HEALTHCARE REGULATORY ROUND-UP - Episode #44

Getting Ready for May 11: The End of the COVID-19 PHE

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Introductions

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National Technology Day

National Eat What You Want Day

National Twilight Zone Day

Hostess Cupcake Day

World Ego Awareness Day

National Nurses Week

CMS Guidance

February 27, 2023

Contact: CMS Media Relations
CMS Media Inquiries

What Do I Need to Know?

CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency

As part of the Centers for Medicare & Medicaid Services' (CMS) ongoing efforts to provide up-to-date information to prepare for the end of the Public Health Emergency (PHE) for COVID-19, which is expected on May, 11, 2023, we are providing a new overview fact sheet on CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency. COVID-19 efforts have been a significant priority for the Biden-Harris Administration, and with the use of whole-of-government approach, the country is in a better place. Over the next several months, CMS will work to ensure a smooth transition back to normal operations.

The CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency provides clarity on several topics including:

- COVID-19 vaccines, testing, and treatments;
- Telehealth services;
- Health Care Access

In the coming weeks, CMS will be hosting stakeholder calls and office hours to provide additional information. Please visit the CMS Emergencies Page for continuous updates regarding PHE sunsetting guidance as information becomes available to the public.

What Do I Need to Know?

CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency

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

This fact sheet will help you know what to expect at the end of the PHE so that you can continue to feel confident in how you will receive your health care. Please note that this information is not intended to cover every possible scenario.

This fact sheet will cover the following:

- COVID-19 vaccines, testing, and treatments;
- Telehealth services;
- Health Care Access: Continuing flexibilities for health care professionals; and
- Inpatient Hospital Care at Home: Expanded hospital capacity by providing inpatient care in a patient's home.

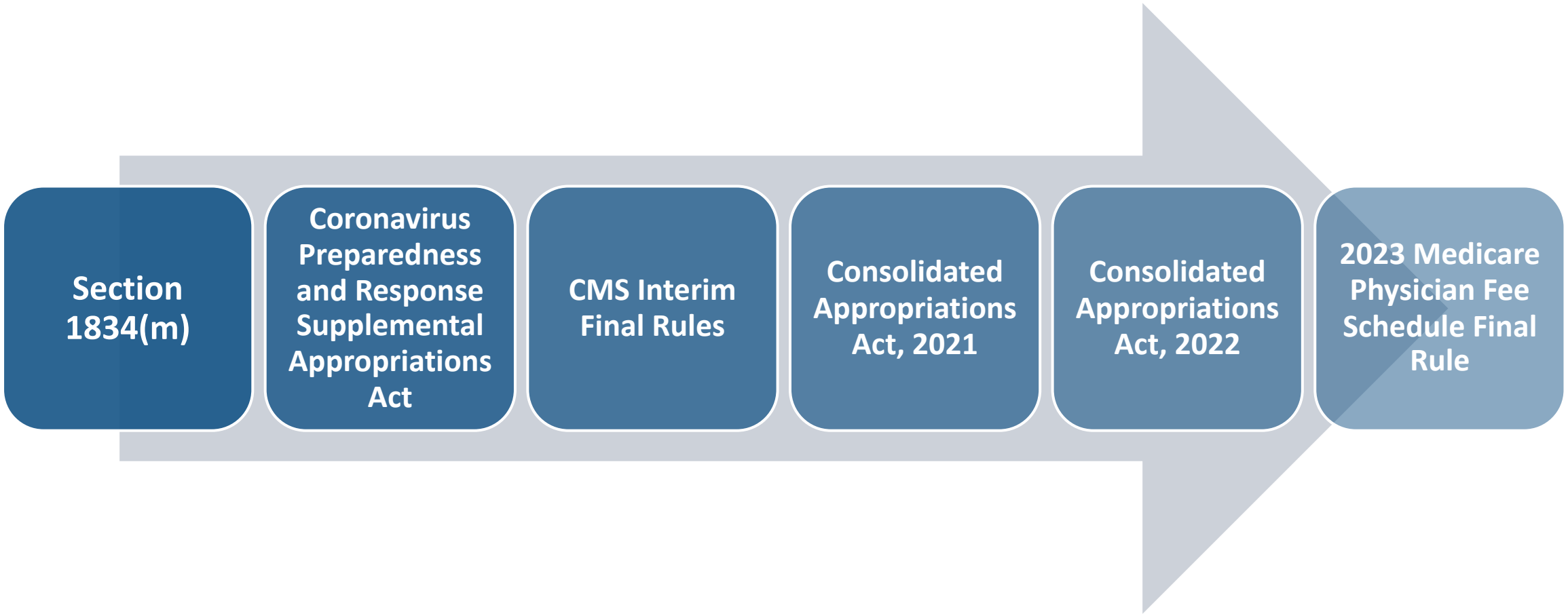
The Administration, States, and private insurance plans will continue to provide guidance in the coming months. As described in previous communications, the Administration's continued response is not entirely dependent on the COVID-19 PHE. There are significant flexibilities and actions that will not be affected as we transition from the current phase of our response. For more information on what changes and does not change across the Department, visit https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.

