December 23, 2020

Eric D. Hargan
Deputy Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

RE: Request for Information on Regulatory Relief to Support Economic Recovery

Dear Deputy Secretary Hargan:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Request for Information (RFI) on Regulatory Relief to Support Economic Recovery which seeks feedback on the regulatory actions that stakeholders believe should remain temporary or become permanent beyond the COVID-19 public health emergency (PHE).

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI's Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges and barriers facing the medical profession.

PAI strongly supports the Department of Health and Human Services' (HHS's) efforts to implement permanent and/or extend current flexibilities that will provide further relief for physicians. Specifically, PAI provides the following key recommendations:

- Provide direct financial, technical, and physical supports that will enable physicians, especially small practices, to continue to treat patients during and after the end of the pandemic, protecting their longer-term viability in the communities where they provide care.
- Prioritize all physicians when it comes to distributing PPE, vaccines, and other resources necessary for confronting the COVID pandemic.
- Streamline and reduce administrative burden for physicians to ensure that they are able to provide efficient and quality care for vulnerable patients.

Impact of COVID-19 on Physician Practices

Over the last several months, PAI has been closely tracking the devastating impact that this pandemic is having on physicians and their ability to practice medicine and care for their patients. A recent Physicians Foundation survey[1] examined the impact of the COVID-19 pandemic on physicians, and the findings are concerning and telling. According to the study, 72% of physicians indicated that COVID-19 would have serious consequences for patient health due to delays in care. Further, 41% of physicians saw a decrease in volume of 26% or more, "which may be difficult or impossible for most physician practices to sustain for more than a few months." This decrease in volume has also led to increased financial burden, with 72% of physicians reporting they experienced a reduction in income, with over half (55%) experiencing income losses of 26% or more. As a result of COVID-19 and to help mitigate its impact, 43% of physicians have reduced staff, and 8% have closed their practices altogether. As the findings from this study indicate, the ability for physician practices to sustain the pandemic and continue caring for patients in a post-COVID world is questionable and worrisome. Physician practices across the nation have struggled to remain viable during the coronavirus pandemic, notwithstanding various flexibilities and financial supports that have been extended by the federal government.

While PAI has been appreciative of federal supports thus far, greater assistance is still needed in order to protect physicians and patients. Below we highlight policies that have been helpful and should be continued on either a permanent or temporary basis post-COVID.

COVID-19 Changes That Have Been Beneficial to Physicians and Patients

In response to COVID-19, federal and state governments have enacted several temporary flexibilities in such areas as: telehealth and communication technology-based services (CTBS), provider supervision requirements and administrative requirements, the Medicare Accelerated and Advance Payment Program (APP), as well as small business supports and relief funding. These and other flexibilities significantly impact both patients and physicians. The following policies have been particularly helpful for physicians:

- Telehealth, remote patient monitoring (RPM), and (CTBS) – waiver of originating site, established relationship, and certain HIPAA requirements to promote immediate expansion of telehealth and other CTBS. This has been coupled with increased coverage and reimbursement for telehealth services, generally at the face-to-face Medicare fee for service rates. Physicians have also been able to waive patient copays associated with such services.
- Waiver of patient cost-sharing for certain COVID-19 services (testing and treatment-related services) and allowing high-deductible health plans (HDHPs) to cover COVID-19-related tests/treatment without jeopardizing their status.
- Health Resources and Services Administration (HRSA) Uninsured Program
- Medicare APP – Temporary expansion of APP to allow for 3-month physician Medicare payment advancements
- Automatic application of the Quality Payment Program's (QPP's) Extreme and Uncontrollable Circumstances (E&UC) policy
- Increased Federal Medicaid Assistance Program (FMAP) dollars
- Dissemination of personal protective equipment (PPE) from the national stockpile
- Recording Hierarchical Condition Category (HCCs) for risk adjustment during telehealth visits
- Relaxing direct supervision requirements
- Flexible consent requirements
- Relaxing of certain Stark/Anti-Kickback statutes

[1] http://physiciansfoundation.org/wp-content/uploads/2020/08/20-1278-Merritt-Hawkins-2020-Physicians-Foundation-Survey.6.pdf

While some policies have been permanently finalized recently as part of the CY 2021 Medicare Physician Fee Schedule (MPFS), other regulatory flexibilities are set to expire on January 21, 2021 unless the current PHE declaration and/or certain waivers and flexibilities are extended. Even so, the impact of the COVID-19 crisis will be realized by physician practices well beyond the length of the PHE. As we transition into a post-COVID landscape in 2021, there are several federal policy concerns and opportunities that practices, and policymakers should be aware of.

