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[Submitted electronically via www.regulations.gov and COVID.Regs@hhs.gov]

Allison Beattie
Assistant Deputy General Counsel
Department of Health and Human Services (HHS)
200 Independence Avenue SW, Room 713F
Washington, DC 20201

Re: Regulatory Relief to Support Economic Recovery; Request for Information (RFI) (ID: HHS-OS-2020-0016-0001)

Dear Ms. Beattie:

The American Pharmacists Association (APhA) is pleased to submit these comments in response to the RFI on Regulatory Relief to Support Economic Recovery.[1]

APhA is the largest association of pharmacists in the United States and the only organization advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, physician offices, clinics, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

As you may know, prior to the RFI, APhA and CEOs of ten other national pharmacy organizations, representing over 300,000+ pharmacists nationwide, proactively submitted comments in response to Executive Order (EO) #13924 on "Regulatory Relief to Support Economic Recovery," on recommendations for temporary authorizations that should be made permanent to accomplish the economic priorities laid out in the EO and get Americans back to work. Please, reference these comments which we build on for our response to this RFI.[2]

Specifically, since the issuance of EO #13924, during the public health emergency (PHE), HHS and CMS have continued to institute a number of regulatory flexibilities for pharmacists and other clinicians to mitigate and prevent COVID-19. Many of these flexibilities, including test-

[1] 85 Federal Register 75720 (Nov. 25, 2020.)
[2]National Pharmacy Association Response. Re: Executive Order #13924 on Regulatory Relief to Support Economic Recovery. August 7, 2020, available at: https://www.pharmacist.com/sites/default/files/National_Pharmacy_Association_Response_to_EO.pdf

treat-immunize and telehealth models, should be made permanent, as they have significantly increased patient access and care.

To assist your efforts to implement EO #13924, we are providing comments in response to the numbered regulatory actions in Appendix A of the RFI which HHS is considering making permanent or modifying in response to the COVID–19 crisis and beyond. Each regulatory action holds a designation under "APhA Recommendation," requested in the RFI ranging from "a.) Should be maintained only for the duration of the PHE and pandemic," to "e.) Should be discontinued immediately." As federal, state and stakeholder response has continued to evolve during the ongoing PHE, we are also including comments on additional regulatory actions not included in Appendix A.

Topic:	HHS Sub-Agency/Type of Action:	APhA Recommendation:	APhA Comments:
COVID-19 Testing	**74. FDA Guidance: Policy for Coronavirus Disease-2019 Tests During the COVID-19 PHE**	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed. .	On August 19, HHS announced, effective immediately, FDA will no longer require premarket review of laboratory developed tests (LDTs). LDTs can still voluntarily request FDA reviews. As a result, substandard COVID-19 tests could be in the marketplace. The action appears to revoke the previous FDA Guidance listed as #74 in the RFI used to remove 27 faulty COVID-19 serology tests from the marketplace and require testing manufacturers to submit applications for Emergency Use Authorization (EUA) in 10 days. In order to ensure providers administering LDTs, including pharmacists that may choose to partner with laboratories, APhA recommends FDA require premarket review of LDTs.

			APhA has recommended pharmacists partnering with labs check that the COVID-19 tests they are administering are approved by the FDA to ensure they are protected under federal immunity coverage.
	110. CMS IFR: Independent Lab Payment for Specimen collection **136. CMS IFR: Laboratory Tests: Payment for COVID-19 Specimen Collection to Physicians, Non-Physician Practitioners and Hospitals**	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed	CMS has stated under both the first and second Interim Final Rule (IFR), that payment for specimen collection only applies for collecting specimens from beneficiaries who are homebound or inpatients and not for direct specimens collected in pharmacies for point of care tests. APhA is concerned that this policy prevents pharmacists from receiving reimbursement for specimen collection for point of care tests. This policy conflicts with FDA guidance recognizing pharmacies as point of care sites for such tests and severely limits the ability of the Administration to successfully utilize all pharmacists and pharmacies to meet its national COVID-19 testing goals. On April 8, 2020, the HHS OASH issued Testing Guidance "authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized." FDA's FAQ states, "we

