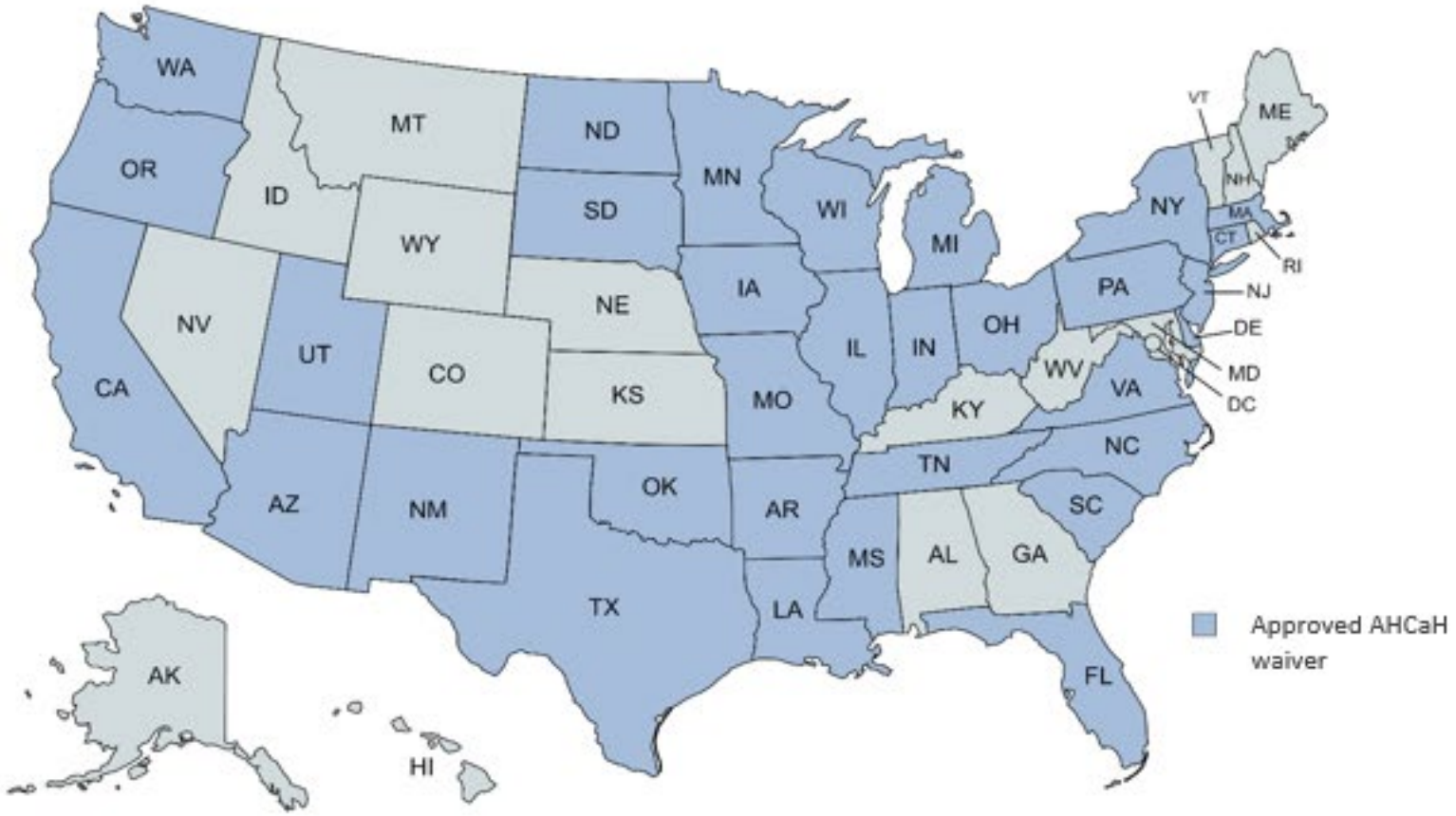
Geographic Distribution of Waiver Uptake



