HEALTHCARE REGULATORY ROUND-UP

The Great Unwind

Preparing for the End of the Federal COVID-19 Public Health Emergency

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Introductions

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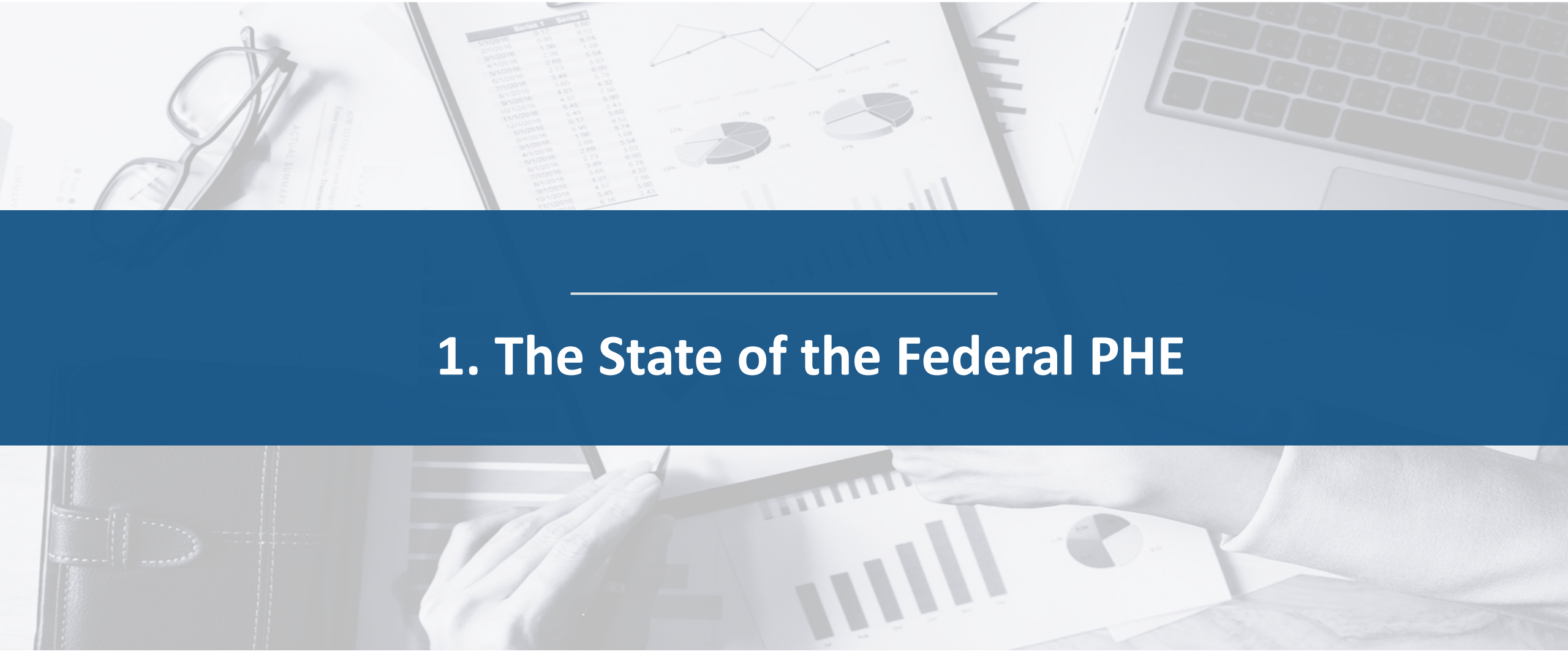
Today's Agenda

1. The State of the Federal PHE
2. Telehealth and Virtual Services
3. Section 1135 Waivers and Flexibilities
4. Medicaid Disenrollment



1. The State of the Federal PHE

The End is Near, But How Close Is It?