Agenda

1. Telehealth and Virtual Services
2. Controlled Substances
3. COVID-19-Related Reimbursement
4. Medicaid Redeterminations
5. Regulatory Waivers and Flexibilities

1. Telehealth and Virtual Services

A Brief History



CAA23 Extends Medicare Telehealth Flexibilities Thru 12/31/24

- ✓ Continuation of waiver of geographic and location requirements
- ✓ Continuation of reimbursement for PT, OT, S/L pathologist, and audiologist telehealth services
- ✓ Continuation of reimbursement for audio-only services
  - Audio-only E/M (CPT 99441-43), specified behavioral health & education services
- ✓ Delay in in-person requirement for initiation of tele-behavioral health services
  - CAA21 permanently eliminated geographic and location requirements for tele-behavioral health services subject to certain requirements + provided coverage for such services furnished by FQHCs and RHCs
- ✓ Continuation of reimbursement to FQHCs and RHCs for medical telehealth services (G2025 - $98.27)
- ✓ Continuation of use of telehealth to re-certify eligibility for hospice and required face-to-face encounter for home health

Outstanding Issues

- Expanded list of telehealth services?
  - Category 3 codes (presently covered through 12/31/23) and non-Category 3 codes (presently covered through 151 days post-PHE)
  - “we anticipate addressing updates to the Medicare Telehealth Services List for CY 2024 and beyond through our established processes as part of the CY 2024 Physician Fee Schedule proposed and final rules”
- Payment parity?
  - Presently ending on 12/31/23 (revert to facility rate)
- Use of telehealth for direct supervision?
  - Presently ending on 12/31/23
- OCR and OIG notices of enforcement discretion?

Other Telehealth Flexibilities Ending May 11

- ✓ For subsequent inpatient visits, use of telehealth limited to once every 3 days
- ✓ For subsequent SNF visits, use of telehealth limited to once every 14 days
- ✓ For critical care consults, use of telehealth limited to once per day
- ✓ For home dialysis, required face-to-face visits cannot be performed via telehealth
- ✓ For inpatient rehab stays, required face-to-face visits cannot be performed via telehealth
- ✓ To the extent NCD or LCD requires face-to-face visit for evaluations and assessments, these visits no longer can be performed via telehealth
- ✓ Opioid treatment programs no longer can furnish periodic assessments by telephone (two-way interactive audio-video communication still permitted)
- ✓ Only teaching physicians in non-MSA residency training sites may use telehealth to meet presence for key portion requirement (but not for complex procedures, endoscopy and anesthesia services)
- ✓ Hospitals and CAHs must comply with CoPs regarding provision of telemedicine services to patients under contract with distant-site hospital or distant-site telemedicine entity

