Frequently Asked Questions:

CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency

While some FAQs are relevant for all programs, including Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and private insurance, other questions are program specific as indicated below.

1. When is the COVID-19 Public Health Emergency expected to end?

Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency for COVID-19 (PHE) declared by the Secretary of the Department of Health and Human Services (Secretary) under Section 319 of the Public Health Service (PHS) Act to expire at the end of the day on May 11, 2023.

2. On April 10, 2023, the President signed H.J.Res.7. into law, which terminated the national COVID-19 emergency immediately. Did this end the COVID-19 PHE declared by the Secretary?

The PHE for COVID-19 declared by the Secretary under section 319 of the PHS Act is not the same as the COVID-19 National Emergency declared by President Trump in 2020, which ended when President Biden signed H.J.Res.7. Therefore, the end of the COVID-19 National Emergency generally does not impact current operations at HHS, and it does not impact the expected May 11, 2023, expiration of the federal PHE for COVID-19 or any associated unwinding plans. Further, any existing waivers currently in effect and authorized under section 1135 of the Social Security Act will remain in place until the end of the PHE for COVID-19 declared by the Secretary under section 319 of the PHS Act.

3. Many of the flexibilities and waivers in place are tied to emergency declarations, legislative actions by Congress, and regulatory actions across government. Can the Centers for Medicare & Medicaid Services (CMS) extend Medicare, Medicaid, and Marketplace flexibilities beyond May 11, 2023, when the Administration is planning to end the PHE?

Thanks to the Administration's whole-of-government approach to combatting the virus, we are in a better place in our response than we were three years ago, and we can transition away from an emergency phase. The emergency declarations, legislative actions by Congress, and regulatory actions across government, including by CMS, allowed for changes to many aspects of health care delivery during the COVID-19 PHE. Health care providers received maximum flexibility to streamline delivery and allow access to care during the PHE. While some of these changes will be permanent or have been extended due to Congressional action, some waivers and flexibilities will expire, as they were intended to respond to the rapidly evolving pandemic, not to permanently replace standing rules.

CMS has released several documents that identify when waivers and flexibilities will end, as well as which waivers and flexibilities have been extended or will remain beyond the end of the PHE. To help individuals served by our programs know what to expect when the COVID-19 PHE ends, CMS released a fact sheet that highlights major impacts. CMS also released provider-specific fact sheets that will help the health care sector transition to non-emergency operations when the PHE ends. In addition, CMS developed a roadmap for the eventual end of the COVID-19 PHE and is sharing information on what health care facilities and providers can do to prepare for future emergencies.

Additionally, we are offering technical assistance to States overseeing Medicaid and CHIP programs and engaging in public education about the necessary steps to prepare for the end of the PHE, including guidance on the end of the Medicaid continuous enrollment condition and the expiration of many other temporary authorities adopted by states during the COVID-19 PHE. For additional information, visit CMS.gov.

MEDICARE:

4. When the PHE ends, will people insured by Medicare pay for COVID-19 vaccines?

People with Medicare coverage will continue to have access to COVID-19 vaccinations without out-of-pocket costs after the end of the PHE.

Once the federal government is no longer purchasing or distributing COVID-19 vaccines, people with Traditional Medicare pay nothing for a COVID-19 vaccination if their doctor or other qualified health care provider accepts assignment for giving the shot. People with Medicare Advantage (MA) plans should contact their plan for details about payment for COVID-19 vaccines, but MA beneficiaries will pay nothing for a COVID-19 vaccination if they receive their vaccinations from an in-network provider.

5. How much will CMS pay health care providers to administer COVID-19 vaccines through the end of the 2023 calendar year?

Under the Medicare Part B preventive vaccine benefit, CMS will continue to pay approximately $40 per dose for administering COVID-19 vaccines through the end of the calendar year in which the Secretary ends the Emergency Use Authorization (EUA) declaration for drugs and biologicals with respect to COVID-19. The COVID-19 EUA declaration has not ended. Note: The COVID-19 EUA declaration is distinct from, and not dependent on, the federal PHE for COVID-19, expected to expire on May 11, 2023, or the COVID-19 National Emergency that ended April 10, 2023.

Effective January 1 of the year following the year in which the EUA declaration ends, CMS will set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Part B preventive vaccines, which is currently approximately $30 per dose.

These payment rates do not apply in settings that are paid at reasonable cost for preventive vaccines and their administration (for example, Federally Qualified Health Centers and Rural Health Clinics).

If someone is enrolled in an MA plan, the provider should submit claims for vaccine administration to the MA plan, and the amount the provider is paid for the vaccine administration service is determined by the contract between the MA plan and the provider, if there is a contract. If there is no contract in place for COVID-19 vaccinations covered by the MA plan, the Medicare payment rate would apply.

6. When the PHE ends, will the additional payment for at-home COVID-19 vaccinations continue?

Medicare will continue to pay an additional amount of about $36 in addition to regular administration fees for the administration of COVID-19 vaccines at home when the PHE ends. This additional Medicare payment for at-home COVID-19 vaccinations will continue through the end of calendar year 2023.