- A total of 187 waivers approved Hospitals
- Waivers across 83 health systems
- Approved waivers in a total of 34 states

As of November 5, 2021

https://qualitynet.cms.gov/acute-hospital-care-at-home/resources

Questions, inquiries and information requests can be emailed directly to the waiver review team at AcuteHospitalCareAtHome@cms.hhs.gov

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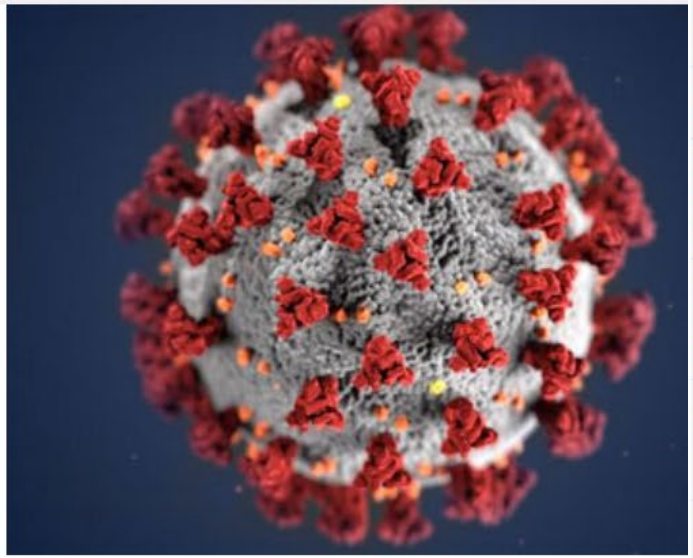
COVID-19 Vaccine and Therapeutics Toolkits

COVID-19 Vaccine Policies & Guidance

We're giving you the information you need to be ready for the COVID-19 vaccine when it's available. If we can prepare a wide pool of providers to administer the COVID-19 vaccine, then we can ensure the vaccine is covered and available free of charge for every American.

Read IFC 4 (PDF)



COVID-19

- Enrollment for Administering COVID-19 Vaccine Shots
- Coding for COVID-19 Vaccine Shots
- Medicare COVID-19 Vaccine Shot Payment
- Medicare Billing for COVID-19 Vaccine Shot Administration
- SNF: Enforcement Discretion Relating to Certain Pharmacy Billing
- Beneficiary Incentives for COVID-19 Vaccine Shots
- CMS Quality Reporting for COVID-19 Vaccine Shots
- *New* Monoclonal Antibody COVID-19 Infusion

Vaccine guidance: https://www.cms.gov/covidvax

Clinician/provider toolkit: https://www.cms.gov/covidvax-provider

FAQs on billing therapeutics: https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

Authorized Age Groups for COVID-19 vaccination

- COVID-19 vaccination is recommended for **everyone 5 years and older** for the prevention of coronavirus disease 2019 (COVID-19) in the United States under the U.S. Food and Drug Administration's (FDA) Emergency Use Authorization (EUA).

For Whom Are COVID-19 Vaccines Authorized or Approved?

Three COVID-19 vaccines are available for use in the United States (initial doses):

- Pfizer-BioNTech for those aged 5 and over
- Moderna for those aged 18 and over
- Janssen (Johnson&Johnson) for those aged 18 and over

For Whom Is an Additional Dose Authorized?

CDC recommends that people with moderately to severely compromised immune systems receive an additional dose of mRNA COVID-19 vaccine at least 28 days after a second dose of Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 Vaccine.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

https://www.cms.gov/newsroom/press-releases/coverage-available-covid-19-vaccinations-eligible-children-ages-5-through-11

COVID-19 Vaccines for Children and Teens

Most Children and All Teens Can Get COVID-19 Vaccines

CDC recommends **everyone ages 5 and older get a COVID-19 vaccine** to help protect against COVID-19.

