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Overview of COVID-Related Regulatory Action

Billy Wynne, J.D.
Wynne Health Group
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Improving Health is our Policy

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+ Unfolding Threads

POTUS invoked but refrained from exercising the DPA in favor of negotiating with companies to manufacture necessary equipment and supplies. Some masks and PPE have been obtained but frontline responders still lack necessary equipment. Negotiations for production of ventilators have been delayed due to debate regarding need.

States have increasingly issued stay-at-home and other social distancing orders, though POTUS has begun exploring the possibility of relaxing national recommendations by April 12.

The Administration is considering launching a special enrollment period for the Healthcare.gov federal exchange.

+ COVID-19 Plan & Provider Guidance

Issue	Details	WHG Perspective
Benefits and Coverage	<ul style="list-style-type: none"> • <u>March 12</u>: CMS issued FAQs to ensure individuals, issuers, and states have clear information on coverage benefits for COVID-19 based on the ACA's EHBs • <u>March 18</u>: CMS issued FAQs to clarify coverage under catastrophic health plans for the diagnosis and treatment of COVID-19 	<ul style="list-style-type: none"> • CMS will permit catastrophic plans to cover COVID-19 diagnostic and treatment services pre-deductible • Enforcement relief does not apply to issuers that reduce other benefits to offset coronavirus-related services
Provider Flexibilities	<ul style="list-style-type: none"> • <u>March 13</u>: CMS released a fact sheet outlining provider flexibilities in response to the national emergency declaration, including Section 1135 waivers of certain Medicare, Medicaid, and CHIP requirements and how they apply to different settings of care 	<ul style="list-style-type: none"> • Temporarily allowing licensed providers to furnish services in states where they are not licensed • Established a hotline for non-certified Part B providers and suppliers to enroll and receive temporary Medicare billing privileges • Waiving a series of appeals processes and requirements
Non-Essential Elective Surgery	<ul style="list-style-type: none"> • <u>March 18</u>: CMS issued tiered recommendations for health care providers on limiting non-essential adult elective surgery and medical and surgical procedures, including all dental procedures 	<ul style="list-style-type: none"> • CMS recommends not postponing only if the patient is high acuity

+ Additional COVID-19 Responses

N95 Masks & PPE

- White House invoked but has not yet activated the Defense Production Act to **accelerate production of N95 masks**. Up to 5M masks could be produced under this authority.
- CMS released guidance on CDC's **PPE recommendations** for all providers, including that protective facemasks are acceptable when respirators are not available.

Telehealth

- Medicare telehealth services **available to all FFS beneficiaries**, regardless of location or site of care (including home).
- CMS reiterated existing MA telehealth authority, offering flexibility for plans to change their benefit packages in response to the COVID-19 outbreak.

Infection Control

- CMS released **guidance** re: key infection control measures.
- Guidance outlines **screening procedures** for staff, patients, and visitors; monitoring and restricting staff if infected; where to place patients with COVID-19; patient transfers; home care; and more.

+ Additional COVID-19 Responses

Diagnostic Tests

- FDA issued the first Emergency Use Authorization (EUA) for a point-of-care COVID-19 diagnostic test on March 21.
- BARDA to fund a fourth COVID-19 diagnostic test.
- FDA announced new **state flexibilities** for authorizing diagnostic tests developed in state labs.

Treatments and Vaccines

- BARDA to support phase 2/3 **clinical trial** to evaluate potential treatment for severely-ill COVID-19 patients (Kevzara).
- New York state launched drug trials for use of hydroxychloroquine in treating COVID-19.
- NIH launched into early clinical trial phase new vaccine.

Section 1135 Waiver Authority

- States may submit section 1135 waiver applications to waive certain Medicare/Medicaid/CHIP prior auth, provider enrollment, et al. requirements.
- To-date, CMS has approved 13 state 1135 waiver applications (including in **CA and NJ**).

Thank You!

*Free access to COVID-19
updates & analysis at
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