HEALTHCARE REGULATORY ROUND-UP #37

Back to the Future: Get Ready for the End of the PHE

October 19, 2022

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WE ARE AN INDEPENDENT MEMBER OF HLB—THE GLOBAL ADVISORY AND ACCOUNTING NETWORK

Introductions

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Status of the PHE

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RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective October 13, 2022, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, and July 15, 2022, that a public health emergency exists and has existed since January 27, 2020, nationwide.

October 13, 2022	/s/
Date	Xavier Becerra

https://aspr.hhs.gov/legal/PHE/Pages/covid19-13Oct2022.aspx

Letter to Governors on the COVID-19 Response

On January 22, 2021, Acting HHS Secretary Norris Cochran reached out to governors across the country to share details of the public health emergency declaration for COVID-19. Among other things, the Acting Secretary Cochran indicated that HHS will provide states with 60 days notice prior to the termination of the public health emergency declaration for COVID-19. To learn more about the extension and other flexibilities that are tied to the public health emergency declaration, please read the full text of Acting Secretary Cochran's letter.

Read Full Text

https://aspr.hhs.gov/legal/PHE/Pages/default.aspx

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Aug 18, 2022

Creating a Roadmap for the End of the COVID-19 Public Health Emergency

By: Jonathan Blum, Chief Operating Officer and Principal Deputy Administrator; Carol Blackford, Director Hospital and Ambulatory Policy Group; and Jean Moody-Williams, Deputy Director of the Center for Clinical Standards and Quality

"CMS encourages health care providers to prepare for the end of these flexibilities as soon as possible and to begin moving forward to reestablishing previous health and safety standards and billing practices."

Provider Fact Sheets

- 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
- 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
- Durable Medical Equipment, Prosthetics, Orthotics and Supplies
- Medicare Advantage and Part D Plans
- Ambulances
- End Stage Renal Disease Facilities
- Participants in the Medicare Diabetes Prevention Program

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

Today's Agenda

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1. Telehealth and Virtual Services

2. Waivers and Flexibilities – Expanded Capacity

3. Waivers and Flexibilities – Reduced Administrative Burden

4. Impact of Medicaid Disenrollment

1. Telehealth

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 Telehealth Coverage Pre-COVID-19

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Exceptions to Geographic and Location Restrictions

- **Telestroke**
  - Effective 01/01/2019, geographic and location requirements do not apply to services furnished to diagnose, evaluate, or treat symptoms of acute stroke
- **ESRD**
  - Effective 01/01/2019, geographic and location requirements do not apply to ESRD services relating to home dialysis
- **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
- **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

- Waiver of ***geographic*** and ***location*** restrictions
- Waiver of certain ***service*** restrictions
  - 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
- Waiver of certain ***provider*** restrictions
  - 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)
- Provides ***reimbursement*** at higher non-facility rates
  - POS = where practitioner normally provides face-to-face services
  - Append modifier 95 to indicate service furnished via telehealth

Medicare Telehealth Coverage Expansion

- ***Office of Civil Rights*** Notice of Enforcement Discretion - Will not impose penalties if, in good faith, use any non-public remote audio/visual communication product (e.g., Zoom, FaceTime)
- ***Office of Inspector General*** Notice of Enforcement Discretion– Permits waiver of co-insurance for telehealth and virtual services
- ***Drug Enforcement Administration*** – Use of telehealth for in-person medical evaluation prior to prescribing scheduled II – V controlled substances

Medicare Part B Telehealth Utilization

Year	Telehealth Eligible Users	Telehealth Users	Percentage of Medicare Users with a Telehealth Service
2020(Q1)	23,992,430	1,665,085	7%
2020(Q2)	21,985,392	10,262,251	47%
2020(Q3)	24,025,623	6,762,255	28%
2020(Q4)	23,859,999	6,633,028	28%
2021(Q1)	22,894,570	6,174,058	27%
2021(Q2)	23,390,837	4,306,696	18%
2021(Q3)	23,606,253	3,830,937	16%
2021(Q4)	23,545,483	3,725,184	16%
2022(Q1)	22,240,382	4,124,894	19%

https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-service-type-reports/medicare-telehealth-trends

Impact

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- 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