Regulatory changes that should be made permanent

As HHS considers regulatory reliefs to support economic recovery during and post-COVID, it is important that the Department focus on supplying tools and resources necessary for care delivery, providing funding relief for practices to ensure patients have continued access to their physicians, and reducing administrative burdens that often act as obstacles to care. PAI believes the following list are regulatory changes that should be made permanent and codified by HHS.

Extending Flexibilities for RPM and CTBS

RPM and CTBS (such as e-visits, virtual check-ins, and telephone assessments via smart phones, tablets, applications, etc.) have increased physicians' abilities to provide additional care and care management services in addition to traditional telehealth and telemedicine services. During the PHE, CMS has relaxed flexibilities related to consent for these services, so that while consent is still required and must be documented, it is no longer an obstacle to patients receiving immediate attention and necessary care. RPM has historically played a critical role in the management of chronic diseases. As we transition out of the PHE, it is vital that we continue to expand access to RPM services for all target populations, especially underserved and vulnerable populations, including but not limited to rural and urban patient populations, hospice and home care patients, and other long term care and rehabilitation facilities and locations. Furthermore, CTBS, and any other asynchronous communication services, will remain a vital touch point for all patients, especially underserved populations, who may lack the resources to capitalize on telehealth platforms available.

PAI Recommendation:
HHS should extend flexibilities for RPM and other CTBS. As well, policymakers should include incentives to ensure that patients are receiving care from their local, established physicians and practices in their communities to preserve the patient-physician relationship. Additionally, it is important that CMS establish responsible guardrails to ensure that these services continue to be provided by appropriately trained providers with clinical expertise, and are not outsourced to third-party vendors with no clinical background or with no direct connection to the beneficiary's primary care provider. Similarly to the telehealth policy recommendation above, it is important that policies should not allow a payment differential between telehealth and in-office visits, especially such payment differentials which could create barriers to continuity to care for patients and prevent them from receiving care from their routine physicians.

Greater Telemedicine Supports

Telehealth has remained a vital component of the U.S. health care system response to COVID-19. Due to relaxations in originating site requirements, established relationship requirements, and certain HIPAA requirements, as well as expansion of the Medicare telehealth-reimbursable list, physicians and other health care professionals have been able to maintain, and in certain cases expand, the reach of their medical services to Medicare and Medicaid populations in need. As federal agencies contemplate policy solutions to expand access to virtual platforms, it is imperative that CMS ensures that any future policies looking to expand telehealth coverage do not expand the scope of practice of non-physician health care professionals beyond that supported by their licensure, education, and training prior to the PHE; nor allow a payment

differential between telehealth and in-office visits, especially such payment differentials which could create barriers to continuity of care for patients and prevent them from receiving care from their routine physicians.

PAI Recommendation:
Telehealth flexibilities and reimbursement rates must continue permanently, as many physician practices and the beneficiaries they serve will remain reliant on telehealth services and platforms for the immediate future (if not longer). As mentioned in the above recommendation, it is critical that policymakers include incentives to ensure that patients receive telehealth care from their local physicians and practices. Small physician practices are struggling due to COVID-19 and any further changes to their patient volume will have serious repercussions on the sustainability of their practices.

Telehealth platforms and technologies are costly investments and physicians and practices should have the continued opportunity to leverage them as part of their routine practice post-COVID. HHS should adopt policies on a more permanent basis that increase access to physician services, especially for vulnerable and underserved urban and rural patient populations. Telehealth flexibilities should be expanded to include ERISA and Federal Employee Benefit Program (FEBP) plans. Physicians should also be able to provide telehealth services in additional settings that include home and community-based settings.

Additionally, PAI urges the Department to continue to reimburse telehealth services at parity with in-person service rates after the COVID-19 PHE concludes. Reimbursement should remain informed by service type, as opposed to setting of care—to the most reasonable extent possible. Physicians should continue to have the flexibility to make a clinically-informed decision about whether a telehealth or in-person visit would be most beneficial for a patient, and they should have this flexibility without unnecessary and/or disconnected pricing incentives. The benefits and challenges of telehealth versus in-person care is dependent on several patient factors, both medical and non-medical. To this end, we believe that telehealth and in-person care should be reimbursed at generally equal rates, with the exception of certain facility and resource-based adjustments when applicable, and that the ultimate differentiator in physician reimbursement should be dependent on the service type as well as value/quality of care provided.