- Renewed through April 16
- Likely to be extended, but for how long?
  - HHS promises 60 days' advance notice (but probably not more)
- Legislative attempts to end PHE
- State and local PHEs
  - Some federal waivers tied to state pandemic plan
- Over before it's over
  - As of March 22, Uninsured Program no longer accepting new claims for testing or treatment for uninsured patients
  - As of April 5, program will no longer accept new claims for COVID-19 vaccinations

2. Telehealth and Virtual Services

Telehealth vs. Virtual Services

Telehealth

- Takes the place of what would otherwise be a face-to-face encounter

Virtual Services

- No equivalent face-to-face service; use of technology key component of service
- Care management; remote monitoring; virtual (telephonic) check-ins and e-visits (no related E/M service)

Medicare Telehealth Coverage Pre-COVID-19

Section 1834(m)

1. **Geographic** - Patient must reside in rural area
2. **Location** - Patient must be physically present at healthcare facility when service is provided (facility fee)
3. **Service –** Coverage limited to CMS' list of approved telehealth services (CPT and HCPCS codes)
4. **Provider –** Service must be provided by physician, non-physician practitioner, clinical psychologist, clinical social worker, registered dietician, or nutrition professional
5. **Technology** - Must utilize telecommunications technology with audio ***and*** video capabilities that permits real-time interactive communication**.**

Medicare Coverage Pre-COVID-19

With Some Exceptions

- **Telestroke**
  - Effective 01/01/2019, geographic and location requirements do not apply to services furnished to diagnose, evaluate, or treat symptoms of acute stroke
- **Substance Use Disorder**
  - Effective 07/01/2019, geographic and location requirements do not apply to services relating to SUD and co-occurring behavioral health conditions
- **End Stage Renal Disease**
  - Effective 01/01/2019, geographic and location requirements do not apply to ESRD services relating to home dialysis
- **Medicare Advantage**
  - Beginning in 2020 plan year, MA plan may eliminate geographic and location requirements
- **Medicare Shared Savings Program**
  - Waiver of geographic and location requirements for ACO participants in risk models
- **CMMI Initiatives**

Medicare Telehealth Coverage Expansion

1. Legislative Action

- Coronavirus Preparedness and Response Supplemental Appropriations Act gave Secretary authority to waive *geographic* and *location* restrictions for duration of PHE
- CARES Act gave Secretary broader authority to waive other Section 1834(m) requirements for duration of PHE

2. CMS Interim Final Rules

- Suspends certain *service* restrictions for duration of PHE
  - Expands list of covered services
  - Eliminates frequency requirements
  - Permits use of telehealth for required face-to-face visits, direct supervision for incident-to billing, teaching physician presence
- Suspends certain *provider* restrictions for duration of COVID-19 PHE
  - Waives Medicare state licensure requirement (but not state law requirements)
  - Permits therapists and S/L pathologists to provide covered services via telehealth
  - Permits FQHCs and RHCs to bill for telehealth services under HCPCS G2025
  - Permits billing for hospital outpatient department and critical access hospital (Method 1 billing) services furnished via telehealth
- Authorizes payment for certain audio-only E/M services (CPT 98966-68, 99441-43)

3. Other Agencies' Actions

- OCR Notice of Enforcement Discretion - Will not impose penalties if, in good faith, use any non-public remote audio/visual communication product
- OIG Notice of Enforcement Discretion– Permits waiver of co-insurance
- DEA – Use of telehealth for in-person medical evaluation prior to prescribing scheduled II – V controlled substances

