AMERICAN PHARMACISTS ASSOCIATION
STATEMENT FOR THE RECORD

BEFORE THE U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

LOWERING PRESCRIPTION DRUG PRICES:
DECONSTRUCTING THE DRUG SUPPLY CHAIN

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Chairwoman Eshoo, Ranking Member Burgess, and Members of the Committee, the American Pharmacists Association (APhA) is pleased to submit the following Statement for the Record for the U.S. House Committee on Energy and Commerce Hearing "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain."

APhA, founded in 1852 as the American Pharmaceutical Association, represents nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, specialty pharmacy, community health centers, managed care organizations, hospice settings and the uniformed services.

Pharmacies are where millions of Americans are first exposed to the impact of complex pharmaceutical pricing policies or confronted with changes in coverage, formularies, prior authorization, deductibles and co-payments or co-insurance, many of which they didn't know existed or understand. Everyday, pharmacists help our patients navigate through confusing and convoluted policies related to the coverage of their medications and management of their out of pocket costs. We are not compensated for this time or directly for most of our patient care services that support optimization of medication therapy. Our comments focus on the following areas – cost versus value, patients' access to medications, pharmacy benefit managers (PBMs), pharmacy access to medications, drug shortages, medications' safety and affordability and importation concerns.

Cost Versus Value

As drugs become more expensive, complex, and personalized, the need to optimize their impact also increases. In order to get the greatest benefit from medications, patients must understand how to use their medications safely and effectively, and pharmacists are best positioned to help patients optimize the medication therapies available to them. Pharmacists have more medication-related education and training than any other health care professional. Pharmacists provide medication management services, which are especially important for patients who have complex care plans, take multiple drugs or have chronic conditions. Additionally, to reduce the risk of hospital readmissions, pharmacists help patients transition between care settings. The most expensive medication is one that is inappropriate for a patient or used incorrectly.

Unfortunately, despite the fact that many states and Medicaid programs are turning to pharmacists to increase access to health care and address medication-related costs, efforts supported by the Centers for Medicare and Medicaid Services (CMS),[1] Medicare Part B does not cover many of the impactful and valuable patient care services pharmacists can provide. Pharmacists are trained to do more than place medication in a container and while 91.7% of Americans live within 5 miles of a community pharmacy[2] many of our Nation's seniors are medically underserved. Pharmacists are an underutilized and accessible health care resource who can positively affect beneficiaries' care[3] and the entire Medicare program.

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[1] CMS/ CMCS Informational Bulletin. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. January 17, 2017, available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf

[2] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

[3] CMS. Evidence Supporting Enhanced Medication Therapy Management. Center for Medicare and Medicaid Innovation. 2016, available at: https://innovation.cms.gov/Files/x/mtm-evidencebase.pdf

APhA strongly believes bipartisan legislation introduced in the 115th Congress, the *Pharmacy and Medically Underserved Areas Enhancement Act* will improve patient care, health outcomes, impact of medications,[4] and consequently, the viability of the Medicare program. Introduced by former Congressmen Brett Guthrie and G.K. Butterfield, H.R. 592 enjoyed the support of 296 bipartisan cosponsors last year, including many Members of this Committee.

This legislation would enable Medicare patients in medically underserved communities to better access health care through state-licensed pharmacists practicing according to their own state's scope of practice. In medically underserved communities, pharmacists are often the closest health care professional and accessible outside normal business hours. Helping patients receive the care they need, when they need it, is a common sense and bipartisan solution that will improve outcomes and reduce overall costs.

The importance of medication-related services cannot be overstated, especially in the Medicare program. Medications are the primary method of managing chronic disease and are involved in 80 percent of all treatment regimens. Moreover, the United States spends nearly $672 billion annually on medication-related problems and nonoptimized medication therapy, including nonadherence.[5] Accordingly, not only will such legislation increase beneficiaries' access to health care, it will help improve their outcomes—particularly those impacted by medications. APhA appreciates the support by many Committee members for the *Pharmacy and Medically Underserved Areas Enhancement Act* and urges its swift passage to allow pharmacists to deliver these vital services as providers in medically underserved areas.

