

# Response from the American College of Physicians To the U.S. Senate Committee on Health, Education, Labor and Pensions On Lowering Health Care Costs March 1, 2019

The American College of Physicians (ACP) is pleased to submit this response and appreciates that Chairman Alexander and Ranking Member Murray have requested information from the health-care community about how to lower health-care costs. We applaud your shared commitment to lowering health-care costs, incentivizing care that improves patient outcomes, and increasing the ability for patients to access information to make informed health decisions. ACP appreciates that the Health, Education, Labor and Pensions Committee (HELP) has been holding hearings on these topics including most recently the February 5th, 2019, hearing entitled, "How Primary Care Affects Health Care Costs and Outcomes." We also hope that this important discussion will provide a platform to act on bipartisan solutions impacting the cost and coverage of health care. Although the health care debate has turned more partisan in recent years, we believe that common ground can be reached on the path forward on policies that share bipartisan support. We wish to assist in the HELP Committee's efforts by offering our input and suggestions; in 2017 ACP released a forward looking document that provides a prescription for Congress to implement a broad array of bipartisan solutions to improve the quality of health care.

The American College of Physicians is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

#### **INVESTMENT IN HIGH-VALUE PRIMARY CARE**

Investing in primary care is critical not only to overall patient health but also to the reduction of costs in the health care system. The National Academy of Medicine defines primary care as "the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community."

The hallmarks of primary care medicine—first contact care, continuity of care, comprehensive care, and coordinated care—are increasingly necessary for taking care of an aging population with growing incidence of chronic disease and have proven to achieve improved outcomes and cost savings. Primary

care physicians provide not only the first contact for a person with an undiagnosed health concern but also the continued care of varied medical conditions, not limited by cause, organ system, or diagnosis.

For many patients, primary care physicians are the first point of contact within the healthcare system. This means they are often the first to see depression, early signs of cancer or chronic disease, and other health concerns. They ensure patients get the right care, in the right setting, by the most appropriate clinician, and in a coordinated way. The two specialties that provide the majority of adult primary care in the United States are internal medicine and family medicine. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. They provide both acute and long-term comprehensive care in the office and the hospital, managing both common and complex or unusual illnesses of adolescents, adults, and the elderly. Internists receive indepth training in the diagnosis and treatment of conditions that affect all organ systems. Internists are specially trained to solve puzzling diagnostic problems and manage patients in both acute and chronic situations where several illnesses may occur and interact at the same time. They are also trained in the essentials of primary care internal medicine, which incorporate an understanding of disease prevention, wellness, substance abuse, and mental health.

The data clearly shows the importance of primary care:

- U.S. adults who have a primary care physician have 19 percent lower odds of premature death than those who only see specialists for their care;
- Adults who see primary care physicians also have 33 percent lower health care costs;
- States with higher ratios of primary care physicians to population have better health outcomes, including decreased mortality from cancer, heart disease, or stroke;
- Medicare spending is also lower in states with more primary care physicians.<sup>1</sup>

Without primary care, the health care system would become increasingly fragmented and inefficient—leading to poorer quality care at higher costs. Several years ago, ACP released a comprehensive annotated summary of more than 100 studies,<sup>2</sup> conducted over the past two decades in the United States and abroad, that shows that the availability of primary care is consistently associated with better outcomes and lower costs of care. In the United States, primary care is only seven percent of healthcare spending and specialists outnumber primary care physicians 2 to 3:1. In other countries, where primary care is 20 percent of health care spending and the specialist to primary care physicians' ratio is 1:1, per capita costs are lower and outcomes are better where there is primary care access.<sup>3</sup> Accordingly, ACP has committed to the Patient Centered Primary Care Collaborative's, "Consensus Recommendations on Increasing Primary Care Investment" in order to support initiatives to provide more funding and resources to primary care.

Given the importance of primary care and its value in reducing costs and improving outcomes, multi-faceted and comprehensive range of policies—which will be explored in greater depth below—are necessary to retain, attract, and support physicians going into primary care, which would encompass:

- Increased funding and reforms to Medicare Graduate Medical Education (GME) program;
- Medicare payment policy to supporting high value primary care;

- Authorization and funding for primary care training programs, the NHSC, and other federal programs to train and retain physicians in primary care;
- Reduction in the administrative burdens imposed on primary care physicians;
- An explicit decision to increase the overall share of federal investments in health to supporting primary care.

Promote high value care assessments to guide clinical decision making. In order to bring greater value for the primary care dollars spent, ACP strongly supports the implementation of high-value care principles into day-to-day clinical decision making of physicians. Therefore, we recommend that our clinical practice guidelines, clinical guidance statements, and best practice advice be actively incorporated into decision-support systems. We also recommend the use of our <a href="High-Value Care">High-Value Care</a> Coordination (HVCC) toolkit as a practical approach that clinicians can take to ensure high-value care. The HVCC Toolkit provides resources to facilitate more effective and patient-centered communication between primary care and subspecialist doctors. This toolkit includes pertinent data sets for referrals, model out-patient referral request and response checklists, ways to ensure patient- and family-centered discussions with patients regarding their decision process, and care coordination agreements. The HVCCC toolkit was developed under the direction of ACP's Council of Subspecialty Societies and informed by the ACP policy paper, The Patient-Centered Medical Home Neighbor: The Interface of the Patient-Centered Medical Home with Specialty/Subspecialty Practices.