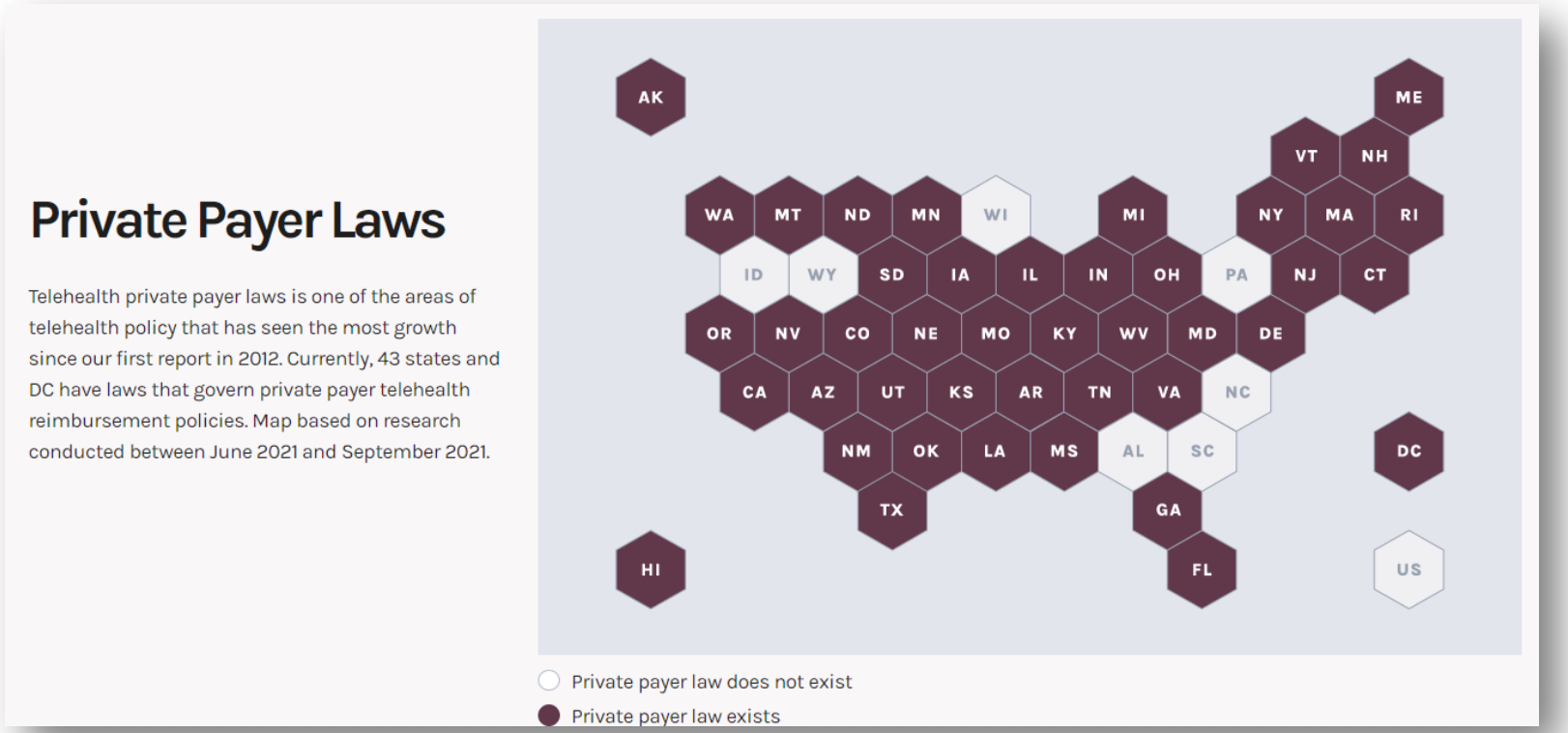
Billing and Payment for Telehealth Services

- Telehealth services paid at non-facility rates to compensate practices for telehealth-associated costs
  - POS = location "that would have been reported had the service been furnished in person…if not for the [PHE]" rather than POS 02
  - Practitioner not required to update Medicare enrollment to list home location if furnishing telehealth from that location
  - Include -95 modifier; do not include CR (catastrophe/disaster related) modifier
- Submit claim to MAC serving provider's location (regardless of beneficiary location)

State Action in Response to COVID-19

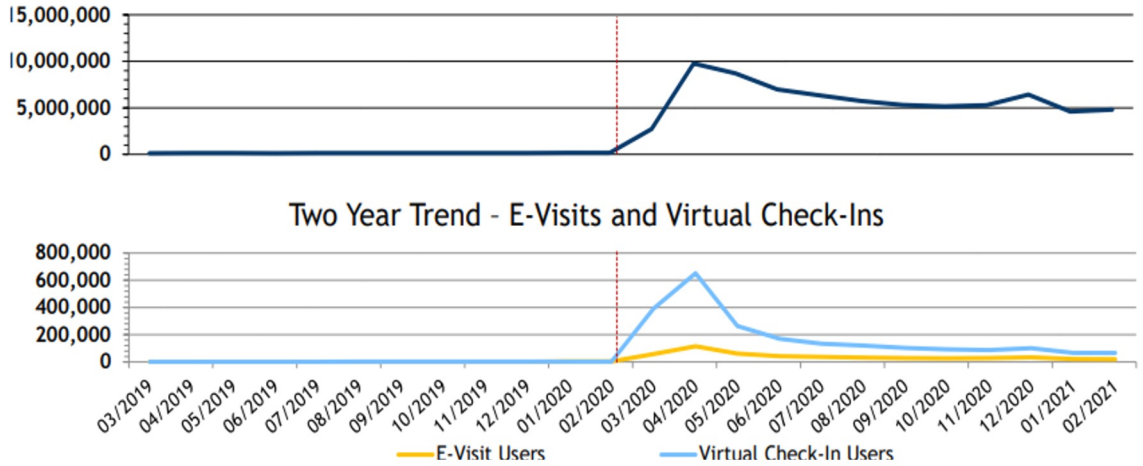
- Relax licensure requirements
- Expand Medicaid coverage
- Require private payer payment parity

