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COVID-19 Policy Developments

Coverage and Payment

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ADVI is a group of former policymakers, payers, academics and industry veterans. A leading healthcare consultancy, together, we harness insights from actual government, payer, industry, and operations experience—then pair them with expert analysis and data insights for leading organizations in lifescience, digital therapeutics, payers and providers.

Timeline of Federal COVID-19 Policy Developments

March 6

HR 6074: The Coronavirus Preparedness and Response Supplemental Appropriations Act

March 13

President Trump's Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease Outbreak

March 18

HR 6201: The Families First Coronavirus Response Act

March 18

President Trump's Executive Order on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of Covid-19

March 27

HR 748, Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

March 30

Centers for Medicare & Medicaid Services (CMS) Interim Final Rule #1

April 24

HR 266: Paycheck Protection Program & Health Care Enhancement Act

April 30

Centers for Medicare & Medicaid Services (CMS) Interim Final Rule #2

Contents:

Telemedicine

Home Infusion

Hospitals Without Walls

State Authorities

Commercial Plans Response

Elective Procedures

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Telehealth

Telehealth: Snapshot

The Coronavirus Preparedness and Response Supplemental Appropriations Act (HR 6074: link) and President Trump's Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease Outbreak (link) gave the HHS Secretary the authority to waive or modify certain existing telehealth policies. HHS has been actively releasing guidance to provide additional information.

There are 2 key pieces to the telehealth flexibilities:

Reimbursement (CMS)

- Effective for services beginning March 6, "and for the duration of the COVID-19 Public Health Emergency," **Medicare** will pay for telehealth services furnished in any healthcare facility and in a beneficiary's home as if they were regular, in-person visits
- **State Medicaid** programs can provide telehealth services without federal approval
- State **Medicare-Medicaid plans** are receiving memos from CMS allowing them to temporarily suspend or limit face-to-face care coordination required under their contracts with CMS as long as they submit a "written plan"
- Many **private payers** are expanding telehealth benefits and publicly releasing information to beneficiaries

Privacy Protections (OCR)

- HHS Office for Civil Rights (OCR) will exercise enforcement discretion and **waive penalties for HIPAA violations** against providers serving patients "in good faith" through everyday communications technologies during the public health emergency
- This is effective immediately
- A covered health care provider that wants to use audio or video communication technology to provide telehealth can use **any non-public facing remote communication product** that is available to communicate with patients

Telehealth Coverage & Payment: **Medicare**

- For the duration of the COVID-19 public health emergency, Medicare will pay for telehealth services furnished in any healthcare facility and in a beneficiary's home as if they were regular, in-person visits as long as there is real-time audio and video communication
  - Exception for certain telephone E/M codes
  - Claims require a Place of Service (POS) equal to what it would have been if the service had been furnished in-person, and modifier 95, indicating that the service rendered was actually performed via telehealth
- HHS OIG is providing flexibility for providers to reduce or waive usual telehealth cost-sharing requirements
- Initially, CMS only said E/M codes could be furnished via telehealth and paid as if they were in-person
  - Since then, both CMS interim final rules (March 30, April 30) have significantly expanded services that can be furnished via telehealth and paid in full (over 200 CPT® codes now covered: link)
- CMS can now add new services to list of Medicare covered telehealth services via sub-regulatory basis (instead of via standard annual rulemaking)
- CMS has waived limitations on the types of clinical practitioners that can furnish Medicare telehealth services
- Many services can be provided to both new and established patients

Medicare Payment for Virtual Check In and e-Visit

CMS is regularly updating FAQs about Medicare FFS billing during the COVID-19 PHE (link).
A recent update included a table on e-visit and virtual check-in payment rates.