U.S. Department of Health and Human Services

Office of Inspector General

Data Brief

September 2022, OEI-02-20-00720

Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks

- ~40% of Medicare beneficiaries used telehealth, 88 times more than prior year
- Identified 1,714 providers out of approximately 742,000 whose billing for telehealth services poses high risk to Medicare (2.3%)
  - Bills both a telehealth service and a facility fee for most visits
  - Bills telehealth services at highest level every time
  - Bills telehealth services for high number of days (300 days/year)
  - Bills both Medicare fee-for-service and MA plan for same service for high % of services
  - Bills high average number of hours of telehealth services per visit
  - Bills telehealth services for high number of beneficiaries
  - Bills telehealth service and orders DME for high % of beneficiaries

United States Government Accountability Office

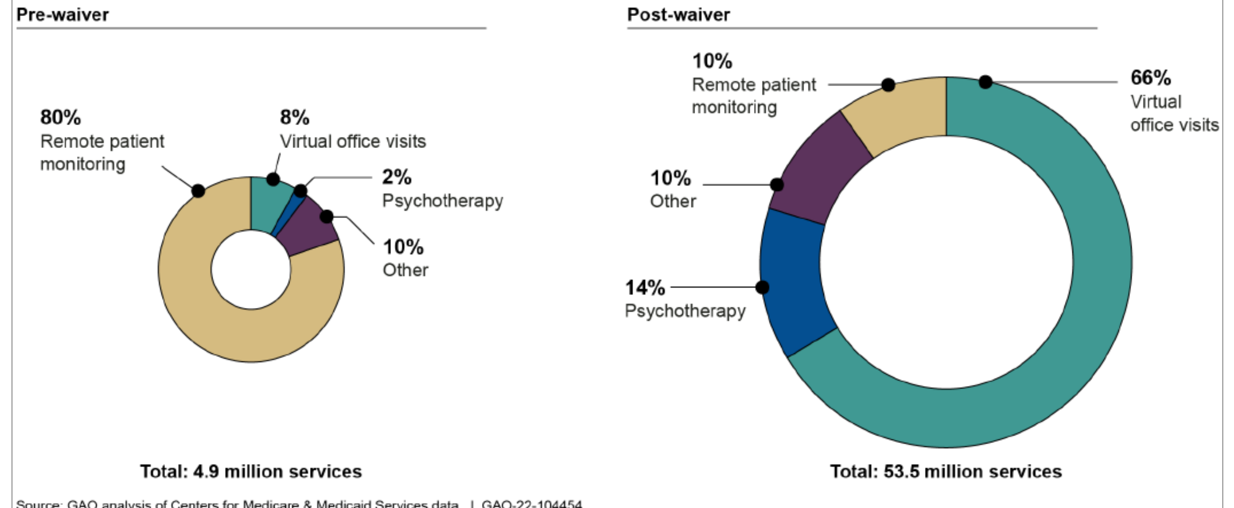
GAO

Report to Congressional Addressees

September 2022

MEDICARE TELEHEALTH

Actions Needed to Strengthen Oversight and Help Providers Educate Patients on Privacy and Security Risks



- Need to fully assess quality of services furnished via telehealth
  - Services delivered in patients' homes
  - Audio-only services
- Need to educate providers regarding platforms' compliance with HIPAA rules

Consolidated Appropriations Act, 2021

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- 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 6 months prior to initial telehealth service + every 12 months thereafter
  - Exception to in-person visit requirement 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)

Consolidated Appropriations Act, 2022

- For 151 days post-PHE –
  - ✓ Continue waiver of geographic and location requirements
  - ✓ Continue coverage for therapist and S/L pathologist telehealth services
  - ✓ Continue coverage for audio-only services
  - ✓ Continue coverage for telehealth services furnished by FQHCs and RHCs
  - ✓ Continue use of telehealth to recertify eligibility for hospice cases
  - ✓ Delay in in-person requirement for initiation of tele-behavioral health services

Advancing Telehealth Beyond COVID-19 Act

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- Passed the House on July 27 by vote of 416-12
- Extend PHE telehealth coverage through December 31, 2024
- Now awaiting action by the Senate