			note that the term point of care in the EUAs may include settings such as hospitals, physician offices, urgent care, outreach clinics, *pharmacies* [emphasis added], and temporary patient care settings that have appropriately trained personnel to perform the test and are operating under a CLIA Certificate of Waiver or Certificate of Compliance." Accordingly, for the duration of the emergency declaration, such tests can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver or Certificate of Compliance. To further complicate matters, CMS has permitted pharmacists to work with a physician or other practitioner to provide assessment and specimen collection services, and the physician or other practitioner can bill Medicare for these "incident to," services. Because community pharmacists generally do not have incident to arrangements with physician practices that would allow their services to be billed incident to a physician or other provider,

			APhA is concerned that without a clear avenue to pay pharmacists for their services, including patient assessment, specimen collection (including for/to rule out influenza virus and respiratory syncytial virus (RSV)), performing the test, interpreting the results, and reporting the results to the patient and appropriate authorities, the Administration's stated public health goal of widespread and accessible testing in communities by pharmacists will not be achieved. We urge HHS/CMS to address this barrier and provide a clear, direct payment pathway for the services associated with point of care tests at pharmacies during the pandemic. For precedent, on June 30, 2020, HHS announced it was extending its partnership with national pharmacy and grocery retail chains until August 2020. HHS explains "[t]he contract utilizes a federal bundled payment program *paid directly* [emphasis added] to retailers that receive a flat fee for each test administered, with participating retailers responsible for coordinating the full end-to-end testing," including specimen collection.

			Thus, APhA urges HHS to provide all pharmacists and pharmacies, including community pharmacies, a clear pathway for direct payment and the same level of payment provided to other healthcare professionals for providing COVID-19 testing services—including specimen collection.
	228. CMS Guidance: Pharmacies Enrolling as Labs **292. CMS Guidance: Coverage of Testing and Testing-Related Services for COVID-19**	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed	CMS has issued Medicare Learning Network (MLN) guidance permitting pharmacies and suppliers to enroll temporarily as independent clinical laboratories. However, "Independent Clinical Laboratory," is a different category from "Independent Diagnostic Testing Facility," and "Pharmacy," on the CMS 855B enrollment application and should be clarified with step-by-step instructions by CMS in the MLN to help address the urgent need for COVID-19 testing. In addition, as stated above, APhA urges HHS to provide all pharmacists and pharmacies, including community pharmacies, a clear pathway for direct payment and the same level of payment provided to other healthcare professionals for providing COVID-19 testing services—including specimen collection.

			APhA also urges CMS to implement an Action-Reason (AR) code to allow pharmacies to bill point-of-care tests (e.g., COVID-19 tests) under the Pharmacy PTAN/NPI. CMS' decision to require pharmacies to enroll as an "Independent Clinical Laboratory," unfairly adds complexity, risk, and future cost to the pharmacy. Pharmacies will be required to maintain enrollment for multiple PTANs to maintain the "Independent Clinical Laboratory," status for point-of-care tests plus the "Pharmacy," status for immunizations and DSMT services. MACs have had difficulty discerning which PTAN to use when a pharmacy maintains multiple PTANs, such as a "Pharmacy," and an "Independent Laboratory," PTAN, for a single NPI.
CMS	**146. CMS Scope of Practice: Pharmacists Working Incident to a Physicians' Service**	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed	APhA applauds CMS for clarifying in the second IFR (85 FR 27557) that medication management is covered under both Medicare Part B and Part D. Pharmacists across the country are sought for their medication and chronic disease management skills, and this clarification resolves longstanding questions about coverage of medication management services in Medicare Part B.