Promote evidence-based benefit design by applying comparative effectiveness research to coverage decisions and cost-sharing. The College supports evidence-based benefit design by applying comparative effectiveness research to coverage decisions and cost-sharing. The College strongly supports evidence-based benefits design and continues to support the role of Patient Centered Outcomes Research Institute (PCORI) and the Agency for Healthcare Research and Quality (AHRQ) in conducting comparative effectiveness research and disseminating evidence-based methods for clinical practice, coverage and pricing decisions, and cost-sharing and benefit design. Congress should reauthorize PCORI funding, which expires after the 2019 fiscal year, for at least 10 years to continue its mission of comparative effectiveness research available to all clinicians. In addition, Congress should fund AHRQ at \$460 million for FY2020 to achieve the level of resources it had before the agency's funding was cut back after the 2010 fiscal year.

Continue to support the critical role played by the Center for Medicare and Medicaid Innovation (CMMI) in testing and funding value-based payment and delivery models. The College strongly supports CMMI and its essential role in developing, financing, implementing, evaluating, and expanding innovative physician-led Advanced Alternative Payment Models (APMs) as authorized by MACRA, as well as in the broader context of value-based payment and delivery system reform. ACP encourages the Centers for Medicare and Medicaid Services (CMS) to fully use its authority under CMMI and the Physician-Focused Payment Model Technical Advisory Committee (PTAC) process to expand the availability of Advanced APMs and other models. The creation of additional APMs, including those that are specialist/subspecialist-focused, would provide additional pathways for practices to transition from traditional fee-for-service (FFS) to more valued-oriented payment approaches. It is also imperative that CMMI continues to have adequate funding to support its critical role in QPP and the movement toward value-based payment.

Promote greater transparency in pricing and outcomes of care. In 2017 with Improving Health Care Efficacy and Efficiency Through Increased Transparency, ACP made several recommendations that would help contain costs for patients. ACP offers considerable guidance for health plans, clinicians, hospitals, and states to help patients by recommending valuable tools to lower costs and avoid the surprise bill: 1) Increased transparency of reliable and valid price information; 2) maintenance of accurate health-plan list of whether a physician is in-network and estimated out-of-pocket costs; 3) development of patient decision-making tools that include estimated price and other data; 4) legislative action at the state level to standardize all payer claims databases (APCD); 5) expansion of APCDs to handle other data from other sources; 6) state-level legislation to prohibit "gag clauses" that prevent the transparency of health data for the patient; 7) grants to states to develop APCDs; 8) support of processes to reduce risk of surprise bills; and 9) legislation that includes support for increased transparency, access to dispute resolution, and adequate assessment of economic impacts on all parties.<sup>4</sup>

ACP also states that network adequacy needs to be not only examined but also addressed so that there are enough in-network physicians in all settings. Health plans also have an affirmative obligation to pay fairly and appropriately for services provided in-network and out-of-network, and regulators should ensure network adequacy in all fields, including emergency care. Evidence exists that narrow networks contribute to higher out-of-network costs. Adequate access to all types of care in the health plan's network could help reduce surprise billing and the need for out-of-network services. Currently, many patients may have no choice but to utilize out-of-network facilities and services, such as in emergency situations.

#### **EXPAND ACCESS AND COVERAGE**

While investing in high-value primary care is vitally important, access and coverage for that care need to be not only maintained but expanded. Currently insured individuals should not lose their coverage as a result of any action or inaction by Congress or the administration. ACP would like Congress to support policies that: 1) Ensure uninterrupted coverage and benefits for the more than 20 million individuals and families covered in states that have expanded Medicaid or purchased qualified health plans offered in the exchanges; 2) Ensure continued and sufficient federal funding to support Medicaid expansion as currently available; 3) Ensure that changes are not made to federal Medicaid funding that would erode benefits, eligibility, or coverage compared to current law; 4) Ensure that waivers and other proposals that address Medicaid coverage should be aligned with ACP policy; 5) Ensure that premium and cost-sharing subsidies are sufficient to make coverage affordable and accessible, especially for vulnerable patients like children and adults with special health care needs, the elderly, and low-income individuals and families; and 6) Ensure that the value of current subsidies should not be eroded.

Patient protections and essential health benefits should remain in place. The administrative rule-making process is being used to change and ultimately weaken coverage protections in the Affordable Care Act (ACA), which will lead to higher costs. The College commented on the 2020 Benefit and Payment Parameters proposed rule to support the patient-centered prescription drug substitution, restrictions on the sale of short-term, limited duration plans, access to medication-assisted treatment,

and efforts to make insurance more affordable. ACP also offered concerns about Association Health Plans Proposed Rule because it allows small businesses and the self-employed to join health plans governed by large group market rules, circumventing the individual and small group health insurance market regulations established by the ACA. ACP's comments regarding the Short-Term, Limited-Duration (STLD) proposed rule expressed great concern about extending short-term, limited-duration insurance, because these plans would be exempt from the ACA requirements on essential health benefit coverage, prohibition on pre-existing condition exclusions, rate restrictions, and others. The CMS Office of Actuary estimates that broadening access to extended STLD plans will cause marketplace premiums to increase and federal spending to rise by over \$38 billion over the next 10 years.8 ACP also strongly opposed Inadmissibility on Public Charge Grounds rule, because widening public charge determinations to include Medicaid, the Medicare Part D Low-Income Subsidy Program, the Supplemental Nutrition Assistance Program, and potentially the Children's Health Insurance Program (CHIP), among others in this way, would make it much more likely that lawfully present immigrants and those seeking to lawfully immigrate to the U.S. could be denied lawful permanent resident status, be denied visas, or even be deported, merely on the basis of seeking essential health, nutrition, and housing services for themselves or their families.