} Refer to *www.cchpca.org/all-telehealth-policies/*

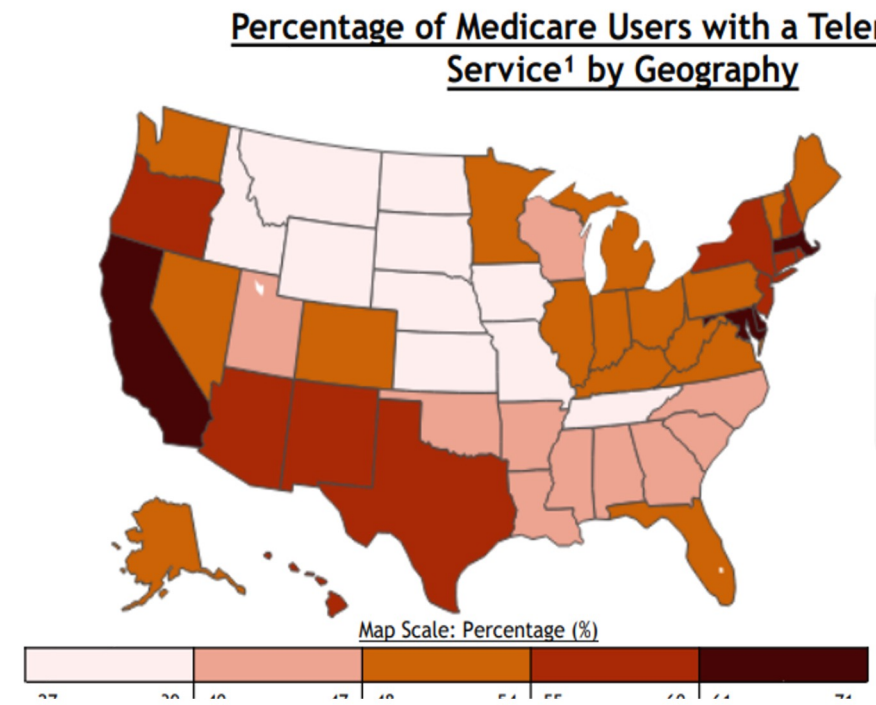


Utilization

Telemedicine Users: Pre-Pandemic and Pandemic Period				
	Total	Telehealth	E-visit[1]	Virtual Check-In
Pre-pandemic (March 1, 2019 - Feb 29, 2020)	**910,490**	892,121	5,220	14,088
Pandemic (March 1, 2020 - Feb 28, 2021)	**28,255,180**	27,691,878	367,467	1,601,033



28,255,180 Unique Telemedicine Users **53%** of Medicare Users



Rural Areas: **44%**

Urban Areas: **55%**

www.cms.gov/files/document/medicare-telemedicine-snapshot.pdf

Impact

- Telehealth follow-up was associated with lower 30- day readmissions than no timely post-discharge follow-up but was associated with slightly higher 30-day readmissions than in-person follow-up.
  - CMS Data Highlight (January 2022) www.cms.gov/files/document/omh-data-highlight-2022-1.pdf
- Data suggests that telehealth expansions improved access to medication treatment and contributed to lower use of inpatient and/or emergency department visits among beneficiaries with OUD.
  - CMS Data Highlight (January 2022) www.cms.gov/files/document/data-highlight-jan-2022.pdf

