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A2HA 2023 Finance Spring Meeting

Impact of Ending PHE and Medicare Waivers

April 17, 2023

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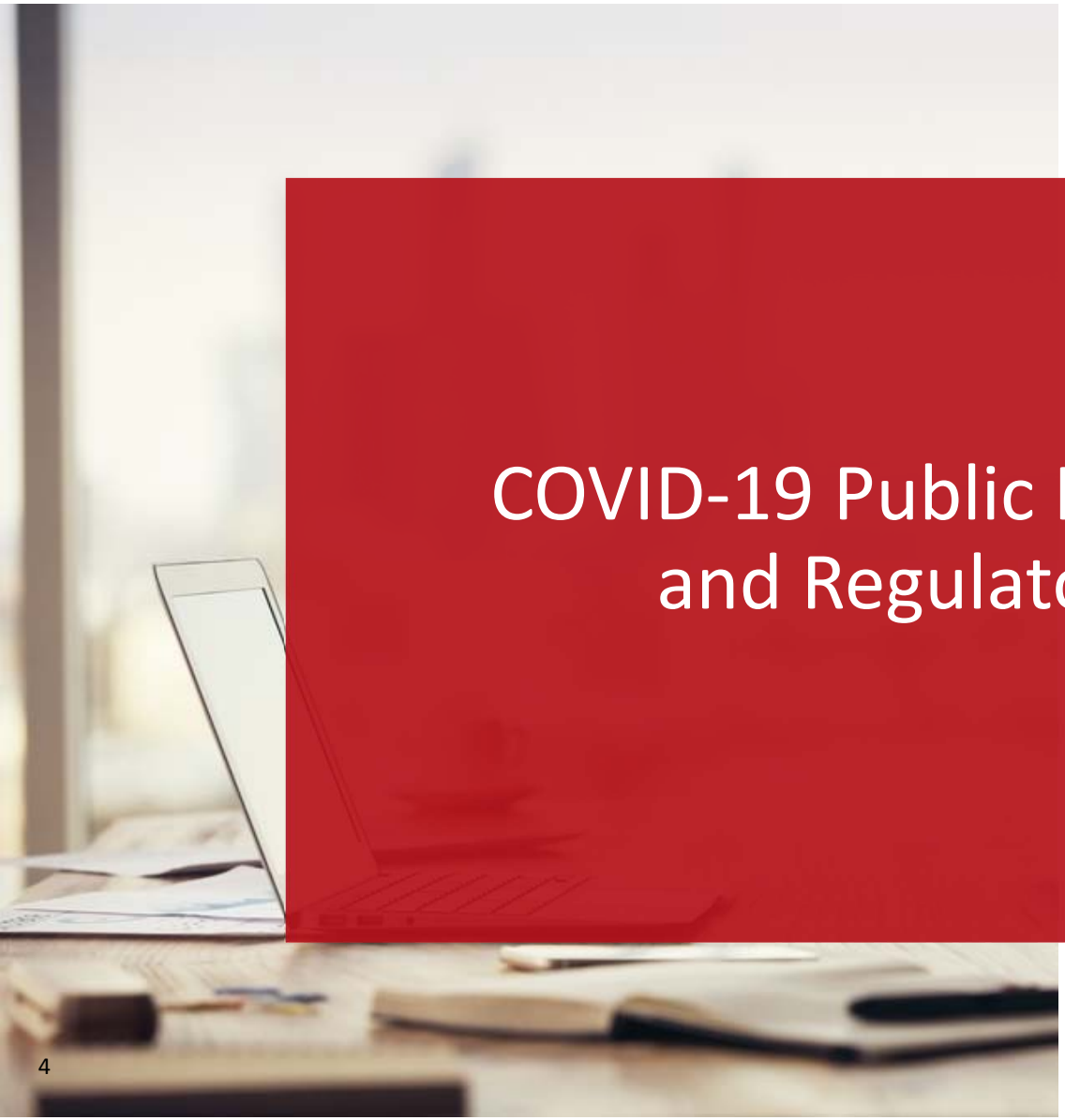
Agenda

- Overview of PHE
- Payment and Coverage
- Telehealth
- Licensure and Enrollment
- Stark Law Waivers
- Others
- Takeaways and Recommendations



COVID-19 Public Health Emergency and Regulatory Flexibility

The PHE

- COVID-19 PHE
  - Public Health Emergency (PHE) declared on January 31, 2020
  - National Public Emergency declared on March 13, 2020
  - Empowered HHS/CMS to provide unprecedented flexibility via waivers, financial support, and enforcement discretion
  - States took similar approach
- Transitioning to regular practices
  - Biden Administration announced the end of the PHE effective May 11, 2023
  - Attempting to balance need to maintain development of and access to COVID-19 vaccines and treatment with goal to transition back to pre-PHE market
- What Now….