ACP has opposed Medicaid work requirement waivers in several states. ACP policy states that work-related or job search activities should not be a condition of eligibility for Medicaid. Assistance in obtaining employment can appropriately be made available provided that it is not a requirement for Medicaid eligibility. Work requirements will impose an unnecessary and unjustified burden on patients to document that they are eligible for an exemption and an unnecessary and unjustified burden on physicians who may be asked to attest that their patients have an exempted medical condition. Work requirements are inconsistent with the mission and purpose of the Medicaid program. ACP participated in an amicus brief for Stewart v. Azar, a lawsuit brought by a group of Kentucky Medicaid enrollees. The brief expressed concern that thousands of enrollees would lose Medicaid coverage because of the work requirement, higher premiums, and other provisions in the state's Kentucky HEALTH waiver. Additionally, "partial" Medicaid expansion may also increase federal spending, because those with incomes in the 100-138% federal poverty level would be covered by marketplace-based coverage that is fully funded by the federal spending.

The continued regulatory efforts to allow sale of insurance that does not meet the ACA's benefit requirements represent a very substantial threat to coverage, putting patients at risk of purchasing health insurance that does not cover the care they need should they get sick, and driving up premiums in the individual insurance market as healthy persons leave the ACA-compliant plans to purchase the less costly AHPs or short-term plans.

**Insurance Market Stabilization.** Rather than permitting the administration to weaken coverage and diminish access, Congress should act decisively to stabilize the market, which would help reduce costs. The health insurance marketplace remains unstable in many parts of the country. Several insurers have exited from the exchange markets in recent years, and those who remain are evaluating the stability of the markets to determine future participation. Numerous studies highlight consumer inability to afford health insurance. For consumers, costs continue to rise, forcing difficult decisions regarding how many family resources to devote to health. The Health Care Cost Institute reported that, in 2016, consumer

out-of-pocket (OOP) spending per person increased, even while growing more slowly than total spending. This slowdown in the rate of OOP spending masked the underlying issue: prices continue to rise at an unsustainable rate. Prices are too high and costs for consumers are rising.

ACP believes principles for federal stabilization of state health insurance markets should: 1) Ensure that premium and cost-sharing subsidies are sufficient to make coverage affordable and accessible, especially for vulnerable patients, like children and adults with special health care needs, older adults, and low-income individuals and families; 2) Develop a long-term solution to the cost-sharing reduction (CSR) payment issue that ensures that insurers are able to meet their legal obligation to reduce deductibles and co-pays for lower-income persons, without further destabilizing the markets by prohibiting practices used by states and insurers to protect subsidized individuals from having to pay more for their coverage; 3) Continue reinsurance and other premium stabilization programs and develop and sufficiently fund long-term premium stabilization programs to enhance the availability of affordable premiums and encourage insurer participation; 4) Enhance outreach and education efforts with adequate funding to encourage a better risk pool and prevent low enrollment, higher premiums, and market destabilization; 5) Reject the expansion of association health plans (AHPs) and short-term, limited-duration insurance (STLDI) plans that are exempt from consumer protections and insurance regulations provided under current law; 6) Ensure incentives for young adults to buy coverage and participate in insurance pools; 7) Expand competition and consumer choice by supporting health insurance exchanges' ability to offer a public insurance option that reimburses physicians at rates which are no less than those of traditional Medicare. 12

## SUPPORT A WELL-TRAINED PHYSICIAN WORKFORCE WITH AN EMPHASIS ON HIGH-VALUE PRIMARY CARE

With the enhancement of high-value primary care and the expansion of coverage, the supply of the primary care clinician workforce, including physicians, will need to be increased. Unfortunately, the existing primary care workforce is poorly distributed. The nation needs workforce policies that include sufficient support to educate and train a supply of health professionals that meets the nation's health care needs and prioritizes physician specialties where millions of patients lack access, including internal medicine specialists trained in comprehensive primary care and armed with the skills needed to treat an aging population with multiple chronic diseases. There are 6,708 primary care Health Provider Shortage Areas (designated by the Health Resources and Services Administration (HRSA) as having shortages of primary medical care, dental, or mental health providers and may be geographic (a county or service area), demographic (low income population), or institutional (comprehensive health center, federally qualified health center or other public facility). According to the Association of American Medical Colleges, the primary care shortage is even worse. AAMC's 2018 findings show a shortfall of between 14,800 and 49,300 primary care physicians by 2030. Over 67 million Americans are impacted by the lack of access to primary care.

Congress should ensure necessary funding for vital federal programs/initiatives designed to support primary care and ensure an adequate physician workforce, including: Title VII Health Professions Primary Care Training and Enhancement (PCTE) grants, the National Health Service Corps (NHSC), and the Teaching Health Centers Graduate Medical Education (THCGME) program. Congress should also make changes to the Graduate Medical Education (GME) Program.

Primary Care Training and Enhancement (PCTE). The PCTE program is the only source of federal training dollars available for general internal medicine, general pediatrics, and family medicine. PCTE received \$48.92 million in FY2019, the same as the FY2018 level, after a much needed and welcome \$10 million increase over the FY2017 enacted level. General internists, who have long been at the frontline of patient care, have benefitted from Title VII training models emphasizing interdisciplinary training that have helped prepare them to work with other health professionals. Congress should fund the program at \$71 million in FY2020 in order to maintain and expand the pipeline for individuals training in primary care.

The National Health Service Corps (NHSC) Supports the Primary Care Workforce. The NHSC provides scholarships and loan forgiveness to 5,711 providers and has a field strength of 10,200 primary care medical, dental, and mental and behavioral health professionals training in rural, urban, and frontier communities (FY2017). In return, health care providers serve for a period of service in a Health Professional Shortage Area (HPSA). The NHSC services a vital purpose in helping to ease this workforce shortage through its scholarships and its loan forgiveness program that helps bring health care to those who need it most. More than 50,000 clinicians have served in the NHSC since its inception. From FY2011 through FY2017, the most recent year of final data available, the NHSC offered more than 39,000 loan repayment agreements and scholarship awards to individuals who agreed to serve for a minimum of two years in a HPSA. Today, nearly 10,200 NHSC members provide care to more than 11 million people.