Tele-Behavioral Health

- Consolidated Appropriations Act, 2020 – eliminate geographic and location restrictions for diagnosis, evaluation, and treatment of mental health disorder
- Must have in-person, non-telehealth service by practitioner in same practice as billing practitioner within 6 months prior to initial telehealth service + each 12 months thereafter
  - Exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with reason documented in beneficiary's medical record)
- May use audio-only communication technology (vs. audio/video required for other telehealth services) but only if -
  - Practitioner has audio/video capability + beneficiary lacks capacity or refuses to use video connection
    - Documented in medical record + include service-level modifier on claim

Telehealth Flexibility Extensions

Enacted March 15, 2022

- For 151 days post-PHE –
  - ✓ Continuation of waiver of geographic and location requirements
  - ✓ Continuation of telehealth reimbursement for therapists and S/L pathologists
  - ✓ Continuation of reimbursement for audio-only services
  - ✓ Continuation of telehealth reimbursement for FQHCs and RHCs
  - ✓ Continuation of use of telehealth to recertify hospice eligibility
  - ✓ Delay of in-person, non-telehealth service requirement for initiation of tele-behavioral health services

Not Extended Post-PHE

- Billing for hospital outpatient department and critical access hospital (Method I billing) services furnished via telehealth*
- Waiver of requirement to be licensed in state in which patient receiving telehealth services is located*
- Use of telehealth to perform –
  - Required in-person visits (ESRD/home dialysis, nursing facility, home health)*
  - In-person medical evaluation for prescription of controlled substances*
  - Direct supervision for incident-to billing for in-person services (now extended thru 12/31/22)
  - For residency training sites within MSA, teaching physician presence for key portions of service
- Reimbursement at non-facility rate (return to use of POS 02; addition of POS 10)
  - Update Medicare enrollment to list practitioner's home?

* ***Most likely requires legislative action***

Not Extended Post-PHE *(continued)*

- Telehealth frequency limits for subsequent inpatient visits (once/3 days), subsequent SNF visits (once/14 days), critical care consults (once/day)
- OCR/OIG enforcement discretion
- Reimbursement for the following as telehealth services

  - Initial Nursing Facility Visits, All Levels (Low, Moderate, and High Complexity) (CPT 99304-99306)
  - Initial hospital care (CPT 99221-99223)
  - Radiation Treatment Management Services (CPT 77427)
  - Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324- 99328)
  - Home Visits, New Patient, all levels (CPT 99341- 99345)
  - Inpatient Neonatal and Pediatric Critical Care, Initial (CPT 99468, 99471, 99475, 99477)
  - Initial Neonatal Intensive Care Services (CPT 99477)
  - Initial Observation and Observation Discharge Day Management (CPT 99218 – 99220; CPT 99234- 99236)
  - Medical Nutrition Therapy (CPT G0271)

  - Reimbursement for Category 3 telehealth services expires 12/31/23 (www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes

Future Legislative Action?

- MedPAC - Submit report to Congress by June 15, 2023, addressing –
  - Utilization of Medicare telehealth services by service, provider type, geographic area, beneficiary type
  - Medicare program expenditures on telehealth
  - Medicare payment policy for telehealth services and alternative approaches
  - Implications of expanded Medicare coverage on beneficiary access to care and quality of care
  - Other areas determined appropriate by MedPAC
- OIG Report - Submit report to Congress by June 15, 2023, on program integrity risks associated with Medicare telehealth services, including recommendations to prevent waste, fraud, and abuse
- CMS Data - Beginning July 2022, CMS to post data quarterly on Medicare telehealth claims, including utilization and beneficiary characteristics.

Future Regulatory Action?

- All eyes on 2023 Medicare Physician Fee Schedule Proposed Rule
  - Billing for telehealth services (POS, Medicare enrollment)
  - List of telehealth services
  - Use of telehealth as substitute for certain in-person requirements
  - Telehealth frequency limitations
- OCR discretion on HIPAA enforcement
- OIG discretion on co-insurance waivers

Virtual Services

- Scope
  - Care management (CCM, Complex CCM, PCM)
  - Remote monitoring (RPM and RTM)
  - Virtual (telephonic) check-ins
  - e-visits
- For duration of PHE -
  - May provide services for new and established patients
    - Still must obtain consent at initiation of services
  - May waive co-insurance (CMP enforcement discretion extends to these services)
  - For remote physiologic monitoring, only 2 days of data collection required for COVID-19 patients (vs. 16 days)