We also encourage the Committee, when considering policy changes to lower drug prices, to look beyond isolated components of health care to determine cost and value. Because health coverage is frequently analyzed by the benefit type such as inpatient, outpatient, and drug coverage, a patient's overall services, costs and outcomes may never be reviewed comprehensively. Policies cannot continue to consider drug and medical coverage, and their related costs and outcomes, separately if we are to achieve true value in health care. Current coverage and payment policies related to prescription drugs place incentives on the short-term, focusing on cost containment for the product rather than weighing the overall clinical benefit to the patient and the impact to their medical costs. Breaking down the many silos within our health care system will help address that billions of dollars spent on medication-related problems—many of which are preventable.[6]

Patients' Access to Medications

As the organization representing pharmacists in all practice settings, APhA has been, and is, a strong supporter of policies which increase patients' access to affordable and cost-effective medicines. Decisions along the entire drug supply chain impact patients' medication costs, including arrangements between manufacturers, wholesalers, insurers, and PBMs. Because of these upstream stakeholder

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[4] *See*, Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment Also, *See*, Avalere Health. Developing Trends in Delivery and Reimbursement of Pharmacist Services. October 2015, available at: http://avalere.com/expertise/managed-care/insights/new-analysis-identifies-factors-that-can-facilitate-broader-reimbursement-o

[5] Watanabe, Jonathan H. Et. al. Cost of Prescription Drug–Related Morbidity and Mortality. Annals of Pharmacology. First Published March 26, 2018, available at: http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full

[6] Ibid.

policies, for most patients, pharmacists have limited options to impact patients' final drug costs. Moreover, complex coverage and payment policies hinder the full potential of community pharmacists' clinical education and training from being realized as much of their day is spent on the phone trying to find an appropriate treatment that is not only covered, but the patient can afford. Consequently, APhA supports a transparent pricing framework which would eliminate such mechanisms as hidden discounts, free goods and post point-of-sale price fees imposed on pharmacies.[7]

PBMs

Both Congress and the Administration have pointed out ongoing PBM practices in the Medicare program negatively impacting patient costs, care and access. Additional proposals from the Administration have emphasized PBMs operate in a consolidated, opaque space and pose a barrier to pharmaceutical companies lowering their prices[8] and spend a significant amount of effort trying to rectify the negative impact certain PBM practices have had on patients and pharmacies.[9]

APhA appreciates the strong bipartisan support of the Committee for recent legislation signed into law that prohibits PBMs' use of so-called pharmacist "gag clauses" in Medicare and private health plans, to support the flow of information between pharmacists and their patients. These laws increase patients' access to more affordable and cost-effective medicines by empowering pharmacists to inform patients that a medication may be less expensive if purchased at the "cash price," rather than through their insurance plan. For years, pharmacists have been frustrated by our inability to help our patients who we knew were struggling with high co-payments. APhA also looks forward to continuing to work with you to lower patients' out-of-pocket costs.

Similarly, APhA hopes the Committee will build off these bipartisan results to pass H.R. 803, the *Improving Transparency and Accuracy in Medicare Part D Spending Act*, that would prohibit Medicare Part D plan sponsors and their PBMs from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D. CMS has acknowledged a notable growth in Direct and Indirect Remuneration (DIR) fees, which have more than tripled in recent years.[10] Prohibiting Medicare Part D plan sponsors/ PBMs from retroactively reducing payment on clean claims submitted by pharmacies would, in turn, increase transparency in drug pricing, decrease beneficiaries' out-of-pocket costs and Medicare catastrophic coverage costs, and reduce the negative impact of these practices on the sustainability of patient access to the services provided by pharmacists.

APhA also supports H.R. 1035, the *Prescription Drug Price Transparency Act*, a bill that will bring greater transparency and accountability by requiring PBMs to disclose the sources used in their Maximum Allowable Cost (MAC) price determinations by ensuring the list is updated every seven days for Medicare Part D, Medicare Advantage and the Federal Employee Health Benefits Program (FEHBP). Most importantly this legislation preserves patient access to the pharmacy they choose.