Though these numbers are substantial, it will likely not be enough to meet the soaring demand for primary care, and continued and stable funding is essential to the future of the program's mission. The NHSC has faced a steep "primary-care cliff" in 2015, 2017, and now in 2019, in which funding completely drops off unless Congress acts to reauthorize it. This short-term funding situation is detrimental to the NHSC's operations and its programs have suffered the consequences of lurching from one short-term funding authorization to another, lacking the needed stability of long-term funding and endangering physician training and patients in underserved communities. Accordingly, ACP believes that it is imperative that Congress reaches bipartisan agreement to reauthorize funding for the NHSC and other essential health programs over the long term.

The NHSC is key not only in providing primary care to underserved areas, but also in encouraging clinicians to pursue a career in primary care to help alleviate the primary care provider shortage. NHSC members greatly contribute to their communities by improving the health of the patients they serve. Most (55 percent) NHSC members continue to practice in underserved areas ten years after service. Another study found that six years after service, 26 percent of NHSC participants were located in the very same HPSA of their NHSC service, and 69 percent were in a HPSA location in general. Tuition debt impacts 72 percent of medical students, and they owe a median of \$180,000. With more resources, the NHSC can award more new applications and help medical students pay off debt while providing primary care.

There is overwhelming interest and demand for NHSC programs, and with more funding, the NHSC could fill more primary care clinician needs. In FY2016, there were 2,275 applications for the

scholarship program, yet only 205 awards were made. There were 7,203 applications for loan repayment and only 3,079 new awards. In 2018, 4,605 open NHSC positions could not be filled because NHSC field strength was not enough to meet the needs of every eligible NHSC site.

Accordingly, the College calls on Congress not only to authorize NHSC funding for the long term, but also to increase that funding significantly—essentially double the overall program funding level—to meet the demand that clearly exists. The NHSC needs a stable funding source to continue its efforts of providing primary care in underserved areas; future funding disruptions could mean that the NHSC cannot process new applications or service existing participants. With a doubling of resources, the NHSC could also increase its overall field strength of primary care clinicians, including physicians.

**Teaching Health Centers Graduate Medical Education (THCGME).** The THCGME program was established by the ACA to provide funding for primary care residents in community settings. This program enriches the training of primary care residents by allowing them to see a wide variety of patients in an office-based setting rather than solely in the hospital. As with the NHSC, THCGME funding expires at the end of FY2019. ACP strongly supports the long-term reauthorization of the THCGME program to ensure stable funding.

**Sustain and prioritize graduate medical education (GME) funding.** In 2016, ACP and the Alliance for Academic Internal Medicine developed a comprehensive <u>proposal</u> for GME innovation and reform. We urge Congress to develop legislation, inclusive of the policies outlined below, to support training of internal medicine specialists with the skills needed to care for an aging population with multiple chronic diseases and to alleviate the growing problem of millions of Americans lacking access to primary care

Congress should increase the number of GME slots by at least 3,000 per year over five years (approximately 15,000 slots) for specialties facing shortages, including internal medicine, and fully fund and support GME, including lifting the GME caps as needed to permit training an adequate number of primary care physicians, including internal medicine specialists, and physicians in other specialties facing shortages. GME funding needs to be sustained and increased on a prioritized basis, to train more physicians in the specialties with the skills and training needed to care for an aging population with multiple chronic diseases, including training of more internal medicine physician specialists.

Congress should combine Direct GME (DGME) and Indirect Medical Education (IME) into a single, more functional payment program and broaden the GME financing structure to include all payers. Consolidating DGME and IME into one payment by using a single per-resident amount with a geographic adjustment would increase functionality and improve transparency. Have all payers—both public and private—contribute to a financing pool to support residencies that meet the nation's policy goals related to supply, specialty mix, and site of training. All payers and the patients insured by them depend on well-trained medical graduates, medical research, and technical advances from teaching programs to meet the nation's demand for high-quality and accessible care, and accordingly, all payers should contribute to GME funding.

Lastly, Congress should Allocate GME funds transparently and specifically to activities that further the educational mission of teaching and training residents and fellows. GME funds should follow trainees into all training settings rather than being linked to the location of service relative to the teaching institutions. Medicare GME payment information should be made publicly available in a concise, timely, and easily accessible report to ensure that these funds are used for the education and training of residents.

#### REDUCE ADMINSTRATIVE BURDENS ON CLINICIANS AND PATIENTS

Congress and the administration should implement a framework to formally assess the source, intent, and impact of existing and new administrative tasks imposed by government, private payers, vendors, and other external entities and provide recommendations to reduce, streamline, or eliminate excessive and burdensome tasks. Excessive administrative tasks divert time and focus from more clinically important activities of physicians and their staffs, such as providing actual care to patients and improving quality, and may prevent patients from receiving timely and appropriate care or treatment. In fact, the literature has consistently found that time spent by clinicians and their staff on billing and insurance-related activities is about 3 to 5 hours per week, and time spent on quality measurement and reporting activities is potentially up to 15 hours per week. In addition, administrative tasks are keeping physicians from entering or remaining in primary care and may cause them to decline participation in certain insurance plans. They're also a major contribution to the epidemic of "physician burn-out."

The administration should consider incorporating into federal rulemaking the cohesive framework for assessing administrative tasks outlined in ACP's position paper "Putting Patients First by Reducing Excessive Administrative Tasks in Health Care." The framework provides a method for better understanding any given task as well as the foundation for specific recommendations on revising or eliminating administrative tasks entirely. Specifically, the College calls on all external sources of administrative tasks to provide impact statements for public review and comment. For those tasks that cannot be eliminated, they must be regularly reviewed and revised or aligned to reduce any associated burden. All key stakeholders must also collaborate on aligning performance measures to minimize burden; collaborate in making better use of existing health IT to facilitate the elimination, reduction, and alignment of administrative tasks; and focus on value over volume of services when reviewing and aligning or eliminating tasks. More research is needed on the impact of administrative tasks on the US health care system and on evidence-based best practices to help physicians reduce administrative burden within their organizations.