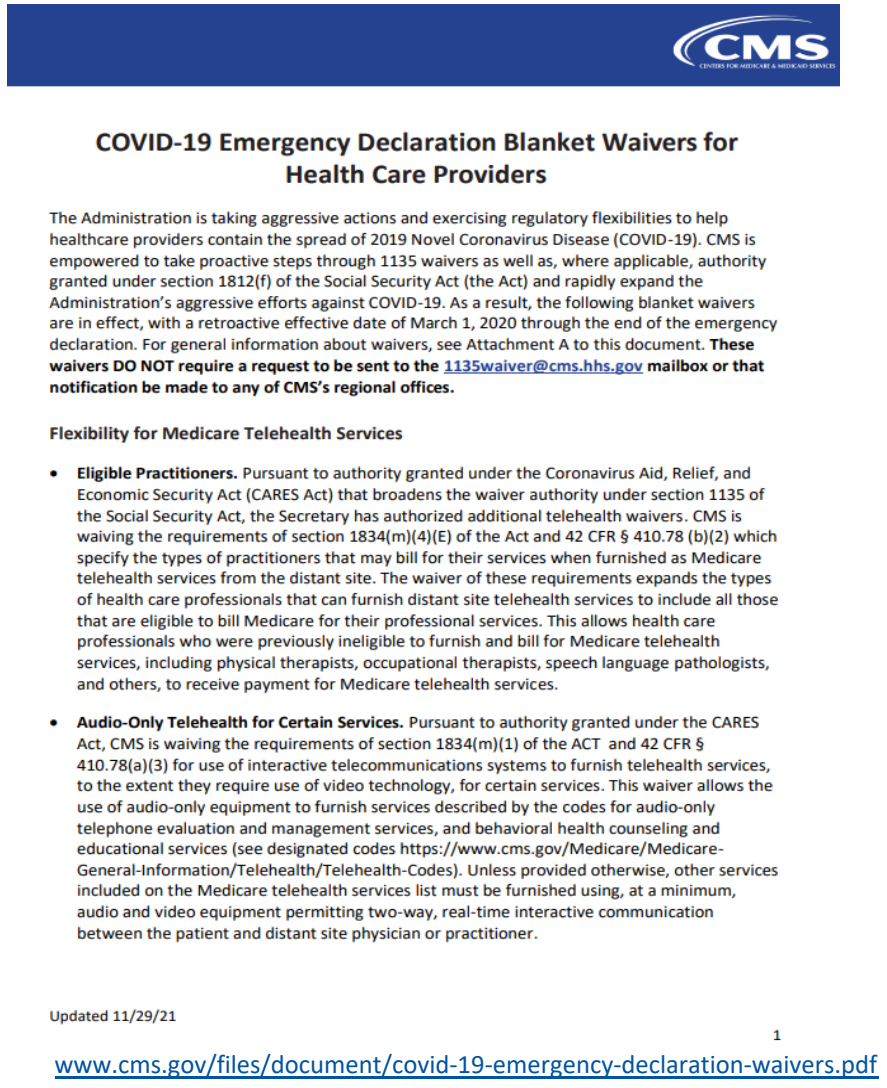
3. Section 1135 Waivers and Flexibilities

Waivers and Flexibilities

- Under Section 1135, HHS can modify or waive certain Medicare, Medicaid/CHIP, and HIPAA requirements during a declared PHE to ensure beneficiary access to care
  - Expand capacity
  - Reduce regulatory burden
- Under this authority, HHS has modified or waived nearly 200 federal regulatory requirements during COVID-19 PHE
- Under separate statutory authority, HHS has approved changes to state Medicaid plans; these remain in effect unless state requests termination

Preparing to Unwind

- Capacity
  - Return all facilities to pre-PHE operations (i.e., modifications made for surge capacity and patient quarantine)
- Regulatory burden – return to “old” normal
  - E.g., verbal orders, medical records, nursing plan of care, respiratory care, CRNA supervision, utilization review, QA/PI, advance directives, information sharing during discharge planning



COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

The Administration is taking aggressive actions and exercising regulatory flexibilities to help healthcare providers contain the spread of 2019 Novel Coronavirus Disease (COVID-19). CMS is empowered to take proactive steps through 1135 waivers as well as, where applicable, authority granted under section 1812(f) of the Social Security Act (the Act) and rapidly expand the Administration’s aggressive efforts against COVID-19. As a result, the following blanket waivers are in effect, with a retroactive effective date of March 1, 2020 through the end of the emergency declaration. For general information about waivers, see Attachment A to this document. **These waivers DO NOT require a request to be sent to the 1135waiver@cms.hhs.gov mailbox or that notification be made to any of CMS’s regional offices.**

Flexibility for Medicare Telehealth Services

- **Eligible Practitioners.** Pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that broadens the waiver authority under section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2) which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals that can furnish distant site telehealth services to include all those that are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services.
- **Audio-Only Telehealth for Certain Services.** Pursuant to authority granted under the CARES Act, CMS is waiving the requirements of section 1834(m)(1) of the ACT and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services (see designated codes https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes). Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

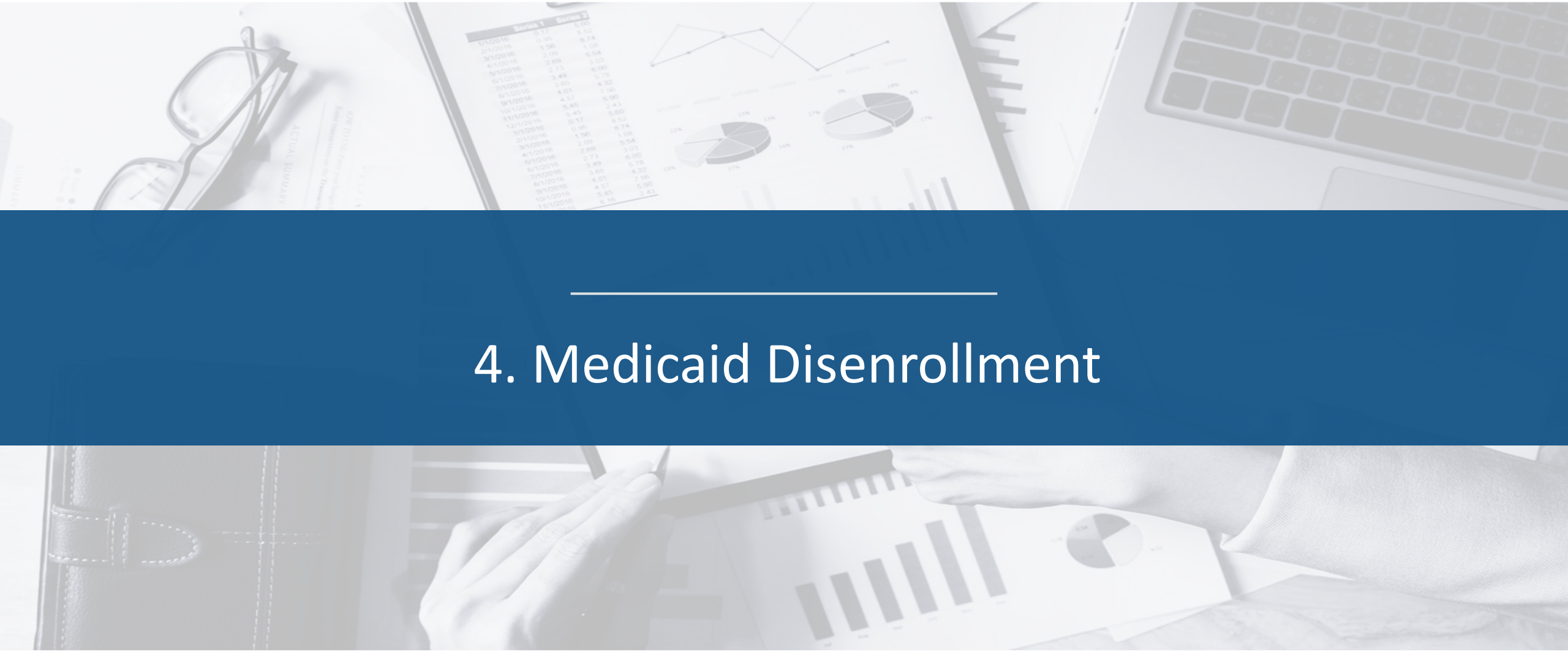
Updated 11/29/21

1

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

Stark Law Waivers