Medicare Virtual Services

- As of May 11, established patient requirement returns for -
  - Remote evaluation of patient-submitted video/images (HCPCS 2010)
  - Virtual check-ins (HCPCS 2012)
  - Remote patient monitoring
- As of May 11, RPM requires 16 days of data for all patients (including patients with suspected or confirmed cases of COVID-19)

Telehealth Services Billed Under Medicare OPPS

- During PHE, hospitals have been able to bill telehealth originating site facility fee (Q3014 - $28.64 in 2023) for telehealth services furnished by physician/practitioner practicing in HOPD (POS 22) to beneficiary at home
  - Physician/practitioner paid at facility rate for such telehealth services
  - Beneficiary's home treated as HOPD
- February 1, 2023, version of CMS' fact sheet, *Hospitals and CAHs (including Swing Beds, DPUs), ASCs and CMHCs: CMS Flexibilities to Fight COVID-19:*
  - "After the PHE ends, this flexibility, to bill the telehealth service provided in the patient's home as if it was provided at the hospital, will end."
- February 23, 2023, version of the same fact sheet *does not* include this sentence
  - Does this mean hospitals *can* bill the telehealth originating site facility fee after May 11??

Hospital-Only Remote Outpatient Therapy and Education Services

- During PHE, OPPS payment available for subset of therapy and education services (including partial hospitalization services) furnished remotely by hospital clinical staff to beneficiaries at home (which qualifies as HOPD)
- After May 11, OPPS payment no longer available because beneficiary home no longer will qualify as HOPD
- New OPPS payment now available for behavioral health services furnished remotely by hospital staff to beneficiary at home subject to following conditions:
  - Beneficiary must receive (a) in-person service within 6 months prior to first time staff provides (unless beneficiary initiated remote services during PHE); and (b) in-person service within 12 months of each remote service (with exceptions)
  - Remote services not recognized as partial hospitalization services (although available to those in partial hospitalization program)
  - May be furnished using audio-only communication

Medicaid and Commercial Telehealth Coverage

- Center for Connected Health Policy (https://www.cchpca.org) maintains inventory of -
  - State Medicaid programs telehealth coverage and policy
  - State telehealth coverage and payment parity laws
- Federal telehealth flexibilities for commercial health insurance
  - Allow telehealth coverage pre-deductible for catastrophic plans (for plan years beginning before 1/1/2024) and HSA-qualified HDHPs (for plan years beginning before 1/1/2025)

2. Controlled Substances

Opioid Treatment Programs (OTP)

- Access to buprenorphine for OUD treatment in OTP
  - December 2022 proposed rule makes permanent PHE flexibility to initiate treatment via telephone (no in-person physical exam)
  - Same proposed rule permits initiation of methadone therapy via audio-visual exam
  - Substance Abuse and Mental Health Services Administration (SAMSHA) committed to interim solution if rule not finalized by May 11
- Expanded methadone take-home doses
  - SAMSHA previously extended PHE flexibilities for one year following end of PHE
  - December 2022 proposed rule would make these flexibilities permanent

NOTE: CAA23 eliminated DATA waiver requirement to prescribe medications for OUD treatment (all practitioners, not just OTPs)