HCPCS	Descriptor	Office-based Payment Rate to the Professional	Facility-based Payment Rate to the Professional
99421	Online digital evaluation and management (E/M) service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	$15.52	$13.35
99422	Online digital E/M service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	$31.04	$27.43
99423	Online digital E/M service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	$50.16	$43.67
G2061	Qualified non-physician healthcare professional online assessment, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	$12.27	$12.27
G2062	Qualified non-physician healthcare professional online assessment service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	$21.65	$21.65
G2063	Qualified non-physician qualified healthcare professional assessment service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21+ minutes	$33.92	$33.56
G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	$14.80	$13.35

Remote Patient Monitoring

In addition to audio/video communication services, Medicare covers remote patient monitoring

- CMS guidance on remote patient monitoring coverage and coding states:
  - “Clinicians can provide remote patient monitoring services to both new and established patients. These services can be provided for both acute and chronic conditions and can now be provided for patients with only one disease. For example, remote patient monitoring can be used to monitor a patient’s oxygen saturation levels using pulse oximetry. (CPT codes 99091, 99457-99458, 99473-99474, 99493-99494)”
  - “We ordinarily require an initiating visit for RPM services, similar to other care management services, but this requirement may be satisfied via a telehealth visit.”
  - “Current CPT coding guidance states that the remote physiologic monitoring service described by CPT code 99454 (device(s) supply with daily recordings or programmed alerts transmission each 30 day(s)), cannot be reported for monitoring of less than 16 days. For purposes of treating suspected COVID-19 infections, Medicare will allow the service to be reported for shorter periods of time than 16 days as long as the other code requirements are met.”

The FDA has also issued guidance to ensure availability of remote monitoring devices during the PHE
Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the COVID-19 PHE
FDA allows expanded use of devices to monitor patients’ vital signs remotely

Coverage/payment for Medicaid is up to each state’s discretion. CMS is allowing waiver applications, SPAs, and managed care contract amendments to extend telehealth and RPM flexibilities as needed

CMS Guidance on Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19, updated 4/29 (link)
CMS COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing, updated 5/15 (link)
FDA Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the COVID-19 PHE, 3/20 (link)
FDA FDA allows expanded use of devices to monitor patients’ vital signs remotely, 3/20 (link)
State Medicaid & CHIP Telehealth Toolkit, updated 4/23 (link)

Telehealth Coverage & Payment: Medicaid

- **State Medicaid programs** can provide telehealth services without federal approval, and the administration has encouraged states to do so
  - States must only submit a disaster relief **state plan amendment** (SPA) if they want to establish payment methodologies for telehealth that differ from those applicable for the same services furnished in a face-to-face setting
  - States may provide payments for services furnished via telehealth if they are made in the same manner as when the service is furnished in a face-to-face setting
    - States may also pay for appropriate ancillary costs
- State **Medicare-Medicaid plans** are receiving memos from CMS allowing for temporary suspension or limited face-to-face care coordination activities required under their contracts with CMS as long as they submit a "written plan" in a timely manner
- States may submit **1135 waiver** requests to ask for temporary modifications for certain Medicare, Medicaid, CHIP, and HIPAA requirements during emergencies

Telehealth: Commercial Policies

Anthem (link)	Humana (link)	Cigna (link)	Blue Cross Blue Shield (link)	Aetna (link)	UnitedHealthcare (link)