			However, the 2021 physician fee schedule rule only allowed payment to physicians and other non-physician practitioners (NPPs) for pharmacists' evaluation and management (E/M) services at the least complex services level (limited to 7 minutes). It is not feasible that a pharmacist providing a 45-minute office visit to manage multiple chronic conditions and multiple medications for a Medicare beneficiary under an incident to arrangement with a physician would be limited to having the service billed as a Level 1 visit (99211), that only has an anticipated time commitment of 7 minutes. Such a provision would eliminate any incentive and/or ability for physicians/NPPs and pharmacists to partner to provide complex health care services. This misaligned Medicare payment policy for pharmacists' services performed in incident to physician services arrangements continues to be a significant barrier to broad use of pharmacists in team-based care models during the PHE and beyond. APhA has collected a number of case studies from pharmacists working in team-based care

			arrangements that illustrate the complexity of care being delivered to Medicare-eligible beneficiaries age 65+. We would welcome the opportunity to share more of these cases with the CMS Agency Review Team. Case example: Patient is a 77-year-old male with type 2 diabetes, heart disease, hypertension, and hyperlipidemia referred by the physician to the pharmacist for a follow-up visit. Patient is experiencing increased fatigue, nocturia, and weight loss. Patient is currently taking 6 medications. Pharmacist reviewed symptoms, evaluated the patient's medication regimen, and discontinued two medications and initiated two new medications in collaboration with the physician. The pharmacist provided education on diet and exercise and counseling on the new medications. The patient does not currently conduct self-blood glucose monitoring (SBGM), and the pharmacist also worked with the patient to initiate SBGM with a plan to consider continuous blood glucose monitoring to monitor progress in the future. A one-month follow-up visit was

			scheduled. The pharmacist's visit details were reviewed and approved by the supervising provider. Total patient visit time: 42 minutes For reference of Congressional intent, APhA also directs HHS to the House-passed 2nd FY2021 Consolidated Appropriations Act (H.R. 7617)—specifically, the language from H. Rept. 116-450, which states: "Pharmacists and Patient Care Services.—The Committee is aware that certain Medicare Part B services and care frameworks have provisions to include pharmacists and their patient care services. However, CMS has few, if any, mechanisms to identify and evaluate pharmacists' contributions to patient care and outcomes or to identify barriers within current service requirements that prevent scalable involvement of pharmacists. The Committee urges CMS to create a mechanism to provide greater visibility into the scope and outcomes of the Medicare services currently provided by pharmacists. In addition, CMS should consider testing such system in a CMMI model to assess barriers to pharmacist

			participation in current Medicare services and to evaluate the contributions of pharmacists to team-based care and better health outcomes in Medicare beneficiaries." In order for CMS to implement HHS' commitment to advancing team-based care and allow pharmacists to meet HHS's goal "to practice at the top of their license," APhA urges HHS to recognize that complex services provided by pharmacists in team-based health care delivery models under incident to arrangements can be billed by physicians and NPPs via E/M codes 99212-215, equivalent with the services delivered by all other healthcare providers or to identify/develop billing codes that appropriately reflect the contributions of pharmacists. APhA also strongly requests that CMS develop mechanisms to better understand and evaluate how health care practitioners, including pharmacists, whose services are billed by physicians and NPPs under incident to arrangements, contribute to access to care needs and the health outcomes of Medicare beneficiaries.

	201. CMS Waiver: Practitioner Locations **298. CMS Section 1135 Waiver**	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	The flexible workforce and workflow arrangements provided through 1135 waivers during the PHE have been essential to supporting healthcare teams. These changes have contributed to a more nimble, responsive healthcare system during the PHE and would provide the same benefits when it ends, including flexibility in license portability and remote tasks. HHS should encourage states and Congress to implement or provide new authorities to permanently allow pharmacists and pharmacy technicians with valid licenses to operate across state lines. Additionally, pharmacists and pharmacy staff should be allowed to permanently conduct routine pharmacy tasks remotely as necessary (i.e., prescription data entry and script verification, medication review and reconciliation), including those licensed outside of a state to ensure business continuity.
	219. CMS Waiver: Signature and Proof of Delivery Requirements **221. CMS Guidance: Part D "Refill-Too-Soon"**	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	CMS sent information reminding Medicare Advantage and Part D plans of their ability to remove prior authorization requirements, waive prescription refill limits, relax the restrictions on