Authorized For	Pfizer-BioNTech	Moderna	J&J / Janssen
4 years and under	No	No	No
5–11 years old	**Yes**	No	No
12–17 years old	**Yes**	No	No
18 years and older	**Yes**	**Yes**	**Yes**

While COVID-19 tends to be milder in children compared with adults, it can make children very sick and cause children to be hospitalized. In some situations, the complications from infection can lead to death.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html

Who is Eligible for a COVID-19 Vaccine Booster shot?

- People 65 years and older, 50–64 years with underlying medical conditions, or 18 years and older who live in long-term care settings should receive a booster shot.
- People 18 years and older should receive a booster shot at least 2 months after receiving their Johnson & Johnson/Janssen COVID-19 vaccine.

IF YOU RECEIVED

Pfizer-BioNTech or Moderna

You are eligible for a booster if you are:

- 65 years or older
- Age 18+ who live in long-term care settings
- Age 18+ who have underlying medical conditions
- Age 18+ who work or live in high-risk settings

When to get a booster:
At least 6 months after your second shot

Which booster should you get?
Any of the COVID-19 vaccines authorized in the United States

IF YOU RECEIVED

Johnson & Johnson's Janssen

You are eligible for a booster if you are:
18 years or older

When to get a booster:
At least 2 months after your shot

Which booster should you get?
Any of the COVID-19 vaccines authorized in the United States

CMS will continue to provide coverage for this critical protection from the virus, including booster doses, without cost sharing

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

https://www.cms.gov/covidvax-provider

Coadministration of Flu & COVID-19 Vaccines

- Simultaneous administration of live and inactivated vaccines yields seroconversion & adverse reaction rates similar to those found vaccines are given separately
- **COVID-19 vaccines may be administered without regard to timing of other vaccines**
  - Includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day
  - Not known if the reactogenicity of COVID-19 vaccines changes with coadministration
  - When deciding whether to co-administer vaccines with a COVID-19 vaccine, consider whether the patient is behind or at risk of becoming behind on recommended vaccines, risk of vaccine-preventable disease, & reactogenicity profile of the vaccines
- Administer each vaccine in a different injection site
- Administer COVID-19 vaccine and vaccines likely to cause local reactions in different limbs

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Coadministration

Myths, Facts and Questions about COVID-19 vaccination

FAQs: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

Myths & Facts: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html

Myths and Facts about COVID-19 Vaccines

Updated July 7, 2021 Languages Print

How do I know which COVID-19 vaccine information sources are accurate?

Accurate vaccine information is critical and can help stop common myths and rumors.

It can be difficult to know which sources of information you can trust. Before considering vaccine information on the Internet, check that the information comes from a credible source and is updated on a regular basis. Learn more about finding credible vaccine information.

Is it safe for me to get a COVID-19 vaccine if I would like to have a baby one day?

Yes. If you are trying to become pregnant now or want to get pregnant in the future, you may get a COVID-19 vaccine when one is available to you.

There is currently no evidence that COVID-19 vaccination causes any problems with pregnancy, including the development of the placenta. In addition, there is no evidence that female or male fertility problems are a side effect of any vaccine, including COVID-19 vaccines.

Can a COVID-19 vaccine make me sick with COVID-19?

No. None of the authorized COVID-19 vaccines in the United States contain the live virus that causes COVID-19. This means that a COVID-19 vaccine **cannot** make you sick with COVID-19.

COVID-19 vaccines teach our immune systems how to recognize and fight the virus that causes COVID-19. Sometimes this process can cause symptoms, such as fever. These symptoms are normal and are signs that the body is building protection against the virus that causes COVID-19. Learn more about how COVID-19 vaccines work.

https://cdc.gov/coronavirus/2019-ncov/vaccines/index.html

Updated CDC Guidance for those fully vaccinated

- Fully vaccinated people should wear a mask in public indoor settings in areas of substantial or high transmission.
- Fully vaccinated people might choose to wear a mask regardless of the level of transmission, particularly if they are immunocompromised or at increased risk for severe disease from COVID-19, or if they have someone in their household who is immunocompromised, at increased risk of severe disease or not fully vaccinated.
- Fully vaccinated people who have come into close contact with someone with suspected or confirmed COVID-19 to be tested 3-5 days after exposure, and to wear a mask in public indoor settings for 14 days or until they receive a negative test result.
- CDC recommends universal indoor masking for all teachers, staff, students, and visitors to schools, regardless of vaccination status.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

