



To be completed by the Office of the
Secretary of the House of Delegates

Item No. 4
Date received: 2/9/2021
Time received: 8:45 PM

**American Pharmacists Association
House of Delegates – March 15, 2021**

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Rachel Barenie (APhA-APPM Delegate)
(Name)

February 9, 2021 APhA-APPM Delegation on behalf of the APhA-APPM Pain, Palliative Care
and Addiction Special Interest Group (SIG)
(Date) (Organization)

Subject: Increasing Access to and Affordability of Naloxone

Motion: To adopt the following policy statements:

1. APhA supports policies and practices that increase the availability of naloxone.
2. APhA supports the availability of naloxone as both a prescription and non-prescription medication.
3. APhA encourages pharmacists and payers to ensure equitable access to and affordability of at least one naloxone formulation regardless of prescription status.
4. APhA encourages payers to provide fair reimbursement to dispensers of naloxone.

Background:

Deaths due to overdoses continue to claim the lives of tens of thousands American every year in the US, with more than half involving an opioid.ⁱ In response, federal, state, and local authorities have made curtailing the opioid overdose crisis a top priority and funneled tremendous resources into efforts to combat it.ⁱⁱ One key measure is ensuring access to naloxone, which is a life-saving medication that acts as an opioid antagonist and used in the event of opioid overdose. The Surgeon General of the United States has recommended that everyone, whether that is a person at-risk for overdose, emergency personnel, or a loved one, have access to naloxone.^{iii,iv} Double-digit increases in

overall drug overdose fatalities were reported by the CDC between May 2019 and May 2020.^v The number of overdose deaths recorded in this 12-month timespan, more than 81,000 overall, was the highest ever reported in one year, the majority of these deaths caused by illegal opioids.⁵ The Health Advisory recommends several strategies to expand the provision and use of naloxone and overdose prevention education.⁵

In recent years, there have been prolific efforts advanced to achieve the Surgeon General's aim. From national guidelines and prescription drug labels that recommend practitioners to co-prescribe to widespread uptake of standing orders that allow pharmacists to co-dispense, naloxone remains a key harm reduction tool to combat the epidemic.^{vi,vii} Prior APhA policies have been phrased to narrowly support specific initiatives, such as state and federal laws that permit pharmacists to furnish the drug; however, all states now have passed laws related to increasing naloxone access via pharmacists and pharmacy staff.^{viii} Research has even shown that laws allowing pharmacists to dispense naloxone without a prescription is associated with significant increases in dispensing rates.^{ix} Thus, it is important that future policies to broaden access go beyond mere regulatory changes, especially during a historic pandemic that continues to disproportionately affect those at the highest risk of fatal and nonfatal overdose and their caregivers. The solution is to make naloxone as accessible and affordable as possible. **Retire statement 4 of Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents (2014): APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose. Support: APhA supports policies and practices that increase the availability and accessibility of naloxone.**

Access to naloxone is distinctly different from access to treatments for opioid use disorder (OUD). Evidence-based treatment for OUD includes medication sometimes in combination with psychosocial support. These medications are **life-sustaining** and include methadone, buprenorphine, and naltrexone. Since it is an "emergency-use" medication, ensuring access to naloxone is a life-saving effort, and the American Society of Addiction Medicine Guidelines recommend that all patients diagnosed with OUD receive naloxone. The FDA also recommends that people using methadone or buprenorphine also receive a naloxone prescription.^x An emphasis should be placed not only on **life-sustaining** treatment for OUD as supported by previous policies passed by APhA but also **life-saving** measures to help prevent unnecessary loss of life and ensure that those managing OUD and their caregivers are able to get the help they need.