Expanding Audio Only Telehealth Services

In the CY 2021 MPFS Final Rule, CMS noted that audio-only E/M codes will not be reimbursed after the end of the PHE and proposed an interim final rule on coding and payment for virtual check-in services to support reimbursement for lengthier audio-only services outside of the PHE. However, these audio-only services can only be used to determine whether the beneficiary requires an in-person services and are not services that can be provided in lieu of in-person services.

Allowing audio-only telehealth services increase access to care for beneficiaries, especially the most vulnerable and underserved beneficiary populations (who may not have the resources or capacity to utilize two-way audio/visual communication technology). Despite extensive financial assistance provided by the Federal Communications Commission (FCC) and the Health Resources and Services Administration (HRSA) to help scale telehealth and virtual care platforms, there remain several regions in the U.S. where access to two-way audio/visual technology remain unfeasible.

PAI Recommendation:
PAI thanks HHS and CMS for the flexibilities provided in the MPFS but urges the Department to permanently permit audio-only technology to be used for all telehealth services to ensure care access and care continuity is maintained for rural and underserved populations, as well as complex and chronically ill patients that have benefited from such services during the COVID-19 PHE. Specifically, additional services like E/M, advanced care planning, and transitional care management should be able to be provided using

audio-only technology. Additionally, it is important such codes are reimbursed at the same rates of equivalent services provided in-person.

Funding for Telehealth/Virtual Programs

Physician practices are among the most vulnerable stakeholders in the health care industry during COVID-19, from both a physical and financial health perspective. While the demand for services may renew post-PHE, the investment requirements and upfront risks necessary to scale virtual/data platforms will remain a debilitating financial/regulator stress for practicing physicians, especially those in small and independent practices.

PAI Recommendation:
It will be critical that HHS continue to financially support such stakeholders to ensure practices can perform at the best of their ability and can remain viable amidst competing health systems and hospitals. This funding could look similar to the Health Information Technology (HITECH) Administrative funding for state Health Information Exchange (HIE) activities through the Medicaid Electronic Health Records (EHR) Incentive Program as authorized by the American Recovery and Reinvestment Act of 2009 (ARRA) at 90 percent match rate for design and development costs through 2021. Furthermore, HHS should continue to enhance funding for broadband expansion initiatives that improve the reach of telehealth and other digital health platforms within rural and underserved regions.

Accelerating Payment for Future PHEs

While the recent temporary flexibilities in Medicare's Advanced and Accelerated Payment Programs (APPs) provided useful financial relief to physician practices, several technical issues experienced with the APPs, as well as the withdrawal of the physician portion of the program, raise concerns for future PHEs.

PAI Recommendation:
HHS should establish a more streamlined process to trigger advanced payments and/or easily acquire APP payments under PHE declaration, and should consider a more reduced and fixed interest rate over longer periods of time for recipients who fail to meet the CMS deadline for recoupment (especially for physicians whose revenue was subsequently reduced due to the PHE and are not able to match previous year's patient volume or revenue as a result of the PHE). HHS must be consistent in offering financial assistance during the PHE to all provider types and specialties, ensuring equitable treatment and consideration of both hospital systems and physician practices. Funding for one should not be later terminated for physicians while still available to hospitals. Lastly cash-strapped states will not have resources to offer accelerated payments to physicians whose primary business is Medicaid and the Children's Health Insurance Program. HHS should extend relief to these practices absent state-led initiatives to do so.

Preparing the PPE Stockpile

As we enter the second wave of this pandemic, physicians and other providers continue to expose themselves to the virus in order to care for their patients. This has resulted in many physicians and nurses having to enter quarantine/self-isolation, further compounding the impact of the pandemic by creating physician workforce and access to care issues. It is critical that physicians have access to the resources and tools necessary for care delivery during a pandemic so that they can safely and effectively care for their patients.

PAI Recommendation:
HHS must develop and continuously work to improve and maintain the quantity and condition of personal protective equipment (PPE) in our U.S. national stockpile (especially considering recent concerns over the durability of certain PPE), as well as timely allocation to those first line of defense community physicians and community health centers. It is especially critical to account for small and individual physician practices

when considering stockpile quantities and distribution plans. A clear plan and logical strategy for distribution, that accounts for transportation logistics and challenges, should be developed and communicated with state-level authorities for any future PHE. This strategy must also ensure engagement with state-level medical authorities. Additionally, to ensure that the PPE needs of community physicians are accurately accounted for and appropriately prioritized, the development of any state-level PPE-allocation formula must ensure active input from state medical societies. State-level needs assessments and data from private sector suppliers can help anticipate supply chain shortages and prevent inequitable distribution.

Addressing and Eliminating Financial Barriers to Care

During this PHE, the federal government acted swiftly to remove potential financial barriers that might cause certain individuals to avoid seeking virus testing or treatment for COVID-19 illness. These policies included, but were not limited to: waiving cost-sharing for COVID-19-related tests and treatment in Medicare and Medicaid, as well as for uninsured individuals; allowing HDHPs to cover COVID-19-related tests and treatment before fulfilling the deductible, without jeopardizing HDHP status; establishing a new Medicaid eligibility pathway to cover COVID-19-related tests and treatment for uninsured individuals; and, establishing a provider relief fund to help cover revenue losses resulting from uncompensated care.

PAI Recommendation:
To continue protecting access to medical care for patients, and to better inform the Federal response to future pandemics, HHS should:

- Eliminate financial barriers to services, including deductibles/cost-sharing and other insurance policy exclusions/requirements to ensure coverage for appropriate services
- Improve coverage transparency requirements so all patients and physicians are aware of cost-sharing obligations (or lack thereof) tied to certain services during a PHE.
- Continue federal payments for services delivered to uninsured patients with COVID-19, COVID-19-related complications, or any future disease causing a PHE. A growing body of evidence shows many patients diagnosed with COVID-19 experience lingering side-effects that may contribute to chronic health conditions for which ongoing treatment will be needed.
- Establish policies that enhance insurance portability in the case of job loss and economic distress, as well as those that protect coverage of COVID-19-related treatment and procedures throughout the emergency period.
- Mandate the development of a National Roadmap to inform state policies for how to safely continue physician services, screenings, etc. during any future surge/PHE. This should include clear strategies for financial assistance and equitable personal protective equipment (PPE) distribution.

Streamlining Reporting Requirements

Funding provided to physicians to balance losses incurred during COVID-19 were vital to the survival of physician practices, especially small physician practices. Due to constant changes in FAQ and other guidance governing the Provider Relief Fund, there remains a lack of clarity over related reporting requirements, and recoupment and audit exposure. Lack of clarity limits physician confidence in seeking and/or accepting Relief Fund assistance.

PAI Recommendation:
Future reporting requirements mandated by the HHS should remain consistent and operationally feasible. Physicians should not be overly burdened with constantly changing compliance and reporting requirements, nor with unduly burdensome administrative tasks while trying to serve patients on the front lines of the COVID-19 pandemic and ensuring that patients continue receiving non-COVID related care.

Flexibilities and Supports That Should Be Continued on a Temporary Basis

While PAI has been appreciative of the temporary COVID-19 flexibilities provided by HHS, we are concerned that post-PHE, physicians will be grappling with long-term implications from COVID-19 both financially and administratively. In order to mitigate these issues, PAI believes the following regulatory changes should be continued on a temporary basis until physicians and other providers are able to provide care similar to pre-pandemic levels and return to a new "normal."

Implementing Liability Protections

While Congress has taken steps to protect medical volunteer liability during COVID-19, and physicians' use of certain drugs and devices (i.e. through certain immunity protections) in the care of COVID-19 patients, physician liability concerns remain critically under-addressed. Physicians of all fields and specialties are practicing under unprecedented and extreme circumstances. The COVID-19 PHE has called for necessary but controversial decisions in resource allocation and patient treatment. Without uniform federal protection, physicians are left vulnerable to costly and time-consuming litigation as they continue to battle on the front lines.

PAI Recommendation:
HHS should work to guarantee liability protections, to the utmost extent possible, for physicians who are 1) changing care delivery practices in response to patient needs in the midst of the PHE, including but not limited to taking additional calls, and seeing new patients as well as providing new services via telemedicine and telehealth solutions, 2) practicing outside their chosen specialty areas to close the gap in patient-care shortages; 3) postponing "elective" surgeries and procedures due to state and/or federal recommendations; and providing direct patient care to those who have been identified and diagnosed with the virus, disease or condition for which the PHE has been established. This protection should also include liability protections for physicians faced with using mass critical care guidelines or other scarce resource standards to make controversial but necessary decisions.

Need for Increased Financial Reliefs and Supports

While the federal government has provided several funding streams and opportunities in response to COVID-19, large, well-capitalized hospitals and health systems have secured a disproportionate level of these supports to-date, while stressed physician practices struggle to stay afloat. These practices include physicians who practice in rural and other underserved areas, whose continued care for their vulnerable patient population is essential to our functioning health care system. This, coupled with the impending end of the sequestration suspension as well as the finalized reimbursement cuts due to the budget neutrality provisions under the CY MPFS, creates an unstable and threatening environment for physicians who are already struggling and are unsure about whether they will still be in practice in a few months.