For individuals enrolled in a MA plan, provider payment rates are determined by the contract between the MA plan and the provider when such a contract is in place and may or may not include additional payments for at-home COVID-19 vaccinations. If there is no contract in place for vaccinations covered by the MA plan, the Medicare payment rate would apply.

7. When will the enforcement discretion end that allows mass immunizers to bill directly to Part B for vaccines furnished to Skilled-Nursing Facility (SNF) patients in a Medicare-covered stay?

Anticipating the end of the COVID-19 PHE on May 11, 2023, the enforcement discretion associated with this policy would end on June 30, 2023. Beginning on July 1, 2023, SNFs will be responsible for billing for vaccines furnished to SNF patients in a Part A stay. Third-party suppliers furnishing these vaccines under arrangement with the SNF would be required to seek payment from the SNF for their services, consistent with SNF Consolidated Billing regulations.

8. Will Medicare continue to cover treatment(s) for patients with COVID-19?

Yes. There is no change in Medicare coverage of treatments for those exposed to COVID-19 once the PHE ends, and in cases where cost sharing and deductibles apply now, they will continue to apply. Generally, the end of the COVID-19 PHE does not change access to oral antivirals, such as Paxlovid and Lagevrio.

For individuals enrolled in a MA plan, the plans must cover treatments that Traditional Medicare covers (with some exceptions), but they may require the individual to see a provider who is in the MA plan's network and may have different cost sharing than Traditional Medicare.

9. How will Medicare cover diagnostic testing for COVID-19?

People with Traditional Medicare can continue to receive COVID-19 PCR and antigen tests with no cost-sharing when the test is ordered by a physician or certain other health care providers, such as physician assistants and certain registered nurses, and performed by a laboratory.

People enrolled in MA plans can continue to receive COVID-19 PCR and antigen tests when the test is covered by Medicare, but their cost-sharing may change when the COVID-19 PHE ends.

Through the end of the COVID-19 PHE, Medicare covers and pays for over-the-counter (OTC) COVID-19 tests at no cost to people with Medicare Part B, including those with MA plans. The demonstration that allowed coverage and payment for OTC tests will end when the PHE ends on May 11; Medicare Advantage plans may continue to cover the tests, so check with your plan for details.

10. Can a pharmacy still perform COVID-19 testing and be paid by Medicare for it?

A pharmacy that acquires a CLIA certificate (including, for example, a certificate of waiver) can enroll with Medicare as a clinical diagnostic laboratory to conduct and bill for clinical diagnostic laboratory tests authorized under their certificate, and many pharmacies have done this to furnish and bill for COVID-19 diagnostic laboratory tests during the PHE. This is permissible under current permanent Medicare policies. After the PHE ends, the test must be ordered by a physician or certain other health care providers, such as physician assistants and nurse practitioners.

11. If a pharmacy enrolled in Medicare as a Laboratory through the MAC hotlines and received temporary billing privileges during the PHE for COVID-19, does the pharmacy need to re-enroll after the end of the PHE?

A. Yes. A pharmacy or other provider/supplier that enrolled as a laboratory through the MAC hotlines and received temporary billing privileges during the PHE for COVID-19 will need to submit an 855 enrollment form to establish full Medicare billing privileges after the end of the PHE for COVID-19. The pharmacy or other supplier/provider will receive a letter from their Medicare Administrative Contractor to initiate this process. All requirements of the relevant provider type must be met to obtain enrollment.

12. What happens for pharmacists with regard to testing and vaccine administration once the PHE ends?

We have been allowing pharmacists, as well as other health care professionals who are authorized to order lab tests under the state scope of practice and other relevant laws, to order COVID-19 tests for Medicare beneficiaries during the PHE. This does not mean that these pharmacists and other health care professionals have been able to enroll in the Medicare program to furnish and bill for services they furnish to beneficiaries; rather, it has allowed Medicare to pay for tests that they order. This will expire at the end of the COVID-19 public health emergency.

As COVID-19 vaccinations are covered under Part B, pharmacists can bill for these just as they do today for other Part B preventive vaccinations, like flu shots.

Pharmacists, and the pharmacies that employ them, are not among the types of physicians or non-physician practitioners that can enroll and be paid directly under Part B for their professional services. However, pharmacists can act as auxiliary personnel to provide services incident to the professional services of a Medicare-enrolled physician or non-physician practitioner who supervises and bills for the services, if payment for the services is not made under the Medicare Part D benefit. This includes providing services incident to the services of the Medicare billing physician or non-physician practitioner and in accordance with the pharmacist's state scope of practice and applicable state law.

CMS also permits an entity or individual who wishes to furnish certain Part B preventive vaccinations -- but may not otherwise qualify as a Medicare provider -- to enroll as a "Mass Immunizer." Such entities or individuals must meet the following requirements:

- They may not bill Medicare for any items or services other than pneumococcal pneumonia vaccines, influenza virus vaccines, COVID-19 vaccines, and the service to administer these vaccines.
- They must submit claims using the roster billing process.
- They must meet all applicable state and local licensure or certification requirements.

Please note that pharmacies already enrolled in Medicare in order to bill under Part B for covered drugs are not required to also enroll as mass immunizers in order to bill under Part B for preventive vaccines and their administration. Therefore, to the extent a pharmacist is employed with a pharmacy that is enrolled in Medicare in this capacity, that pharmacy can bill and receive payment from Medicare for administering preventive vaccines.