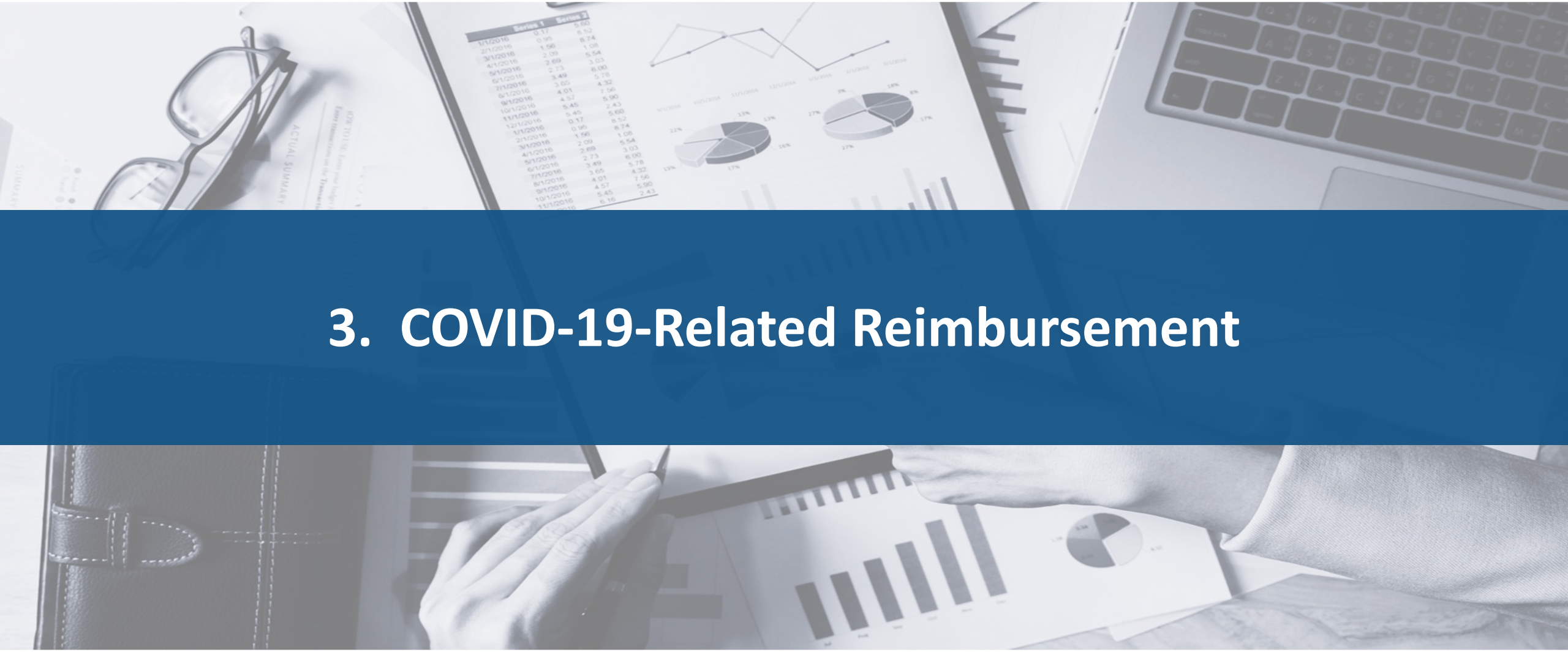
Prescribing Controlled Substances Via Telehealth

- Ryan Haight Online Pharmacy Consumer Protection Act requires practitioner to conduct one in-person medical evaluation prior to prescribing controlled substance
  - May prescribe via telehealth thereafter (no follow-up in-person evaluation required, no time limit between evaluation and prescribing)
- Exceptions
  - Covering practitioner
  - Public health emergency
    - DEA policy permits telehealth prescribing without in-person evaluation from 3/31/20 through end of PHE
  - Registered telemedicine provider
    - DEA has not formally proposed registration process (proposed rule at OMB since March 2022)

DEA Proposed Rule (comments due 3/31/23)

Relationship between prescribing medical practitioner and patient	Prescribing a non-controlled medication	Prescribing Schedule III, IV, or V non-narcotic controlled medications	Prescribing buprenorphine as medication for opioid use disorder	Prescribing Schedule II and/or narcotic controlled medications
Prior in-person medical evaluation by prescribing medical practitioner	Permitted	Permitted	Permitted	Permitted
Referral under the proposed rules from medical practitioner who conducted prior in-person medical evaluation	Permitted	Permitted	Permitted	Permitted
Telehealth visit without: • **Prior in-person medical evaluation by prescribing medical practitioner; or** • **Referral from a medical practitioner who conducted prior in-person medical evaluation**	Permitted	• Up to 30-day initial prescription • In-person visit required for additional prescription	• Up to 30-day initial prescription • In-person visit required for additional prescription	Not permitted

