April 7, 2020

The Honorable Nancy Pelosi
Majority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Chuck Schumer
Minority Leader
United States Senate
Washington, DC 20510

Dear Speaker Pelosi, Minority Leader McCarthy, Majority Leader McConnell, Minority Leader Schumer:

The Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) thank you for your continued leadership in the federal response to the COVID-19 pandemic and the three major pieces of legislation you have enacted so far. Our members' focus is the prevention, diagnosis, treatment and cure of infectious diseases, and we are on the frontlines of this pandemic. We continue to lack the essential equipment, workforce and resources necessary to confront this unprecedented public health crisis. We urge Congress to continue supporting the federal response by conducting oversight to ensure appropriated funding is optimally utilized and providing new policy flexibility and resources to meet urgent needs. Below we offer specific recommendations regarding essential medical equipment, testing capacity, workforce, secondary bacterial infections and for populations at higher risk, the insufficient access to health care and support services necessary to control the spread of the virus. In particular, we need to point out that when things return to "normal", this virus will still be circulating in cycles until enough of us are immune or a vaccine is available—and that means that we will continue to need an adequate workforce, testing supplies and public health support to conduct contact tracing for new infections. Before the pandemic the fabric of our public health system had been torn, and the pandemic shows us that this critical infrastructure must be repaired for the future.

IDSA and HIVMA are happy to continue to be a resource to you throughout this pandemic and its aftermath when it will be necessary to rebuild and retool our infrastructure to be prepared for future public health crises. In addition to policy recommendations, we can answer any questions you may have about COVID-19 and the response, and our members would be happy to participate in telebriefings with their Members of Congress to help answer constituents' questions.

National Strategy to Ensure Availability of Personal Protective Equipment (PPE) and Critical Care Medical Supplies

We thank you for recent legislation that will provide critical funding for the purchase of essential medical supplies, including PPE, testing supplies and ventilators. Unfortunately, we continue to experience firsthand the inadequacy of PPE supplies. **We urge you to 1) establish a national, long term strategy for the rapid manufacture and appropriate distribution of medical supplies that directs the administration to fully utilize all available mechanisms, including complete activation of the Defense Production Act, 2) require transparency in the decision-making for the distribution of medical supplies and equipment to ensure distribution to the regions most in immediate need, 3) a central coordinator to oversee these efforts, and 4) conduct thorough oversight to ascertain what additional funding or policies may be necessary**. It is critical to move quickly to ensure that all health care facilities, including nursing homes and long-term care facilities, have access to the PPE and medical supplies and equipment that they need. We greatly appreciate steps taken so far, but a more comprehensive approach is needed.

Lack of PPE significantly increases the risk that health care providers will contract COVID-19, spread it to patients and/or no longer be able to provide care. This cascade further interferes with our efforts to get ahead of this deadly virus. A lack of ventilators and other lifesaving critical care equipment such as life support machines (extracorporeal membrane oxygenation) and acute kidney dialysis machines (continuous veno-venous hemofiltration) for our sickest patients will cost many lives. As we have seen in Italy, these resource constraints will determine how many patients will live or die.

Rapid Scale Up of Testing Capacity

We appreciate that recent legislation requires coverage of testing and that the FDA has granted academic clinical laboratories the appropriate regulatory flexibility to develop tests; these tests now comprise a significant portion of our testing capacity and often provide the most rapid results.

However, we continue to experience inadequate access to testing on the front lines and extraordinary delays in some locales for testing results to return from send-out laboratories. Increased testing capacity for both lab-based nucleic acid and point of care testing, as well as the development and scaled deployment of antibody tests, is critical to help inform the time to resume normal activities and to limit the possibility of a second COVID-19 surge as is now occurring in several countries. Widespread access to testing that allows for early detection and isolation of individuals, particularly for health care workers with possible exposure to coronavirus, is critical to stop transmission.