PHE Waivers

- CMS has used a combination of emergency authority waivers, regulations, and sub-regulatory guidance to ensure and expand access to care and to give health care providers the flexibilities needed to respond to COVID-19
- This included blanket waivers and provider-specific 1135 waivers
- HHS waived or modified nearly 200 federal regulations
- CMS processed more than 250,000 1135 waiver requests
- Impacted nearly every category of federal regulation

PHE Termination – Resources (Govt.)

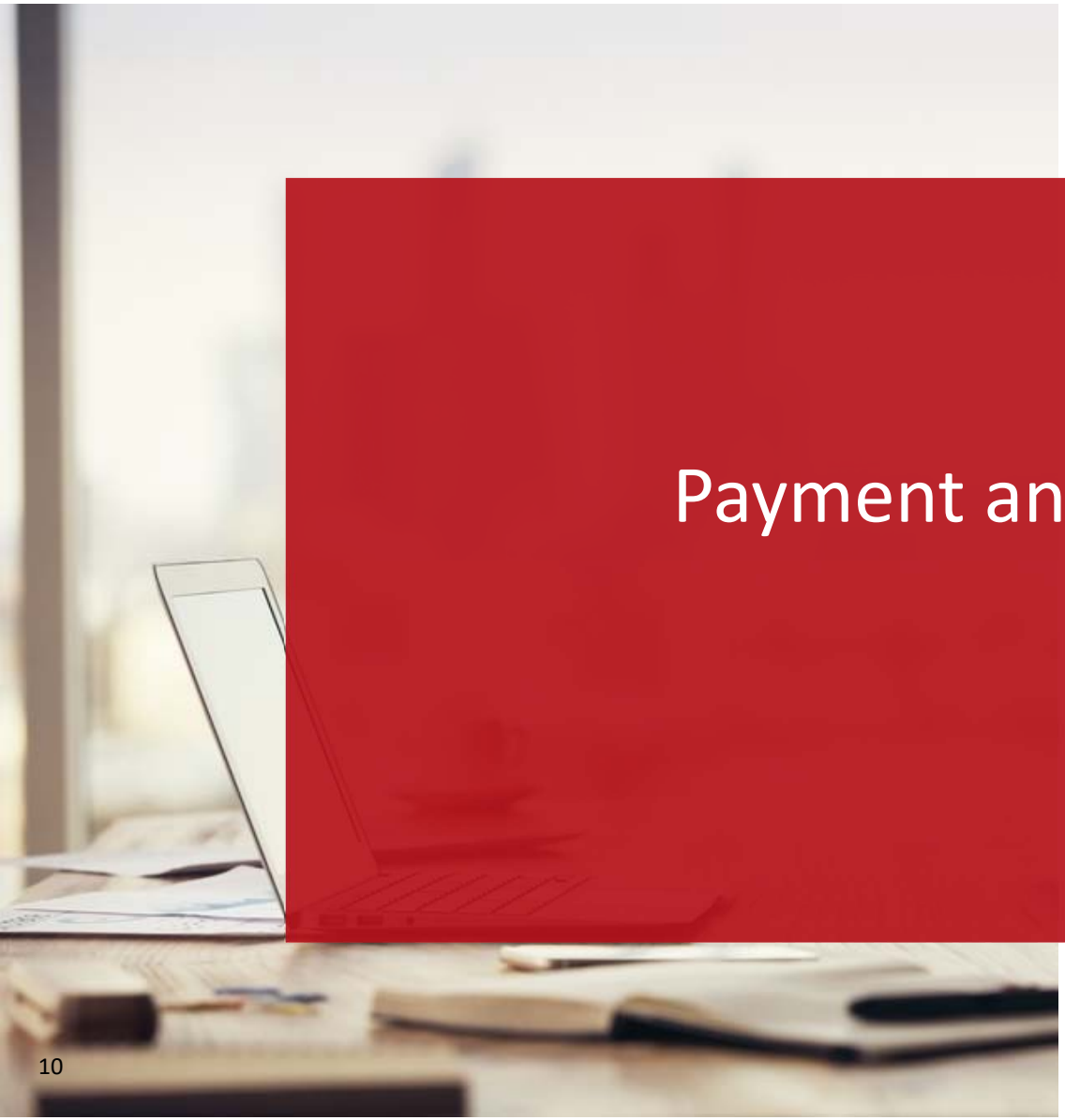
- Federal government and states have been working to extend, make permanent, or roll back regulatory flexibilities
- Some helpful government resources include:
  - HHS COVID-19 Public Health Emergency Transition Roadmap
  - CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency
  - Hospitals and CAHs (including Swing Beds, DPUs), ASCs and CMHCs: CMS Flexibilities to Fight COVID-19
  - HIPAA Guidance
  - OIG Note: OIG's Covid-19 PHE Flexibilities End on May 11, 2023, Upon Expiration of the COVID-19 PHE
  - Government Open Door Forums and Mailboxes (can use to ask specific questions)