13. How will maintenance of Public Readiness and Emergency Preparedness (PREP) Act liabilities to October 1, 2024, affect Medicare coverage for COVID-19 tests ordered and/or administered by pharmacists?

How, if at all, does a pharmacy's continued participation in a federal program like CDC's Increasing Community Access to Testing (ICATT) affect Medicare coverage requirements post-PHE under the PREP Act?

PREP Act declarations do not have any bearing on Medicare payment or coverage requirements.

On April 14, 2023, HHS Secretary Becerra announced that in the coming weeks, he will issue an amendment to the declaration under the PREP Act for medical countermeasures against COVID-19. Over the past three years, the PREP Act declaration for COVID-19 has expanded the pool of providers who – with outlined training and supervision – are "covered persons" authorized to administer medical countermeasures against COVID-19, including vaccines, tests, and treatments.

Under the PREP Act, these covered persons – which now include pharmacists, pharmacy technicians, and pharmacy interns – are immune from suit and liability under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure, if a declaration under the PREP Act has been issued with respect to such countermeasure.

Medicare coverage and payment requirements are not affected by a PREP Act declaration, and this is true regardless of the status of the PHE. Therefore, a pharmacy's continued participation in a federal program like CDC's Increasing Community Access to Testing (ICATT) will not affect Medicare coverage requirements post-PHE.

14. Will Medicare Advantage plans be allowed to apply deductibles, copayments, or coinsurance if testing is conducted by an out of network pharmacy? Or even limit coverage solely to in-network pharmacies?

Yes. When the COVID-19 PHE ends, MA plans will be allowed to apply cost sharing for COVID-19 PCR and antigen tests when the test is covered by Medicare. Some MA plans, like HMOs and POS MA plans, may limit coverage of COVID-19 testing to only in-network providers, but MA enrollees should check with their plan to see if any Medicare services are covered when delivered through out-of-network providers.

15. Will the waiver of the three-day hospital stay requirement prior to a SNF stay continue, or will it end with the PHE?

Many flexibilities, including the waiver of the Medicare three-day qualifying hospital stay (QHS) requirement prior to a Medicare-covered SNF stay, will no longer be in effect for the Medicare fee-for-service program once the PHE ends.

For any Medicare Part A-covered SNF stay which begins on or prior to May 11, 2023, without a QHS, that stay can continue for as long as the beneficiary has Part A SNF benefit days available and for as long as the beneficiary continues to meet the SNF level of care criteria (e.g., requiring daily skilled care). For any new Medicare Part A-covered SNF stay which begins after May 11, 2023, (including stays which experience a break in Part A coverage that exceeds three consecutive calendar days before resuming SNF coverage), these stays will require a QHS.

However, a doctor or other provider who is part of an Accountable Care Organization (ACO) may still be able to send their patients for a Medicare-covered SNF stay even if they have not stayed as an inpatient in a hospital for at least three consecutive days first. For someone to qualify for this benefit, the doctor or other provider has to decide that SNF care is needed and certain other eligibility requirements are met.

Additionally, MA plans may elect to furnish coverage of post-hospital SNF care in the absence of the prior qualifying hospital stay as part of their Medicare-covered services. MA enrollees should check their Evidence of Coverage document for coverage requirements related to SNF care.

16. When the PHE ends, can individuals continue to see providers virtually using telehealth?

Yes, in most cases. During the PHE, individuals with Medicare had broad access to telehealth services, including in their homes, without the geographic or location limits that usually apply. These waivers were included as provisions of The *Consolidated Appropriations Act, 2023*, which extended many telehealth flexibilities through December 31, 2024, such as:

- People with Medicare can access telehealth services in any geographic area in the United States, rather than only in rural areas.
- People with Medicare can stay in their homes for telehealth visits that Medicare pays for rather than traveling to a health care facility.
- Certain telehealth visits can be delivered using audio-only technology (such as a telephone) if someone is unable to use both audio and video (such as a smartphone or computer).

However, if an individual receives routine home care via telehealth under the hospice benefit, this flexibility will end at the end of the PHE.

MA plans may offer additional telehealth benefits. Individuals in an MA plan should check with their plan about coverage for telehealth services. Additionally, after December 31, 2024, when these flexibilities expire, some ACOs may offer telehealth services that allow primary care doctors to care for patients without an in-person visit, no matter where they live.

17. At the end of the PHE, when can hospitals bill for:

i. The originating site facility fee (HCPCS code Q3014)?
ii. The clinic visit (HCPCS code G0463)?
iii. Remote mental health services (HCPCS codes C7900 - C7902)?

Following the anticipated end of the PHE (May 11, 2023):

i. Hospitals cannot bill for this code after the PHE unless the beneficiary is located *within a hospital* and the beneficiary receives a *Medicare telehealth service from an eligible distant site practitioner*. Only in these cases can the hospital would bill for the originating site facility fee (HCPCS code Q3014). See question 17 for additional details.
ii. If the beneficiary is *within a hospital* and receives a *hospital outpatient clinic visit* (including a mental/behavioral health visit) from a practitioner in the same physical location, then the hospital would bill for the clinic visit (HCPCS code G0463).
iii. If the beneficiary is *in their home* and receives a *mental/behavioral health service from hospital staff through the use of telecommunications technology* and no separate professional service can be billed, then the hospital would bill for the applicable HCPCS C-code describing this service (HCPCS codes C7900 - C7902).