We urge you to conduct appropriate oversight to ensure the administration significantly ramps up the manufacturing and distribution of tests and testing supplies (including collection devices, swabs, transport media, extraction reagents, and PPE) and ensures appropriate nationwide distribution to health care facilities, including nursing homes and long-term care facilities.. For institutions where testing capacity is adequate, emergency funding is required to hire, train, and equip a temporary surge of healthcare workers to perform and process tests. Additional funding for safe testing facilities, data entry and analysis, and patient contact tracing are also essential.

Beyond detection, **we urge Congress to support the organized sequencing of isolates to trace networks of spread and to monitor for mutations within the virus that might impact virulence or transmissibility as a critical national priority**. A robust public health surveillance system is required to track community and target responses based on local risk.

Pandemic Response Workforce

An adequate supply of infectious diseases (ID) physicians is essential to the response. Mounting numbers of patients and increasing numbers of clinicians exposed and falling ill threaten our workforce capacity.

Capacity in the field of infectious diseases was already a challenge before COVID-19. There has been a 21.6% decline in the number of applicants to infectious diseases fellowship training programs from 2011-2016. The last few years saw only modest improvements that have plateaued. IDSA surveyed internal medicine residents in 2014 and found financial concerns were the chief barrier to pursuing ID. Data published by Medscape in 2019 indicate that average annual salaries for infectious diseases physicians are below all other medical specialties except pediatrics, family medicine, endocrinology and public health, and even below the average salary for general internal medicine. ID training and certification requires an additional 2-3 years of study. Salaries for the highest-paying specialties are nearly double the salaries for infectious diseases. Given that the average medical student debt is $200,000, the infectious diseases specialty is not a financially feasible choice for many who might otherwise choose ID.

We recommend several steps to support the pandemic response workforce and ensure a stable, healthy workforce necessary to respond to the current and future public health emergencies.

Hazard Pay

We enthusiastically support the inclusion of hazard pay for frontline workers, including physicians, nurses, and other health care workers and first responders. These individuals are putting themselves at significant risk to care for COVID-19 patients, often currently without appropriate protective equipment to be safe. Health care workers that are eligible for hazard pay should include all physicians that are responding to the COVID-19 pandemic, including infectious diseases physicians.

J-1 Visa Reforms

Over the past decade, about one third of physicians entering the ID/HIV specialty have come from countries other than the US. The J-1 Visa program plays an important role in ensuring a strong ID/HIV physician workforce. Many ID doctors have used the J-1 Visa program to continue to practice in America after their fellowships have ended and are currently playing an invaluable role in caring for patients with COVID-19 in underserved communities. Unfortunately, current limits on the number of waivers often do not allow states to grant J-1 visas to a sufficient number of physicians to meet surging patient needs and our members are reporting a tremendous need for additional J-1 visa slots for ID/HIV physicians in the COVID-19 pandemic.

IDSA and HIVMA ask Congress to urge the State Department to temporarily extend visas and other protected status for physicians and medical residents through the COVID-19 national emergency, and to expedite approvals of extensions and changes of status for physicians and medical residents practicing or otherwise lawfully present in the U.S. Additionally, Congress should allow each state additional Conrad State 30 J-1 Visa program

waiver FLEX spots, for specialties deemed essential to pandemic response and allow these slots to be used in all geographic areas, as even areas not deemed medically underserved are experiencing shortages of these providers . Further, we urge the creation of J-1 Visa waiver slots at academic medical centers regardless of whether or not the facility is in a Health Professional Shortage Area (HPSA) for physicians in specialties deemed essential to pandemic response.

Additional Section 1135 Flexibility
Under section 1135 of the Social Security Act, which requires both a public health emergency determination as well as a Presidential declaration of a major disaster or emergency pursuant to the Stafford Act, the Secretary has the authority to temporarily waive or modify certain Medicare, Medicaid, CHIP, and HIPAA Privacy rule requirements. Waivers or modifications under section 1135 of the SSA may be retroactive to the beginning of the emergency period (or to any subsequent date). The waiver or modification terminates either upon termination of the emergency period or 60 days after the waiver or modification is first published (subject to 60-day renewal periods until termination of the emergency).