PHE Termination – Resources (Hall Render)

- Hall Render webinars, podcasts, and alerts
  - Website
  - Federal Public Health Emergency Ending May 11: What Health Care Organizations Need to Know (On-Demand Webinar)
  - Virtual Care – Critical Planning for Expiration of the Federal PHE (On-Demand Webinar)
  - Preparing for the End of Stark Law Blanket Waivers: Insights and Strategies for Health Care Providers (On-Demand Podcast)
  - Key Areas of Focus for Skilled Nursing Facilities as the Public Health Emergency Ends (Client Alert)

PHE Termination – Planning

- Inventory Implemented Flexibilities *(if not already done…)* including:
  - Waivers and other flexibilities
  - Temporary licenses
- Provide Education and Notice to Those Affected (almost everyone)
- Review Operations
  - Reliance on waivers and flexibilities issued by HHS/CMS, State, and other agencies
  - Patient census and admissions
  - Temporary enrollments
  - Location and provider-specific reviews



Payment and Coverage

COVID Vaccines, Testing & Treatment

- COVID Vaccines
  - Medicare – Will continue to cover COVID vaccines w/o cost sharing; will set new rates in 2024
  - Medicaid – Must cover until 9/30/24 (ARPA of 2021)
- COVID Testing
  - Medicare – Will cover laboratory testing w/o cost sharing for testing ordered by a provider
  - Medicaid – Must cover w/o cost sharing until 9/30/24 (ARPA of 2021)
  - Private insurance – Will not be required to cover w/o cost sharing after PHE
  - Free over-the-counter testing will end with expiration of PHE
- COVID Treatment
  - Higher payments for novel COVID treatments will continue through the end of fiscal year 2023; after CMS will pay as it does for other biological products
  - Medicaid – Must cover w/o cost sharing until 9/30/24 (ARPA of 2021)

COVID-19 Patient DRG Add-Ons

- Ending with PHE: Medicare's 20% add-on payments for patients diagnosed with COVID-19 to offset the cost of complex COVID-19 patient care
- Continuing: Enhanced payment for certain new COVID-19 treatments equal to the lesser of: 1) 65% of the operating outlier threshold for the claim; or 2) 65% of the costs of the case beyond the operating Medicare payment (for inpatients)
- Ending with PHE: separate Medicare payment for certain FDA-authorized drugs and biologicals to treat COVID-19. After PHE, again packaged into APC

Access to Care

- *Temporary Expansion Sites*. Waiver allowing for temporary expansion sites. Ending with PHE.
- *Acute Hospital at Home (HaH).*
  - HaH programs are designed to offer at-home, acute, hospital-level treatment to certain patients who require acute inpatient care, but whose care can be delivered in the home via telemedicine, combined with home visits by nursing and other appropriate personnel, and supportive services.
  - The HaH waivers are only available for services to patients who enter HaH programs from the hospital's inpatient service or emergency department.
  - Over 100 health systems and 250 hospitals are participating in the HaH program.
- Acute Hospital Care at Home program extended by legislation through December 31, 2024.
- Swing-Beds. Allowing PPS hospitals to provide post-hospital SNF-level swing bed services in hospital. Ending with PHE.
- CAH Bed Count and Length of Stay. Waiving 25-bed and 96-hour length of stay. Ending with PHE

Access to Care

- Others Ending with PHE
  - SCH requirements: MACs will resume evaluation of eligibility requirements after PHE.
  - MDH requirements: resume evaluation after PHE; will not cancel MDH based on cost reporting periods that include any portion of PHE
  - Allowing acute care inpatients to be roomed in other facilities or non-acute care units including:
    - Excluded units
    - Procedure space
  - Provider-Based temporary expansion sites
- State Medicaid Eligibility Determinations
  - States will begin these eligibility reviews and notify beneficiaries