	Edits and Maximum Day Supply **222. CMS Guidance: LTC Dispensing** **224. CMS Part D Enforcement Discretion** **227. CMS Home or Mail Delivery of Part D Drugs**		home or mail delivery of prescription drugs, and reprioritize audit activities and audit reviews. Furthermore, CMS released a policy relaxing Medicare Part D audit requirements for signature logs. Given the burden reduction of these flexibilities, these flexibilities should remain in place long term and be required moving forward. There is potential for decreased medication adherence in vulnerable populations, particularly amongst older adults, after the PHE ends, thus, proactive support for these flexibilities would ensure consistent access to medications in all settings.
	349. CMS: Medicaid Disaster Relief SPA: Adjust Days' Supply or Quantity Limit	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed	APhA supports allowing states to increase the day supply or quantity limit for covered outpatient drugs.
Compounding	**66. FDA Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency**	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and	FDA has issued temporary guidance granting flexibility for pharmacists to compound hand sanitizer, use of PPE during compounding, and certain necessary medications under 503A at community pharmacies for hospitalized patients without patient-

	67. FDA Guidance: Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised) **68. FDA Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry (Revised)** **69. FDA Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency** **71. FDA Policy for Temporary Compounding of Certain Alcohol Based Hand**	what modifications are being proposed	specific prescriptions to address COVID-19. FDA has added drugs to the list of necessary medications (e.g., morphine sulfate) urgently needed for hospitalized COVID-19 patients as need arises. As this health crisis continues, pharmacies, wholesalers, and manufacturers are experiencing or are likely to experience shortages of additional prescription drug products that are needed for patient care. FDA should permanently implement FDA's guidance to address COVID-19 and expand this compounding flexibility to additional medications in shortage for other health care conditions. Permitting pharmacists to compound drugs in shortage that are not included under the current guidance will help ensure our nation's hospitals have the medications they need for optimal care for all of their patients.

	Sanitizer Products During the Public Health Emergency **273. CMS Waiver: Sterile Compounding**		
DSCSA ("Track and Trace")	**30. FDA Guidance: Exemption and Exclusion from Certain Requirements of the DSCSA During the COVID-19 PHE**	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed	Despite pharmacy organizations' requests for delay, FDA did not delay enforcement of a DSCSA requirement that "dispensers," including pharmacies, must only engage in transactions (e.g., buy or sell) of products that have the required product identifier on the package. This requirement went into effect on November 27, 2020. HHS should provide flexibility for the November 2020 deadline for dispenser to only buy serialized product. APhA members and pharmacists across the country have been asking for this reprieve from the DSCSA so that they can focus their attention and efforts on COVID-19 testing, vaccination, and continued care of their patients. Without enforcement discretion of these DSCSA requirements, there could be significant disruptions to pharmacy operations that might impact patient access to medications. This is unacceptable during a pandemic.

Telehealth/ Digital Health	**4. HHS/OCR Notification of Enforcement Discretion for Telehealth Remote Communications**	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	In order to meet public health needs, APhA supports HHS' exercise of enforcement discretion to not impose penalties for HIPAA violations against pharmacists in connection with their good faith provision of telehealth using remote communication technologies during the COVID–19 PHE and beyond.
	111. CMS IFR: Communication Technology-Based Services (CTBS)	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed	Pharmacists are highly involved in the delivery of CTBS that are inherently non-face-to-face. For example, pharmacists can deliver CGM utilizing CTBS to help reduce the $327 billion annual cost of diabetes in America. Accordingly, APhA urges CMS to use enforcement discretion during the PHE and beyond to also allow pharmacists to provide all applicable CTBS (i.e, E-Visits, etc.).
	112. CMS IFR: Direct Supervision by Interactive Telecommunications Technology	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	In order to accommodate the provision of telehealth services during the PHE, CMS relaxed its rule requiring physicians to provide "direct supervision" of auxiliary personnel, including pharmacists, in situations where direct supervision currently is required by regulation. In these situations, during the PHE, physicians may

			provide "virtual supervision" of pharmacists. Although pharmacists are fully capable and trained to provide patient care services autonomously or under general supervision, the flexibility provided during the PHE for virtual supervision instead of direct supervision, at the very least, should be made permanent regardless of whether there is a declared PHE.
	125. CMS IFR: Payment for Medicare Telehealth Services **149. CMS IFR: Updating the Medicare Telehealth List on a Subregulatory Basis** **215. CMS Waiver: Eligibility for Telehealth**	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed	We strongly urge HHS to use the new authority under the recently passed "Coronavirus Aid, Relief, and Economic Security Act" or the "CARES Act" (P.L. 116-136) under Sec. 3703. Expanding Medicare Telehealth Flexibilities that eliminated requirements in the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (P.L. 116-123) and allows the HHS Secretary to waive telehealth restrictions under 1834(m) to enable beneficiaries to access telehealth, including in their home, from a broader range of providers—including pharmacists. Accordingly, given the significant burdens on the health care system posed by the pandemic, APhA urges the HHS Secretary to use this new authority under Sec.