18. The *Consolidated Appropriations Act, 2023* extended certain Medicare telehealth flexibilities through the end of CY 2024. Has the Hospitals Without Walls Initiative been extended as well?

No. The Hospitals Without Walls Initiative will expire with the PHE. The PHE is anticipated to end at the end of the day on May 11, 2023.

19. If the Hospitals Without Walls Initiative expires at the end of the day on May 11, 2023, why are beneficiaries able to receive mental/behavioral health services in their home from hospital staff through the use of telecommunications technology after that date?

The flexibilities currently in place under the Hospital Without Walls Initiative during the COVID-19 PHE allowed hospitals to bill for services furnished by hospital clinical staff to beneficiaries in their homes using telecommunications technology, because the home was considered a provider-based department of the hospital. The services included a subset of hospital outpatient therapy, counseling, and educational services, beyond just mental/behavioral health services.

After the PHE ends, in some circumstances, hospitals will continue to be able to bill for mental/behavioral health services furnished to beneficiaries in their homes by hospital staff using telecommunications technology permanently. This policy only applies when no separate professional service is billable, as finalized in the calendar year 2023 Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems final rule (87 FR 71748). These services are considered "remote mental health services."

However, once the beneficiary's home is no longer considered a provider-based department of the hospital after the end of the PHE, the hospital staff will no longer be able to bill for other outpatient services furnished to beneficiaries in the home.

Notably, in accordance with the *Consolidated Appropriations Act, 2023,* eligible distant site physicians and practitioners may still be able to bill as a Medicare telehealth service under the Medicare physician fee schedule for professional services furnished via telehealth to individuals in their homes through December 31, 2024.

20. After the end of the PHE, can hospitals bill for the originating site facility fee (HCPCS code Q3014) when a beneficiary is not in the hospital but a hospital-based outpatient department physician furnishes a Medicare telehealth service and the hospital provides administrative and clinical support?

No. Following the anticipated end of the PHE (May 11, 2023), hospitals will no longer be able to bill HCPCS code Q3014 to account for the resources associated with administrative support for a professional Medicare telehealth service.

21. [UPDATED] Following the end of the PHE, can hospitals bill for outpatient physical therapy (PT), occupational therapy (OT), speech language pathology (SLP) services, Diabetes Self-Management Training (DSMT), or Medical Nutrition Therapy (MNT) provided to beneficiaries in their homes through telecommunication technology by hospital-employed staff?

In context of the end of the PHE, we have received a number of inquiries from interested parties regarding the expiration of this policy. We have reviewed all of the relevant guidance, including applicable billing instructions and external feedback, and recognize the confusion around these policies. We also recognize that the therapists and many of the other practitioners who provide these services remain on the list of distant site practitioners for Medicare telehealth services.

However, for DSMT services, we understand that some other types of hospital clinical staff, beyond those identified as eligible distant site practitioners for Medicare telehealth, can provide these services in some cases. To allow these services to continue to be furnished to patients in their home through telecommunication technology through the end of CY 2023, we are exercising enforcement discretion in reviewing the telehealth practitioner status of the clinical staff personally providing any part of a remotely furnished DSMT service, so long as the practitioner is otherwise qualified to provide the service.

Through the end of CY 2023, PT, OT, SLP, DSMT, MNT providers should continue to bill for these services when furnished remotely in the same way they have been during the PHE.

22. After the end of the PHE, how often will Medicare provide payment for a subsequent nursing facility or subsequent inpatient visit when furnished via Medicare telehealth?

We have received a number of inquiries from interested parties regarding temporarily continuing our suspension of these frequency limitations beyond the end of the PHE, specifically our requirement that CPT codes 99231-99233 may only be furnished via Medicare telehealth once every 3 days, and our requirement that CPT codes 99307-99309 may only be furnished via Medicare telehealth once every 14 days. We are exercising enforcement discretion and will not consider these frequency limitations through December 31, 2023, as we anticipate considering our policy further through our rulemaking process.

23. Will teaching physicians be allowed to use virtual presence and bill for services involving residents in residency training sites outside of a MSA after the PHE ends?

CMS is exercising enforcement discretion to allow teaching physicians in all teaching settings to be present virtually, through audio/video real-time communications technology, for purposes of billing under the PFS for services they furnish involving resident physicians. We are exercising this enforcement discretion through December 31, 2023, as we anticipate considering our policy for services involving teaching physicians and residents further through our rulemaking process.

24. Can patients who received Remote Monitoring or other Communication Technology-Based services through a waiver in place during the PHE be considered an "established patient" for purposes of continued receipt of such services, even without an initiating service?

Yes. A patient who received Remote Monitoring or other Communication Technology-Based services while the PHE Waiver (85 FR 19230, 19244, 19264) was in effect will be considered an "established patient" for continued receipt of remote monitoring and other communication technology-based services after the end of the COVID-19 PHE. This rule applies as long as the patient consented to receive subsequent remote monitoring and other communication technology-based services. This consideration would be the case even if the patient did not have an in-person or telehealth-eligible initiating service. The patient's consent to receive subsequent services should be documented in the patient's medical records and should be available to CMS upon request.

