THE FEDERAL GROUP, INC.

To: Greg Chavez, CEO
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From: Patrick Cooney

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Re: Coronavirus Federal Update

The Senate is scheduled to return to Washington, DC, next week to begin additional legislation to address the coronavirus (COVID-19) pandemic. The House of Representatives is not scheduled to convene next week due to member concerns about the virus. It is not known when the House will reconvene, but it is clear that preparations and negotiations for the next COVID-19 legislative phase are under way. It appears the next legislative effort may be more contentious than previous bipartisan efforts.

One issue that has been raised is the funding of states and local governments as they deal with the downturn in the economy and address the pandemic. While Republicans have not shared much yet on what they want to see in the next legislative vehicle, Senator Mitch McConnell (R-KY) did indicate recently that he wants immunity for businesses during this pandemic period.

Democrats have outlined several proposals that may be of interest to the DTA membership. Details on those proposals are outlined below for your review. The first two are partisan proposals to address the supply chain and frontline worker hazard pay. The third is a bipartisan proposal to build upon the Cures for the 21st Century Act. It is not clear whether the Democrat proposals will end up on the President's desk, but it is important for DTA members to be knowledgeable about what is being proposed as these proposals would impact their operation.

Proposal to Federalize the Medical Supply Chain

Senator Tammy Baldwin (D-WI) and Senator Tim Murphy (D-CT) both members of the U.S. Senate Health, Education, Labor and Pensions Committee, as well as Senate Democratic Leader Chuck Schumer, on Wednesday, April 29th announced legislation that lays out a framework for an effective COVID-19 response by federalizing and adding critical oversight and transparency to the supply chain for critical medical supplies and equipment. The Medical Supply Transparency and Delivery Act requires the president to utilize all available authorities under the Defense Production Act to mobilize a federal response to the pandemic through an equitable and transparent process. 46 Senate Democrats support this legislation, as well as AFL- CIO, SEIU, the National Nurses United, and United Steelworkers. Representatives Katie Porter (D-CA), Jason Crow (D-CO), Elissa Slotkin (D-MI), and Tim Ryan (D-OH) will introduce the House companion of this legislation.

The Medical Supply Transparency and Delivery Act would:

- Require publicly reported national assessments on a weekly basis to determine national critical equipment supply and requirements.

- These reports will also identify industry sectors and manufacturers most ready to fill orders, stockpiles that can be refurbished or repaired, manufacturers that could expand production into PPE and medical supplies, and supplies and equipment that can be redistributed to new hotspots.

- These reports would also include direct outreach with essential employees and healthcare workers.

- Establish an Executive Officer to oversee acquisition and logistics for COVID-19 equipment production and delivery.

- The Executive Officer will have all the authorities available under the DPA.

- The Executive Officer is required to issue major purchase orders under DPA for supplies identified in the assessments, oversee all distribution of critical medical supplies, and make recommendations to the President on increasing national production capacity of supplies.

- The Executive Officer will be a civilian position appointed by the Secretary of the Defense and will be authorized additional uniformed and DOD civilian personnel in supporting roles.

- The Executive Officer will ensure that all unused supplies in excess of need will be turned over to the Strategic National Stockpile.

- The Executive Officer will terminate after confirming to Congress that all State and territorial medical supply needs have been met and national stockpiles have been replenished.

- Increase transparency regarding the distribution of supplies and equipment.

- The Executive Officer is required to publicly post all states' requests for assistance, metrics and criteria for amount and destination of distribution, metrics for determining hotspots and areas of future concern, and production and procurement benchmarks.

- Require a comprehensive plan for COVID-19 testing, including viral and antibody testing.

- Establish a comprehensive plan to address necessary supply chain issues in order to rapidly scale up production of a COVID-19 vaccine.

- Require a GAO report to identify lessons learned and make recommendations on future pandemic response.

- Establish an Inspector General to oversee implementation of the Act.

Proposal for Frontline Workers Hazard Payments

On April 7th, Senate Democratic Leader Chuck Schumer (D-NY), Senate Committee on Health, Education, Labor, and Pensions Ranking Member Patty Murray (D-WA), Senate Committee on Banking, Housing, and Urban Affairs Ranking Member Sherrod Brown (D-OH), Senate Committee on Aging Ranking Member Bob Casey (D-PA), Senate Committee on Indian Affairs Vice Chairman Tom Udall (D-NM), and Senate Committee on Homeland Security and Governmental Affairs Ranking Member Gary Peters (D-MI) unveiled the COVID-19 “Heroes Fund,” Senate Democrats’ proposal for the provision of pandemic premium pay to reward, retain, and recruit essential workers.

The proposal would provide:

1. A $25,000 pandemic premium pay increase for essential frontline workers, equivalent to a raise of an additional $13 per hour from the start of the public health emergency until December 31, 2020.

2. A $15,000 recruitment incentive for health and home care workers and first responders to attract and secure the workforce needed to fight the public health crisis.

Structure of the Pandemic Premium Pay

To meet the goals of reward, retention, and recruitment, they propose a set dollar amount per hour with a maximum amount for the year, for a definite duration, and with an additional bonus for workers who sign up to do such essential work during this crisis.

Amount of Pay Premium

- Uses a flat-dollar amount per hour premium model in order to ensure it is clear, simple, and lifts up particularly those workers making lower wages.

- Would give each essential frontline worker $13/hour premium pay on top of regular wages for all hours worked in essential industries through the end of 2020.

- Would cap the total maximum premium pay at $25,000 for each essential frontline worker earning less than $200,000 per year and $5,000 for each essential worker earning $200,000 or more per year.