			3703 to specifically include pharmacists as practitioners (providers) for the Medicare Telehealth Benefit in order to fully utilize their expertise during this health crisis. HHS should also add pharmacy services provided by pharmacists using telehealth, particularly pharmacy services provided outside of inpatient settings, to the telehealth list. Many patient care services provided by pharmacists are clinically appropriate for telehealth, including: medication management services, chronic condition management (e.g., diabetes, hypertension), medication reconciliation, transitions of care, pharmacogenomics, interpretation of diagnostic tests and providing test results, and consultations with patients and health care providers. NOTE: These are different from medication therapy management under Part D.
	354. CMS: Medicaid Disaster Relief SPA: Payments for Telehealth Services	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	APhA supports removing existing state plan language restricting use of telehealth/telephonic delivery of services and paying for such services at either the same face-to-face state plan rates or alternative rates—which can include many evidence-based, proven pharmacist-provided patient care

			services that improve health and lower costs.
	CMS: Accredited and Recognized Diabetes Self-Management Training (DSMT) Programs, Eligible to Bill Medicare Part B Directly for DSMT Services, May Furnish and Bill for DSMT Services Provided via Telehealth (Not listed in Appendix A)	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	APhA appreciates CMS' guidance clarifying that accredited and recognized diabetes self-management training (DSMT) programs, eligible to bill Medicare Part B directly for DSMT services, may furnish and bill for DSMT services provided via telehealth during the COVID-19 PHE, and urges the agency to make this authority permanent. Adding DSMT programs to the list of "professionals" eligible to provide telehealth services removes the final regulatory barrier preventing pharmacists in DSMT accredited pharmacies from furnishing DSMT services via telehealth and enhances patients with diabetes' access to care.
HIPAA	**5. HHS/OCR: Notification of Enforcement Discretion for Business Associates** **6. HHS/OCR: Notification of Enforcement Discretion for Community-Based Testing Sites**	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	Pharmacists providing COVID-19 testing services, under Prep Act authority, for "covered countermeasures," should receive flexibility under HIPAA in order to meet public health needs during a PHE.
REMS	**64. FDA Guidance: Policy for Certain REMS Requirements**	a. Should be maintained only for the duration of the PHE and pandemic	In order to ensure patient access to REMS drugs during the COVID-19 PHE, APhA appreciates FDA not

	During the COVID-19 PHE Guidance for Industry and Health Care Professionals		taking enforcement action and allowing health care providers prescribing and pharmacists dispensing REMS drugs to use their professional judgment in weighing the benefits and risks of continuing treatment in the absence of laboratory testing and imaging studies. However, given the importance of REMS in protecting patient health, APhA believes that this enforcement policy should be maintained only for the duration of the PHE.
Opioids/Opioid Treatment Programs (OTPs)	**2. SAMHSA Guidance: Take Home Medication**	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	The HHS Office of the Inspector General (OIG) has recently flagged that patients with opioid use disorders (OUDs) may experience difficulty accessing medication-assisted treatment (MAT), resulting in under-utilization of an effective treatment. APhA supports allowing OTPs to permit take-home medication for patients receiving MAT of up to 28 days during and after the COVID-19 PHE to improve access to MAT for OUD patients.
	121. CMS IFR: Requirements for OTPs	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	CMS revised § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished

			using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the COVID-19 PHE if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met. APhA supports making this permanent. Emerging data is demonstrating that meeting people with their available technology expands care, counseling, and referral. This is a health equity measure. See, "Expanding Telemedicine to Enhance Equity for Persons with Opioid Use Disorder: Position Statement of the Association for Multidisciplinary Education, Research in Substance use and Addiction (AMERSA)" (Dec. 2020).
	140. CMS IFR: OTP-Furnishing Periodic Assessments via Communication Technology	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	The COVID-19 pandemic has made it clear that telehealth is here to stay. In order to improve access to OUD treatment, especially in rural and other underserved areas, APhA supports making permanent allowing OTPs to furnish periodic assessments via telehealth.