25. Will remote Partial Hospitalization Program (PHP) services be covered under Medicare for HCPCS codes, such as G0410 (Group Psychotherapy) and G0177 (Education and Training Services), after the end of the PHE?

Under current law, there is a prohibition on furnishing PHP services in an individual's home as well as the inpatient or residential setting. Specifically, section 1861(ff)(3)(A) of the Social Security Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting.

The ability to deliver remote PHP services during the PHE is tied to the Hospitals Without Walls (HWW) waivers that were under section 1135 authorities, so they will end at the end of the PHE when section 1135 authorities expire. Under HWW, a patient's home could be considered a temporary expansion location of a hospital (or CMHC). Under these waivers, the patient's home was considered a provider-based department of the hospital, which allowed remote partial hospitalization services to be covered under Medicare.

In the CY 2023 Outpatient Prospective Payment System final rule, CMS established a policy that allows clinical staff of hospitals to provide certain mental health services via a telecommunications system to patients in their homes after the PHE. We established 3 new codes and code descriptors (C7900-C7902) for these remote mental health services furnished by hospital outpatient department (HOPD) staff. Because HCPCS codes C7900 – C7902 describe remote mental health services furnished by hospital staff to a patient in their home, and the statute prohibits PHP services from being furnished in an individual's home, these are not considered PHP services, and CMHCs can't furnish these remote services. However, patients receiving PHP services from a CMHC or hospital-based PHP could receive the remote mental health services from clinical staff of a HOPD. The policy discussion starts around (87 FR 72014).

26. Can remote Partial Hospitalization Program (PHP) and Intensive Outpatient Program (IOP) services be provided and paid for by Medicare after the PHE ends?

Intensive Outpatient Program services are not currently covered or paid under the Medicare program. Section 4124(b) of the *Consolidated Appropriation Act, 2023* (CAA, 2023) established Medicare coverage for intensive outpatient services effective for items and services furnished *on or after January 1, 2024*.

The amendments made by the CAA, 2023 generally applied the same conditions to IOP services as apply to PHP services. This includes the requirement in section 1861(ff)(3)(A) of the Social Security Act that specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, *in a location other than an individual's home or inpatient or residential setting*. Rural health clinics and federally qualified health centers will also be able to furnish IOP services beginning in 2024 under the CAA, 2023 provision.

With regard to remote mental health services, in the CY 2023 Outpatient Prospective Payment System (OPPS) final rule, CMS established a policy that allows clinical staff of hospitals to provide certain mental health services via a telecommunications system to patients in their homes after the PHE. We established 3 new codes and code descriptors (C7900-C7902) for these remote mental health services furnished by hospital outpatient department (HOPD) staff. Because HCPCS codes C7900 – C7902 describe remote mental health services furnished by hospital staff to a patient in their home, and the statute prohibits PHP services from being furnished in an individual's home, these are not considered PHP services, and CMHCs can't furnish these remote services. However, patients receiving PHP services from a CMHC or hospital-based PHP could receive the remote mental health services from clinical staff of an HOPD. (87 FR 72014).

CMS anticipates policies related to IOP services as added in section 4124 of the CAA, 2023, will be implemented through rulemaking for the upcoming calendar year 2024 payment rules.

27. Can the three HCPCS codes, C7900, C7901, and C7902, which were included in the Outpatient Prospective Payment System (OPPS) Final Rule last year, be used multiple times in a day and also be used for group therapy?

Yes. HCPCS codes C7900, C7901, and C7902 can be billed under the OPPS for either individual or group therapy furnished remotely to a beneficiary in their home. These codes can be billed multiple times per day if multiple therapy services are furnished to a beneficiary. Our longstanding OPPS policy limits the aggregate payment for specified mental health services furnished to a single beneficiary on the same date to the payment for a day of partial hospitalization services provided by a hospital.

28. What impact will the end of the COVID-19 PHE have on the reporting requirements imposed on nursing homes, hospitals, and critical access hospitals?

Nursing home COVID-19 vaccination reporting requirements for nursing home residents and staff will continue until CMS takes other regulatory action. All of the other non-vaccine COVID-19 reporting requirements are in effect through December 2024. Regardless of the COVID-19 PHE, nursing homes are still required to have an effective infection prevention and control program, which is a longstanding requirement to prevent the transmission of infectious diseases (which would include COVID-19).

In the August 10, 2022, Fiscal Year 2023 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) final rule, CMS revised the hospital and critical access hospitals (CAHs) infection prevention and control Condition of Participation so that hospitals and CAHs will continue to report on a reduced number of COVID-19 data elements after the conclusion of the COVID-19 PHE until April 30, 2024, unless the Secretary establishes an earlier end date.

29. At the end of the PHE, how will CMS' review contractors conduct medical reviews for claims billed during the PHE based on approved waivers or flexibilities?