More information available at https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities



3. COVID-19-Related Reimbursement

COVID-19 Vaccines

- Medicare will continue to cover without cost sharing
  - CMS will continue to pay $40/dose through end of 2023; annual rate adjustment consistent with other Part B preventive vaccines
- All State Medicaid programs must continue to cover without cost sharing through 09/30/2024; thereafter, coverage will vary by state
- Most commercial health plans must continue to cover COVID-19 vaccines furnished by in-network provider without cost sharing
- Uninsured and underinsured individuals will pay out-of-pocket

Note: Neither healthcare provider vaccine mandates nor OSHA emergency temporary standard for occupational exposure to COVID-19 impacted by end of PHE

COVID-19 Testing

- Traditional Medicare will continue to cover without cost sharing, but following will terminate with end of PHE–
  - ✓ Program to provide free over-the-counter COVID-19 tests for Medicare beneficiaries
  - ✓ CMS rule permitting provider to bill CPT 99211 when clinical staff assess patient and collect specimen for COVID-19 test
  - ✓ Separate payment to HOPDs for COVID-19 symptom assessment and specimen collection using HCPCS C9803
  - ✓ Medicare coverage for beneficiary's first test without physician/practitioner order (post-PHE, all testing performed by lab must have physician/practitioner order)
  - ✓ Medicare's higher payment rates for COVID-19 tests making use of high-throughput technologies
- Medicare Advantage plans must continue coverage but cost sharing requirements will vary
- All state Medicaid programs must continue coverage without cost sharing through 09/30/2024; thereafter, coverage will vary by state
- Commercial health plan coverage no longer mandated; coverage will vary by plan
- Uninsured and underinsured will pay out of pocket

Note: Requirement for providers to post cash price for COVID-19 tests on website will terminate

Payments for COVID-19 Treatment

- Changes to Medicare reimbursement
  - 20% increase in DRG payment for COVID-19 inpatients terminates at end of PHE
    - Admitted prior to but discharged on or after May 11?
  - Separate payment for drugs and biologics authorized or approved to treat COVID-19 administered in HOPD terminates at end of PHE (packaged into payment for C-APC when services billed on same outpatient claim)
  - Enhanced payment for eligible inpatient cases involving use of certain new products authorized or approved to treat COVID-19 continue through end of 2023
- All State Medicaid programs will continue to cover without cost sharing through 09/30/2024; thereafter, coverage will vary by state
- End of PHE will not impact private health insurance coverage

Note: End of PHE does *not* impact FDA emergency use authorization

4. Medicaid Redeterminations

Unwinding of Continuous Coverage Requirement

- Phase down of Families First FMAP increases

	Medicaid Matching Rate Increase (Percentage Points)	CHIP Matching Rate Increase (Percentage Points)
January 1 - March 31, 2023	6.2	4.34
April 1 - June 30, 2023	5.0	3.5
July 1 – September 30, 2023	2.5	1.75
October 1 – December 31, 2023	1.5	1.05

- Continuous coverage requirement ends on March 31, 2023, and states will have one year to initiate all redeterminations (with two additional months to complete process)
  - Those who no longer meet state Medicaid income requirements will be disenrolled
  - As a condition of receiving phased down FMAP, states must adhere to federal requirements to avoid procedural disenrollments
  - States must meet monthly data reporting requirements or lose up to 1% of regular FMAP
- ~5 million likely to become uninsured through renewal process (not eligible for other coverage)