2022 Medicare Physician Fee Schedule Final Rule

- Category 3 codes
  - Coverage to continue through 12/31/23 to develop case for permanent inclusion under Category 1 or 2
  - Still subject to geographic and location restrictions beginning Day 152 post-PHE
- Continue use of telehealth to provide direct supervision to continue through 12/31 of year in which PHE ends
  - CMS still considering whether to make permanent

2023 MPFS Proposed Rule - Telehealth Services List

- Extend coverage for all services included on temporary basis for 151 days post-PHE
  - https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes
- Identify those services included on temporary basis for which coverage **will not** be continued through 12/31/23 (Table 10)
  - Telephone E/M visit codes (CPT 99441-43)
  - Initial care (observation, hospital, nursing facility, domiciliary/rest home, home)
- Add new Category I codes
  - GXXX1-3 (prolonged inpatient, nursing facility, home/residence services by physician/NPP)

HCPCS	Short Descriptor
77427	Radiation tx management x5
92002	Eye exam new patient
92004	Eye exam new patient
92550	Tympanometry & reflex thresh
92552	Pure tone audiometry air
92553	Audiometry air & bone
92555	Speech threshold audiometry
92556	Speech audiometry complete
92557	Comprehensive hearing test
92563	Tone decay hearing test
92565	Stenger test pure tone
92567	Tympanometry
92568	Acoustic refl threshold tst
92570	Acoustic immitance testing
92587	Evoked auditory test limited
92588	Evoked auditory tst complete
92601	Cochlear implt f/up exam <7
92625	Tinnitus assessment
92626	Eval aud funcj 1st hour
92627	Eval aud funcj ea addl 15
93750	Interrogation vad in person
94002	Vent mgmt inpat init day
94003	Vent mgmt inpat subq day
94004	Vent mgmt nf per day
96125	Cognitive test by hc pro
99218	Initial observation care
99219	Initial observation care
99220	Initial observation care
99221	Initial hospital care
99222	Initial hospital care
99223	Initial hospital care
99234	Observ/hosp same date
99235	Observ/hosp same date
99236	Observ/hosp same date
99304	Nursing facility care init
99305	Nursing facility care init
99306	Nursing facility care init
99324	Domicil/r-home visit new pat
99325	Domicil/r-home visit new pat
99326	Domicil/r-home visit new pat
99327	Domicil/r-home visit new pat
99328	Domicil/r-home visit new pat
99341	Home visit new patient
99342	Home visit new patient
99343	Home visit new patient
99344	Home visit new patient
99345	Home visit new patient
99441	Phone e/m phys/qhp 5-10 min
99442	Phone e/m phys/qhp 11-20 min
99443	Phone e/m phys/qhp 21-30 min
99468	Neonate crit care initial
99471	Ped critical care initial
99475	Ped crit care age 2-5 init
99477	Init day hosp neonate care

2023 MPFS Proposed Rule - Claims and Payment

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- Through Day 151 -
  - Will continue to pay non-facility rate for claims with modifier 95
  - Report POS code that would have been reported if service furnished face-to-face
- Day 152 and thereafter –
  - Discontinue modifier 95; use POS 02 (telehealth provided other than patient's home) or POS 10 (telehealth provided in patient's home)
  - Payment at lower facility rate ("We believe that the facility payment amount best reflects the practice expense, both direct and indirect, involved in furnishing services via telehealth")
  - Include modifier 93 for audio-only services (including RHCs, FQHCs, and OTPs)
- CMS will issue sub-regulatory guidance as needed to implement Telehealth Flexibilities Extension following end of PHE