We also support H.R. 2376, the *Prescription Pricing for the People Act of 2019*, recently passed on a bipartisan basis by the House Judiciary Committee, which shares jurisdiction with the Energy and

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[7] *See*, Addendum: APhA House of Delegates Policies Related to Drug Pricing.
[8] HHS. American Patients First - The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018, available at: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf
[9] HHS/ OIG. Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Proposed Rule. February 6, 2019, available at: https://www.regulations.gov/document?D=HHSIG-2019-0001-0001
[10] See, Wakely Consulting Group analysis. 2017, available at: http://www.ncpa.co/pdf/wakely-report.pdf

Commerce Committee. H.R. 2376 would require the Federal Trade Commission (FTC) to evaluate whether PBMs charge certain payers, including Medicare and Medicaid, a higher price than reimbursement rates for competing pharmacies while reimbursing pharmacies in which the PBMs have an ownership interest at the rate charged to payers; steer patients to pharmacies in which the PBM has an ownership stake; and use formulary designs to depress the market share of low-cost, lower-rebate prescription drugs.

In 2018, APhA's House of Delegates passed a resolution stating "APhA opposes retroactive direct and indirect remuneration (DIR) fees and supports initiatives to prohibit such fees on pharmacies."[11] As recognized by CMS, certain PBM practices can result in higher prices at the point-of-sale and consequently, higher beneficiary co-pays. DIR fees were originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, DIR fees by PBMs are now being used beyond their original purpose to retroactively adjust pharmacies' payment months after the sale, sometimes below the price paid for the product by the pharmacy. As stated by CMS in the November 2017 proposed Medicare Part D rule, "[b]etween 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs, according to the cost and price concession data Part D sponsors submitted to CMS for payment purposes."[12]

There is simply no connection between price concessions given by manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Thus, DIR fees "recovered" from pharmacies by PBMs are totally illogical (i.e., recovering money from pharmacies that pharmacies did not "receive" in the first place). Because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before DIR is extracted, many beneficiaries actually pay higher out-of-pocket costs. CMS has cited numerous research that further suggest higher cost-sharing can impede beneficiary access and adherence to necessary medications, which leads to poorer health outcomes and higher overall medical care costs for beneficiaries and Medicare. Therefore, APhA strongly urges the Committee to prohibit PBMs' use of such fees as part of their payment methodology for pharmacies.

As you know, Medicare-enrolled seniors pay pharmacies a co-pay for medications, while the full price of the drug is credited against the patient's coverage limit. The PBM administering Medicare's prescription benefit decides to use retroactive DIR fees to take back a portion of the product reimbursement to the pharmacy for the actual costs of the patient's medication, often causing pharmacies to ultimately dispense a medication below their product cost, which jeopardizes the sustainability of patient access. In addition, the original higher price – not the DIR adjusted price – is still counted against the patient, pushing them more quickly into Medicare's "doughnut hole" coverage gap in which they become responsible for a much greater portion of their prescription costs. Even after the coverage gap closes in 2020, the use of DIR fees significantly increases costs as these patients enter Medicare's catastrophic coverage phase, in which taxpayers are now on the hook for 80% of each patient's health care expenses.

An additional problem facing some pharmacies' ability to offer medications to patients is the inability to enter into contracts with health plans due to the growth in narrow networks. APhA urges the Committee to require Part D plans to contract with any pharmacy willing to accept their contractual

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[11] APhA. House of Delegates. Current Adopted Policy Statements 1963-2018. (JAPhA 58(4):356 July/August 2018). Pg. 115, available at: https://media.pharmacist.com/hod/APhA_Policy_and_Procedures_2018.pdf

[12] CMS. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Proposed Rule. November 28, 2017, available at: https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare

terms and conditions. Increasing patient choice will not only improve patients' access to benefits and services, but will likely positively impact patient satisfaction and outcomes, such as adherence.

Pharmacy Access to Medications

Another issue impeding patient access to medications from a pharmacy of their choice is manufacturer-imposed limited distribution policies. As more costly and complex medications are being developed, some manufacturers and/or distributors restrict distribution by identifying few pharmacies who may purchase and subsequently provide the medication to patients. Often, these limited distribution policies will impose requirements beyond those required by the state or Food and Drug Administration (FDA). Assuming a pharmacist eventually identifies, deciphers and meets the requirements to obtain the medication, they may still be denied the ability to purchase the medication. Consequently, patients are effectively forced to receive care from multiple pharmacists which leads to siloed and fragmented care. To address these issues, APhA encourages the Committee examine limited distribution of certain medications and the impact these mechanisms have on patients and competition. Patients should have access to medications from pharmacy providers of their choice who are willing to meet reasonable and meaningful expectations that support optimal outcomes from provided medications.