The Food and Drug Administration has approved naloxone in multiple, prescription-only formulations, such as Narcan (nasal spray) and Evzio (intramuscular autoinjector) most recently.^{xi} Its onset of action is rapid, although dependent upon the route of administration, with the intravenous (IV) and intranasal routes demonstrating its effect within minutes to reverse potentially fatal effects of respiratory depression.^{xii,xiii} The drug can be administered by both laypersons and medical professionals, and it does not cause physical or psychological dependence.^{xiv,xv} This medication is extraordinarily safe, with no serious side effects associated with its use. Administering naloxone to an individual who is not suffering from an opioid overdose will not cause any harm. While the medication is not a treatment for opioid use disorder, it certainly is a key component of a set of harm reduction interventions for people who use drugs.^{xvi,xvii}

In recent years, there have been numerous initiatives to minimize barriers and improve access to naloxone.^{xviii} States have passed laws regarding authorized dispensing methods; immunity (civil, criminal, and/or disciplinary immunity for the prescriber/dispenser); and training (certification/education requirements). A majority of states permit third-party prescribing in a potential opioid overdose situation, in order to bypass the general prescriber-patient relationship requirement for prescribing medications to a patient, naloxone to be prescribed to a third-party patient (parent, caregiver, friend), so they can administer it to another person at-risk of an overdose

risk.^{xix} Several states have even promulgated laws allowing standing orders for naloxone administration and dispensing. Such orders may include a collaborative pharmacy practice agreement between the prescriber and a pharmacist, and a minority of states have enacted laws that permit some or all pharmacists to prescribe naloxone on their own authority.

States have also opted to pass “Good Samaritan Law” to help increase access to naloxone.^{xx} Witnesses of opioid overdoses are frequently afraid to get involved and report the situation, fearing their own arrest for a drug-related crime. To urge witnesses to call for emergency help, the majority of states modified laws to offer protection from prosecution and arrest against minor drug possessions for the person placing such emergency calls in good faith. Most of these laws provide a person who calls for emergency responders in good faith protection from prosecution for minor drug possessions. Almost all of those laws offer the same protection to the victim of the overdose as well. Some laws even expand protection to shield individuals from probation/ parole violations or even other drug-related crimes.^{xxi}

Recent research, however, suggests that only a fraction of patients who need the medication may actually be dispensed it. For example, recent claims database analyses suggest that merely 0.5% to upwards of 2% of patients who were at high-risk for an opioid-related overdose were dispensed the medication.^{xxii,xxiii} While this does not account for paying cash for the medication or obtaining it through a government sponsored distribution program, it does signal that access remains difficult to access for numerous reasons, such as cost, stigma, staffing shortages (lack of personnel with time to educate about need), regulatory issues, patient-related problems (discomfort with the program setting), patient preferences (some at-risk patients did not want an overdose kit) and legal concerns (patients’ concerns that having the kits would result in legal problems).^{xxiv} An effective policy intervention to increase naloxone co-prescribing and co-dispensing are state laws requiring naloxone prescriptions for patients receiving higher dose opioids, opioid-benzodiazepine combinations, those with an OUD diagnosis, and people who have a history of overdose.^{xxv} **APhA supports policies and practices that increase the availability of naloxone.**

State and federal governments recognize this medication is of premier public health importance. For example, in 2019, the FDA even developed over-the-counter labeling for naloxone.^{xxvi,xxvii} Yet, no manufacturer to-date has stepped up to manufacture it. More recently, the FDA added co-prescribing naloxone to the drug labeling on opioids and medications for opioid use disorder.^{xxviii} Making naloxone available as a non-prescription drug could substantially minimize the stigma patients may face when asking for naloxone at their pharmacy or having a claim billed to their insurance for it. This would offer patients an alternative means to access the medication. **APhA supports the availability of naloxone as both a prescription and non-prescription medication.**

With improved access must come improved affordability because the cost of naloxone may be one reason persons who need it do not have it. Recent research shows that the cost of naloxone—even when patients have insurance—is expensive, especially the brand-name formulation Evzio.^{xxix,xxx} If naloxone becomes available as a non-prescription medication, it will be important that it not only remains reasonably priced, but also is part of the optional coverage by insurers as a non-prescription medication.^{xxxi} Just as expanding Medicaid coverage is associated with a reduction in county-level opioid overdose deaths, it’s likely that maintaining coverage of naloxone by payers as a non-prescription drug will sustain this outcome trend.^{xxxii} **APhA encourages pharmacists and payers to ensure equitable access to and affordability of at least one naloxone formulation regardless of prescription status.**

In addition to access and affordability, fair reimbursement must also be supported for the dispenser of naloxone. A recently published article regarding pharmacy reimbursement found that pharmacies observed increases in generic drug prices by 50% or more during a recent two-year period, but the health plan and pharmacy benefit reimbursement did not parallel increasing

prices.^{xxxiii} More specifically, reimbursement only kept up with the rising prices 16% of the time.³³ These findings underscore the fact that pharmacies are often positioned to make difficult decisions when their costs increase without adequate reimbursement, which has likely contributed to an ongoing number of closures among retail pharmacies around the U.S. in recent years.^{33,xxxiv,xxxv} These closures are more likely to occur in communities with characteristics that are associated with higher drug overdose prevalence, thus further diminishing the impact of pharmacy-based naloxone.^{xxxvi}

APhA encourages payers to provide fair reimbursement to dispensers of naloxone.

Current Related APhA Policy & Bylaws:

2011 Potential Conflicts of Interest in Pharmacy Practice

- 1. APhA reaffirms that as health care professionals, pharmacists are expected to act in the best interest of patients when making clinical recommendations.**
- 2. APhA supports pharmacists using evidence-based practices to guide decisions that lead to the delivery of optimal patient care.**
- 3. APhA supports pharmacist development, adoption, and use of policies and procedures to manage potential conflicts of interest in practice.**
- 4. APhA should develop core principles that guide pharmacists in developing and using policies and procedures for identifying and managing potential conflicts of interest.**

(JAPhA NS51(4) 482;July/August 2011)(Reviewed 2016)

2019 Patient-Centered Care of People Who Inject Non-Medically Sanctioned Psychotropic or Psychotropic Substances

- 1. APhA encourages state legislatures and boards of pharmacy to revise laws and regulations to support the patient-centered care of people who inject non-medically sanctioned psychotropic or psychoactive substances.**
- 2. To reduce the consequences of stigma associated with injection drug use, APhA supports the expansion of interprofessional harm reduction education in the curriculum of schools and colleges of pharmacy, postgraduate training, and continuing professional development programs.**
- 3. APhA encourages pharmacists to initiate, sustain, and integrate evidence-based harm reduction principles and programs into their practice to optimize the health of people who inject non-medically sanctioned psychotropic or psychoactive substances.**
- 4. APhA supports pharmacists' roles to provide and promote consistent, unrestricted, and immediate access to evidence-based, mortality- and morbidity-reducing interventions to enhance the health of people who inject nonmedically sanctioned psychotropic or psychoactive substances and their communities, including: sterile syringes, needles, and other safe injection equipment, syringe disposal, fentanyl test strips, immunizations, condoms, wound care supplies, pre- and post-exposure prophylaxis medications for human immunodeficiency virus (HIV), point-of-care testing for HIV and hepatitis C virus (HCV), opioid overdose reversal medications, and medications for opioid use disorder.**
- 5. APhA urges pharmacists to refer people who inject non-medically sanctioned psychotropic or psychoactive substances to specialists in mental health, infectious diseases, and addiction treatment; to housing, vocational, harm reduction, and recovery support services; and to overdose prevention sites and syringe service programs.**

(JAPhA 59(4):e17July/August 2019)

2016 Medication-Assisted Treatment

APhA supports expanding access to Medication Assisted Treatment (MAT), including but not limited to pharmacist-administered injection services for treatment and maintenance of substance use disorders that are based on a valid prescription.

(JAPhA 56(4); 370 July/August 2016)

2011 The Role and Contributions of the Pharmacist in Public Health

In concert with the American Public Health Association's (APHA) 2006 policy statement, "The Role of the Pharmacist in Public Health," APhA encourages collaboration with APHA and other public health organizations to increase pharmacists' participation in initiatives designed to meet global, national, regional, state, local, and community health goals.

(JAPhA NS51(4) 482; July/August 2011)(Reviewed 2012)(Reviewed 2016) (Reviewed 2020)

1983 Stocking a Complete Inventory of Pharmaceutical Product

APhA supports the rights and responsibilities of individual pharmacists to determine their inventory and dispensing practices based on patient need, practice economics, practice security, and professional judgment.

(Am Pharm NS23(6):52 June 1983) (Reviewed 2004) (Reviewed 2010) (Reviewed 2015)

2005,1977 Government-Financed Reimbursement

1. APhA supports only those government-operated or -financed, third-party prescription programs which ensures that participating pharmacists receive individualized, equitable compensation for professional services and reimbursement for products provided under the program.

2. APhA regards equitable compensation under any government-operated or -financed, third party prescription programs as requiring payments equivalent to a participating pharmacist's prevailing charges to the self-paying public for comparable services and products, plus additional, documented, direct and indirect costs which are generated by participation in the program.

3. APhA supports those government-operated or -financed, third-party prescription programs which base compensation for professional services on professional fees and reimbursement for products provided on actual cost, with the provision of a specific exception to this policy in those instances when equity in professional compensation cannot otherwise be attained.

(JAPhA NS17:452 July 1977) (JAPhA NS45(5):558 September/October 2005) (Reviewed 2009)(Reviewed 2011)(Reviewed 2012)(Reviewed 2017)

2005,1981 Third-party Reimbursement Legislation

APhA supports enactment of legislation requiring that third-party program reimbursement to pharmacists be at least equal to the pharmacists prevailing charges to the self-paying public for comparable services and products, plus additional documented direct and indirect costs, which are generated by participating in the program.

(Am Pharm NS21(5):40 May 1981) (Reviewed 2005) (Reviewed 2009)(Reviewed 2014)(Reviewed 2019)

2016 Opioid Overdose Prevention

1. APhA supports access to third-party (non-patient recipient) prescriptions for opioid reversal agents that are furnished by pharmacists.

2. APhA affirms that third-party (non-patient recipient) prescriptions should be reimbursed by public and private payers.

(JAPhA 56(4); 370 July/August 2016)(Reviewed 2020)

2019,2016 **Substance Use Disorder**

1. APhA supports legislative, regulatory, and private sector efforts that include pharmacists' input and that will balance patient/consumers' need for access to medications for legitimate medical purposes with the need to prevent the diversion, misuse, and abuse of medications.

2. APhA supports consumer sales limits of nonprescription drug products, such as methamphetamine precursors, that may be illegally converted into drugs for illicit use.

3. APhA encourages education of all personnel involved in the distribution chain of nonprescription products so they understand the potential for certain products, such as methamphetamine precursors, to be illegally converted into drugs for illicit use. APhA supports comprehensive substance use disorder education, prevention, treatment, and recovery programs.

4. APhA supports public and private initiatives to fund treatment and prevention of substance use disorders.

5. APhA supports stringent enforcement of criminal laws against individuals who engage in drug trafficking.

(JAPhA 56(4); 369 July/August 2016)(JAPhA 59(4) e28 July/August 2019)

2019 **Referral System for the Pharmacy Profession**

1. APhA supports referrals of patients to pharmacists, among pharmacists, or between pharmacists and other health care providers to promote optimal patient outcomes.

2. APhA supports referrals to and by pharmacists that ensure timely patient access to quality services and promote patient freedom of choice.

3. APhA advocates for pharmacists' engagement in referral systems that are aligned with those of other health care providers and facilitate collaboration and information sharing to assure continuity of care.

4. APhA supports attribution and equitable payment to pharmacists providing patient care services as a result of a referral.

5. APhA promotes the pharmacist's professional responsibility to uphold ethical and legal standards of care in referral practices.

6. APhA reaffirms its support of development, adoption, and use of policies and procedures by pharmacists to manage potential conflicts of interest in practice, including in referral systems.

(JAPhA 59(4):e16 July/August 2019)

2014 **Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents**

1. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.

2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.

3. APhA supports pharmacists' access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.

4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.

5. APhA supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.

(JAPhA 54(4) July/August 2014)(Reviewed 2015)(Reviewed 2018)

1993 Pharmacists' Services

1. APhA supports development of pharmacy payment systems that include reimbursement of the cost of any medication or device provided; the cost of preparing the medication or device; the costs of administrative services; return on capital investment; and payment for both the dispensing-related and non-dispensing-pharmacy services.