Supervision Requirements

- Supervision of Diagnostic Tests
  - Permanent expansion to include nurse practitioners, clinical nurse specialists, physician assistants, certified registered nurse anesthetists, and certified nurse midwives (if allowed under state scope of practice and state law)
  - Except for IDTF – requires physician supervision
- Virtual Supervision
  - Allows direct supervision to be provided through virtual, real-time audio-visual presence
  - Will end on December 31, 2023
- CMS requested comments on permanent extension to virtual supervision

Long Term Care Facilities

- *Three-Day Prior Hospitalization*. CMS waived the three-day prior hospitalization requirement and authorized a one-time renewed skilled nursing facility coverage without a 60-day "wellness period" for certain beneficiaries. Ending with PHE.
- *Pre-Admission Screening and Annual Resident Review*. During the PHE, CMS allowed facilities to suspend assessments for 30 days for new nursing home residents with a mental illness or intellectual disability. After the 30-day suspension, facilities were to administer the assessments as soon as resources became available. Ending with PHE.
- *Nurse Aide Training for Nursing Home*s. Waivers allowed facilities to employ nurse aides who had not completed approved training within four months. Facilities will have four months (until 9/10/23) to ensure all nurse aides hired prior to the end of the PHE complete state-approved training programs. Nurse aides hired after PHE will have four months from their hiring date to complete the mandatory trainings.

Telehealth and Virtual Care

Telehealth Flexibilities

- Throughout PHE, Federal government, state governments, and private payers took steps to increase access to virtual care
- Use of telehealth soared in 2020 and 2021
- Still well-above pre-PHE levels
- Waivers and flexibilities touched on nearly every aspect of telehealth:
  - Coverage (covered services, originating site, patient site, in-person requirements)
  - Payment
  - Mode of delivery (audio only)
  - Licensure and supervision
- Some permanent, others extended, and a few ending immediately

Virtual Care Reimbursement

Medicare Telehealth Coverage

- **Defined by Statute**
  - Social Security Act 1834(m)(4) Definitions
    - A) Distant site: The term "distant site" means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.
    - (B) Eligible telehealth individual: The term "eligible telehealth individual" means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

Virtual Care Reimbursement

- (C) Originating site: Location of the Medicare beneficiary, includes Physician/Practitioner Office, CAH, RHC, FQHC, hospital, hospital/CAH-based renal dialysis center, SNF, CMHC, renal dialysis facility (limited), home of an individual (limited)
- (D) Physician: The term "physician" has the meaning given that term in section 1861(r).
- (E) Practitioner: The term "practitioner" has the meaning given that term in section 1842(b)(18)(C).
- (F) Telehealth service: (i)In general
  - The term "telehealth service" means **professional** consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241-99275, 99201-99215, 90804-90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

Telehealth Coverage

Medicare Coverage Prior to Public Health Emergency

- Limited: defined terms within SSA
  - Geographic restriction for location of the patient ("originating site")
    - Generally required a rural geographic location
    - Pro fee was only covered if patient was located at one of the originating sites listed in Section 1834(m) of the SSA and only by certain practitioners
  - "Distant site" (location of the practitioner) not restricted as long in the U.S. but for FQHCs/RHCs
  - Defined set of "telehealth" services in the SSA and as updated by the Secretary of HHS
  - Generally required HIPAA-compliant two-way audio/visual communication

Telehealth Coverage

Medicare Coverage Prior to Public Health Emergency

- Regulation: 42 CFR § 410.78
  - Distant Site Practitioners
    - Physician
    - Physician Assistant
    - Nurse Practitioner
    - Clinical Nurse Specialist
    - Nurse Mid-Wife
    - Clinical Psychologist
    - Clinical Social Worker
    - Registered Dietitian or Nutritional Professional
    - Certified Registered Nurse Anesthetist

Telehealth Coverage

Medicare Coverage Prior to Public Health Emergency

- March 17, 2020, CMS Fact Sheet https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

Summary of Medicare Telemedicine Services

TYPE OF SERVICE	WHAT IS THE SERVICE?	HCPCS/CPT CODE	Patient Relationship with Provider
MEDICARE TELEHEALTH VISITS	A visit with a provider that uses telecommunication systems between a provider and a patient.	Common telehealth services include: • 99201-99215 (Office or other outpatient visits) • G0425–G0427 (Telehealth consultations, emergency department or initial inpatient) • G0406–G0408 (Follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals or SNFs) For a complete list: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes	For new* or established patients. *To the extent the 1135 waiver requires an established relationship, HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during this public health emergency
VIRTUAL CHECK-IN	A brief (5-10 minutes) check in with your practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed. A remote evaluation of recorded video and/or images submitted by an established patient.	• HCPCS code G2012 • HCPCS code G2010	For established patients.
E-VISITS	A communication between a patient and their provider through an online patient portal.	• 99421 • 99422 • 99423 • G2061 • G2062 • G2063	For established patients.