Drug Shortages

Drug shortages are another factor that can negatively affect patients in terms of cost and the availability of their treatments. APhA urges the Committee to consider mechanisms to both better control the price of medications in shortage and improve tracking and prediction systems used to identify drugs in shortage. APhA also strongly supports the appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.

Medications' Safety and Affordability

APhA supports congressional efforts to increase patients' access to appropriate, safe, effective, and affordable prescription medications. We encourage the development and implementation of a framework by the FDA for determining biologic product interchangeability. APhA opposes practices which circumvent the intent of drug product review laws and negatively impact the pharmacist's ability to substitute medications for safe, effective, lower-cost alternatives. Conversely, APhA supports pharmacists collaborating with prescribers and patients to design cost-effective treatment regimens, identify formulary or generic products as a means to reduce costs, and intervene on behalf of the patient to identify alternate therapies.

Importation Concerns

Although APhA supports congressional efforts to address patients' medication costs, APhA has significant concerns with turning to drug importation to achieve lower prices. We believe proposals to legalize importation of non-FDA approved drugs is not a comprehensive solution to the complex issue of drug pricing, threatens patient safety, disrupts care, and directly conflicts with efforts by Congress and federal agencies to increase the integrity and security of the U.S. drug supply pursuant to the *Drug Supply Chain Security Act* (DSCSA). Furthermore, APhA is concerned savings, if any, will be short-term and importation will instead result in long-term costs to patients and the health care system.

Because drug importation policies effectively encourage patients to buy medications online from foreign sources, APhA fears patients will be at an even greater risk of taking ineffective, adulterated or harmful medications, including controlled medications they were not prescribed. The lack of a strong regulatory framework for internet pharmacies in certain foreign countries has led to a large number of illegitimate

foreign internet pharmacies. APhA's concerns regarding foreign internet pharmacies are compounded by the large number of internet "pharmacies" which have increased and become more sophisticated in recent years, making them difficult to track and permanently stop.

Importantly, broader importation laws will further fragment care and hinder the progress made by Congress to move U.S. health care delivery and payment towards coordination and value. Value-based care models and other efforts to produce savings and promote quality, such as outcomes-based reimbursement, will be more difficult to measure and optimize if patients are allowed to receive uncoordinated care outside the model's mechanisms to drive results.

Because Canadian pharmacists may only fill prescriptions written by Canadian prescribers, expanded importation policies will encourage Americans to seek care from foreign prescribers and pharmacists, whose systems and standards are not integrated into, or consistent with, U.S. systems or care. Therefore, in March 2019, APhA issued a joint statement with the Canadian Pharmacists Association (CPhA) in opposition to U.S. federal legislation authorizing personal and commercial importation of prescription drugs from Canada because of the risks these policies pose to patient safety and continuity of care.[13]

As previously noted, obtaining safe and effective medications is only one part of appropriate medication use. It also requires a health practitioner's knowledge of the patient's complete medication profile and an understanding by the patient of how to take the medication, side effects and/or potential interactions — all of which could be negatively affected by importation proposals. APhA believes importation of non-FDA approved drugs could hurt the very patients intended to benefit from importation proposals. Consequently, the risks to patient safety from harmful or ineffective products or avoidable medication errors due to fractured care outweighs any increase in access or cost-savings.

APhA would like to thank the Committee for continuing to work with us and other pharmacy stakeholders to lower drug prices and increase transparency of PBM practices for pharmacies and patients. We also appreciate your ongoing leadership addressing the barriers to innovation which continue to increase America's rising health care costs. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at AMica@aphanet.org or by phone to (202) 429-7507 to arrange a meeting with us to discuss the many services pharmacists provide to improve patient care, outcomes and reduce costs.