Administration Expands Vaccination Requirements for Health Care Settings

- The Biden-Harris Administration will require COVID-19 vaccination of staff within all Medicare and Medicaid-certified facilities to protect both them and patients from the virus and its more contagious Delta variant.
- Facilities across the country should make efforts now to get health care staff vaccinated to make sure they are in compliance when the rule takes effect.

- The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Centers for Disease Control and Prevention (CDC), announced that emergency regulations requiring vaccinations for nursing home workers will be expanded to include hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies, among others, as a condition for participating in the Medicare and Medicaid programs.

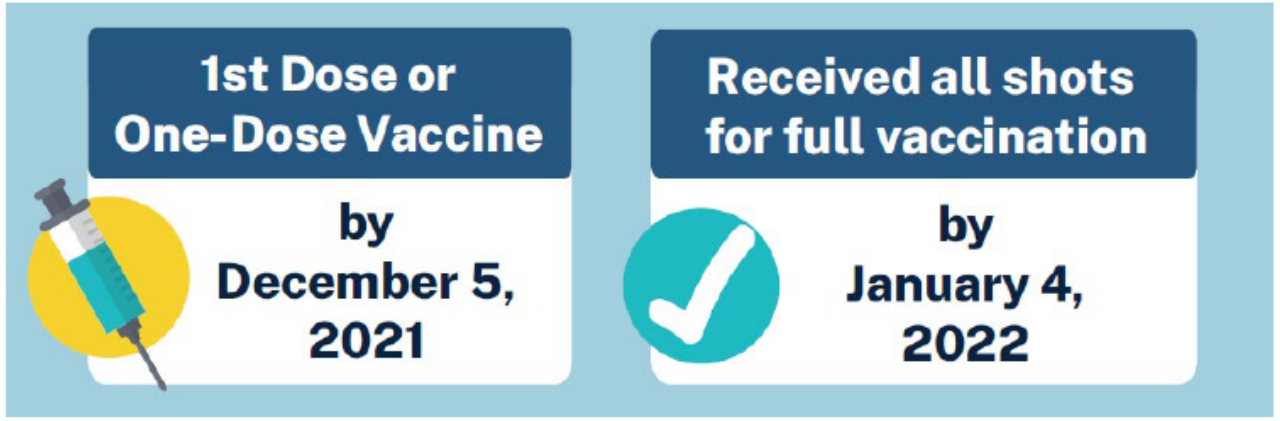
- The decision was based on the continued and growing spread of the virus in health care settings, especially in parts of the U.S. with higher incidence of COVID-19.

https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care

Requirements – What must my facility do?

- You must have your process or plan in place for vaccinating staff, providing exemptions and accommodations, and tracking and documenting staff vaccinations within 30-days (by December 5, 2021)

- Additionally, your process or plan for vaccinating staff must ensure that all eligible staff receive:
  - 1st Dose or One-Dose Vaccine by December 5, 2021
  - Received all shots for full vaccination by January 4, 2022



https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care

Eligibility – Who is included?

Requirements apply to **facilities** regulated under the Medicare Conditions of Participation (CoPs)

This Includes:

- Ambulatory Surgery Centers
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- Community Mental Health Centers
- Comprehensive Outpatient Rehabilitation Facilities
- Critical Access Hospitals
- End-Stage Renal Disease Facilities
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Long Term Care Facilities
- Programs for All-Inclusive Care for the Elderly Organizations (PACE)
- Psychiatric Residential Treatment Facilities
- Rural Health Clinics/Federally Qualified Health Centers

So What? – If you are one of the above providers or suppliers, this regulation applies to you and you must abide by the requirements

https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care

Requirements – Who in my facility must be vaccinated?