Improve EHR Interoperability. Electronic Health Records (EHRs) are meant to house critical data about a patient's health and should facilitate the ability of clinicians to access the data they need to make the best medical decisions for their patients. ACP's recent <u>comments</u> on the Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs to the Office of the National Coordinator for Health Information Technology (ONC) reiterated its ongoing concerns around the federal government's definition of interoperability. Specifically, the College believes the definition and measurement of interoperability should not focus solely on volumes of data transferred or access to every piece of health information ever collected. Interoperability should focus on the breadth and depth of information involved in useful clinical management of patients as they transition through the

healthcare system, the exchange of useful, meaningful data at the point of care, and the ability to incorporate clinical perspective and query health IT systems for up-to-date information related to specific and relevant clinical questions.

Recommendations for the administration to improve interoperability include:

- promoting the adoption of Fast Healthcare Interoperability Resource (FHIR) standards;
- promoting the use of open application programing interface (API) functionality;
- targeting the high-yield clinical data that have shown to be the most useful in current health information exchange practices;
- developing through the ongoing maintenance and publication of the Interoperability
   Standards Advisory, standards to ensure that important clinical and institutional context moves along with the data elements that are deemed necessary for exchange; and
- promoting best practices for data reconciliation (i.e., develop and universally implement best practices for detailed data reconciliation as well as best practices for medication and other data deduplication to prevent sending back the same information already shared from a data source).

While much discussion has focused on the need for EHRs to be able to effectively communicate with one another (i.e. interoperability), equal attention should be paid to EHRs operating effectively in their own right (i.e. operability). Congress should focus on improving operability in the following areas, all of which currently add unneeded administrative burden on physicians.

**Prior Authorization.** On a daily basis, clinicians are often required to seek approval from a patient's health insurer in order to prescribe a certain medication, known as "prior authorization." This process involves varying forms, data elements, and submission mechanisms and forces the clinician to enter unnecessary data in the EHR or perform duplicative tasks outside of the clinical workflow. Moreover, prior authorization rules are imposed by payers and vary by state with local regulatory requirements affecting and complicating how prior authorization is deployed. This often inhibits clinical decision-making at the point of care and creates unnecessary burden. Ideally, the need for prior authorization would decrease as the health care system continues to evolve to a more widespread value-based payment system, particularly for clinicians participating in risk-bearing alternative payment models. A great first step toward the ideal would be for public and private payers and EHR vendors to accept the same clinical definitions for data elements and report formats, and to work transparently with all necessary stakeholders, so that health IT could be programmed to generate and send the necessary prior-authorization criteria automatically.

The College agrees with the ONC's recent recommendation within their draft strategy to reduce health IT burden for payers to disclose publicly, in a searchable electronic format, a payer's requirements (including prior authorization requirements and patient cost-sharing information) for coverage of medical services. This publicly available information will be useful and necessary for vendors to begin to automate the process. Additionally, the various portals of data transmission across payers are a significant burden, and there is a need not only for standardization in processes and requirements, but also for standardization of methods of data transfer across payers. By decreasing time spent on documentation necessary for prior authorizations and allocating that time to more useful and

productive tasks that improve care, the industry will be able to achieve the end goal of providing high-value, patient-centered care. If this harmonization of standards and automation of prior-authorization across the industry were achieved, it would dramatically reduce practice costs for data interfaces, reduce the time clinicians and their staff spend completing additional forms, and reduce the time payers spend reviewing prior authorization requests – freeing up time and resources to promote high-value patient care such as care management services. Congress and the administration should compel public and private payers, EHR vendors, physician organizations, and other necessary stakeholders to collaborate to establish agreed-upon clinical definitions for data elements and report formats.

Clinical Documentation Guidelines. The ability of EHRs to collect, display, and share usable information among clinicians and with patients and families is directly impacted by coding and other regulatory requirements. Template-driven documentation originated as a consequence of the 1995 and 1997 Evaluation and Management (E/M) Documentation Guidelines—which redefined the cognitive office visit by what was documented, rather than what service is actually provided. EHRs then digitized these templates and created software to make sure that what was required for a particular E/M CPT code (e.g. how physicians report their services) was addressed within the patient record, losing the patient's story along the way. The purpose of clinical documentation should return to supporting excellence in patient care and to preserving the patient narrative.

ACP appreciates the actions taken to reduce documentation burden in CMS's 2019 Physician Fee Schedule (PFS) final rule, but we still have a number of concerns with the payment changes tied to the documentation updates, which are outlined in our comments on the <u>proposed</u> and <u>final</u> 2019 QPP and PFS rules. However, we believe this is a critically important opportunity to improve documentation through enhancements in health IT. Sufficient time is needed to engage the physician community to develop and pilot-test alternatives that improve documentation clarity and value, decrease burden, and further EHR usability, interoperability, and better care – all while maintaining the principle that more complex and time-consuming E/M services must be paid appropriately while simplifying E/M documentation and ensuring program integrity. ACP and other clinical societies should be actively involved in developing guidelines for what is necessary to improve clinical documentation based on elements relevant to their practice and what is needed to optimize clinical care rather than meet billing requirements – and should be involved in the ongoing governance of the established documentation requirements.

Given the opportunity provided in the 2019 PFS, ACP plans to develop resources to promote clinical documentation that tells the patient's story in a meaningful manner and plans to develop strategies for the effective dissemination and uptake of best practices in documentation. Another component of ACP's work in this area is developing specific examples of modifications to EHRs and health IT to improve clinical documentation.