IDSA and HIVMA ask that Congress establish an additional section 1135 waiver to include Medicare coding and payment for outbreak activation, similar to Medicare's existing trauma activation coding and payment policies and require that outbreak activation reimbursements are appropriately and proportionately directed to ID/HIV physicians. As part of this approach, the Secretary could designate existing codes as well as create new codes or modifiers for certain activities that are relevant to the particular outbreak situation. In addition, the Secretary could designate a specific "bump up" of the reimbursement of such codes during the emergency period. This approach could impact the specialty decisions of current residents, helping to boost those applying for specialties essential to responding to the current COVID-19 pandemic and future pandemics, including infectious diseases, thereby strengthening our workforce very soon. In the longer term, this mechanism could help make the field of infectious diseases more financially feasible for more physicians, helping to ensure the workforce necessary to respond to future public health emergencies.

Technical Expert Panel to Review Evaluation & Management Codes
The significant compensation disparity between infectious diseases physicians and physicians who primarily provide procedure-based care is due to undervaluation of evaluation and management (E/M) codes, which cover more than 90 percent of ID/HIV physician services. E/M codes have not been comprehensively updated in 30 years, and they do not reflect the complexity of care provided by ID/HIV physicians.

We urge Congress to direct CMS to establish and convene an expert panel to develop recommendations on how to appropriately define, document, and value all E/M services (inpatient and outpatient) within the Medicare Physician Fee Schedule and to ensure that the valuation of E/M services is data driven and reflects the current practice of medicine. Initiation of this task will send an important signal to current medical residents that the federal government is working to ensure fair and appropriate compensation for infectious diseases physicians, which could impact specialty selection in both the immediate and long term, boosting the workforce for the current pandemic and helping to secure the workforce for future outbreaks.

Student loan repayment for public health

ID/HIV health professionals in state and local health departments operate state and local laboratories to help facilitate testing, ensure public health surveillance and data sharing, communicate about COVID-19 to the public, and conduct medical evaluation and testing. Unfortunately, the public health workforce has dwindled over the past decade, as state and local health departments have lost nearly a quarter (23%) of their workforce since 2008, and nearly half of the workforce may leave in coming years.

COVID-19 has demonstrated that we ***must*** have a robust workforce to respond to present and future public health emergencies. **IDSA and HIVMA urge Congress to establish a loan repayment program that could be modeled on the National Health Service Corps, for**

health professionals who agree to serve two years in a state, local, county, or tribal health department.

Addressing Secondary Bacterial Infections and Antimicrobial Resistance

While there is still much to learn about COVID-19, there is already evidence of secondary infections among coronavirus patients. It is unclear exactly how significant secondary bacterial infections will be in this pandemic, but serious viral respiratory infections typically pose some risk that increases when patients need to be hospitalized or placed on a ventilator. In a recent study of 41 patients, 10 percent had secondary infections.[1] Of those, 31 percent were admitted to intensive care units.[2] In a broader study of 99 coronavirus patients, bacterial cultures revealed infections of superbugs including *A baumannii, K pneumoniae, A flavus, C glabrata, and C albicans*.[3] *A baumannii* can be extremely resistant to antibiotics and puts patients at risk of septic shock, a life-threatening condition that damages the organs.[4] Another report on 191 patients found that 50% of patients who died had a secondary infection.[5]

We are deeply concerned that our antibiotic research and development capacity was already insufficient to meet patient needs before COVID-19. In 2019, two small antibiotic companies with new antibiotics on the market filed for bankruptcy. On March 16, 2020, another small antibiotic company—Tetraphase— was acquired by another pharmaceutical company for only $14 million, despite having a valuable new antibiotic on the market. This extremely low valuing of antibiotics has caused large pharmaceutical companies and the venture capitalists that sustain smaller companies to exit antibiotic R&D.