Telehealth Coverage

Medicare Coverage During the Public Health Emergency

- Authority:§1135 waivers, CARES Act, IFRs
- Geographic restrictions removed
  - Patient can be located at an originating site anywhere in the U.S., including in the home; distant-site practitioner pro fees can be covered regardless of geographic location of the patient
  - Payment rule established for RHCs and FQHCs as the location of the distant site practitioner
- Patient can be a new or established patient
- All practitioners authorized to bill Medicare for professional services can furnish and bill for telehealth services
  - For example, PTs and OTs but not pharmacists

Telehealth Coverage

Medicare Coverage During the Public Health Emergency

- Category 3 services (temp services added during PHE)
- Use of virtual technologies to meet conditions of payment
  - Permits physicians to supervise clinical staff using virtual technologies, when appropriate, instead of requiring in-person presence ("incident to" services)
  - Amended definition of "direct supervision" at 42 CFR 410.32 to permit virtual presence through real-time audio/visual communication during duration of PHE (diagnostics)
- Other "virtual services" also covered (ex. RPM, RTM)
- *Permanent telehealth changes to geographic location, eligible providers and originating sites require statutory changes*

Telehealth Flexibilities Extended

- Expanded Coverage through 12/31/2024 via CAA of 2023
  - Health care providers eligible to bill Medicare can bill for telehealth services regardless of where the patient or provider is located (i.e., the patient can be at home).
  - The list of providers eligible to deliver telehealth services remains expanded to include physical therapists, occupational therapists, speech language pathologists, and audiologists.
  - The acute hospital care at home program can continue to be utilized to provide hospital services to patients in their homes, including through telehealth.
  - Telehealth can be used to conduct recertification of eligibility for hospice care.
  - FQHCs and RHCs can provide telehealth services to Medicare beneficiaries, rather than being limited to being an originating site provider for telehealth
  - Audio-only coverage for certain E/M and non-behavioral health services
  - In-person visit within 6 months of an initial behavioral telehealth service not required
  - Higher reimbursement rates are scheduled to end this year

Telehealth Flexibilities Permanent

- Permanent Changes (Not Ending)
  - FQHCs & RHCs can serve as a distant site provider for behavioral telehealth services
  - Medicare patients can receive telehealth services for behavioral health care in their home.
  - No geographic restrictions for originating site for behavioral telehealth services
  - Behavioral telehealth services can be delivered using audio-only communication platforms
  - Rural hospital emergency department accepted as an originating site.

Telehealth Flexibilities Ending

- Providers offering telehealth or RPM services to Medicare beneficiaries may no longer reduce or waive any cost-sharing obligations that patients may owe for such services
- RPM services again limited to “established patients.” During PHE, CMS waived the “established patient” requirement and allowed practitioners to bill for RPM for new patients.
- Virtual direct supervision will expire at the end of this year unless CMS revises its policy in future rulemaking
- OCR will resume enforcement of penalties on providers for noncompliance with HIPAA rules for technology use

Licensure and Enrollment

Prepare for Return to Compliance with Pre-PHE State Licensure, Conditions of Participation, and Accreditation Requirements

- Monitor CMS Updates on End of PHE:
  - https://www.cms.gov/blog/creating-roadmap-end-covid-19-public-health-emergency
- CMS COVID-19 Waivers and Flexibilities for Providers
  - Physicians and Other Clinicians
  - Hospitals and CAHs (including Swing Beds, DPUs), ASCs and CMHCs
  - Teaching Hospitals, Teaching Physicians and Medical Residents
  - Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities)
  - Home Health Agencies
  - Hospice
  - Inpatient Rehabilitation Facilities
  - Long Term Care Hospitals & Extended Neoplastic Disease Care Hospitals
  - Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
  - Laboratories
  - Medicare Shared Savings Program
  - Durable Medical Equipment, Prosthetics, Orthotics and Supplies
  - Medicare Advantage and Part D Plans
  - Ambulances
  - End Stage Renal Disease (ESRD) Facilities
  - Participants in the Medicare Diabetes Prevention Program