**Integration of PDMP Data.** Clinicians need access to appropriate, timely, and accurate patient information in order to make the best, and most valuable, clinical decisions at the point of care. Unfortunately, the ability to access key information, such as the patient's prescribing history with the state, and to integrate that data into a clinician's EHR is woefully lacking. ACP policy strongly supports reducing administrative burdens associated with the use of prescription drug monitoring programs

(PDMPs), as well as other efforts to improve physician clinical workflow. ACP has long-supported the establishment of a national Prescription Drug Monitoring Program (PDMP), but until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program.

#### REDUCE THE COST OF PRSECRIPTION DRUGS

ACP has <u>stated</u> that the best way to ease the burden of prescription drug costs is by promoting policies that encourage competition, transparency, assessment of value, and price negotiation. The public is mostly kept in the dark as to the methodology behind how prescription drug prices are set and how much they actually cost to consumers. Policymakers should support transparency in the pricing, cost, and comparative value of pharmaceutical products, including rigorous transparency standards for drugs developed from taxpayer funded basic research.

**Prevent Practices that impede generics going to market.** ACP provides the following recommendations to Congress to prevent a number of techniques that brand-name drug companies use to block access and approval of generic drugs to compete with their products in the marketplace, including extending market exclusivity, product hopping, evergreening, and pay-for-delay tactics.

- Data exclusivity periods for biologics- Pharmaceutical companies claim that long exclusivity
  periods are needed to support innovation, allow a return on their investment, and promote
  future innovation. Marketing exclusivity is granted by the FDA upon approval, during which a
  competitor, typically a generic drug, is prohibited from being marketed. Data exclusivity
  prohibits a competitor from using the data collected by an originator company to gain approval
  of their drug.
- Increase oversight of companies that engage in product-hopping or evergreening In these
  practices, companies prevent generic competition from entering the market by making small
  adjustments to a drug with no real therapeutic value that grant the company longer patent
  protection, or companies remove the drug from market, forcing patients to switch to a
  reformulated version of the same drug.
- Enforce restrictions against pay-for-delay practices- Pay for delay, also known as "reverse payment settlement," is a patent settlement strategy in which a patent holder pays a generic manufacturer to keep a potential generic drug off the market for a certain period. The Congressional Budget Office estimated that enacting legislation restricting pay-for-delay settlements would cut the federal deficit by \$4.8 billion over 10 years.

Senators Grassley and Klobuchar recently introduced <u>S. 64, The Preserve Access to Affordable Generics and Biosimilars Act</u>. This legislation would prohibit brand-name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market. ACP calls for robust oversight and enforcement of pay-for-delay agreement in order to limit anti-competitive behaviors that keep lower-cost alternatives off the market, and we appreciate that Senators Grassley and Klobuchar have introduced legislation with the intent to address these harmful tactics.

Increase Transparency in the Marketplace. For decades, pharmaceutical manufacturers have claimed that drug pricing is based on research and development cost and innovation and is well regulated by market forces. The spike in prices and increase in the price of drugs already on the market have made many stakeholders wary, especially because many of these new therapies treat small populations, and there are few data to support that overall health care costs are reduced. In 2018, a number of drug manufacturers announced they would not raise prices on drugs, noting the public concern about increasing drug prices. However, these decisions created a false sense of confidence that the issue was being addressed and in late 2018, most of companies reneged on these announcements and raised the prices of their products.

ACP supported several bills in the last Congress to improve the disclosure of information from pharmaceutical companies concerning their research and development costs and information regarding price increases of their products. These bills include:

- The Drug Price Transparency in Communications Act- This legislation, offered by Senator Durbin, would require drug companies to disclose the Wholesale Acquisition Cost of an Rx in Direct-to-Consumer Advertising. We are pleased that a similar measure offered by Senator Durbin to support mandatory price disclosures in DTC ads passed the Senate in the last Congress. ACP also applauds an announcement by the Department of Health and Human Services (HHS) to issue a new regulation requiring pharmaceutical companies to list prices of their prescription drugs in DTC advertisements.
- The Fair Accountability and Innovative Research (FAIR) Pricing Act- This legislation, offered by Senator Baldwin, would require manufacturers to disclose and provide more information about planned drug price increases, including research and development costs.

Congress should also leverage the bulk purchasing power of Medicare and other publicly funded health programs and give these programs the flexibility to negotiate prescription drug prices directly with pharmaceutical companies. Such authority can add to potential cost savings. As prices rise for innovative new drugs and older drugs alike, patients and policymakers are putting an increased emphasis on the concept of value.

Stakeholders should consider novel approaches to value-based decision making including value frameworks, bundled payments, evidence-based benefit design, and elimination of the restriction on the Patient Centered Outcomes Research Institute (PCORI) from considering quality adjusted life years in its research.

Finally, Congress and the administration should curb anti-competitive practices that keep lower-cost alternative drugs off the market and encourage the biosimilar market. Specifically, Congress should support the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act which aims to stem abuses of risk evaluation and mitigation strategies (REMS) that keep generic competition off the market. There have been anti-competitive practices by a few manufacturers of brand-name drugs to prevent or delay other companies from developing alternative lower-cost products. These few brand-

name manufacturers utilize the FDA's Risk Evaluation and Mitigation Strategies (REMS) process and its accompanying Elements to Assure Safe Use (ETASU) requirements in a manner that prevents development of lower-cost alternatives. In some instances, the REMS process and ETASU requirements have been used to deny availability of drug samples and participation in FDA safety protocols. Using the REMS process and ETASU requirements in this way by a few brand-name drug companies keeps lower-cost generics and biologicals off of the market, thereby decreasing patient access to lower-cost medications.