Redeterminations

- December 2022 survey by Urban Institute/Robert Wood Johnson Foundation found 64.3% of adults enrolled in Medicaid or with an enrolled spouse, partner, or child were unaware of redetermination process
- Provider outreach to Medicaid/CHIP beneficiaries
  - Explanation of redetermination process and need to respond to requests
  - Coverage options

https://www.medicaid.gov/resources-for-states/downloads/unwinding-comms-toolkit.pdf

5. Regulatory Waivers and Flexibilities

Waivers and Flexibilities

- Under Section 1135, HHS can waive/modify certain Medicare, Medicaid/CHIP, and HIPAA requirements during declared PHE to ensure beneficiary access to care
  - Expand physical space
  - Enhance workforce capacity
  - Reduce regulatory burden
- Under this authority, HHS has modified/waived nearly 200 federal regulatory requirements during COVID-19 PHE
- Under separate statutory authority, HHS has approved changes to state Medicaid/CHIP plans
  - “In no case will any of these waivers extend past the last day of the public health emergency (or any extension thereof)”

Provider Fact Sheets

- Physicians and Other Clinicians
- Hospitals and CAHs, ASCs, and CMHCs
- Teaching Hospitals, Teaching Physicians, and Medical Residents
- Long Term Care Facilities
- Home Health Agencies
- Hospice
- Inpatient Rehabilitation Facilities
- Long Term Care Hospitals & Extended Neoplastic Disease Care Hospitals
- Rural Health Clinics and Federally Qualified Health Centers
- Laboratories
- Medicare Shared Savings Program
- DME, Prosthetics, Orthotics, and Supplies
- Medicare Advantage and Part D Plans
- Ambulances
- End Stage Renal Disease Facilities
- Medicare Diabetes Prevention Program

https://www.cms.gov/coronavirus-waivers

Updated February 23, 2023

5. Regulatory Waivers and Flexibilities
A. Expand Physical Space

Hospitals Without Walls

- Expanding locations for delivery of inpatient services
  - Non-patient care areas, distinct part units, community facilities
- Providing offsite EMTALA screenings
- Creating new or relocating existing HOPDs
  - Adopting temporary extraordinary circumstances relocation exception policy for on-campus PBDs and excepted off-campus PBDs
  - Including patient home for services furnished in person by hospital clinical staff (e.g., wound care, infusion)
- Adding swing beds to provide SNF services
- Expanding CAH bed count and length of stay; establishing non-rural off-site surge locations
- Maintaining classification as Sole Community or Medicare Dependent Hospital despite changes in volume, patient mix

Acute Hospital Care at Home

- Individual (vs. blanket) waiver of hospital CoP requiring nursing services to be provided on premises on 24/7 basis
  - Approved hospitals receive full DRG patient although some or all acute care services furnished in patient home following ER visit or inpatient admission
- 260 hospitals (114 health systems) in 37 states approved for participation
  - 20+ hospitals added since 6/1/2022
  - Early data shows low utilization rates but low rates of unexpected mortality and escalation
- CAA23 extended waiver through 12/31/24

Coverage for SNF/Swing Bed Stays

Pre-PHE: Qualifying Hospital Stay

- Prior medically necessary inpatient hospital stay of 3 consecutive days or more, starting with day of inpatient admission but not including day of discharge
- Must enter SNF within short period of time (generally 30 days) following hospital discharge

Waiver of Qualifying Hospital Stay terminates at end of PHE

- Admitted to SNF prior to May 11 but not discharged until that day or after?
- Waivers associated with Medicare APMs (e.g., MSSP) not impacted

Conflicting Guidance?

May 2020	May 2021	May 2022	August 2022
• "The qualifying hospital stay waiver applies to all SNF-level beneficiaries … regardless of whether the care the beneficiary requires has a direct relationship to COVID-19."	• "CMS is waiving the requirement for a 3-day prior hospitalization for coverage of a SNF stay … for those people who experience dislocations or are otherwise affected by COVID-19."	• "We [waived] the SNF 3-day prior hospitalization requirement for a SNF covered stay during the [PHE] . This gives temporary SNF services emergency coverage to a patient without a qualifying hospital stay who experiences a dislocation or those affected by COVID-19."	• "CMS temporarily waived the requirement for a three-day prior hospitalization for coverage of a skilled nursing facility (SNF) stay. This waiver provides temporary emergency coverage of SNF services without a qualifying hospital stay."