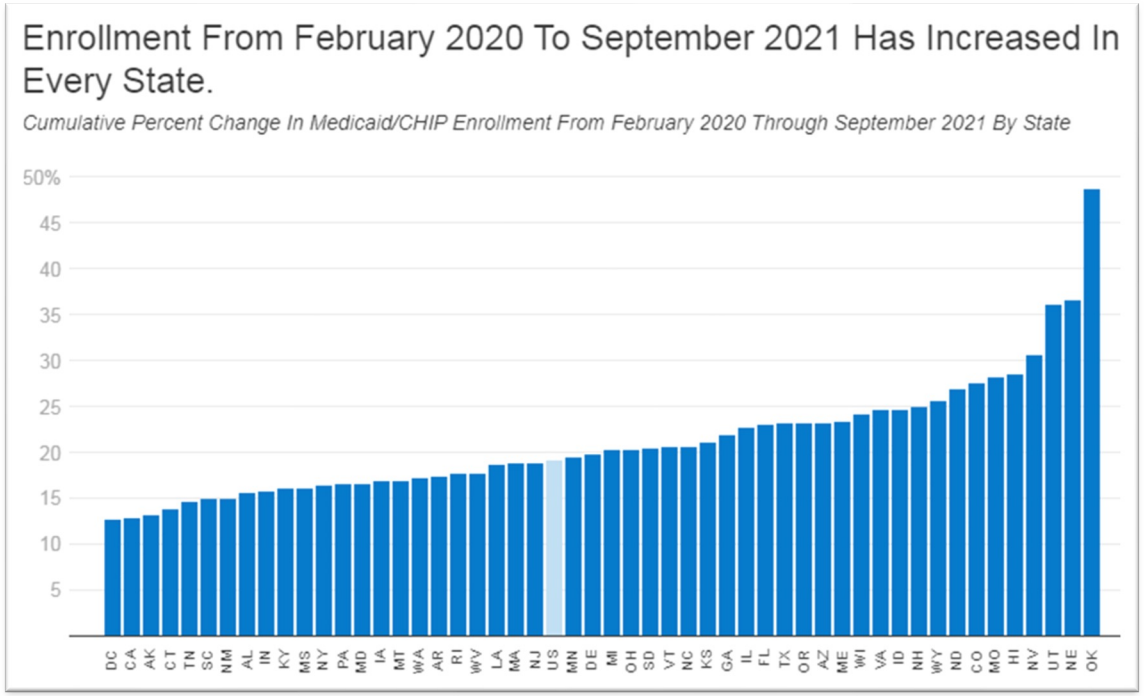
- Waiver of sanctions under Stark Law for otherwise prohibited financial arrangements made necessary to achieve COVID-19-related purpose
  - Fair market value for renumeration and rental charges
  - Medical staff incidental benefits and non-monetary compensation
  - Interest rates and terms of loans
    - Appropriate repayment terms agreed to during PHE may continue post-PHE, but all disbursement of loan proceeds must occur during PHE
  - Referrals to facilities in which physician/family member has ownership interest
  - Compensation arrangements that fail to meet writing/signature requirements



4. Medicaid Disenrollment

Medicaid Continuous Coverage

- As condition of receiving 6.2% increase in FMAP, states agreed to continuous coverage requirement
  - Cannot disenroll from Medicaid unless individual requests disenrollment, moves out of state, or dies
- Medicaid/CHIP enrollment increased by 13.6 million (19.1%) between 02/20 to 09/21
  - State enrollment growth ranged from 12.6% to 48.7%



CMS, Medicaid & CHIP: Monthly Application and Eligibility Reports, last updated February 28, 2022

Renewal and Disenrollment

- Following end of PHE, states will have up to 12 months to return to normal eligibility and enrollment operations
  - Initiate renewals for *all* beneficiaries through automated processes, sending renewal notices and requests for information
  - Incentives created by end of FMAP increase
- Anticipate *significant* disruption in Medicaid coverage, despite CMS' guidance encouraging smooth transition to other coverage (e.g., marketplace)
- Impact on providers?

Our Next Health Care Regulatory Round-Up:

Latest Developments in 340B

Wednesday April 6, 2022

How Can We HELP?

A national healthcare advisory services firm providing consulting, audit, and tax services