Provisions Impacting Pharmacists in SA 1578 (KEEPING AMERICAN WORKERS PAID AND EMPLOYED ACT) to H.R. 748:

- Sec. 3101. National Academies report on America's medical product supply chain security.
- Sec. 3102. Requiring the strategic national stockpile to include certain types of medical supplies.
- Sec. 3112. Additional manufacturer reporting requirements in response to drug shortages.
- Sec. 3201. Coverage of diagnostic testing for COVID-19.
- Sec. 3202. Pricing of diagnostic testing.
- Sec. 3203. Rapid coverage of preventive services and vaccines for coronavirus.
- Sec. 3214. United States Public Health Service Modernization.
- Sec. 3215. Limitation on liability for volunteer health care professionals during COVID-19 emergency response.
- Sec. 3221. Confidentiality and disclosure of records relating to substance use disorder.
- Sec. 3224. Guidance on protected health information.
- Sec. 3402. Health workforce coordination.
- Sec. 3403. Education and training relating to geriatrics.
- Sec. 3702. Inclusion of certain over-the-counter medical products as qualified medical expenses.
- Sec. 3703. Increasing Medicare telehealth flexibilities during emergency period.
- Sec. 3713. Coverage of the COVID-19 vaccine under part B of the Medicare program without any cost-sharing.
- Sec. 3714. Requiring Medicare prescription drug plans and MA–PD plans to allow during the COVID-19 emergency period for fills and refills of covered part D drugs for up to a 3-month supply.
- Sec. 3851. Regulation of certain nonprescription drugs that are marketed without an approved drug application.
- Sec. 3855. Annual update to Congress on appropriate pediatric indication for certain OTC cough and cold drugs.
- Sec. 3862. Fees relating to over-the-counter drugs.

Provision	Description	Impact on Pharmacists
Sec. 3101. National Academies report on America's medical product supply chain security.	In 60 days after enactment, HHS Secretary will enter into a contract with NASEM to "examine, and, in a manner that does not compromise national security, report on, the security of the United States medical product supply chain." The report will assess and evaluate the dependence of the United	Calls for NASEM to consult with **pharmacists** and others on a study on the medical product supply chain, shortages, reliance upon foreign sources, etc. in developing recommendations to HHS which could become polices for implementation in the future.

	States, including the private commercial sector, States, and the Federal Government, on critical drugs and devices that are sourced or manufactured outside of the United States, which may include an analysis of— (A) the supply chain of critical drugs and devices of greatest priority to providing health care; (B) any potential public health security or national security risks associated with reliance on critical drugs and devices sourced or manufactured outside of the United States, which may include responses to previous or existing shortages or public health emergencies, such as infectious disease outbreaks, bioterror attacks, and other public health threats; C) any existing supply chain information gaps, as applicable D) potential economic impact of increased domestic manufacturing; and (2) provide recommendations, which may include a plan to improve the resiliency of the supply chain for critical drugs and devices…and to address any supply vulnerabilities or potential disruptions of such products that would significantly affect or pose a threat to public health security or national security, as ap propriate, which may include strategies to— (A) promote supply chain redundancy and contingency planning; (B) encourage domestic manufacturing, including consideration of economic impacts, if any; C) improve supply chain information gaps;	

	(D) improve planning considerations for medical product supply chain capacity during public health emergencies; and (E) promote the accessibility of such drugs and devices. (c) INPUT.—In conducting the study and developing the report under subsection (b), the National Academies will consider input from the Department of Health and Human Services, the Department of Homeland Security, the Department of Defense, the Department of Commerce, the Department of State, the Department of Veterans Affairs, the Department of Justice, and any other Federal agencies as appropriate; and 2) consult with relevant stakeholders, which may include conducting public meetings and other forms of engagement, as appropriate, with health care providers, medical professional societies, based societies, public health experts, State based societies, public health experts, State and local public health departments, State medical boards, patient groups, medical product manufacturers, health care distributors, wholesalers and group purchasing organizations, **pharmacists,** and other entities with experience in health care and public health, as appropriate.	
Sec. 3102. Requiring the strategic national stockpile to include certain types of medical supplies.	Clarifies that the Strategic National Stockpile can stockpile medical supplies, such as "personal protective equipment, ancillary medical supplies, and other applicable	Pharmacists in states with shortages of this equipment could recommend their Governors ask the federal government to tap the Strategic

	supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile.	National Stockpile for this equipment.
Sec. 3112. Additional manufacturer reporting requirements in response to drug shortages.	In 6 months after enactment- Requires drug manufacturers to submit more information when there is an interruption in supply, including information about active pharmaceutical ingredients, when active pharmaceutical ingredients are the cause of the interruption. -Requires manufacturers to maintain contingency plans to ensure back up supply of products. -Requires manufacturers to provide information about drug volume.	HHS/FDA/ CMS will receive more information from drug manufacturers on drug shortages and if API is the reason for the shortages. Manufacturers will also need to have back-up supplies when this occurs.
Sec. 3201. Coverage of diagnostic testing for COVID-19.	Clarifies that all testing for COVID-19 is to be covered by private insurance plans without cost sharing, including those tests without an Emergency Use Authorization by the FDA	Clarifies for pharmacists that any State-approved/ HHS-approved COVID-19 test will be covered for patients without cost-sharing.
Sec. 3202. Pricing of diagnostic testing.	For COVID-19 testing covered with no cost to patients, requires an insurer to pay either the rate specified in a contract between the provider and the insurer, or, if there is no contract, a cash price posted by the provider. Both must be posted to a public website by providers.	For pharmacists and your patients, a key point, is this provision requires providers to post the cash price for the COVID-19 diagnostic test.
Sec. 3203. Rapid coverage of preventive services and vaccines for coronavirus.	Provides free coverage without cost-sharing of a vaccine within 15 days for COVID-19 that has in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force or a recommendation from the Advisory Committee on Immunization Practices (ACIP).	All private health plans must provide free coverage without cost-sharing of an approved COVID-19 vaccine.

Sec. 3214. United States Public Health Service Modernization.	Establishes a Ready Reserve Corps to ensure we have PHSC respond to COVID-19 and other public health emergencies.	May include pharmacists in the Ready Reserve Corps in the U.S. Public Health Service to respond to a public health or national emergency.
Sec. 3215. Limitation on liability for volunteer health care professionals during COVID-19 emergency response.	Makes clear that "health care professionals" who provide volunteer "health care services," including "A) the diagnosis, prevention, or treatment 19 of COVID-19; or (B) the assessment or care of the health of a human being related to an actual or suspected case of COVID-19 during the public health emergency related to COVID-19," have liability protections.	Licensed, registered, or certified pharmacists under Federal or State law to provide health care services who volunteer to provide COVID-19 "health care services" will receive federal liability protection. You can still receive reimbursement for "items to be used exclusively for rendering health care services in the health care professional's capacity," and for room and board and travel up to 75 miles from principal place of residence.
Sec. 3221. Confidentiality and disclosure of records relating to substance use disorder.	Allows for additional care coordination by aligning the 42 CFR Part 2 regulations, which govern the confidentiality and sharing of substance use disorder treatment records, with Health Insurance Portability and Accountability Act (HIPAA), with initial patient consent.	Allows for sharing patient information more easily after initial patient consent for health care treatment, payment and health care operations.
Sec. 3224. Guidance on protected health information.	In 6 months, requires the HHS Secretary to issue guidance on what is allowed to be shared of patient record during the public health emergency related to COVID-19.	Pharmacists involved in COVID-19 treatment will want to know what information they can share from patient's records.
Sec. 3402. Health workforce coordination.	Directs the HHS Secretary to develop a comprehensive and coordinated plan for health workforce programs at HHS within 1 year, which may include performance measures and the identification of gaps between the outcomes of such programs and relevant workforce projection needs. The HHS Secretary must report	Pharmacists may be included in the coordinated plan for health workforce programs at HHS to address any shortages/ needs identified by the Health Resources and Services Administration (HRSA).