	278. CMS Guidance: Opioid Safety Edits	c. Should be extended for a period of time after the expiration of the PHE or the end of the pandemic without being made permanent	Due to the increased burden on the healthcare system as a result of the COVID–19 PHE, APhA supports the waiver of this requirement during the PHE in order to lessen the administrative burden on prescribers and pharmacists. APhA believes that it is important to study opioid prescribing to prove these edits had an effect on prescribing (if possible) and did not cause access issues for patients with legitimate needs before re-instating them. We have a natural experiment of the opioid safety edits being lifted during the PHE, so we can follow the change year over year.
Pharmacist-Administered Vaccinations	**OASH: Authority of Pharmacists to Order and Administer COVID-19 Vaccine(s) and Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns Acting under the Supervision of the Qualified Pharmacist to Administer these Vaccines (Not listed in Appendix A)** **OASH: Authority for Pharmacists to Order and Administer ACIP-Recommended**	b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent	HHS took these important steps to significantly increase access to lifesaving vaccines and decrease the risk of vaccine-preventable disease outbreaks among the public and as children across the United States return to daycare, preschool and school. In its authorization, HHS cites CDC data on the declines in routine pediatric vaccine ordering and doses administered as the reason why this activation of pharmacists to administer vaccines is necessary

	Childhood Vaccines and Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns Acting under the Supervision of the Qualified Pharmacist to Administer these Vaccines (Not listed in Appendix A)		during the public health emergency. HHS' action acknowledges the fact that overall vaccination rates are falling, and families' visits to healthcare providers are still below pre-pandemic levels, influenced by vaccine hesitancy or loss of employment during COVID-19. Engaging pharmacists to increase immunization access and capacity across the U.S. will provide increased prevention and facilitate needed referrals to primary care providers. HHS should support regulatory or statutory changes to make permanent pharmacists' authority for administration of childhood vaccines, and COVID-19 tests, vaccines, and treatments after the PHE.
	CMS/Treasury: Administration Rates for Medicaid and Private Insurance (Not listed in Appendix A)	d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed	In the announcement of the 4th IFR, CMS is "encouraging state policymakers and other private insurance entities to utilize the information on the Medicare reimbursement strategy to develop their vaccine administration payment plan in the Medicaid program, CHIP, the Basic Health Program (BHP), and private plans. Using the

			Medicare strategy as a model would allow states to match federal efforts in successfully administering the full vaccine to the most vulnerable populations." All states received additional Medicaid funding and are supposed to pay vaccine administration rates out of that funding. However, they may defer, particularly in managed care states, to pharmacy benefit managers (PBMs), which could lower these rates below costs. Some states pay lower Medicaid rates for flu that do not cover administration costs and would likely do the same for COVID-19. While CMS does not have direct oversight of payment rates for states and commercial plans, CMS is in a strong position to work closely with the states and should issue a CMS letter to state Medicaid Directors and Commercial Payors and a HHS Secretary letter to the state Governors to reference the appropriately determined Medicare vaccine administration rates, as a first option, to ensure equitable implementation of COVID-19 vaccine administration coverage for all patients

			across the country, regardless of health care coverage. Additionally, guidance should be issued to reference the Medicare Administration rates, as a first option, from the Center for Consumer Information and Insurance Oversight (CCIIO) for the Health Insurance Marketplace plans and the Labor and Treasury Departments for private plans, ERISA plans (self-funded, fully-insured), etc.

Thank you for the opportunity to provide feedback on the RFI and consideration of our comments to assist your efforts to make temporary regulatory changes permanent and to modify others, as noted above. These actions by HHS are necessary in order to maximize the use of pharmacists and other health care practitioners to meet the public health needs of our nation during and after this pandemic. We stand ready to work with HHS to help protect our nation's economy as we navigate this novel virus and get America back to work. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

Sincerely,

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs