

March 1, 2019

The Honorable Lamar Alexander
Chairman
Committee on Health, Labor,
Education and Pensions
United States Senate
430 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Alexander:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing in response to your letter dated December 11, 2018, inviting comments and recommendations from key stakeholders to help identify the drivers of and solutions to rising health care costs. The AMA appreciates your leadership on this important topic and the steps you and the Committee are taking to improve access to and the quality of health care in our nation.

The U.S. spent \$3.5 trillion on health care in 2017. That represents \$10,739 per person, as summarized in a recent [Health Affairs](#) article. Between 2007 and 2017, health care spending increased from 15.9 percent to 17.9 percent of gross domestic product. The drivers of increasing spending include the rising costs associated with providing medical care to patients, including:

- **Administrative Costs:** Eight percent of health care spending goes toward “administration and governance,” which includes activities relating to planning, regulating, and managing health system payment and insurance systems, according to a March 2018 [JAMA report](#). By comparison, only one percent of health spending goes toward such costs in France and Japan. For physicians and hospitals, insurance company prior-authorization requirements, discussed more below, can be a huge administrative expense. For example, the Cleveland Clinic reported that it had 175 “caregivers” assigned to PA-processing tasks in 2015 at a cost of \$9 million. And medical practices [report](#) spending an average of two business days a week per physician to comply with health plans’ prior-authorization requirements. The AMA advocates for [administrative simplification](#) and has outlined reforms to lessen the burdens of [prior authorization](#).
- **Prescription Drugs:** The U.S. spent \$333 billion on prescription drugs in 2017. The share the nation spends for pharmaceuticals has risen significantly, accounting for 5.6 percent of total health spending in 1990 and growing to nearly 10 percent in 2017. Three major market players contribute to spiking drug prices and spending: 1) pharmaceutical companies make and sell drugs, but do not explain pricing or why costs can greatly exceed research-and-development expenses—some even buy existing drugs, spend nothing on research and development, and still raise prices; 2) pharmacy benefit managers (PBMs) strike deals between drug makers and health insurers but these middlemen do not share their pricing agreements and it is unknown if savings ever reach patients; and 3) health insurance companies approve treatments, set co-payments, and price out

with PBMs how much patients pay for drugs. The AMA's [TruthinRx.org](https://www.truthinrx.org) campaign is working to expose the opaque process that pharmaceutical companies, PBMs, and health insurers engage in when pricing prescription drugs and to rally grassroots support to demand drug price transparency.

- **Chronic Disease:** A 2017 Rand [report](#) found that in 2014, 60 percent of American adults had one chronic condition and 42 percent had more than one. On average, Americans with 5 or more chronic conditions (12 percent of the population) had spending that was 14 times the spending of persons with no chronic conditions. And, the spending of that group accounted for 41 percent of total health care spending. A November 2017 *JAMA* [study](#) showed that two of the top three fastest-growing chronic conditions over the 1996 to 2013 period, in terms of costs, were diabetes and hypertension. Annual spending on diabetes care grew by \$64.4 billion during this period, with \$44.4 billion of that tied to spending on drugs. More people are living with diabetes, and they are generally older. They are prescribed more drugs to properly treat their condition, and the costs of those drugs keep increasing. Hypertension, meanwhile, saw a \$47.6 billion growth in spending during this same period. The AMA is working to prevent chronic diseases such as [type 2 diabetes](#) and [heart disease](#).

Our comments below provide a more detailed discussion on these and other factors that have an impact on costs and include some potential recommendations. Your letter requests comments on steps Congress can take to lower costs, so our comments include suggestions that may be beyond the Committee's jurisdiction.

Prior Authorization

Newly released results from a December 2018 AMA survey of 1,000 practicing physicians underscore the major administrative burdens and costs to both patients and physician practices associated with health plans' prior authorization (PA) programs.¹ The time spent waiting for PA decisions from health plans can impede care delivery, with 91 percent of surveyed physicians reporting that PA delays access to necessary care, and 75 percent indicating that PA can lead to patients abandoning a recommended course of treatment. These delays and interruptions can result in patient harm: 91 percent of physicians say that PA can have a negative impact on patient clinical outcomes, and more than one-quarter (28 percent) report that PA has led to a serious adverse event (e.g., death, hospitalization, disability/permanent bodily damage, or other life-threatening event) for a patient in their care.