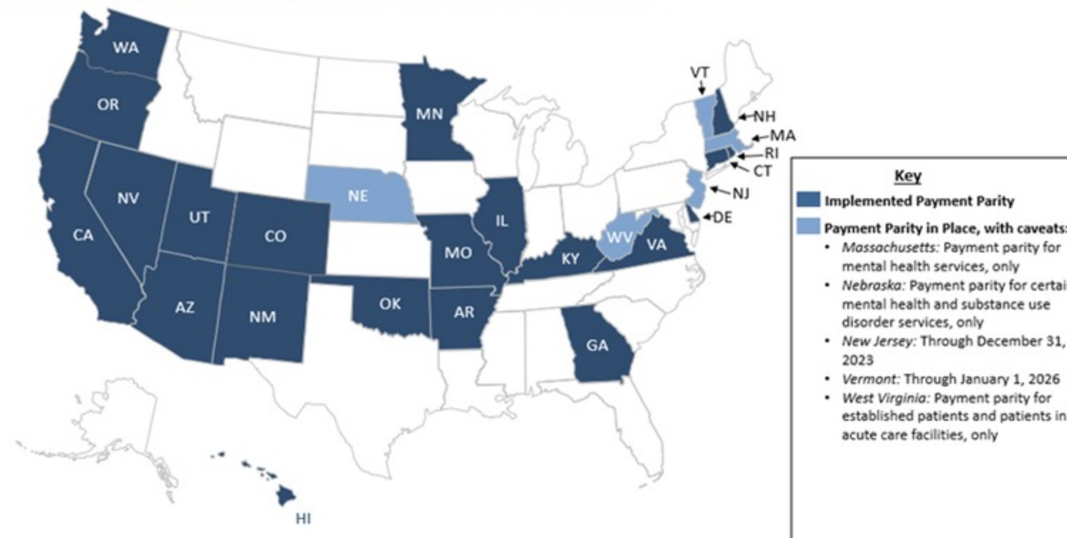
Ending With the End of the PHE

- Use of telehealth to perform –
  - Required in-person visits (ESRD/home dialysis, nursing facility, home health, hospice)
  - Prescription of controlled substances (waiver of in-person medical evaluation)
  - For residency training sites within MSA, teaching physician presence for key portions of service
- Telehealth frequency limits for subsequent inpatient visit (once/3 days), subsequent SNF visit (once/14 days), critical care consult (once/day)
- Enforcement discretion on waiver of co-insurance

State Action in Response to COVID-19

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

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



Manatt, *Executive Summary: Tracking Telehealth Changes State-by-State in Response to COVID-19* (Aug. 26, 2022) available at www.manatt.com/insights/newsletters/covid-19-update/executive-summary-tracking-telehealth-changes-stat

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2. Waivers and Flexibilities – Expanded Capacity

Waivers and Flexibilities

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- 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
  - "In no case will any of these waivers extend past the last day of the public health emergency (or any extension thereof)"

Hospitals Without Walls

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- Expanding locations for delivery of inpatient services
  - Non-patient care areas, distinct part units, community facilities (e.g., hotels)
- Providing offsite EMTALA screenings
- Creating new or relocating existing HOPDs
  - Including patient homes for therapy, counseling, and education services and partial hospitalization services furnished by remote hospital clinical staff
  - 2023 OPPS proposed rule – hospital clinical staff may provide mental health services remotely to patients in their homes (same limits as MPFS)
  - No impact on payment rates (site neutrality)
- Adding swing beds to provide SNF services
  - Must contact MAC and attest to local SNFs' inability to accept patients
- 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

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- 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
- 256 hospitals (114 health systems) in 37 states approved for participation
  - 21 hospitals added since 6/1/2022
  - Early data shows low utilization rates but low rates of unexpected mortality and escalation
- What’s next?
  - More robust data to be released through RESDAC process
  - Hospital Inpatient Services Modernization Act would extend waiver by 2 years post-PHE
  - Center for Medicare & Medicaid Innovation could implement as demonstration project

Skilled Nursing Facilities

- Sending patients to SNFs without qualifying 3-day stay
  - May 2020: “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.”
  - May 2021: “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.”
  - May 2022: “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.”
  - August 2022: “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.”
- Granting beneficiaries who exhausted SNF benefits onetime renewed SNF coverage without having to complete 60-day “wellness period” but only if due to COVID-19 emergency
- Permitting SNFs to use temporary locations – waiver terminated June 6, 2022

3. Waivers and Flexibilities – Reduced Administrative Burden

Early Termination

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- SNF/NF
  - Reporting Minimum Data Set – requirements reinstated May 10, 2021
  - Staffing data submission – requirements reinstated on June 25, 2020
  - Participation in resident groups – waiver terminated May 7, 2022
  - Quality Assurance and Performance Improvement – waiver terminated May 7, 2022
  - Nursing Assistant in-service training – deadlines for completing training reinstated June 6, 2022
  - Information Sharing for discharge planning – requirements reinstated May 7, 2022
  - Provision of clinical records to residents – requirements reinstated May 7, 2022
- Provider enrollment
  - Several flexibilities relating to enrollment process (site visits, criminal background checks, application fees) previously discontinued
- Physical environment
  - Waivers applicable to inpatient hospice, ICF/IID, and SNF/NF terminated