5. Regulatory Waivers and Flexibilities
B. Enhance Workforce Capacity

Workforce Waivers Terminating at End of PHE

- Medical staff requirements
  - Specific requirements relating to credentialing and privileging process
- Physician services
  - Requirement that all Medicare patients must be under care of physician
- Anesthesia services
  - CRNA supervision requirements (states may apply to waive these requirements)
- Respiratory care services
  - Designate in writing personnel qualified to perform specific procedures and required level of supervision
- CAH-specific
  - Additional federal personnel requirements for CNS, APRN, PA
  - Additional federal requirements regarding CAH staff licensure, certification, and registration
  - Physician must be physically present to provide medical direction, consultation and supervision

Workforce Waivers

Teaching Hospitals, Teaching Physicians and Medical Residents

- After May 11 –
  - Teaching hospital cannot count resident's time for activities at his/her home or patient's home for purposes of Medicare DGME payments or IME payments
  - Teaching hospital that sends residents to other hospitals cannot claim those residents in its IME and DGME FTE resident counts
    - Residents' presence at non-teaching hospitals will trigger establishment of IME and/or DGME FTE resident caps at those non-teaching hospitals (and for DGME, it will trigger establishment of PRAs at those non-teaching hospitals)
  - Any added beds will be considered in determining hospital's IME payments
  - Any change to teaching inpatient psych facility's or teaching inpatient rehab facility's average daily census will be considered in determining facility's teaching status adjustment payments

5. Regulatory Waivers and Flexibilities
C. Reduce Administrative Burden

Renewed Regulatory Burden – Partial List

- Authentication of verbal orders within 48 hours
- Reporting requirements relating to death of ICU patients with soft wrist restraints
- Providing information regarding post-acute providers during hospital discharge planning
- Form/content of medical records, retention requirements, and deadlines for completion of records
- Providing information to patients on advance directive policies
- Utilization review and QAPI requirements
- Maintenance of nursing plan of care for each patient
- Life Safety Code
  - Alcohol-based hand rub dispensers
  - Fire drills
  - Temporary walls and barriers
- Provider enrollment
  - CMS to resume normal application processing times
  - Discontinue early cancellations of opt-out status
  - Practitioner must report home address on Medicare enrollment if furnishing telehealth services from home more than occasionally
- Updates to therapeutic diet manual
- Signature requirements for Part B drugs and DME (cannot be obtained due to COVID-19)

Note: Hospital COVID-19 data reporting requirements continue through 4/30/24 unless HHS establishes earlier end date
Long-term care facilities' notification requirements continue through 12/31/24

Stark Law

- Waiver of sanctions under Stark Law for otherwise prohibited financial arrangements made necessary to achieve COVID-19-related purpose
  - Fair market value for renumeration and rental charges
  - Medical staff incidental benefits and non-monetary compensation
  - Interest rates and terms of loans
  - Referrals to facilities in which physician/family member has ownership interest
  - Compensation arrangements that fail to meet writing/signature requirements
- All waivers expire at end of PHE
  - Must amend compensation terms to be fully compliant with exceptions – particularly fair market value
  - "Appropriate repayment terms agreed to prior to the termination of the blanket waivers may continue beyond the termination of the blanket waivers . . . . "
  - "However, any disbursement of loan proceeds after the termination of the blanket waivers, or additional remuneration after the termination of the blanket waivers for office space, equipment, items, or services furnished by or to an entity or physician, must satisfy all requirements of an applicable exception."

Our Next Healthcare Regulatory Round-Up:

PHE Waivers & Flexibilities Checklist

March 15, 2023