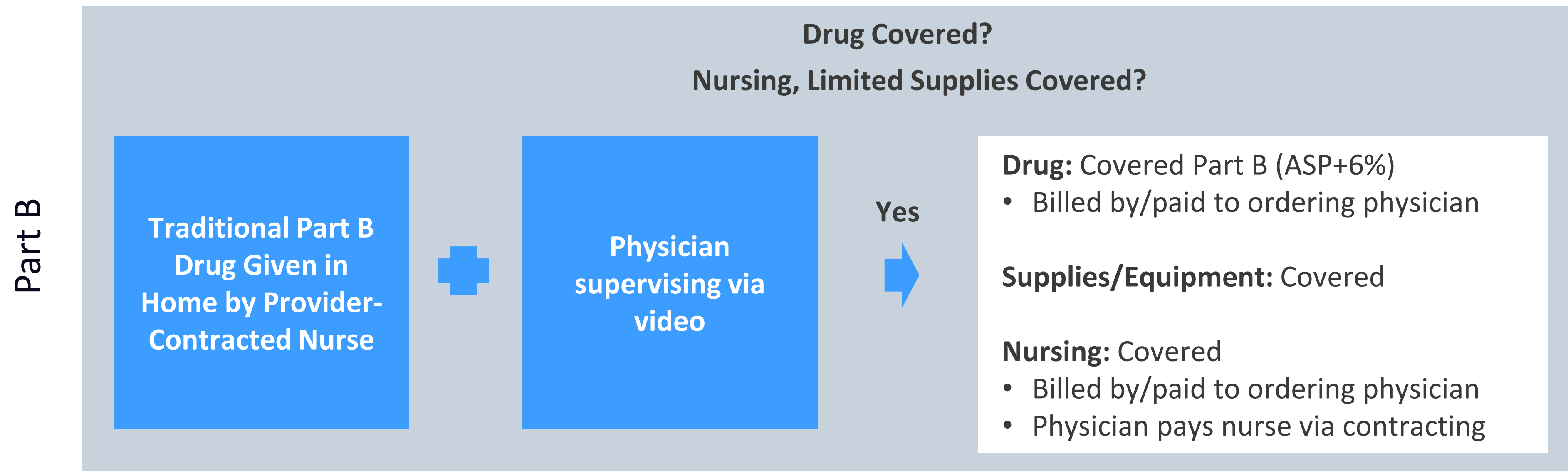
• Waiving member cost-share for telehealth visits, including for behavioral health for employer, individual, MA plans, and where permissible, Medicaid plans
• Cost sharing and copays will be waived for members using Anthem's telemedicine service, LiveHealth Online, and care received from other providers delivering virtual care
• For 90 days effective March 19, affiliated health plans will cover telephonic-only visits with in-network providers.
• Providing telehealth only coverage for 90 days effective March 17, 2020
	• Through the end of 2020, waiving member out-of-pocket costs for telehealth with participating in-network providers, including routine visits for primary and specialty care and behavioral health services.
	• Expanded coverage includes audio-only telephone consultations as well as online visits with current healthcare providers if they are set up to offer telehealth services.
		• Waives customer cost-sharing for telehealth screenings for COVID-19 through May 31, 2020.
		• Cigna will waive customers' out-of-pocket costs for COVID-19 testing-related visits with in-network providers, whether at a doctor's office, urgent care clinic, emergency room or via telehealth, through May 31, 2020.
		• Cigna customers can also receive virtual medical care not related to COVID-19 by physicians and certain providers with virtual care capabilities through May 31, 2020. Out-of-pocket costs may apply.
			• All 36 independently-operated BCBS companies and the Blue Cross and Blue Shield Federal Employee Program are expanding coverage for telehealth services for 90 days.
			• Includes waiving cost-sharing for telehealth services for fully-insured members and applies to in network telehealth providers who are providing appropriate medical services.
			• Expanding access to telehealth and nurse/provider hotlines.
				• Offering a $0 copay for telemedicine visits for the next 90 days, until June 4, 2020.
				• Costs will be waived for all telemedicine visits through:
				  • Tele-doc options through the Aetna Health app
				  • Network providers who deliver virtual care, such as live video-conferencing
				  • Other virtual care apps or services provided as part of plan
				• Through September 30, offering zero co-pay primary care and behavioral health telemedicine visits with network providers to all Individual and Group MA members.
					• For members with a telehealth benefit through their employer-sponsored plan, cost-sharing will be waived until June 18, 2020.
					• Cost-sharing is waived for in-network telehealth visits from March 31, 2020, until June 18, 2020, for members with MA, Medicaid, Individual and Group Market fully insured health plans.
					• Out-of-network and cost-sharing will apply, if applicable.
					• Waived cost-sharing for a COVID-19 testing-related telehealth visit during the national emergency.