The Great Unwind – Partial List

- Authentication of verbal orders within 48 hours
- Reporting requirements relating to death of ICU patients with soft wrist restraints
- Information sharing on post-acute providers during hospital discharge planning
- Form and content of medical records, record 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
- Updates to therapeutic diet manual
- Signature requirements for Part B drugs and DME (cannot be obtained due to COVID-19)
- Medical staff credentialing and privileges process
- CRNA supervision requirements
- Responsibilities of physicians in CAHs (physically present to provide medical direction)

Stark Law Waivers

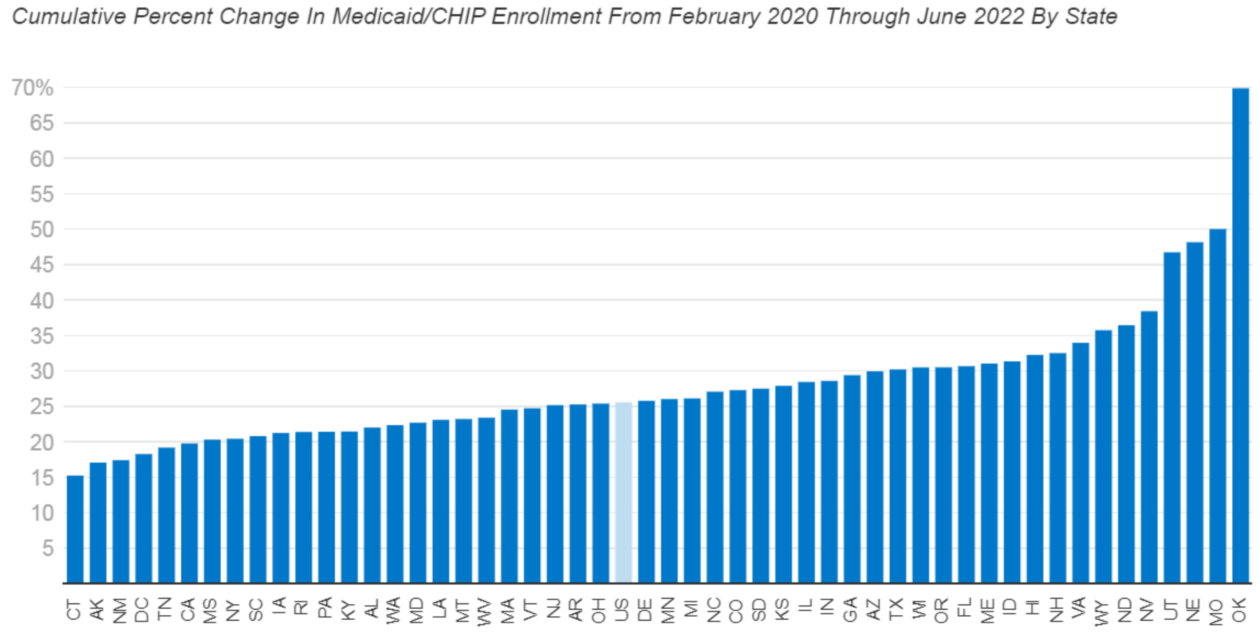
- Waiver of sanctions under Stark Law for otherwise prohibited financial arrangements made necessary to achieve COVID-19-related purpose
  - Fair market value for renumeration and rental charges
  - Medical staff incidental benefits and non-monetary compensation
  - Interest rates and terms of loans
    - 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
- "When the PHE ends, the waivers with terminate and physicians and entities must immediately comply with all provisions of the Stark Law."

PYA

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 18.75 million (25.6%) between 02/20 and 06/22
  - State enrollment growth ranged from 15.2% to 69.9%



https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/

Renewal and Disenrollment

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- 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 but face workforce challenges
- HHS estimates 15 million will lose Medicaid coverage
  - Some will regain coverage in individual market under Inflation Reduction Act's extension of ACA premium tax credits through end of 2025

Our Next Healthcare Regulatory Round-Up

Hospital Price Transparency – Where Do We Go From Here?

Tuesday, November 1, 2022

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