2. APhA believes that appropriate incentives for the pharmacist providing care should be part of any payment system.

(Am Pharm NS33(7):53 July 1993) (Reviewed 2005) (Reviewed 2007) (Reviewed 2009) (Reviewed 2010)(Reviewed 2011)(Reviewed 2012)(Reviewed 2017)

2018 Direct and Indirect Remuneration Fees

APhA opposes retroactive direct and indirect remuneration (DIR) fees and supports initiatives to prohibit such fees on pharmacies.

(JAPhA 58(4):356 July/August 2018)

2018 Pharmacist Workplace Environment and Patient Safety

1. APhA supports staffing models that promote safe provision of patient care services and access to medications.

2. APhA encourages the adoption of patient centered quality and performance measures that align with safe delivery of patient care services and opposes the setting and use of operational quotas or time-oriented metrics that negatively impact patient care and safety.

3. APhA denounces any policies or practices of third-party administrators, processors, and payers that contribute to a workplace environment, which negatively impacts patient safety. APhA calls upon public and private policy makers to establish provider payment policies that support the safe provision of medications and delivery of effective patient care.

4. APhA urges pharmacy practice employers to establish collaborative mechanisms that engage the pharmacist in charge of each practice, pharmacists, pharmacy technicians, and pharmacy staff in addressing workplace issues that may have an impact on patient safety.

5. APhA urges employers to collaborate with the pharmacy staff to regularly and systematically examine and resolve workplace issues that may negatively have an impact on patient safety.

6. APhA opposes retaliation against pharmacy staff for reporting workplace issues that may negatively impact patient safety.

(JAPhA 58(4):355 July/August 2018)(Reviewed 2020)

2018,2013 Revisions to the Medication Classification System

1. APhA supports the Food and Drug Administration's (FDA's) efforts to revise the drug and medical device classification paradigms for prescription and nonprescription medications and medical devices to allow greater access to certain medications and medical devices under conditions of safe use while maintaining patients' relationships with their pharmacists and other health care providers.

2. APhA supports the implementation or modification of state laws and regulations to facilitate pharmacists' implementation and provision of services related to a revised drug and medical device classification system.
3. APhA supports a patient care delivery model built on coordination and communication between pharmacists and other health care team members in the evaluation and management of care delivery.
4. APhA affirms that pharmacists are qualified to provide clinical interventions on medications and medical devices under FDA's approved conditions of safe use.
5. APhA urges manufacturers, FDA, and other stakeholders to include pharmacists' input in the development and adoption of technology and standardized processes for services related to medications and medical devices under FDA's defined conditions of safe use.
6. APhA supports the utilization of best practices, treatment algorithms, and clinical judgment of pharmacists and other health care providers to guide the evaluation and management of care delivery related to medications and medical devices under FDA's approved conditions of safe use.
7. APhA encourages the inclusion of medications, medical devices, and their associated services provided under FDA's defined conditions of safe use within health benefit coverage.
- 8. APhA supports compensation of pharmacists and other health care professionals for the provision of services related to FDA's defined conditions of safe use programs.**

(JAPhA 53(4): 365 July/August 2013)(JAPhA 58(4):356 July/August 2018)

2017,2012 **Contemporary Pharmacy Practice**

1. APhA asserts that pharmacists should have the authority and support to practice to the full extent of their education, training, and experience in delivering patient care in all practice settings and activities.
2. APhA supports continuing efforts toward establishing a consistent and accurate perception of the contemporary role and practice of pharmacists by the general public, patients, and all persons and institutions engaged in health care policy, administration, payment, and delivery.
3. APhA supports continued collaboration with stakeholders to facilitate adoption of standardized practice acts, appropriate related laws, and regulations that reflect contemporary pharmacy practice.
4. APhA supports the establishment of multistate pharmacist licensure agreements to address the evolving needs of the pharmacy profession and pharmacist-provided patient care.
5. APhA urges the continued development of consensus documents, in collaboration with medical associations and other stakeholders, that recognize and support pharmacists' roles in patient care as health care providers.
- 6. APhA urges universal recognition of pharmacists as health care providers and compensation based on the level of patient care provided using standardized and future health care payment models.**