A clear market failure exists for antibiotics. Companies develop and manufacture antibiotics that are critical to patient care, public health and national security, and those antibiotics are held in reserve for the patients who most need them. While this judicious use is essential to ensure optimal patient outcomes and preserve the efficacy of new antibiotics, this approach diminishes the ability for companies to make revenue through traditional sales volume. A novel approach to sustain the robust infrastructure of antibiotic research and development is needed.

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[1] https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2930183-5
[2] https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2930183-5
[3] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30211-7/fulltext
[4] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30211-7/fulltext
[5] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext#tbl2

IDSA and HIVMA join experts from academia in calling for a new business model for antimicrobial drugs based on a subscription model.[6,7] Such an approach would provide a mechanism to provide predictable return on investment for antibiotic developers without tying that revenue to volume of sales, ensuring that these drugs are properly conserved for the patients who need them. We strongly encourage you to include such a new business model for antibiotics in the next COVID-19 response legislation.

Access to Vaccines
While research is underway to develop a vaccine for COVID-19, structural inequities exist that threaten to restrict access to this and other necessary vaccines. Medicare beneficiaries – seniors who are at particular risk for serious illness and death from COVID-19 – are subject to cost sharing for vaccines covered under Medicare Part D, including the Tdap and shingles vaccines.

We support inclusion of the Protecting Seniors Through Immunization Act (H.R.5076/ S.1872), a bipartisan bill that would eliminate cost-sharing for vaccines under Part D, putting them in line with those vaccines under Part B. This legislation would improve education and access to recommended vaccines with the goal of increasing vaccination rates. Ensuring that seniors are protected against vaccine-preventable illnesses will save lives and prevent overwhelming hospital capacity.

Medicare Coverage of Home Infusion of Antibiotics
We greatly appreciate the many steps Congress has taken to allow patients to receive care without leaving their homes. To strengthen this effort, **we request that Medicare provide reimbursement of supplies for self-administration of IV antibiotics at home for Medicare patients**. Currently, Medicare patients prescribed IV antibiotics are required to stay in inpatient facilities or travel to their physicians' offices or outpatient infusion centers for regular treatments. Coverage of supplies for at-home infusion would better allow these patients to practice recommended social distancing.

Ensuring Global Health Security
Providing immediate funding to meet the short-term needs of the COVID-19 response is essential, but insufficient to protect us from future global outbreaks that are certain to occur. Additional and sustained funding to strengthen capacities to prevent, detect and respond to infectious disease threats in the countries where they originate is essential for ensuring American and global health security and preventing pandemics.

We thank Congress for providing additional funding for CDC global health protection activities in previous COVID-19 emergency supplemental packages and ask for similar increases for USAID's global health security program. USAID requires additional resources to promote and implement One Health policies and practices to mitigate the threat of zoonotic infections like SARS CoV-2 and other coronaviruses, including conducting research on emerging zoonotic infections, training health workforces, and helping countries develop strong preparedness and response plans. Through funding provided by the first COVID-19 emergency supplemental package, USAID is able to extend the PREDICT Project – a ten-year program initiated in 2009 to strengthen health security and global capacity to detect and discover zoonotic viruses with pandemic potential. This vital program, which expired in 2019, has been extended for six

[6] https://healthaffairs.org/do/10.1377/hblog20200211.544900/full/
[7] https://scholarship.law.bu.edu/cgi/viewcontent.cgi?article=1095&context=faculty_scholarship

months, but requires sustained support and resources to continue its critical work in detecting novel viruses before outbreaks occur. **At least $200 million in additional funding for USAID's global health security efforts will ensure this and other vital programs are sustained.**

Federal Communications Commission's 's (FCC) Lifeline Program
The FCC's Lifeline Program is truly serving as a lifeline for low income individuals allowing them to stay connected to critical health care and social services and to prevent social isolation while they adhere to social distancing guidelines. **We urge Congress to provide at least $18 billion in funding for this program to support the provision of unlimited minutes for a period of at least six months to low income individuals and to expand access to this program**. Some infectious disease and HIV physicians have had a difficult time transitioning some patients to telehealth visits because of patients' limited access to cell phone service and no access to the Internet. In rural areas where there is limited or no access to broadband service, support for expanding this critical tool for maintaining health is badly needed. For people with HIV, it is very important for them to stay connected to their care providers to reduce the risk of compromising their health status. **We also urge additional support for the FCC to ensure**

everyone in the U.S. has access to broadband Internet at least for the next 60 days to support the continued delivery of education and health care services.