CMS contractors (Medicare Administrative Contractors, Recovery Audit Contractors, and Supplemental Medical Review Contractors) conduct medical reviews on a very small percentage of Medicare Fee-for-Service claims each year. During the PHE, CMS and its contractors applied flexibilities across claim types. All claims will be reviewed using the applicable rules and restrictions that were in place at the time of the date(s) of service on the claim. For example, during the PHE, CMS has not enforced certain National Coverage Decision (NCD) and Local Coverage Decision (LCD) requirements that otherwise would have restricted coverage for certain durable medical equipment (DME) items. Once the PHE ends, CMS will primarily focus DME medical reviews on claims with dates of service post-PHE, for which clinical coverage requirements apply. We note that we may still review the claims for certain DME items, as well as other items or services furnished during the PHE, if needed to address aberrant billing behaviors or potential fraud. If this were to occur, the appropriate review contractor website would be updated with the review topic. The HHS-Office of the Inspector General may perform reviews as well, if necessary. The Comprehensive Error Rate Testing (CERT) program will continue to review a statistically valid stratified random sample of claims to determine if they were paid properly under Medicare coverage, coding, and payment rules in place at the time of the date(s) of service on the claim.

30. What does this mean for medical review of DME supplies or ongoing DME rental claims?

For certain DME supplies and ongoing rental items provided during the PHE, CMS allowed certain flexibilities and has not enforced certain NCD and LCD requirements. We note that statutory and regulatory requirements for DME items remained applicable. Since medical need for supplies and ongoing rentals is typically established and documented when the item is initially provided, we plan to primarily focus our medical reviews on claims with initial dates of service after the COVID-19 PHE. We may still review these DME items, as well as other items or services rendered during the COVID-19 PHE, if needed to address aberrant billing behaviors or potential fraud. All claims will be reviewed using the applicable rules in place at the time of the claim dates of service. In the event that claim review occurs, CMS or its contractors (Medicare Administrative Contractors, Recovery Audit Contractors and the Supplemental Medical Review Contractors) will provide additional information based on the supply or rental item selected for review.

31. Since Continuous Glucose Monitors (CGMs) and related supplies require a face-to-face follow up within six months, how will CMS review contractors conduct medical review for CGMs that were initially obtained during or prior to the PHE?

When evaluating for compliance with the face-to-face requirement, the Medicare Administrative Contractors, Supplemental Medical Review Contractors, and the Recovery Audit Contractors will generally focus on CGM claims with dates of service six months beyond the end of the PHE to ensure the treating practitioner had an in-person visit or a Medicare-allowed telehealth visit with the beneficiary. Therefore, potential medical reviews for CGMs (for which we did not enforce certain NCD and LCD requirements that otherwise would have restricted coverage) would focus on the six months after the anticipated end of the PHE (May 11, 2023), and every six months thereafter. In other words, the treating practitioner visit will be used to assess beneficiary adherence to their CGM regimen and diabetes treatment plan. All claims will be reviewed using the applicable rules for the claim dates of service.

32. When the waivers of sanctions under the physician self-referral law terminate at the end of the PHE, will a physician practice be able to rely on the in-office ancillary services exception in order to bill for Part D outpatient prescription drugs that they mail or deliver to a beneficiary's home?

No. During the COVID-19 PHE, physician practices that relied on the in-office ancillary services exception to the physician self-referral law were able to bill for Part D drugs that were mailed or delivered to a beneficiary's home because CMS waived the "location" requirement of the exception, as described in a blanket waiver document (see https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf). This waiver was authorized under section 1135 of the Social Security Act (the Act) and, therefore, must end along with the anticipated conclusion of the PHE on May 11, 2023. This means that, on May 12, 2023, as described below, a physician practice will no longer be able to rely on the in-office ancillary services exception to bill for Part D drugs that are mailed or delivered to a beneficiary's

home, but **Medicare beneficiaries will still be able to get the outpatient prescription drugs they need through their Part D plans' networks of mail order and other pharmacies.**

Although otherwise prohibited under the physician self-referral law, the statutory in-office ancillary services exception allows a physician practice to furnish certain designated health services, including outpatient prescription drugs, to beneficiaries in the practice's office subject to certain conditions. CMS policy regarding whether an item is considered to be furnished in the practice's office was established through notice and comment rulemaking and has not changed since it was finalized in 2001 (see 66 FR 856). Under this policy, a beneficiary must receive an item in a "same building" or "centralized building" (which are defined in our regulations and referred to as the "location requirement"). The location requirement would not be satisfied if a beneficiary receives an item from the physician practice by mail (or otherwise) outside one of these locations, as described in an FAQ posted in 2021 regarding this longstanding CMS policy (see https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf).

After the PHE concludes, physician practices that wish to mail or deliver Part D drugs to beneficiaries' homes would need to satisfy all requirements of an applicable exception to the physician self-referral law other than the in-office ancillary services exception (see 42 CFR Part 411 Subpart J). Any changes to the regulatory exceptions to the physician self-referral law would need to be made through notice and comment rulemaking. Section 1877(b)(4) of the Act authorizes the Secretary to establish exceptions only for financial relationships which the Secretary determines, and specifies in regulations, do not pose a risk of program or patient abuse.