ACP supports the passage of the Creating and Restoring Equal Access to Equivalent Samples
 Act- This legislation was introduced in the last Congress by Senators Grassley, Leahy, Lee, and
 Klobuchar and was reported out of the Judiciary Committee for consideration by the Senate.
 We urge Senators to reintroduce and pass this legislation in this Congress. It attempts to stop
 brand-name companies from misusing the REMS process and ETASU requirements by
 determining when the denial of adequate samples and impending participation in joint-safety
 protocol have occurred and creates a process pathway for the lower-cost manufacturer to bring
 a cause of action in federal court for injunctive relief.

### CONTINUE TO IMPROVE THE QUALITY PAYMENT PROGRAM (QPP)

As Medicare's Quality Payment Program (QPP) enters its third year, the administration continues to make improvements to the Merit-based Incentive Payment System (MIPS) to make it more meaningful for clinicians and patients and to create more opportunities for advanced alternative payment models (APMs), particularly those that are physician-led and specialty-focused. ACP embraces the shift from a volume-based payment and delivery system to one of value, accountability, and patient-centered care. The College supported enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and continues to support its goals of promoting high value, patient-centered care, and has been active in providing feedback on implementation priorities to the Centers for Medicare & Medicaid Services (CMS), including most recently our comments regarding the final rule with revisions to payment policies under the Medicare Physician Fee Schedule (PFS), QPP and other Part B changes for 2019. Following are several top priorities to ensure that implementation of the MIPS program satisfies Congress' original intent to create a unified, streamlined program that facilitates meaningful improvement in patient outcomes while minimizing burden and costs in our system.

- Through its oversight authority, Congress must ensure CMS does more to streamline reporting requirements and scoring for MIPS. Currently, the program features four distinct performance categories, each with their own set of unique reporting requirements, reporting timelines, and scoring methodologies. CMS must drastically simplify MIPS scoring by basing point values for individual measures on their relative value to the total MIPS score, taking every opportunity to award cross-category credit and align metrics with other public and private payers, and finalizing a consistent, 90-day minimum reporting period for all categories.
- Congress should extend the Secretary's discretionary authority to weight the Cost Category to
  allow sufficient time for an ongoing effort to significantly overhaul existing cost measures.
   CMS is currently overhauling<sup>13</sup> the two core MIPS cost measures to address longstanding
  concerns related to inappropriate attribution and insufficient risk-adjustment methodologies,
  as well as adding dozens of new condition-specific cost measures. Practices should not be

- evaluated on cost measures that CMS has openly acknowledged are flawed and will hardly resemble their current forms in a few years' time. ACP believes holding clinicians accountable for cost and utilization is important, but it is only productive to do so when the metrics are proven to be accurate and reliable indicators of impact on utilization of health services.
- CMS must expediently develop more Advanced APMs, particularly for small and specialty practices, including testing and adopting new physician-focused payment models (PFPMs) that have been tested in the private sector and come recommended by the PFPM Technical Advisory Committee (PTAC). Congress established the Physician Focused Payment Model (PFPM) Technical Advisory Committee (PTAC) in MACRA as a way to expedite the implementation of innovative physician-led APMs that have proven effective in the private sector. Yet, to date CMS has approved none of the dozens of models that the committee has recommended either for full scale implementation or limited scale testing. These models present a real opportunity to meaningfully improve care for patients and achieve savings for the healthcare system, including ACP's own Medical Neighborhood Model, which was developed in partnership with NCQA and requires clinical practice transformation, a mandatory pre-consult system that directs patients to the most appropriate point of care, and improves coordination between specialists, primary care clinicians, and patients.
- Extend the 5 percent bonus for earning Qualified Participant status in Advanced APMs to continue encouraging participation in APMs beyond 2022. The 5% lump sum bonus for significant participation in Advanced APMs is set to expire at the end of the 2022 performance year without further Congressional intervention. Unfortunately, participation in Advanced APMs is far behind original projections due in large part to slower than expected development of new national models that qualify as Advanced APMs. Currently, there are only eight Medicare APMs available nationally that quality as Advanced APMs, and one of those is only available in certain geographic regions. ACP is encouraged by indications from the current Administration that more models are coming but at this moment, participation in APMs is far behind where Congress originally envisioned it would be when it passed MACRA. In 2015, the year Congress passed MACRA, the administration had set an aggressive goal of tying half of clinician payments to APMs by the end of 2018. Currently however, only one-third of payments are tied to APMs. In addition, Congress allowed for the All-Payer Combination Option to start in 2019, but CMS will not count private payer models toward this until 2020. To continue fostering the growth of APM participation, which is one of the keys to the success of the QPP, Congress should extend the 5 percent bonus for participating in Advanced APMs for one additional year at a minimum. This would replace the current one year gap in the 2025 performance year during which time Advanced APM participants would receive no bonus and a 0 percent PFS update, while clinicians participating in MIPS would earn up to a 9 percent bonus. It is important that Congress align incentives appropriately to ensure clinicians who are actively putting their payments at risk to participate in these innovate payment models are encouraged, not penalized for their support of value-based reimbursement.
- CMS should reduce the overall number of measures required for full participation in MIPS
  and use a flexible set of measures that are proven to be statistically reliable, clinically valid,
  outcomes focused, and, most importantly, patient-centered. Clinicians are being evaluated on
  a minimum of 18 distinct measures, up to 39. These requirements are for Medicare alone;
  dozens of other payers have their own unique quality reporting requirements. ACP supports

holding clinicians accountable for cost and quality outcomes within their control, but the current maze of disjointed check-the-box requirements spreads resources thin, minimizing the ability to meaningfully impact key clinical priority areas while adding unnecessary burden that detracts from patient care. CMS should create a set of evidence-based, outcomes focused measures that hold clinicians to cost and quality standards while allowing flexibility to determine how to most effectively and efficiently do so for their patients that can also be applied across multiple payers. In line with Congress' vision to score using a sliding scale approach, CMS should not award a clinician or group a score of zero for an entire performance category for failure to report one measure, as it currently does for the Promoting Interoperability Category, which measures use of Certified Electronic Health Record Technology. In addition, no clinician should have payments impacted by quality, cost or other measures that do not meet stringent standards for clinical validity, statistical reliability, and that are proven to impact patient outcomes. Unfortunately, ACP's Performance Measurement Committee rated half of 2019 MIPS measures as invalid for one or more of these reasons. 14