(JAPhA NS52(4) 457 July/August 2012)(Reviewed 2016) (JAPhA 57(4): 441 July/August 2017)(Reviewed 2019)

References:

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- i. Centers for Disease Control and Prevention. Drug Overdose Deaths, at <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited September 20, 2020).
- ii. US Department of Health and Human Services, Strategy to Combat Opioid Abuse, Misuse, and Overdose, at <<https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf>> (last visited September 20, 2020).
- iii. U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General’s Report on Alcohol, Drugs, and Health. Washington, DC: HHS, November 2016.
- iv. Department of Health and Human Services. US Surgeon General's Advisory on Naloxone and Opioid Overdose. Available at: <https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html> (last accessed September 20, 2020).
- v. Centers for Disease Control and Prevention. Increase in Fatal Drug Overdoses Across the US Driven by Synthetic Opioids Before and During the COVID-19 Pandemic, at <https://emergency.cdc.gov/han/2020/han00438.asp> (last visited February 3, 2021).
- vi. Centers for Disease Control and Prevention. CDC guidelines for prescribing opioids for chronic pain—United States, 2016. *MMWR*. 2016;65(1):1–49.
- vii. Food and Drug Administration. FDA requiring labeling changes for opioid medicines, opioid use disorder medicines regarding naloxone. July 23, 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding> (last accessed September 20, 2020).
- viii. The Network for Public Health Law. Legal interventions to reduce overdose mortality: naloxone access and overdose Good Samaritan laws. www.networkforphl.org/_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf. Accessed August 24, 2017.
- ix. Gangal NS, Hincapie AL, Jandarov R, et al. Association Between a State Law Allowing Pharmacists to Dispense Naloxone Without a Prescription and Naloxone Dispensing Rates. *JAMA Netw Open*. 2020;3(1):e1920310. doi:10.1001/jamanetworkopen.2019.20310
- x. Food and Drug Administration. New recommendations for naloxone, at <https://www.fda.gov/drugs/drug-safety-and-availability/new-recommendations-naloxone> (last accessed February 3, 2021).
- xi. Drugs@FDA. Naloxone. Available at: <https://www.accessdata.fda.gov/scripts/cder/daf/> (last accessed September 20, 2020).
- xii. Wheeler E, Jones TS, Gilbert MK, Davidson PJ. *Opioid overdose prevention programs providing naloxone to laypersons - United States, 2014*. *MMWR Morb Mortal Wkly Rep*. 2015 Jun 19;64(23):631–635.
- xiii. Narcan prescribing information, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.
- xiv. Clark AK, Wilder CM, Winstanley EL. *A systematic review of community opioid overdose prevention and naloxone distribution programs*. *J Addict Med*. 2014;8(3):153-163.
- xv. Narcan prescribing information, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.
- xvi. Alcohol and Drug Foundation, available @: <https://adf.org.au/reducing-risk/pharmaceuticals/naloxone-harm-reduction/>.
- xvii. Wheeler E, Davidson PJ, Jones TS, Irwin KS. Community-based opioid overdose prevention programs providing naloxone - United States, 2010. *MMWR Morb Mortal Wkly Rep*. 2012 Feb 17;61:101.
- xviii. Penn LDI. Expanding access to naloxone: A review of distribution strategies, at <<https://ldi.upenn.edu/brief/expanding-access-naloxone-review-distribution-strategies>> (last visited September 1, 2020).
- xix. Gabay, M, Increasing Access to Naloxone and Legal Issues, *Hosp Pharm*, Sept 2016, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5030873/>.
- xx. NCLS. Drug Overdose Immunity and Good Samaritan laws. June 5, 2017. Available at: <https://www.ncsl.org/research/civil-and-criminal-justice/drug-overdose-immunity-good-samaritan-laws.aspx> (last accessed September 20, 2020).
- xxi. Gabay, M, *Increasing Access to Naloxone and Legal Issues*, *Hosp Pharm*, Sept 2016, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5030873/>.

