Wynne Health Group

Memorandum *March 19, 2020*

SENATE REPUBLICANS' "PHASE 3" CORONAVIRUS STIMULUS PACKAGE

On March 19, **Senate Majority Leader Mitch McConnell (R-KY)** released the **"phase 3" coronavirus stimulus package** (attached). The Senate is expected to vote on the package early next week.

Below is a summary of the health-related provisions that address supply shortages, coverage of COVID-19 diagnostic testing, support for health care providers, Medicare flexibilities, among other issues (Title I of Division D, beginning on p. 94).

Subtitle A – Addressing Supply Shortages

Part I – Moving the Strategic National Stockpile to the Assistant Secretary for Preparedness and Response (ASPR)

- **Sec. 4101. Strategic National Stockpile** – Transfers the responsibility of the Strategic National Stockpile from the Centers for Disease Control and Prevention (CDC) to ASPR.

Part II – Medicare Product Supplies

- **Sec. 4111. NASEM Report on Medical Product Supply Chain Security** – Requires the Department of Health and Human Services (HHS) to contract with the National Academies of Sciences, Engineering, and Medicine (NASEM) to study the security of the United State medical product supply chain. The report will be used to evaluate the dependence of the U.S. on other countries for critical drugs and devices and the potential economic impact of increase domestic manufacturing.

- **Sec. 4112. Medical Supplies in the Stockpile** – Requires the National Strategic Stockpile to include the following supplies: personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccine, and other biological products, medical devices, and diagnostic tests.

- **Sec. 4113. Respiratory Protective Devices –** Considers respiratory protective devices approved by the National Institute for Occupational Safety and Health (i.e., N95 respirators) to the list of covered countermeasures under the PREP Act (details), meaning use of such products is immune from liability for any loss caused or related to the use of such countermeasures during declared public health emergencies.

Part III – Mitigating Emergency Drug Shortages

- **Sec. 4121. Prioritize Reviews of Drug Applications; Incentives** – Requires the HHS Secretary to prioritize and expedite the review and inspection of a new drug application to mitigate or prevent such shortage, if HHS suspects that there may be a drug shortage.

- ***Sec. 4122. Additional Manufacturer Reporting Requirements in Response to Drug Shortages*** – Requires a manufacturer of a drug that is critical to the public health during a public health emergency to notify the HHS Secretary if the drug is discontinued or production is interrupted. Notification must include reasons for discontinuation or interruption, if an active ingredient is the reason for discontinuation or interruption, and the source of the active ingredient. A manufacturer that produces a drug that is critical to the public health must develop a contingency and redundancy plan to help prevent or mitigate interruption in the supply of the drug. The HHS Secretary is required to transmit a report regarding the current drug shortage list every 90 days to the Centers for Medicare and Medicaid Services (CMS).

- **Sec. 4123. GAO Report on Intra-Agency Coordination** – Requires the Government Accountability Office (GAO) to submit a report examining the FDA's intra-agency coordination, communication, and decision making in assessing drug shortage risks, and taking correction action (due within two years).

- **Sec. 4124. Report on Incentives to Address Drug Shortages** – Requires the HHS Secretary, in coordination with the FDA and CMS, to submit a report on recommendations to incentivize manufacturing drugs in shortage, and technologies to address drug shortage challenges.

Part IV – Preventing Essential Medical Device Shortages

- **Sec. 4131. Discontinuance or Interruption in the Production of Medical Device Shortages** – Requires a manufacturer of a device that is critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care to notify the HHS Secretary of a discontinuance or interruption in manufacturing. Notification must be made at least 6 months in advance of the discontinuance or interruption and the information will be made publicly available.

  If the Secretary concludes that a shortage is likely, the Secretary may prioritize and expedite the review and inspection of medical devices to mitigate or prevent the shortage. Additionally, the Secretary is to establish a medical device shortage list to be made available to the public.

- **Sec. 4132. GAO Report on Intra-agency Coordination** – Requires GAO to submit a report examining the FDA intra-agency coordination, communication, and decision-making in assessing device shortages and risk associated with the supply chain (due within 18 months)

Part V – Emergency Use of Laboratory Developed Tests

- **Sec. 4141 Emergency Use of Laboratory Developed Tests** – Allows the following diagnostic tests intended to diagnose COVID-19 to marketed in the U.S during the public health emergency if the test (1) is developed in State labs in which the State intends to authorize the test; (2) is developed in laboratories that are certified to conduct high-complexity testing and are pursuing Emergency Use Authorization (EUA); and (3) is an in vitro diagnostic test for which the manufacturer meets the requirements imposed on laboratories certified to conduct high-complexity testing pursuant to EUA

<u>Subtitle C – Innovation</u>

- **Section 4301. Removing the Cap on Other Transactions Authority (OTA) –** Requires that competitive procedures be used when the Biomedical Advanced Research and Development Authority (BARDA) is entering into other transactions, other than procurement contracts, grants, and cooperative agreement

- **Sec. 4302: Extending Priority Review Program** – Eliminates the sunset clause that would end the priority review program, which awards priority review vouchers to manufacturers of medical countermeasures to national security threats, after October 1, 2023

- **Sec. 4303. Priority Zoonotic Animal Drugs –** Requires the HHS Secretary to expedite the review and approval process of new animal drugs if the preliminary clinical evidence indicates that the drug has the potential to treat a zoonotic disease that poses a serious threat to humans. The sponsor of the new animal drug may also request a "priority zoonotic animal drug" designation to expedite the approval process.