CMS is committed to ensuring beneficiaries' access to their prescription drugs, and we do not anticipate any access issues in returning to the longstanding policy that was in place before the COVID-19 PHE. **CMS will closely monitor patient complaints to watch for any issues affecting patient access.** The Medicare Part D program is robust, and Part D sponsors must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that beneficiaries enrolled in Part D plans have convenient access to network pharmacies. More than 99 percent of Part D plans specifically include mail order delivery to a beneficiary's home as part of their benefit, and all Part D plans have retail pharmacy networks that meet or exceed required convenient pharmacy access standards described in Part D regulations at 42 CFR 423.120.

MEDICAID AND THE CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP)

33. What is the end of the Medicaid continuous enrollment condition, and is it tied to the end of the PHE?

No. The end of the continuous enrollment condition for individuals enrolled in Medicaid is no longer linked to the end of the COVID-19 PHE. Instead, it ended on March 31, 2023.

In March 2020, Congress enacted the *Families First Coronavirus Response Act* (FFCRA), which made a temporary increase in the federal medical assistance percentage (FMAP) available to states that met certain conditions, including a condition under which states had to maintain the

enrollment of any person enrolled in Medicaid as of or after March 18, 2020 (continuous enrollment condition). Primarily due to the continuous enrollment condition, Medicaid enrollment has grown substantially compared to before the pandemic, and the uninsured rate has dropped. As of December 2022, over 92 million people were enrolled in Medicaid and CHIP.

On December 29, 2022, President Biden signed into law the *Consolidated Appropriations Act, 2023* (CAA, 2023). This legislation ended the continuous enrollment provision on March 31, 2023. The CAA, 2023 also phases down the FFCRA temporary FMAP increase until December 31, 2023. All states, including states that accept the FFCRA temporary FMAP increase, began to return to normal eligibility operations as soon as April 1, 2023. This process includes restarting Medicaid and CHIP eligibility renewals for all enrollees and terminations of coverage for individuals who are no longer eligible. States have up to 12 months to return to normal eligibility and enrollment operations. All states must meet certain reporting and other requirements during this return to normal enrollment and eligibility operations regardless of whether states continue to claim the FFCRA temporary FMAP increase.

It is a top CMS priority that people retain coverage, whether through Medicaid, CHIP, Marketplace, Medicare, or employer-sponsored health insurance. In an effort to minimize the number of people who lose Medicaid or CHIP coverage, CMS is working with states and stakeholders to inform people currently enrolled in Medicaid and CHIP about renewing their coverage and exploring other available health insurance options if they no longer qualify for Medicaid or CHIP, including through the Marketplaces. To find information about how to renew Medicaid or CHIP in your particular state, please visit our interactive map at Medicaid.gov. Additional information and resources can be found on CMS' Medicaid Unwinding web page.

34. When the PHE ends, will Medicaid continue to cover COVID-19-vaccines, testing, and treatments?

Generally, yes. As a result of the *American Rescue Plan Act of 2021* (ARPA), states must provide Medicaid and CHIP coverage, without cost-sharing, for COVID-19 vaccinations, testing, and treatments through the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE. If the COVID-19 PHE ends as expected on May 11, 2023, this coverage requirement will end on September 30, 2024.

After that date, many Medicaid and CHIP enrollees will continue to have coverage for COVID-19 vaccinations. After the ARPA coverage requirements expire, Medicaid and CHIP coverage of COVID-19 treatments and testing may vary by state.

Additionally, 18 states and U.S. territories have opted to provide Medicaid coverage to uninsured individuals for COVID-19 vaccinations, testing, and treatment. Under federal law, Medicaid coverage of COVID-19 vaccinations, testing, and treatment for this group will end when the PHE ends.

35. What Medicaid telehealth flexibilities will end, and what flexibilities will remain in place?

No flexibilities will end. For Medicaid and CHIP, telehealth flexibilities are not tied to the end of the PHE and have been offered by many state Medicaid programs long before the pandemic. Medicaid and CHIP telehealth policies will ultimately vary by state. CMS encourages states to continue to cover Medicaid and CHIP services when they are delivered via telehealth.

To assist states with the continuation, adoption, or expansion of telehealth coverage, CMS has released the State Medicaid & CHIP Telehealth Toolkit and a supplement that identifies for states the policy topics that should be addressed to facilitate widespread adoption of telehealth.

PRIVATE INSURANCE

36. What is the "Unwinding SEP," and how can consumers qualify?

CMS has announced a temporary Special Enrollment Period (SEP) for qualified individuals and their families who are losing Medicaid or CHIP coverage due to the end of the continuous enrollment condition. During this process, known as "unwinding," millions of individuals could lose their Medicaid or CHIP coverage and need to transition to other forms of coverage, including through the Marketplaces.

Due to the volume of individuals who could lose their Medicaid or CHIP coverage, state Medicaid and CHIP agencies may be unable to provide timely information about the termination of coverage and alternative plan options that would enable consumers to make an informed decision about their health care coverage options within 60 days. For example, a consumer may need clarity as to whether a loss of Medicaid or CHIP coverage was procedural, such as a failure to update information, or due to ineligibility, before deciding whether to pursue Marketplace coverage.