Addendum: APhA House of Delegates Policies Related to Drug Pricing

[13] CPhA/ APhA. American and Canadian pharmacist associations warn that drug importation policies could put patients at risk. Joint Statement. March 2019, available at: https://www.pharmacist.com/sites/default/files/audience/Joint%20Statement%20APhA%20and%20CPhA%20Importation%20.pdf

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)

2004, 1968 **Manufacturers' Pricing Policies**
APhA supports pharmaceutical industry adoption of a "transparent pricing" system which would eliminate hidden discounts, free goods, and other subtle economic devices.
(JAPhA NS8:362 July 1968) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016) (Reviewed 2018)

1985 **Pharmaceutical Pricing**
APhA supports a system of equal opportunity with the same terms, conditions, and prices available for all pharmacies.
(Am Pharm NS25(5):52 May 1985) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

2004, 1977 **Prescription Drug Advertising**
APhA does not oppose the dissemination of price information to patients, by advertising or by any other means.
(JAPhA NS17:448 July 1977)(JAPhA NS44(5):551 September/October 2004)(Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

1999 **Direct-to-Consumer Advertising of Medications**
1. APhA supports legislative and regulatory activities permitting direct-to-consumer advertising concerning medical or health conditions treatable by prescription or nonprescription drug products. These advertisements must conform to rules and regulations that ensure complete, comprehensive, and understandable information that informs consumers of potential benefits and risks of the product.
2. APhA opposes false or misleading advertising for prescription or nonprescription drugs or any promotional efforts that encourage indiscriminate use of medication.
3. APhA supports the availability of accurate information to consumers about medication use and recognizes the responsibility of pharmacists to provide appropriate responses to consumer inquiries stimulated by direct-to-consumer advertising as a compensated pharmaceutical service. In addition, APhA recommends that health care professionals, including but not limited to pharmacists, receive new product information on direct-to-consumer advertising campaigns prior to this information being made available to consumers.
(JAPhA 39(4): 447 July/August 1999)(Reviewed 2004) (Reviewed 2006)(Reviewed 2011) (Reviewed 2016)

2016, 1994 **Pharmacy Services Benefits in Health Care Reform**
A single set of pricing rules, eliminating class-of-trade distinctions, for medications, medication delivery systems, and other equipment so that no payer, patient, or provider is disadvantaged by cost shifting.
The right for every American to choose his/her own provider of medications and pharmacists' services and for all pharmacists to participate in the health plans of their choice under equally applied terms and conditions.
(Am Pharm NS34(6):58 June 1994) (Reviewed 2004) (Reviewed 2010) (Reviewed 2011)(JAPhA 56(4); 379 July/August 2016) (Reviewed 2018)

2016 **Biologic, Biosimilar, and Interchangeable Biologic Drug Products**

APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products.
(JAPhA 56(4); 369 July/August 2016)

2005, 1977 **Government-Financed Reimbursement**
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.
(JAPhA NS17:452 July 1977) (JAPhA NS45(5):558 September/October 2005) (Reviwed 2009(Reviewed 2011)(Reviewed 2012)(Reviewed 2017)

2012 **Drug Supply Shortages and Patient Care**
APhA encourages the active investigation and appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.
(JAPhA NS52(4) 457 July/August 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)*

1967 **Drugs Provided Under Social Security Act: Guidelines for Pharmaceutical Service**
Since it is probable or likely that APhA may have to consider and act upon some proposals in the area of drug costs before the next annual meeting, we recommend that APhA Board of Trustees be guided by whether the proposals: (a) Permit pharmacists to select and dispense a quality drug product; (b) Establish some mechanism to assist pharmacists in selecting quality, drug products under the cost and other criteria established; (c) Permit the use of any available drug product when unique medical circumstances so require; (d) Establish a reasonable remuneration base for pharmacists rendering services under the program; (e) Guarantee recipients free choice of pharmacy; and (f) Limit the reimbursement for pharmacists' services to those provided by duly licensed pharmacists.
(JAPhA NS7:315 June 1967) (Reviewed 2005) (Reviewed 2009)(Reviewed 2014)

2013, 1980 **Medication Selection by Pharmacists**
APhA supports the concept of a team approach to health care in which health care professionals perform those functions for which they are educated. APhA recognizes that the pharmacist is the expert on drugs and drug therapy on the health care team and supports a medication selection role for the pharmacist, based on the specific diagnosis of a qualified health care practitioner.
(Am Pharm NS20(7):62 July 1980) (Reviewed 2003) (Reviewed 2007) (Reviewed 2008) (Reviewed 2009)(Reviewed 2011)(Reviewed 2012)(JAPhA 53(4):366 July/August 2013) (Reviewed 2018)

2017 **Pharmacy Performance Networks**
APhA supports performance networks that improve patient care and health outcomes, reduce costs, use pharmacists as an integral part of the health care team, and include evidence-based quality measures.
(JAPhA 57(4): 441 July/August 2017)