- Congress should encourage CMS to establish a consistent, transparent process by which to
  evaluate all current and new measures and should not approve any measures that do not
  have the support of critical stakeholders, including ACP's own Performance Measurement
  Committee, the Core Quality Measures Collaborative, and the Measure Application Partnership
  (MAP). Ongoing support from patient organizations, clinical specialties, and other stakeholders
  is absolutely essential to the responsible development and maintenance of clinically accurate,
  patient-centered measures.
- CMS must implement policies to level the playing field between small and large practices, including establishing separate Advanced APM Qualified Participant (QP) and MIPS performance thresholds and providing in-kind or financial support to invest in new technologies. In 2017, the average MIPS performance scores for small practices was 20 points lower than large practices. While it is important to encourage all practices, including small practice, to transition to value-based reimbursement, it is unreasonable to expect small practices to achieve transformation at the same proportion or same speed when they simply do not have the same level of administrative support or financial capital to invest in EHRs and other expensive technologies that facilitate successful participation in the program.
- To continue facilitating the transition to value-based reimbursement, it is critical that Congress extends the 0.5% Medicare payment update beyond the 2019 performance year. Due in large part to the lack of available APMs, participation in APMs is well behind where CMS and Congress originally envisioned when MACRA was passed. In 2015 and through 2019, PFS payment rates are set to update by 0.5% annually before being frozen for five years (2020-2025). Congress delayed and modified the misvalued code process for 2019 in the Bipartisan Budget Act of 2018, because there are simply not enough services with sufficient volume left to review and revalue. In the recent past, Medicare has repeatedly fallen short of the misvalued code target and the scheduled 0.5 percent payment increase has been reduced year after year as a result. In fact, the application of the misvalued code policy has resulted in a total payment increase of 0.7 percent from 2015-2018, less than half of what was called for under MACRA. ACP urges Congress to do everything possible in the future to ensure positive and stable updates to physicians to support their transition to new delivery models, as Congress intended

- under the MACRA law. Accordingly, we urge Congress to extend the 0.5 percent payment update.
- ACP supports required use of 2015 Certified Electronic Health Record Technology (CEHRT). However, given the release of ONC's Interoperability and Information Blocking proposed regulation, and the numerous updates to the Health IT Certification program contained with the proposed regulation, we strongly reiterate our previous concerns around rushing implementation timelines to meet regulatory requirements. The College recommends that CMS allow at least six months, if not a full year, for implementation of upgraded health IT systems before clinicians are graded on their use of the new technology. Moving to more up-to-date standards and functions is important, but it is important physicians have adequate time to train clinical staff and test and implement the upgrades once the new versions of 2015 CEHRT are available from their vendors to help ensure a smooth transition to the new technology.
- ACP appreciates changes to streamline scoring within the Promoting Interoperability
  Performance Category. However, ACP strongly recommends that the Agency considers
  additional refinements to further improve flexibility and reduce burden including incorporating
  a broader list of optional health IT activities from which clinicians can choose and eliminating
  the use of required "all-or-nothing" EHR functional-use measures.

#### **CONCLUSION**

ACP sincerely appreciates Chairman Alexander and Ranking Member Murray for this request for information and for the shared bipartisan commitment to contain health care costs and to ensure that patients have access to quality primary care services. We appreciate the HELP Committee inviting input from the health-care community, and our hope is that the information we shared will provide the committee with a clinician perspective. We stand ready to continue to serve as a resource and welcome the opportunity to continue to work with you in developing policy on health-care costs during the 116th Congress. Please contact Jared Frost, Senior Associate, Legislative Affairs, by phone at (202) 261-4526 or via email at <a href="mailto:ifrost@acponline.org">ifrost@acponline.org</a> with any further questions or if you need additional information. Thank you.

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<sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> Allan H. Goroll, MD. JAMA Internal Medicine. Does Primary Care Add Sufficient Value to Deserve Better Funding? Accessed at: <a href="https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2721034">https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2721034</a>

<sup>&</sup>lt;sup>4</sup> American College of Physicians. Improving Health Care Efficacy and Efficiency Through Increased Transparency. Philadelphia: American College of Physicians; 2017: A Position Paper. Page 2. Accessed at <a href="https://www.acponline.org/acp-policy/policies/improving-health-care-efficacy-and-efficiency-through-increased-transparency-2017.pdf">https://www.acponline.org/acp-policy/policies/improving-health-care-efficacy-and-efficiency-through-increased-transparency-2017.pdf</a>

<sup>&</sup>lt;sup>5</sup> American College of Physicians. Improving Health Care Efficacy and Efficiency Through Increased Transparency. Philadelphia: American College of Physicians; 2017: A Position Paper. Page 1.

<sup>&</sup>lt;sup>6</sup> Ibid. Page 2 and 13.

<sup>&</sup>lt;sup>7</sup> Ibid. Page 13.

https://www.urban.org/sites/default/files/publication/97371/changes\_in\_marketplace\_premiums\_2017\_to\_2018\_0.pdf <sup>13</sup> lbid.

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