Additionally, many Medicaid and CHIP beneficiaries may have moved or changed addresses since last receiving communications from their state. As a result, they may not receive termination notices from their state Medicaid or CHIP agency within 60 days or at all. Given these exceptional circumstances, CMS has made this SEP, also referred to as the "Unwinding SEP," available so consumers can maintain coverage.

The Unwinding SEP will allow individuals and families in states with Marketplaces served by the HealthCare.gov platform to enroll in Marketplace coverage. Marketplace-eligible consumers who submit a new application or update an existing HealthCare.gov application between March 31, 2023, and July 31, 2024, and attest to a last day of Medicaid or CHIP coverage during the same time period will be eligible for the Unwinding SEP. Consumers who are eligible for the Unwinding SEP will then have 60 days after they submit their application to select a plan with coverage that will start on the first day of the month after they select a plan. Consumers will not be required to submit documentation of a qualifying life event to receive the Unwinding SEP.

37. What impact will the end of PHE have on private insurance coverage of vaccines?

Most forms of private health insurance, including all Affordable Care Act-compliant plans, must continue to cover without cost-sharing COVID-19 vaccines furnished by an in-network health care provider. People with private health insurance may need to pay part of the cost if an out-of-network provider vaccinates them.

38. What impact will the end of the PHE have on private insurance coverage of COVID-19 diagnostic testing?

Mandatory coverage for over-the-counter and laboratory-based COVID-19 PCR and antigen tests will end after the expected end of the PHE on May 11, 2023, though coverage will vary depending on the health plan. If private insurance chooses to cover these items or services, there may be cost sharing, prior authorization, or other forms of medical management may be required.

39. What impact will the end of the PHE have on private insurance coverage of treatments?

Nothing. The transition forward from the PHE will not change how treatments are covered, and in cases where cost sharing and deductibles apply now, they will continue to apply.

40. What is the impact of the end of the use of telehealth in private insurance?

Nothing. As is currently the case during the PHE, coverage for telehealth and other remote care services will vary by private insurance plan after the end of the PHE. When covered, private insurance may impose cost-sharing, prior authorization, or other forms of medical management on telehealth and other remote care services. For additional information on your insurer's approach to telehealth, contact your insurer's customer service number located on the back of your insurance card.

41. Under what conditions will pharmacies/pharmacists be allowed to bill commercial insurers for pharmacist-<u>administered</u> COVID-19 tests?

Under what conditions will pharmacies/pharmacists be allowed to bill commercial insurers for pharmacist-<u>ordered</u> COVID-19 tests?

Will commercial insurers be allowed to apply deductibles, copayments, or coinsurance if testing is conducted by an out of network pharmacy? Or even limit coverage solely to in-network pharmacies?

Subject to applicable state law, plans and issuers have discretion over coverage of COVID-19 test administration by a pharmacist or in a pharmacy. As explained in guidance issued by the Departments of Labor, Treasury, and Health and Human Services on March 29, 2023, a group health plan or health insurance issuer offering group or individual health insurance coverage is not required under the *Families First Coronavirus Response Act* (FFCRA) or the *Coronavirus Aid, Relief, and Economic Security Act* (CARES) to cover COVID-19 diagnostic tests and associated items or services furnished after the PHE ends. Any plan or issuer that provides

coverage for COVID-19 diagnostic testing furnished after the PHE ends, including over-the-counter (OTC) COVID-19 diagnostic tests purchased after the PHE ends is not prohibited from imposing cost-sharing requirements, prior authorization, or other medical management requirements for those items and services. **However, plans and issuers are encouraged to continue to provide this coverage, without imposing cost sharing or medical management requirements, after the PHE ends.**

In general, an item or service is furnished on the date the item or service was rendered to the individual (or for an OTC COVID-19 diagnostic test, the date the test was purchased) and not the date the claim is submitted. Plans and issuers should look to the earliest date on which an item or service is furnished within an episode of care to determine the date that a COVID-19 diagnostic test is rendered, when the test involves multiple items or services. For example, if a health care provider collects a specimen to perform a COVID-19 diagnostic test on the last day of the PHE but the laboratory analysis occurs on a later date, the plan or issuer should treat both the specimen collection and laboratory analysis as if they were furnished during the PHE and are therefore subject to the FFCRA and CARES Act requirements.

Non-grandfathered health insurance plans purchased by individuals and small employers, including qualified health plans purchased on the Exchanges, must provide coverage for ten categories of essential health benefits (EHB). In some states and under some plans, some or all COVID-19 diagnostic testing [by a pharmacist] may be covered as an EHB. However, the exact coverage details and cost-sharing amounts for individual services may vary by state and by plan.

42. How will maintenance of Public Readiness and Emergency Preparedness (PREP) Act liabilities to October 1, 2024, affect commercial insurer coverage requirements for COVID-19 tests ordered and/or administered by pharmacists?

The PREP Act authorizes HHS to issue a PREP Act Declaration ("Declaration") that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency. In general, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a Declaration. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct. Neither group health plans, nor issuers of group or individual health insurance coverage, are involved in the development, manufacture, testing, distribution, administration, or use of COVID tests. Rather, plans and issuers merely provide reimbursement for the cost of such tests. Thus, HHS COVID-19 PREP Act authorizations are not relevant to private market coverage or payment.