<u>Subtitle B – Access to Health Care for COVID-19 Patients</u>

Part I – Coverage of Testing and Preventive Services

- **Sec. 4201. Coverage of Diagnostic Testing for COVID-19 –** Requires that all group health plans and health insurance issuers on an Affordable Care Act (ACA) Exchange must provide coverage of diagnostic testing and items and services furnished during provider visits that result in a diagnostic test (including physician offices, urgent care centers, and emergency rooms). Further, it would require that the aforementioned services be covered without the imposition of any cost-sharing requirements (including deductibles) or any prior authorization or other medical management requirements.

- **Sec. 4202. Pricing of Diagnostic Testing –** Applies negotiated rates between health plans and providers for the reimbursement of administering diagnostic tests. If a negotiated rate does not exist, the bill would require a health plan to reimburse the provider for the cash price of the diagnostic test "as listed by the provider on a public internet website." In relation to the reference to a publicized cash price, each provider of a diagnostic test for COVID-19 would be required to make the cash price of the test publicly available on a public-facing internet site of the provider. HHS would be permitted to impose a civil monetary penalty that does not comply with the requirement to publicize a diagnostic test's cash price of up to $300 per day that the provider is in violation of the requirement.

- **Sec. 4203. Rapid Coverage of Preventive Services and Vaccines for Coronavirus –** Requires group health plans and ACA plan issuers to cover any qualifying COVID-19 preventive service. Qualifying preventive services are defined on p. 126 of the bill text.

Part II – Support for Health Care Providers

- **Sec. 4211. Supplemental Awards for Health Centers –** Appropriates $1.32 billion to Health Centers (as defined under Section 330 of the Public Health Service Act) for fiscal year 2020 for supplemental awards directed towards COVID-19 prevention, diagnosis, and treatment.

- **Sec. 4212. Allowing Permanent Direct Hire of NDMS Health Care Professionals –** Authorizes HHS to directly hire intermittent disaster response personnel within the National Disaster Medical System if additional personnel are deemed necessary.

- **Sec. 4213. Telehealth Network and Telehealth Resource Grant Programs –** Makes changes to and broadens the scope of telehealth network grants available through the Telehealth Network Grant Program, administered by the Health Resources and Services Administration (HRSA).

- **Sec. 4214. Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement Grant Programs –** Enhances and broadens the scope of grants available through the rural emergency medical service training and equipment assistance program.

- **Sec. 4215. United States Public Health Service Modernization –** Clarifies rules around deployment of the Commissioned Corps and Ready Reserve Corps that permits deploying them in times of a public health emergency (instead of only during a national emergency), among other technical changes.

- **Sec. 4216. Limitation on Liability for Volunteer Health Care Professionals During COVID-19 Emergency Response –** Limits liability under federal and state law on health care providers acting as volunteers for any harm caused in the process of treating COVID-19 during the public health emergency.

Part III – Miscellaneous Provisions

- **Sec. 4221 – Confidentiality and Disclosure of Records Relating to Substance Use Disorder –** Amends Health Insurance Portability and Accountability Act (HIPAA) rules around sharing of patient records with substance use disorder. These changes include allowing a covered entity under HIPAA to share a patient's records for purposes of treatment, payment, and health care operations after consent is given once and for all by the patient.

- **Sec. 4222. Nutrition Services –** Authorizes HHS to allow a state agency or area agency on aging (AAA) to transfer funds for use however the state or AAA sees fit to meet the needs of the area served. In addition to serving those who are homebound because they are ill, home-delivery nutrition services are also authorized for individuals who are unable to obtain food because of social distancing due to the emergency. For the meals provided, dietary guidelines are waived.

- **Sec. 4223. Guidance on Protected Health Information –** Within 180 days of enactment HHS will issue guidance on sharing patients' protected health information that includes compliance with HIPAA as well as any other policies that may take effect during the emergency.

- **Sec. 4224. Reauthorization of Healthy Start Program –** Reauthorizes the program and appropriates $122,500,000 each fiscal year from 2020 through 2024. Makes technical changes related to evaluations and other elements and requires a GAO report within four years.

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Subtitle D – Finance Committee

- **Sec. 4401. Safe Harbor for HDHPs Relating to Telehealth** – Establishes a safe harbor for high deductible health plans (HDHPs) that provide benefits for telehealth and other remote care services before patients satisfy the applicable minimum deductible (applies to plan years beginning on or after December 31, 2021). Therefore, these plans would still be treated as HDHPs.