People Living with HIV/AIDS – Ryan White HIV/AIDS Program
The Ryan White HIV/AIDS Program is playing an important role in helping individuals with HIV maintain access to care and treatment during this public health crisis. More than 60 percent of individuals served by the Ryan White Program live below the federal poverty line and the COVID-19 pandemic has left them even more medically and economically vulnerable. The $90 million included in CARES Act, H. R. 748, was an important first step in helping programs funded by the Ryan White HIV/AIDS Programs begin to address the immediate needs of their patients. **As the impacts of the pandemic spread and accelerate throughout the country additional funding for the Ryan White HIV/AIDS Program will be critical to help people with HIV stay in care and on treatment and to help prevent the spread of the coronavirus among this population.** Funding is urgently needed for the following needs:

- To purchase personal protective equipment (PPE) and COVID-19 testing materials and supplies;
- To provide home delivery of medications for patients;
- To purchase phones and phone service for patients to be able to conduct telehealth visits and to purchase new medical equipment such as tele stethoscopes for telehealth visits;
- To help patients address basic living needs including food and housing;
- To provide temporary shelter for patients who need to quarantine and are unable to due to space or being unstably housed; and
- To support enhanced mental health and behavioral services.

As economic impacts are taking hold including dramatic increases in unemployment and in the number of uninsured, this will translate to an increased demand for basic Ryan White services that was not previously anticipated and that will require new funding. In addition to resources to provide the emergency services noted above, Part F funding for the AIDS Education Training Centers will be critical to support the HIV clinical workforce in managing the mental health impacts of responding to COVID-19 and the transition to managing patients via telehealth and to

meet the increased demand for dental care as more people are anticipated to be in need of Ryan White services.

Individuals in Criminal Justice Settings

If a comprehensive strategy to mitigate and control the spread of COVID-19 in prisons and jails is not implemented immediately, we will have very serious public health crises occurring in these institutions across the country. Close quarters and inconsistent standards for sanitation and health care services, leave criminal justice settings at high risk for rapid spread of the coronavirus. We urge Congress to act quickly to support the following for local, state and federal prisons, jails and detention centers:

- **Incentivize safe releases from local, state and federal prisons, jails, and detention centers;**
- **Fund COVID-19 testing and treatment for the incarcerated or detained at no cost to them;**
- **Fund the purchase of supplies of hand sanitizers, soap, masks and surface cleaners at no charge to the incarcerated so they can follow the CDC's recommendations for preventing transmission;**
- **Fund suitable temporary shelter for newly released individuals who need to be quarantined;**
- **Fund re-entry services including medical and behavioral health care, substance use disorder treatment, housing, food support and workforce development for individuals released due to COVID-19; and**
- **Provide temporary flexibility for state Medicaid programs to provide coverage prior to release**.

Immigrant Communities

To control the spread of the coronavirus, it is critical that we ensure all residents in the country have access to health care and other critical services, regardless of their immigration status. For COVID-19-- like other communicable diseases-- it is in the best interest of our country's health and security to ensure access to testing and treatment without cost sharing for everyone who needs it. **We encourage Congress to ensure that individuals who are immigrants including those who are undocumented are in no way discouraged from accessing health care and services during this public health crisis by temporarily suspending rules that serve as a deterrent such as the public charge rule. In addition, dedicated funding is needed for the Centers for Disease Control and Prevention to conduct outreach in multiple languages to reach and educate these communities**.

Once again, IDSA and HIVMA thank you for your ongoing leadership and commitment to the federal response to COVID-19. If you have any questions or if we can support your efforts, please contact Amanda Jezek at ajezek@idsociety.org and Andrea Weddle at aweddle@hivma.org.

Sincerely,

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