Duration of Premium

- Must be for a specified and clear duration of time to ensure workers can rely on it for their economic security and plan for needs like additional child care.

- Should cover all hours worked by each essential frontline worker through December 31, 2020, or until the worker's salary-based maximum premium pay is reached.

Premium Pay as a Recruitment and Retention Incentive

- Would provide a one-time $15,000 premium for signing on to do essential work.

- Would limit eligibility for this incentive premium to essential health and home care workers and first responders that are experiencing severe staffing shortages impeding the ability to provide care during the COVID-19 pandemic.

Premium Pay and Worker Incentives Delivery Mechanism

The proposal would fully federally-fund the premium pay and recruitment and retention incentive. The new federal fund would partner with entities designated as an "eligible employer" – states, localities, tribes, and certain private sector employers – to issue the funds premium payments to eligible workers. Frontline federal employees would also be granted the new benefit of up to $25,000.

The new COVID-19 Heroes Fund would provide funds directly to eligible employer-partners so that they could distribute the premium payments.

- Employers in industries engaged in "essential work" would apply to the Heroes Fund for funds to be used to add line-item premium pay to employees' or independent contractors' paychecks. The eligible employer would track these payments, provide payroll records demonstrating premium payments, and return any unspent funds to the agency.

- No employer would be required to participate, but all would be strongly encouraged to and the program would be widely advertised.

- An entity that contracts directly with the state, locality, Tribe, or the federal government (e.g., to provide care to people with Medicare and Medicaid coverage) would be considered a private sector employer, and employees of this entity who are designated as "essential" would be eligible for premium pay. Similarly, an eligible employer is also an individual who hires someone designated as "essential" through programs established through the State (e.g., self-directed care arrangements).

- Eligible employers would submit applications for the recruitment and retention incentive premium on a rolling basis.

Proposal to Expand Upon the Cures for the 21st Century Act – CURES 2.0

The 21st Century Cures Act is helping to advance medical research and foster a new era of medical innovations that may one day establish new cures for the world's cruelest diseases. The current pandemic is a stark reminder that more is needed.

Efforts on a "Cures 2.0" package continue, including a number of policies that could be beneficial to the work the federal government is doing in response to the current pandemic.

Summary of the Cures 2.0 Proposal

TITLE I: PUBLIC HEALTH

National Testing and Response Strategy for Current and Future Pandemics: requires a national strategy that addresses testing, data sharing infrastructure, administration of vaccines and therapeutics, and medical supply readiness to mitigate current and future pandemics.

COVID-19 Rare Disease Support Program: establishes a program to help financially vulnerable individuals with rare diseases and their families by providing financial assistance for COVID-19-related expenses.

Pandemic Preparedness Program for Patients: establishes a federal grant program for organizations to develop plans to help patients overcome challenges in pandemics.

Improving U.S. Pandemic Preparedness and Response through Support of Antimicrobial Resistance Product Commercialization: provides resources and regulatory authorities necessary to bolster the commercial market for new antibiotics.

Vaccine and Immunization Programs: improves the education of all Americans on the importance of vaccines and strengthens and supports the capacity of the Immunization Information System (IIS) within the Centers for Disease Control and Prevention.

TITLE II: CAREGIVER INTEGRATION

Educational programs and training for caregivers: funds educational programs and training for caregivers to learn skills which would allow them to augment a care team and complement, not compete with, a clinical visit.

TITLE III: PATIENT ENGAGEMENT IN HEALTH CARE DECISION-MAKING

Increasing Health Literacy to Promote Better Outcomes for Patients: requires the Centers for Medicaid and Medicare Services (CMS) to solicit input on how the agency can work with federally subsidized health care program stakeholders to encourage and promote greater health literacy.

TITLE IV: CLINICAL TRIALS

Diversity in Clinical Trials: ensures that Medicaid covers the routine care costs of clinical trial participation for enrollees with life-threatening conditions; requires an update from the U.S. Food and Drug

Administration (FDA) on efforts to improve diversity in clinical trials: requires the Department of Health and Human Services (HHS) to utilize its multiple programs and communication channels to increase awareness and understanding of clinical trials; and establishes a task force on making clinicaltrials.gov more user- and patient-friendly.

Trial Sites at Care Sites: calls on CMS, in collaboration with FDA and the National Institutes of Health, to take steps to improve access to already covered medical services at clinical trial sites.

TITLE V: FDA

Coordinated FDA Approach on Digital: requires (1) updates from FDA on coordination of digital efforts across the agency; (2) guidance on digital endpoints for regulatory review, acceptance of decentralized trials, and use of digital health technologies in patient-focused development of products; and (3) updates on how FDA will coordinate with foreign regulators to ensure harmonization on the regulation and use of digital health technologies.

FDA Grant-making Authority and Funding: provides grants in the area of innovative clinical trial design and patient-focused drug development to further build the science in these areas.

Increasing Use of Real-World Data/Evidence: builds on FDA's efforts by (1) requiring guidance on utilizing real-world evidence (RWE) in Breakthrough Therapy and Accelerated Approval drugs; (2) requiring HHS to establish a consistent framework for RWE; and (3) establishing a task force to develop recommendations on ways to encourage patients to engage in real-world data generation.

Improve FDA-CMS communication regarding transformative new therapies: establish an automatic communication requirement between FDA and CMS for Breakthrough Therapy drugs.

TITLE VI: CMS Modernization

The sponsors are asking for policy input on:

• General Coverage Modernization

• Cell and Gene Therapies

• Medical Products for Small Patient Populations

- What are the biggest impediments to new cures development for these important populations?
- What steps can policymakers take to address these impediments, if any?

• Genomic Sequencing

• Breakthrough Coverage