- **Sec. 4402. Inclusion of Menstrual Care Products as Qualified Medical Expenses** – Adds menstrual care products to the list of qualified medical expenses that may be paid with health savings accounts (HSAs), Archer MSAs, flexible spending arrangements (FSAs), or health reimbursement arrangements (HRAs) (applies to amounts paid after December 31, 2019).

- **Sec. 4403. Direct Primary Care Service Arrangements** – Prohibits direct primary care service arrangements from charging an individual more than $150 per month; states that procedures that require the use of general anesthesia, and laboratory services (not typically administered in an ambulatory primary care setting) are not considered primary care services; and treats direct primary care service arrangement fees as medical expenses for the purposes of HSAs (applies to months beginning after December 31, 2019)

- **Sec. 4404. Medicare Telehealth Flexibilities** – Allows Medicare payment for telehealth services furnished by a provider to a patient even if the provider does not have an existing relationship with that patient (limited to the duration of the public health emergency).

- **Sec. 4405. Medicare Telehealth for FQHCs and RHCs** – Requires HHS to pay for telehealth services that are furnished by a Federally qualified health center (FQHC) or a rural health clinic (RHC) to Medicare beneficiaries during the emergency period (payment will be based on comparable telehealth services under the physician fee schedule).

- **Sec. 4406** – **Home Dialysis Waiver –** Authorizes HHS to waive the requirement for face-to-face clinical assessments for individuals with end stage renal disease receiving home dialysis during the emergency period.

- **Sec. 4407 – Home Health Services** – Allows a nurse practitioner, clinical nurse specialist, or a physician assistant to provide home health services to Medicare beneficiaries and Medicaid beneficiaries for the purposes of payment.

- **Sec. 4408. Adjustment of Sequestration** – Temporarily suspends Medicare sequestration for May 1-December 31, 2020. Extends direct spending reductions through 2030 instead of through 2029.

- **Sec. 4409. Medicare Hospital Inpatient Prospective Payment System Add-On Payment for COVID-19 Patients During Emergency Period** – Increases the weighting factor by 15 percent for all discharges with a principal or secondary diagnosis of COVID-19 and this change will not be considered with respect to budget neutrality.

- **Sec. 4410. Revising Payment Rates for Durable Medical Equipment Under the Medicare Program Through Duration of Emergency Period** – Modifies Medicare payment rates for DME in rural areas, noncontiguous areas, and areas that are neither rural or noncontiguous.

- **Sec. 4411. Providing Home and Community-Based Services in Acute Care Hospitals** – Allows home and community-based services to be provided in acute care hospitals in certain circumstances in light of COVID-19 including when identified in an individual's person-centered plan of services and supports, or a comparable plan.

- **Sec. 4412. Treatment of Technology-Enabled Collaborative Learning and Capacity Building Models as Medical Assistance** – Allows states to provide medical assistance through technology-enabled collaborative learning and capacity building models used by providers under the state plan or another waiver regardless of requirements related to statewideness, comparability, and freedom of choice of providers (as otherwise is currently required). Makes federal financial assistance for this type of medical assistance available when providers use the technology-enabled collaborative learning and capacity building model to train health professionals in protocols for responding to public health emergencies during the emergency period, and any future period related to COVID-19. Other limitations and requirements are discussed.

- **Sec. 4413. Encouraging the Development and Use of Disarm Antimicrobial Drugs** – Makes additional payments for DISARM antimicrobial drugs available under Medicare for discharges between Oct 1, 2021-October 1, 2026. Additional payments will be made available after a public comment period. Defines DISARM antimicrobial drugs as a drug approved by the FDA as a qualified infectious disease product or antibacterial or antifungal product, within certain limitations. A list of DISARM antimicrobial drugs will be listed in the Federal Register between Oct 1, 2021 and Oct 1, 2025. Calls for studies focused on removing barriers to the development of DISARM microbial drugs, with a report to be submitted by October 1, 2025.

- **Sec. 4414. Novel Medical Products** – The Secretary will modify the Healthcare Common Procedure Coding System (HCPCS) code set at least once per quarter to expedite coding of novel medical products. New HCPCS codes will potentially be assigned to products designated as breakthrough therapies, breakthrough devices, or regenerative advance therapies. Such codes will allow data tracking and collection related to utilization and outcomes. Trade secrets and confidential information will not be disclosed.

  Defines novel medical products as drugs, biological products, or medical devises that have not been assigned HCPCS codes, have been designated as breakthrough therapies, breakthrough devices, or regenerative advance therapies. A code modifier will be established within the hospital inpatient prospective payment system for inpatient products.

  Directs the Secretary to facilitate an efficient and expedited coverage pathway to expedite a national coverage decision for products described here with "coverage with evidence development". Within 4 years of issuing national coverage determination, the Secretary will submit to Congress and the manufacturer a report with options and recommendations for alternative payment models for the novel medical product or class of products.

Within 12 months, the Secretary will convene a public meeting to discuss strategies for improving coordination between FDA and CMS in preparation for making novel medical products available. Defines meeting participants and topics.

Within 18 months of the public meeting, the HHS Secretary will update guidance and will finalize guidance within 12 months after that.