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- ^{xxii}. Follman S, et al. Naloxone prescriptions among commercially insured individuals at high risk of opioid overdose. *JAMA Netw Open*. 2019;2(5):e193209.
- ^{xxiii}. Barenie RE, et al. Rates and Costs of Dispensing Naloxone to Patients at High Risk for Opioid Overdose in the US, 2014-2018. *Drug Safety*. 2020;43:669-675.
- ^{xxiv}. Winstanley, et al. *Barriers to Implementation of Opioid Overdose Prevention Programs in Ohio*, *Subst Abus*, Jan 2017, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4848747/>.
- ^{xxv}. Green TC, Davis C, Xuan Z, Walley AY, Bratberg J. Laws Mandating Coprescription of Naloxone and Their Impact on Naloxone Prescription in Five US States, 2014-2018. *Am J Public Health*. 2020;110(6):881-887. doi:10.2105/AJPH.2020.305620
- ^{xxvi}. Food and Drug Administration. Statement from FDA Commissioner Scot Gottlieb, MD, on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths. January 17, 2019. Available at: <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over> (last accessed September 20, 2020).
- ^{xxvii}. Spivey CA et al. Evaluation of naloxone access, pricing, and barriers to dispensing in Tennessee retail community pharmacies. *JAPhA*. 2020. doi.org/10.1016/j.japh.2020.01.030.
- ^{xxviii}. Food and Drug Administration. FDA requiring labeling changes for opioid medicines, opioid use disorder medicines regarding naloxone. July 23, 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding> (last accessed September 20, 2020).
- ^{xxix}. Gupta et al. The Rising Price of Naloxone--Risks to Efforts to Stem Overdose Deaths. *N Engl J Med*. 2016;375:2213-2215.
- ^{xxx}. Guadamuz JS, Alexander GC, Chaudhri T, Trozky-Sirr R, Qato DM. Availability and Cost of Naloxone Nasal Spray at Pharmacies in Philadelphia, Pennsylvania, 2017. *JAMA Netw Open*. 2019;2(6):e195388. doi:10.1001/jamanetworkopen.2019.5388
- ^{xxxi}. Coursole A, McCaman E. Coverage of over-the-counter drugs in Medicaid. December 4, 2019. Available at: <https://healthlaw.org/resource/coverage-of-over-the-counter-drugs-in-medicaid/> (last accessed February 3, 2021).
- ^{xxxii} Kravitz-Wirtz N, Davis CS, Ponicki WR, et al. Association of Medicaid Expansion With Opioid Overdose Mortality in the United States. *JAMA Network Open*. 2020;3(1):e1919066. doi:10.1001/jamanetworkopen.2019.19066
- ^{xxxiii}. Silverman, Ed, *Pharmacy reimbursement often lags for generics undergoing price hikes, jeopardizing patient access*, *STAT*, April 14, 2020. Available at: <https://www.statnews.com/pharmalot/2020/04/14/pharmacies-generics-drug-prices/>. Last accessed September 25, 2020.
- ^{xxxiv}. Declining Pharmacy Reimbursement: The Facts. Rx Safe. Available from: <https://rxsafe.com/declining-reimbursement-the-facts/>. Last accessed September 29, 2020.
- ^{xxxv}. Twedt S. Citing declining reimbursements, longtime Indiana, PA., pharmacy closes. *Pittsburgh Post-Gazette*. July 2, 2020. Available at: <https://www.post-gazette.com/business/healthcare-business/2020/07/02/Gatti-Pharmacy-Pharmacy-Benefit-Manager-PBM-reimbursement-independent-reimbursement/stories/202007020064>. Last accessed September 29, 2020.
- ^{xxxvi}. Guadamuz JS, Alexander GC, Zenk SN, Qato DM. Assessment of Pharmacy Closures in the United States From 2009 Through 2015. *JAMA Internal Medicine*. Published online 2019;1. doi:10.1001/jamainternmed.2019.4588

***Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item Content.**

New Business Items are due to the Speaker of the House by **February 10, 2021** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.