- The vaccination requirements **apply to all eligible staff**, both current and new, working at a facility regardless of clinical responsibility or patient contact, including:
  - Facility Employees
  - Licensed Practitioners
  - Students
  - Trainees
  - Volunteers
  - Contracted Staff

- The vaccination requirements also apply to staff who perform duties offsite (e.g. home health, home infusion therapy, etc.) and to individuals who enter into a CMS regulated facility
  - Example: A physician with privileges in a hospital who is admitting and/or treating patients onsite

- This requirement does not apply to full time telework staff

https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care

Requirements – How do exemptions work?

CMS requires facilities to allow for the following exemptions to staff in accordance with federal law:

- Recognized medical conditions for which vaccines are contraindicated
- Religious beliefs, observances, or practices

Basics for Medical Exemptions:

- Facilities must develop a process for permitting staff to request a medical exemption
- Facilities must ensure all documentation is signed and dated by a licensed practitioner
- Documentation must contain all information specifying why the COVID-19 vaccines are clinically contraindicated for the staff member
- Documentation must included a statement by the authenticating practitioner recommending the staff member be exempted

Basics for Religious Exemptions:

- Facilities must develop a process for permitting staff to request a religious exemption
- Facilities must ensure all requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of the facility's policies and procedures

https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care

New Requirements for Surprise Billing

On July 1, 2021, the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury, along with the Office of Personnel Management (OPM) released an interim final rule with comment period (IFC), entitled "Requirements Related to Surprise Billing; Part I." **This rule related to Title I (the No Surprises Act)** of Division BB of the Consolidated Appropriations Act, 2021 establishes protections from surprise billing and excessive cost-sharing for consumers receiving health care items and services.

This Interim Final Rule with Comment (IFC) implements many of the law's requirements for:

- Group health plans,
- Health insurance issuers,
- Carriers under the Federal Employees Health Benefits (FEHB) Program,
- Health care providers and facilities, and
- Air ambulance service providers.

https://www.cms.gov/newsroom/fact-sheets/requirements-related-surprise-billing-part-i-interim-final-rule-comment-period

Definitions

Balance billing is when a provider charges a patient the remainder of what their insurance does not pay. This practice is currently prohibited in both Medicare and Medicaid. A "balance bill" may come as a surprise for many people. Under this IFC, surprise billing for items and services covered by the rule generally is not allowed.

Surprise medical bill is an unexpected bill from a health care provider or facility. This can happen when a person with health insurance unknowingly gets medical care from a provider or facility outside their health plan's network. Surprise billing happens in both emergency and non-emergency care.

An unexpected balance bill is called a surprise bill.

Who will benefit from this rule?

These surprise billing protections **apply to you if you get your coverage through your employer** (including a federal, state, or local government), **or through the federal Marketplaces, state-based Marketplaces, or directly through an individual market health insurance issuer**.

The rule does **not** apply to people with coverage through programs such as Medicare, Medicaid, Indian Health Services, Veterans Affairs Health Care, or TRICARE. **These programs already prohibit balance billing.**

How does this rule help?

If a health plan provides or covers any benefits for emergency services, this rule requires emergency services to be covered:

- Without any prior authorization (meaning you do not need to get approval beforehand).
- Regardless of whether a provider or facility is in-network.

Under this IFC, the total amount to be paid to the provider or facility, including any cost sharing, is based on:

- An amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act.
- If there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law.
- If there is no such applicable All-Payer Model Agreement or specified state law, an amount agreed upon by the plan or issuer and the provider or facility.

Applicability Date

The regulations are generally applicable to group health plans and health insurance issuers for plan and policy years **beginning on or after January 1, 2022.**

- The HHS-only regulations that apply to health care providers, facilities, and providers of air ambulance services are applicable beginning on January 1, 2022.

- The OPM-only regulations that apply to carriers under the FEHB Program are applicable to contract years beginning on or after January 1, 2022.

https://www.cms.gov/newsroom/fact-sheets/what-you-need-know-about-biden-harris-administrations-actions-prevent-surprise-billing

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