PAI Recommendation:
Physician practices must receive the following financial reliefs with an eye to how to help them make it through the next few months to the transition phase when things start returning to "normal":

- Increased and more equitable dissemination of provider relief funding to physicians, especially for safety net physicians that serve the most vulnerable and underserved communities. Specifically, additional funding should be provided to improve telehealth capabilities and adjust for ancillary practice costs (including, but not limited to, drug acquisition and maintenance costs). Importantly, there needs to be clear guidance that these funds are not taxable.
- Direct FTC broadband funding to group homes, nursing homes, physician offices, and hospitals in both rural and urban areas.

- Extension of the current Medicare sequestration moratorium through the end of 2021, or at a minimum until the end of the COVID-19 PHE.
- Increased Federal Medicaid Assistance Program (FMAP) dollars and supports.
- Increased Medicaid physician payments to Medicare parity throughout the PHE and at least two years beyond to maintain a stable network of physicians available to treat low-income Americans. To achieve these changes, corresponding adjustments must be made to regulatory Federal Medicaid Upper Payment Limits (UPL) and State Federal Medical Assistance Percentages (FMAP) (described below).
- Expand federal and state financial supports and insurance protections for physician practices to help them meet demands of both patients and employees, specifically increased options for more affordable business insurance. At the very least, existing insurance policies should cover and not be permitted to exclude the medical practice and physician care services that are provided in response to a national crisis.
- Due to the budget neutrality provisions the MPFS is subject to, there are often "winners" and "losers" when reimbursement rates under the MPFS are adjusted. However, in the CY 2021 MPFS, this has resulted in a negative 10% budget neutrality adjustment that has a significant negative impact on physicians, especially specialty physicians, who will see reduced rates beginning January 1, 2021. Similar to the Medicare sequestration moratorium, we urge HHS to help address the budget neutrality adjustments through 2021.

Reduced Administrative Burdens

In the midst of trying to manage and survive COVID-19, physicians are also being required to act in response to new and changing non-COVID regulatory policies. On November 20, there was a flurry of rules which included an interim final rule on a mandatory Most Favored Nation (MFN) model demonstration, as well as final rules implementing overhauling regulatory updates to the Anti-Kickback Statute and the Physician Self-Referral (Stark) Law. Given the current environment, while we are supportive of some of the policies being proposed and finalized, it is difficult for the physician community to adopt and change their practices in response to both COVID-19 and these other regulatory efforts. Additionally, PAI has been long advocating for the need to modernize the Anti-Kickback Statute and Stark Law to reflect the shift and greater adoption of value-based models and increased care coordination and management delivery models.

PAI Recommendation:
We applaud HHS for efforts to modernize these regulations. However, greater guidance and flexibilities are still needed as many of the finalized policies as part of these rules still create incentives for industry consolidation and closure of small and independent practices. We also recommend regulatory relief in the form of delays and increased guidance on these and other rules so that physicians have adequate time, staffing, and other resources to make necessary changes and make sure they are in compliance with new regulations. Specifically, we are requesting that implementation of the MFN model be delayed and also restructured as the current approach negatively impacts both physicians and patients and would restrict access to necessary medications for high-needs patients.[2] Furthermore, we request reporting flexibilities for the QPP in the form of automatic application of the Extreme and Uncontrollable Circumstances (E&UC) policy to physicians and other clinicians for the 2020 and 2021 performance year. Alternatively, at a minimum we request lower reporting thresholds and participation requirements that would protect physicians from being subject to a negative adjustment under the program.

Conclusion

[2] In the IFR, CMS expects that many patients may not have access to certain drugs because physicians will not buy them, creating access issues and concerns.

Overall, PAI supports the Department's efforts to assess the various temporary deregulatory actions they have taken to fight COVID–19 and determine which temporary regulatory actions should be made permanent. The associations represented on the PAI Board of Directors welcome the opportunity to work with HHS and its agencies to further modify existing policies and advance new policies. We look forward to exploring ways that allow physicians to provide higher quality, coordinated, integrated, and holistic care to their patients, while decreasing costs and increasing competition and choice in the health care market for patients and physicians. We reaffirm our belief that opportunities exist to improve the health care system and believe this should be done by enacting policies and modernizing antiquated regulations, which serve to foster innovative approaches to physician collaboration that will bring the benefits of competition to patients.

If you have any questions, please contact me at k2strategiesllc@gmail.com.

Sincerely,

Kelly C. Kenney
CEO, Physicians Advocacy Institute