Prepare for Return to Compliance with Pre-PHE State Licensure, Conditions of Participation, and Accreditation Requirements

- State Professional Licensure Flexibilities:
  - Identify date that any licensure flexibilities (e.g., recognition of out-of-state licensure, supervision requirements) will end
  - Ensure that individual professionals working on temporary licenses or under licensure flexibilities are prepared to comply with state professional licensure requirements
- State Facility Licensure Flexibilities:
  - Identify waived state licensure requirements in use, as well as the State licensure authority's plan to resume enforcing such requirements
  - Identify heightened requirements initiated during PHE and confirm whether State will continue to enforce
  - Coordinate with State licensure authorities if facility may be unable to return to compliance pre-pandemic requirements
- Federal and State Vaccination, Personal Protective Equipment Mandates
  - Continue to comply with facility-specific CMS vaccine mandates
  - Monitor state and local vaccine, PPE mandates
- EMTALA:
  - Identify any off-site patient screening locations and prepare to discontinue use of such locations
  - Identify other ED processes/practices that rely on a PHE waiver (e.g., use of hallway beds, processes for screening mental health patients)
  - Begin re-educating all ED staff, including registration, nursing, and physician staff, on termination of EMTALA flexibilities
  - Provide any necessary notice of changes in screening locations to EMS providers

Medicare and Medicaid

- For Hospitals
  - Review and update practice location listings
  - Review provider-based billing compliance
  - Did we take advantage of the swing bed waiver?
- For Ambulatory Surgery Centers
  - Have you been operating as a Hospital outpatient department during the PHE
  - Review policies and procedures to function as an ASC
- For Skilled Nursing Facilities
  - Ensure all staff are aware of expiration of waivers

Provider Enrollment / Profile Clean-Up

- Practice location listing review
- Reassignments – providers staying / leaving
- Related licenses – confirm post–PHE compliance
- Good opportunity to review entire profile for changes of information

Stark Law Considerations

Stark Law Blanket Waivers

- Background
  - Waive several Stark Law requirements related to COVID-19 physician arrangements
  - Arrangements must relate to a COVID-19 purpose
  - Waivers intended to provide additional Stark Law flexibility
- Common Uses of Blanket Waivers
  - Payments to physicians that may be over FMV
  - Space or equipment rental payments that are less than FMV
  - NMC that exceeds annual limits

Stark Law Blanket Waivers

- Next Steps
  - Unwind/Modify Arrangements that still utilize the waivers
  - Ensure Internal Documentation is accurate and complete

- Other Stark Law Flexibilities Going Forward
  - Wellness Exception
  - Limited Remuneration to Physicians
  - Value-Based Arrangements

Other Miscellaneous

Other Items

- Some Medicaid waivers end with the PHE, others extend beyond
- Changes to reporting requirements for COVID-19 lab results and vaccine data
- Supervision Requirements
- HIPAA
  - OCR has been exercising enforcement discretion throughout the COVID-19 pandemic regarding telehealth and remote communications
  - OCR has indicated in guidance that its enforcement discretion will end at the expiration of the PHE
- OIG
  - During the PHE, OIG indicated that it would not enforce certain provisions of the Beneficiary Inducement Statute or the Anti-Kickback Statute that prohibit routine reductions or waivers of costs owed by federal health care program beneficiaries for services provided via telehealth
  - OIG's enforcement discretion terminates with PHE
- Provider Relief Fund Reporting and Auditing Continues (balance billing limitation?)

Takeaways

Breaking PHE Habits / Keeping Good Habits

- Continue to monitor guidance made available by HHS/CMS, State Agencies, and others
- Educate and provide relevant information to those impacted by waivers
  - Waivers have been in practice for over 3 years and have become the "normal course"
  - Unfortunately, the "normal course" is changing again

Important Tasks/Lists

- Inventory
  - Waivers
  - Flexibilities
  - Temporary Licenses
  - Current Census/Patient Types
- Operations Review
  - Reliance on Waivers
  - Temporary Enrollments
  - Commercial Payors

Important Tasks/Lists

- Location-Specific Review including
  - Temporary Expansion …
    - Locations
    - Beds
- Provider-Type Specific Review
  - Space Use
    - Excluded units
    - Procedure space
    - Use of space previously used for administrative purposes

Please visit the Hall Render Blog at http://blogs.hallrender.com for more information on topics related to health care law.

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