Home Infusion

CMS IFR: Traditional Part B Drugs Can be Administered in the Home, Remains Part B Coverage

CMS Interim Final Rule (IFR) on COVID-19: **creates an extension of the physician office to the patient's home, *if the physician is willing***

- Under Medicare Part B, services that are supplied incident to a physician's services require direct supervision from the physician
  - Direct supervision has been defined to mean that physician must be available in the office suite to provide immediate assistance and direction. The physician does not need to be in the same room where the incident to service is performed.
  - CMS recognizes that during the Public Health Emergency (PHE), there are cases where incident to services can be provided safely to a patient without a physician physically present.
- For the duration of the PHE, CMS is changing the definition of direct supervision to the following:
  - "the necessary presence of the physician for direct supervision includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider"
- Physicians will continue to buy and bill "incident to" items. Any auxiliary clinical staff that is contracted to perform the procedure or service will seek reimbursement from the physician.



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CMS Interim Final Rule, March, 30, 2020 (link)

Stakeholder Reaction: CMS IRF Allowing Part B Drugs Administered in the Home

Oncologists: ADVI Advisors' Thoughts

Overall	Administrative burdens	Safety issues	Workforce shortage
• Very concerned about this policy; home infusion is a "suboptimal" way to provide infusion services. • "This could work in very limited circumstances, like with antibiotics."	• "Practices are already so overwhelmed, too much is being asked of them." • "Telemedicine is already so challenging." • "The idea of suddenly being able to get a contract in place with a Home Health agency seems crazy."	• Oncology: There are serious safety concerns with oncology infusions; "every day, emergencies happen at our practice that require close supervision." • "We've already reduced our office volume by 80% to make the office setting a safe environment."	• "We already have nursing shortages with the pandemic, so how will you find a nurse that has time to drive 45 minutes to administer a drug?" • "The only way this could work is if you have high concentration of patients in a geographic area. Also, the practice would have to be ready to go with audio and visual telehealth capabilities, and they must be able to quickly contract with a home health agency. There are so many hurdles."

ASCO: Special Report

- May 19, 2020 (link): A Guide to Cancer Care Delivery During the COVID-19 Pandemic
- "Oncologists have shared concerns regarding the safely and appropriateness of home infusion for anti-cancer drug administration and, generally, do not recommend it for most drugs. The decision to administer chemotherapy in this setting should be made by the treating physician in consultation with the patient after consideration of precautions necessary to protect medical staff, patients, and caregivers from adverse events associated with drug infusion and disposal and risk of COVID-19 infection.
- Oncologist providers may consider home infusion for supportive care, such as hydration and anti-emetics."

National Home Infusion Association (NHIA)

- April 6, 2020 (link)
- IRF "does not establish a practical path."
- The vast majority of physicians do not have the time, resources, and relationships to extend their services to the home through real-time audio and video means.
- NHIA believes barriers to Medicare home infusion can be removed by establishing a comprehensive, bundled payment for professional services, supplies, and equipment — similar to the commercial payer model — that is paid to home infusion providers for each day of infusion.

Community Oncology Alliance (COA)

- April 9, 2020 (link)
- Cites safety concerns for cancer patients, but supports this in other specialties

House Sign-on Letter

- April 13, 2020 (link)
- 181 bipartisan House Members sent letter to CMS urging the administration to temporarily allow Part B infusions in the home to prevent COVID-19 exposure

Guest Editorial on COVID-19 and Cancer Addresses Home Infusion in Oncology

6 THE CANCER LETTER | MAY 8, 2020 | VOL 46 | ISSUE 19

GUEST EDITORIAL

COVID-19 and community cancer care

A PANORAMA OF A CATASTROPHE

The COVID-19 pandemic has been catastrophic to health care in the US.

By Debra Patt, MD, MPH, MBA
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Senior advisor, ADVI Health

Much has been written about the impact on hospitals and on the health care professionals enduring horrific stress to support the acutely ill. These providers are heroes, and we are all indebted to them. But less attention has been paid to the indirect effects of the pandemic on health care, particularly the care delivered to those with chronic medical illnesses.

What has happened to cancer patients? Although we will be able to trace the course of the acute infectious elements of COVID, which play out over weeks and perhaps a couple of months, the impact on cancer care will likely play out over many months and even years.

