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March 26, 2020 (as of 8:00 a.m. ET)

COVID-19: Health System Policy and Guidance Updates on Selected Issues (as of March 26, 2020)

To help our clients and friends navigate a complex and rapidly changing landscape, Manatt Health is providing this summary of developments related to selected issues for health systems and providers as of Thursday morning, March 26, 2020. Please note that policy guidance, funding authorizations and associated timing remain extremely fluid.

Included in this briefing:
1. Update on federal funding authorizations to date and implications for providers
2. Update on Section 1135 waivers and associated regulatory flexibilities for providers
3. Update on telehealth guidance
4. Additional developments of interest

I. Federal Stimulus Package

Passage of a $2 trillion stimulus package is expected imminently. This will be the third federal funding package related to the COVID-19 emergency. The first $8.3 billion package largely focused on federal agency preparedness and vaccine funding. The second $100 billion-plus package largely focused on expanded coverage for COVID-19 testing, sick leave benefits and food aid. *Please see the Attachments to this document for more information on the enacted legislation.*

- **TBD Week of March 23, 2020 – Third Stimulus Package**

Late Wednesday night, March 25, the U.S. Senate unanimously voted to approve a bipartisan $2 trillion economic stabilization plan that will include relief funding for multiple sectors of the U.S. economy, including direct funding for healthcare providers. The bill provides emergency assistance and healthcare response for individuals, families and businesses affected by the 2020 coronavirus pandemic and will be the largest economic relief package in U.S. history. The U.S. House of Representatives is expected to pass the bill on Friday, sending it to President Trump for signature.

The bill includes provisions for small businesses (including loans with loan forgiveness for certain uses of funds), expanded unemployment insurance, direct payments and tax relief for individuals, business tax relief, and additional provisions for labor, education and aviation.

Specifically related to **funding for providers**, the bill will (among other things):

- Provide $100 billion in funding (to be distributed through grants or other mechanisms) for healthcare providers impacted by the COVID-19 emergency
- Provide $150 billion for state, territory and tribal government efforts related to the response
- Temporarily lift the Medicare sequester (the 2% cut to payments for Medicare fee-for-service claims, enacted in 2013)
- Increase the Medicare weighting factor that would otherwise apply to diagnosis-related groups (DRG) for COVID-19 patients by 20% (with the Secretary of HHS directed to provide additional guidance on defining relevant discharges)

- Expand an existing Medicare hospital accelerated payment program, under which qualified facilities(most hospitals and critical access hospitals) would be able to request up to a six month advanced lump sum or periodic payment
- Extend the work geographic index floor under the Medicare program through December 1, 2020
- Delay Medicaid DSH state allotment reductions (which would otherwise take effect May 22, 2020)
- Increase access to telehealth, post-acute care and home health
- Include supplemental appropriations to provide billions in additional funding for community health centers, the Veterans Health Administration, the Indian Health Service and TRICARE

Manatt is closely following developments and will be analyzing the final bill.

Manatt's COVID-19 resource center: www.manatt.com/COVID-19

II. Federal Emergency Declaration and Section 1135 Waivers

President Trump's declaration of a national emergency on March 13, 2020, coupled with the January public health emergency declaration by Health and Human Services (HHS) Secretary Azar, provides HHS with expanded authority under Section 1135 of the Social Security Act (SSA), allowing the Secretary to temporarily waive or modify certain Medicare, Medicaid and Children's Health Insurance Program (CHIP) requirements to ensure that sufficient healthcare items and services are available to meet the needs of individuals enrolled in SSA programs in the emergency area(s) and time periods and that providers who provide such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).

- CMS has released a fact sheet on a series of broad provider regulatory flexibilities already enacted under this authority.
- CMS also issued Frequently Asked Questions (FAQ) guidance related to Medicare Provider Enrollment simplification and relief under the 1135 authority.

In addition, several states have submitted requests for 1135 waivers, and HHS has been rapidly approving them. These waivers end no later than the termination of the national or public health emergency; until that time, Secretary Azar may renew the waiver authority in 60-day increments. 1135 waivers allow states (among other things) to:

- Waive prior authorization requirements in fee-for-service programs
- Permit providers located out of state/territory to provide care to another state's Medicaid enrollees impacted by the emergency
- Temporarily suspend certain provider enrollment and revalidation requirements to increase access to care
- Temporarily waive requirements that physicians and other healthcare professionals be licensed in the state in which they are providing services, so long as they have an equivalent licensing in another state

To date, CMS has approved 1135 waiver requests for 13 states: Alabama, Arizona, California, Florida, Illinois, Louisiana, Mississippi, New Hampshire, New Jersey, New Mexico, North Carolina, Virginia and Washington.

CMS has also recently released a COVID-19 State/Territory Request Template: https://www.medicaid.gov/state-resource-center/downloads/1135-checklist-template.pdf

Blanket HIPAA Waivers under 1135 Authority

In addition, HHS issued a **waiver to temporarily relieve hospitals of certain administrative obligations imposed under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule**. HHS provides for hospitals **a time-limited waiver of sanctions and penalties arising from noncompliance with HIPAA privacy requirements related to**: obtaining a patient's agreement to speak with family members or friends, distribution of privacy practices, and a patient's right to request privacy restrictions or confidential communication. These HIPAA waivers become effective for 72 hours from the implementation of a hospital disaster protocol and are available only for the duration of the national or public health emergency, or 60 days from the date of the waiver publication.

> For more information about the HIPAA waivers, see: https://www.manatt.com/Insights/Newsletters/COVID-19-Update/HHS-Issues-COVID-19-HIPAA-Waivers

Other Medicaid Waiver Options for States

Section 1135 waivers are not the only pathway for states to access flexibilities. Under Medicaid, states can pursue **Section 1115 waivers to expedite access to coverage and healthcare services** for individuals affected by an emergency. In past disasters, states have used 1115 waivers to expand coverage to individuals not otherwise eligible for Medicaid benefits, streamline application and eligibility verification processes, temporarily suspend or delay renewals for existing enrollees, waive cost-sharing, and/or expand benefits for specific population groups and/or within specific geographic areas of a state.

States may also request **emergency amendments to 1915(c) home and community-based services waivers** (via "Appendix K") and request **Disaster State Plan Amendments (SPAs)**. All states are currently reviewing and developing proposals for additional Medicaid flexibility, **which will have implications for providers**.

> On March 22, CMS released a series of checklists and tools for states in developing their requests for flexibility.

III. Telehealth Updates

Medicare

CMS has been moving quickly to clarify telehealth guidance, make technical corrections and clarifications to earlier guidance, and provide additional flexibility.

On March 17, CMS released a detailed new Medicare telehealth fact sheet and a helpful coding chart:

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.

CMS also released a companion Medicare telehealth billing FAQ document.

In addition, the HHS Office of Civil Rights (OCR) released a series of FAQs for providers related to **HIPAA and telehealth during the public health emergency period**. OCR also released a Notification of Enforcement Discretion for Telehealth Remote Communications with guidance on public-facing technologies that can be used and those that should not be used.

Medicaid

CMS has encouraged states to expand telehealth options under their Medicaid program. Last week, CMS released guidance to assist states in understanding policy options for paying Medicaid providers that use telehealth technology to deliver services.

Controlled Substances

The Drug Enforcement Administration (DEA) has issued new guidance on the ability to prescribe controlled substances via telemedicine during a national public health emergency. In addition, the DEA COVID-19 webpage contains helpful links to updated guidance on **Medication-Assisted Treatment (MAT)** during the emergency period and **Substance Abuse and Mental Health Services Administration (SAMHSA)** guidance for opioid treatment during this period.

IV. Additional Updates of Interest

- On Monday, March 23, **New York** Governor Andrew Cuomo signed an **Executive Order** **requiring all New York hospitals to develop 50% additional inpatient capacity** to prepare for the state's anticipated surge of coronavirus patients.
    - New York is also building a 1,000-bed temporary hospital at the Jacob K. Javits Convention Center in Manhattan and has identified four additional sites for temporary hospitals with the Army Corps of Engineers.
- **NYU's Grossman School of Medicine** is reportedly offering students in the 2020 graduating class an opportunity **to graduate early and to immediately begin working as interns** to help increase available frontline clinical staff and combat burnout as New York's cases grow.
- On Tuesday, March 24, **Texas** Governor Greg Abbott signed an **Executive Order** requiring **daily reporting by hospitals to the state on their bed capacity**.
- On March 24, the **FDA** provided new guidance on the use of and access to **convalescent plasma** collected from recovered COVID-19 patients.
- The **OCR** issued **new HIPAA guidance** on March 24 specific to **disclosures to law enforcement, paramedics, other first responders and public health authorities**.
- Several states are mobilizing corps of **Emergency Volunteer Health Practitioners** and/or **modifying their state licensure laws**.
    - As of 2020, 18 states and the District of Columbia have enacted Uniform Emergency Volunteer Health Practitioner Act (UEVHPA) legislation, which allows any state that has enacted it to recognize out-of-state licenses for a variety of health practitioners during a state of declared emergency.
    - The Federation of State Medical Boards (FSMB) has published a list of actions and emergency flexibilities passed in each state as of March 24: https://www.fsmb.org/siteassets/advocacy/pdf/state-emergency-declaration-licensures-requirements-covid-19.pdf
    - FSMB has also published a set of recommendations for state medical boards related to licensure portability: https://www.fsmb.org/siteassets/advocacy/pdf/memo-fsmb-license-portability-recommendationds.pdf
    - The National Conference of State Legislatures is also tracking state actions related to implementing emergency licensure flexibility: https://www.ncsl.org/research/labor-and-employment/covid-19-occupational-licensing-in-public-emergencies.aspx

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We welcome your feedback and comments on additional issues and most pressing concerns. Please email bpawlak@manatt.com.

ATTACHMENTS

Recap of Federal Coronavirus Stimulus Packages to Date

March 6, 2020 – Coronavirus Preparedness and Response Supplemental Appropriations Act

The first coronavirus-related funding package provides $8.3 billion in emergency funding for federal agencies to respond to the coronavirus outbreak and for vaccine development.

Manatt has published an **infographic on both the uses of funds and recipients**.

For a written summary of provisions, see: https://www.manatt.com/Insights/Newsletters/COVID-19-Update/COVID-19-Health-System-Policy-and-Guidance-on-Sele.

- Update on health center funding: **Health Resources and Services Administration (HRSA)** announced March 24 that $100 million in funding from this stimulus package had been awarded to be used for increased medical supplies, testing and telehealth needs related to the coronavirus response by community health centers. HRSA calculated the award amounts using a $50,464 base and then adding $0.50 per patient reported in the 2018 Uniform Data System and $2.50 per uninsured patient reported in the system.

March 18, 2020 – Families First Coronavirus Response Act

The March 18 stimulus package includes healthcare provisions that largely focus on ensuring access to free coronavirus testing as well as Medicaid fiscal relief. In addition, the act includes emergency supplemental appropriations to agencies on the front lines of the response to the pandemic, $1 billion in food aid, the establishment of an emergency paid leave benefits program and the extension of sick leave benefits for some. **Of specific interest to healthcare providers**, the act, among other provisions:

- Contains **technical clarifications related to Medicare's temporary expanded telehealth coverage.**
- Requires **private insurance** carriers to cover, without cost sharing, COVID-19 testing as well as screening provided during a telehealth office visit.
- Prohibits **Medicaid and Children's Health Insurance Program (CHIP)** from charging cost sharing for the administration of COVID-19 testing or any testing-related services.
- **Gives states the option to extend Medicaid eligibility to uninsured patients for purposes of SARS-CoV-2** diagnostic testing and testing-related services during the duration of the public health emergency (states that elect this option would see their medical and administrative costs fully matched by the federal government).
- **Temporarily increases by 6.2 percentage points the regular (e.g., non-expansion) Medicaid Federal Medical Assistance Percentage (FMAP) matching rate**, for both states and territories, retroactive to January 1, 2020, and lasting through the last day of the calendar quarter in which the emergency ends (states are required to satisfy a maintenance of effort (MOE) requirement).
    - On March 24, CMS issued detailed guidance for states on how to access the FMAP increase.

For more detailed information on healthcare-related provisions, see: https://www.manatt.com/Insights/Newsletters/COVID-19-Update/COVID-19-Manatt-Health-Update.

For more detailed information on FMLA and emergency short-term paid sick leave provisions, see: https://www.manatt.com/Insights/Newsletters/COVID-19-Update/President-Signs-Substantially-Revised-Families.

For a helpful snapshot of the key provisions across agencies, see: https://www.kff.org/global-health-policy/issue-brief/the-families-first-coronavirus-response-act-summary-of-key-provisions/ or https://appropriations.house.gov/sites/democrats.appropriations.house.gov/files/Families%20First%20summary.pdf.

CMS Quality Reporting Program Relief

On Sunday, March 22, CMS announced temporary relief for clinicians, hospitals and facilities participating in Quality Reporting Programs. The Secretary of HHS is using his authority to implement additional "extreme and uncontrollable circumstances" policy exemptions and extensions for upcoming quality measure reporting and data submission deadlines for the following programs:

Provider Programs	2019 Data Submission	2020 Data Submission
Quality Payment Program – Merit-based Incentive Payment System (MIPS)	Deadline extended from March 31, 2020, to April 30, 2020. MIPS-eligible clinicians who have not submitted any MIPS data by April 30, 2020, will qualify for the automatic extreme and uncontrollable circumstances policy and will receive a neutral payment adjustment for the 2021 MIPS payment year.	CMS is evaluating options for providing relief around participation and data submission for 2020.
Medicare Shared Savings Program Accountable Care Organizations (ACOs)		

Hospital Programs	2019 Data Submission	2020 Data Submission
Ambulatory Surgical Center Quality Reporting Program	Deadlines for October 1, 2019, to December 31, 2019 (Q4): Data submission is optional. If Q4 data is submitted, it will be used to calculate the 2019 performance and payment (where appropriate). If data for Q4 is unable to be submitted, the 2019 performance will be calculated based on data from January 1, 2019, to September 30, 2019 (Q1-Q3), and other available data.	CMS will not count data from January 1, 2020, to June 30, 2020 (Q1-Q2), for performance or payment programs. Data does not need to be submitted to CMS for this time period. * For the *Hospital-Acquired Condition Reduction Program and the Hospital Value-Based Purchasing Program*, if data from January 1, 2020, to March 31, 2020 (Q1), is submitted, it will be used for scoring in the program (where appropriate).
CrownWeb National End-Stage Renal Disease (ESRD) Patient Registry and Quality Measure Reporting System		
ESRD Quality Incentive Program		
Hospital-Acquired Condition Reduction Program		
Hospital Inpatient Quality Reporting Program		
Hospital Outpatient Quality Reporting Program		
Hospital Readmissions Reduction Program		
Hospital Value-Based Purchasing Program		
Inpatient Psychiatric Facility Quality Reporting Program		
PPS-Exempt Cancer Hospital Quality Reporting Program		

Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals		

Post-Acute Care Programs	2019 Data Submission	2020 Data Submission
Home Health Quality Reporting Program	Deadlines for October 1, 2019, to December 31, 2019 (Q4): Data submission is optional. If Q4 data is submitted, it will be used to calculate the 2019 performance and payment (where appropriate).	Data from January 1, 2020, to June 30, 2020 (Q1-Q2), does not need to be submitted to CMS for purposes of complying with quality reporting program requirements. * *Home Health and Hospice Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey* data from January 1, 2020, through September 30, 2020 (Q1-Q3), does not need to be submitted to CMS. *For the *Skilled Nursing Facility (SNF) Value-Based Purchasing Program*, qualifying claims will be excluded from the claims-based SNF 30-Day All-Cause Readmission Measure (SNFRM; NQF #2510) calculation for Q1-Q2.
Hospice Quality Reporting Program		
Inpatient Rehabilitation Facility Quality Reporting Program		
Long Term Care Hospital Quality Reporting Program		
Skilled Nursing Facility Quality Reporting Program		
Skilled Nursing Facility Value-Based Purchasing Program		

For those programs with data submission deadlines in April and May 2020, submission of those data will be optional based on the facility's choice to report. In addition, no data reflecting services provided January 1, 2020–June 30, 2020, will be used in CMS's calculations for the Medicare quality reporting and value-based purchasing programs in order to reduce providers' data collection and reporting burden as they are responding to the COVID-19 pandemic.

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