	the plan to Congress in 2 years after enactment.	
Sec. 3403. Education and training relating to geriatrics.	Would require the HHS Secretary to award grants, contracts, or cooperative agreements for up to 5 years to…health professions schools or programs approved by the Secretary, for the establishment or operation of Geriatrics Workforce Enhancement Programs.	Pharmacists could be eligible for these federal grants in geriatric training "employed in an accredited health professions school or graduate program that is approved by the Secretary." The HHS Secretary may require, assurances that the individual has a full-time faculty appointment in a health professions institution and documented commitment from such eligible entity that the individual will spend 75 percent of the individual's time that is supported by the award on teaching and developing skills in interdisciplinary education in geriatrics. While physicians will get grants of $75,000, the HHS Secretary will decide the amount for individuals "who are not physicians."
Sec. 3702. Inclusion of certain over-the-counter medical products as qualified medical expenses.	Removes an Affordable Care Act provision restricting HSA/FSA use to prescription medicines only.	Patients will no longer need prescriptions to use HSAs/ FSAs to purchase OTC products at pharmacies, etc.
Sec. 3703. Expanding Medicare Telehealth Flexibilities:	This section would eliminate the requirement in Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (Public Law 116-123) that limits the Medicare telehealth expansion authority during the COVID-19 emergency period to situations where the physician or other professional has treated the patient in the past three years. This would enable beneficiaries to access telehealth, including in their home, from a broader range of providers.	This gives the HHS Secretary authority (really CMS) to consider waiving any telehealth restrictions/ rules on anyone, from anywhere in the future to treat the coronavirus, including potentially pharmacists, telepharmacy, etc.
Sec. 3713. Coverage of the COVID-19 vaccine under part B	This section would enable beneficiaries to receive a	Pharmacists can administer these vaccine(s), when available, under current

of the Medicare program without any cost-sharing.	COVID-19 vaccine in Medicare Part B with no cost-sharing.	Medicare rules - as "suppliers" and/ or when Part B compensates pharmacists as mass immunizers.
Sec. 3714. Requiring Medicare prescription drug plans and MA–PD plans to allow during the COVID-19 emergency period for fills and refills of covered part D drugs for up to a 3-month supply.	The provision requires Part D and Medicare Advantage (MA)-PD plans to allow a 3-month fill/ re-fill during the emergency (safety edits still apply).	Pharmacists will be able to fill/ re-fill 3-month scripts during the coronavirus emergency (safety edits still apply).
Sec. 3851. Regulation of certain nonprescription drugs that are marketed without an approved drug application.	Reforms the regulatory process for over-the-counter (OTC) drug monographs by allowing the FDA to approve changes OTC drugs administratively, rather than going through a full notice and comment rulemaking. Currently, FDA can approve all other drugs without going through a full notice and comment rulemaking, and this legislation makes sure OTC medicines receive the same treatment as other drugs. Grants companies an 18-month market-exclusivity for new OTC drugs.	This provision will allow FDA to approve OTC monographs quicker and could lead to more or new OTC drugs.
Sec. 3855. Annual update to Congress on appropriate pediatric indication for certain OTC cough and cold drugs.	Requires an annual update to Congress regarding FDA's progress in evaluating certain pediatric indications for certain cough and cold monograph drugs for children under age six.	The provision is meant to approve pediatric indications for certain cough and cold monograph drugs for children under age six.
Section 3862. Fees relating to over-the-counter drugs	Establishes a new FDA user fee to allow the agency to hire additional staff members to ensure there is adequate agency oversight to approve changes to OTC drugs.	Establishes an OTC user fee which will help staff FDA with additional resources to potentially approve more OTC drugs.