These effects are important to address from several perspectives, including those of the patient, the provider, the payers, and the research enterprise. Potential lasting effects, both good and

"Recently, CMS allowed home infusion of intravenous cancer therapies. Of course, the rule is complicated and full of restrictions. It requires an accredited home care agency. It requires telemonitoring during the infusion. It requires a complicated financial relationship between the physician and the home care agency providing the infusion.

The overwhelming majority of infusion therapies for cancer require direct physician supervision. Adverse events, like allergy or clinical decompensation, occur frequently in an infusion room and require physician intervention.

The overwhelming majority of infusion therapies for cancer require direct physician supervision. Adverse events, like allergy or clinical decompensation, occur frequently in an infusion room and require physician intervention. **But the patient receiving the trastuzumab for a year, or one receiving denosumab for bone health, or leuprolide for prostate cancer could easily be managed at home.** The key to the realization of this remote monitoring and therapy is the payers."

Source: The Cancer Letter (link), May 8, 2020

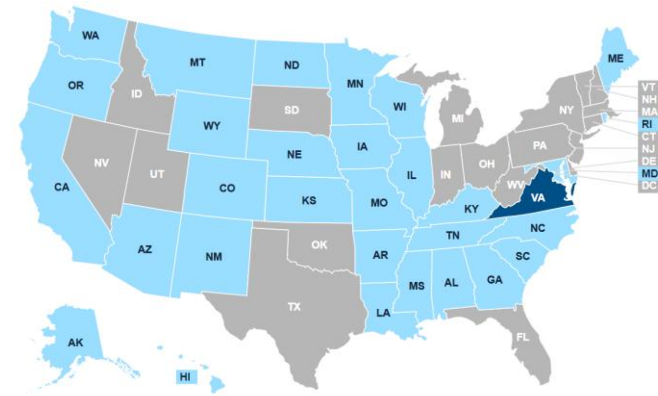
Hospitals Without Walls

“Hospitals Without Walls”

- **The CMS “Hospital Without Walls” initiative intends to increase site of service flexibilities so that hospitals, clinics, and other healthcare facilities can expand their capacity during the pandemic**
- Most flexibilities came in the form of blanket waivers, which providers can take advantage of immediately without needing federal approval
- A few flexibilities include:
  - Transferring/discharging residents between long-term care facilities (LTCH) based on COVID-19 status
  - ASCs can temporarily enroll as hospitals
  - Licensed independent freestanding emergency departments (EDs) can participate in Medicare and Medicaid
  - Medicare-enrolled pharmacies and other suppliers may enroll as independent clinical diagnostic laboratories
  - Certain expanded practitioner authority, such as allowing nurse practitioners, clinical nurse specialists, and physician assistants to provide care previously limited to physician certification
  - Hospitals without teaching programs that accept residents will not be penalized

State Authorities

State Can Apply For Flexibilities via 1135 Waivers and SPAs



Section 1135 Waivers

- States may submit 1135 waiver requests to ask for temporary modifications for certain Medicare, Medicaid, CHIP, and HIPAA requirements during emergencies
- All 50 states and DC have approved 1135 waivers, and many are in their second and third rounds of approvals
- 50 states are allowing out-of-state providers to provide care to Medicaid beneficiaries in the waiver's state
- 49 states are postponing deadlines for revalidation of provider
- 43 states are suspending fee-for-service (FFS) prior authorizations, and 38 are requiring FFS providers to extend pre-existing prior authorizations

State Plan Amendments - Medicaid

- Disaster Relief State Plan Amendments (SPA) allow states to make temporary changes to their Medicaid state plans and address access and coverage issues during the public health emergency
- Actions taken under SPAs include flexibilities toward Medicaid eligibility, enrollment, premiums and patient cost sharing
- 13 states have expanded coverage for testing and related services to uninsured individuals affected by COVID-19, as of May 14

Source: Medicaid.gov (link, link), Kaiser Family Foundation (link)

Commercial Plan Response

Commercial Action & Expanded Coverage

- Per CARES Act, COVID-19 testing must be covered by private insurance without member cost sharing
- Commercial payers are temporarily suspending prior authorization requirements for *(not standard across all payors)*:
  - COVID-19 diagnostic tests and treatment
  - Patient transfers
  - Early prescription drug refills for maintenance medications
- Expansion of commercial coverage and additional offerings in response to the pandemic varies across each entity

Humana

- Covering all medical costs related to COVID-19 treatment, as well any FDA-approved medications or vaccines
- Waive member cost share for all telehealth services furnished by in-network providers
- Providing financial relief for the health care provider community
- Deployed $50M in immediate short-term and long-term relief with national and community service organizations

Humana

Cigna

- Covering all medical costs related to COVID-19 treatment
- Staffing a second phone line for customers
- Launching pilot program to increase social connectivity among its Medicare Advantage customers
- Providing medications to Washington University School of Medicine to initiate a clinical trial that will evaluate treatments for COVID-19

UnitedHealth

- Covering all medical costs related to COVID-19 treatment
- Waiving cost sharing for in-network, non-COVID-19 telehealth visits
- Accelerate nearly $2B in payments and other financial support to health care providers across the country
- Donating $5M to Mayo Clinic in their efforts to expand the availability of investigational convalescent plasma treatments for COVID-19

Source: America's Health Insurance Plans, AHIP (link, updated May 14, 2020)

Reopening and Elective Procedures

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Guidance from the White House

The Administration released guidelines for "Opening Up America Again", a 3-phased approach based on the advice of the Centers for Disease Control and Prevention (CDC) and other public health experts

Phase 1

- For states and regions that satisfy the "gating" criteria
- Prohibited visits to senior living facilities and hospitals
- Elective surgeries can resume, in the outpatient setting only

Phase 2

- For states and regions with no evidence of a rebound and that satisfy the gating criteria a second time
- Prohibited visits to senior living facilities and hospitals
- Elective surgeries can resume, in both the outpatient and inpatient setting

Phase 3

- For states and regions with no evidence of a rebound and that satisfy the gating criteria a third time
- Visits to senior living facilities and hospitals can resume

White House Guidelines released April 16: (link)

Guidance from CMS

Following the Administration's unveiled plans for "Opening Up America Again", CMS offered recommendations for re-opening facilities to provide non-essential care, including guidance on the following topics:

- Usage of personal protective equipment (PPE)
- Adequate safety protocols for the healthcare workforce
- Sanitation standards are met
- Ensuring there is adequate supply of medical equipment, medications and supplies
- COVID-19 testing capacity

CMS has issued recommendations for providers to limit all non-essential planned surgeries and procedures until further notice, following a 3-tiered approach:

Tiers	Definition	Action
Tier 1	**Low Acuity Treatment or Service**	Consider postponing service or follow-up using telehealth, virtual check-in, or remote monitoring
Tier 2	**Intermediate acuity treatment or service:** Not providing the service has the potential for increasing morbidity or mortality	Consider initial evaluation via telehealth; triage to appropriate sites of care as necessary; If no current symptoms of concern, consider virtual follow-up
Tier 3	**High acuity treatment or service:** Lack of in-person treatment or service would result in patient harm	CMS does not recommend postponing in-person evaluation; consider triage to appropriate facility/level of care as necessary

"OPENING UP AMERICA AGAIN" Guidance Memo released by CMS on April 19, 2020 (link)
CMS Non-Emergent, Elective Medical Services, and Treatment Recommendations released on April 7, 2020 (link)

ADVI Angle

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- CMS has issued unprecedented levels of flexibility for providers during the public health emergency
- They continue to issue guidance and respond to public comments as the climate of COVID-19 evolves across the country
- Which temporary policies are here to stay long-term is still unknown
  - Industry experts have suggested that the shift towards telemedicine may stick, although in a reduced manner
- We expect much of the biopharma focus to be on supply chain issues, as President Trump has touted "Buy American" Executive Order
- Diagnostic and device manufacturers will work on CURES 2.0, focusing on FDA approval, deeming coverage, and other issues
- Remote monitoring and home infusion exceptions may not persist but advocacy could be persuasive here if data supports use

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