The online hub of the AMA's grassroots PA reform campaign, [FixPriorAuth.org](https://www.fixpriorauth.org), captures [written](#) and [filmed](#) patient and physician stories that put a human face on the clinical harms, care disruptions and delays, and interference with clinical decision-making associated with PA. To date, the FixPriorAuth campaign has gathered over 500 patient and physician stories and collected more than 89,000 signatures on a petition to Congress for PA improvements. The negative clinical outcomes and serious adverse events reported in both the AMA survey and gathered via the FixPriorAuth campaign highlight health plans' faulty economic logic on the PA issue. **The costs to both patients and our overall health care system of delaying medically necessary care are significant**, particularly if the patient's condition deteriorates to the point of requiring more intensive, acute care. For example, while a health plan may

¹ Survey summary available at <https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf>.

achieve short-term savings by denying PA for insulin, the costs of a subsequent hospitalization for diabetic complications far outweigh any immediate financial benefit. Here is how one patient put it:

I went almost two weeks without long-acting insulin and two days without even short-acting insulin waiting for prior authorizations. This landed me in the ER three times and sent me into a pancreatitis flare. And wasted about three hours of my doctor's time to get insulin. This was not new either; I have been diabetic since I was a kid, so about 25 years. They also made me switch to what kind I use, and that caused my sugar to be out of control for weeks, even after I finally got the insulin, while I determined my correct bolus dose of the new insulin. – Kimberly S.

In addition to the extremely concerning impact on patients' clinical status, the AMA's survey results also reveal the considerable administrative hassles associated with the PA process. Practices report completing an average of 31 PAs per physician per week, a workload that consumes the equivalent of nearly two business days (14.9 hours) of physician and staff time—time that could be much better spent on direct patient care. **Over one-third (36 percent) of physicians report having staff who work exclusively on PA, which emphasizes the high administrative costs associated with this process.** The significant practice burdens related to PA continue to grow, with 86 percent of physicians describing PA burdens as high or extremely high, and 88 percent reporting that PA burdens have increased over the last five years.

In January 2018, the AMA, along with the American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association, and Medical Group Management Association, released the Consensus Statement on Improving the Prior Authorization Process.² This document reflects an agreement between health care professionals and health plans on reforms needed to ensure patients' timely access to care and reduce administrative burdens, including a reduction in the overall volume of prior authorization requirements, increased transparency, protections for care continuity, and automation to improve efficiency of what is currently a very manual process.

The Consensus Statement represented a landmark agreement on what is traditionally a contentious issue between the physician and health plan communities. Unfortunately, overall progress on PA reforms is negligible, with few meaningful changes to plans' PA programs evident more than a year since the release of the document.

While we hope that health plans voluntarily take immediate steps to improve the PA process, we urge Congress to act to protect Americans' access to medically necessary care. **We urge the HELP Committee to hold hearings to gather data on the impact of health plans' PA requirements on patients and physicians and evaluate legislative actions that could reduce costs associated with PA-related patient harms and administrative burdens. We also urge Congress to review the increased use of utilization management tools (including both PA and step therapy) in the Medicare Advantage and Medicare Part D programs and legislatively address these changes that threaten to limit Medicare beneficiaries' access to critical treatment.** All Americans, whether insured through government programs or through commercial health plans, deserve access to timely, appropriate care.

² Consensus Statement available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

Transparency

The AMA supports efforts to increase health care price and data transparency to empower patients, improve the quality of health care, and lower health care costs. The lack of complete, accurate, and timely information about the cost of health care services prevents health care markets from operating efficiently. As the health care market evolves, patients increasingly are becoming active consumers of health care services.

The AMA supports the following specific measures to expand the availability of health care pricing information that allows patients and their physicians to make value-based decisions when patients have a choice of provider or facility:

- All health care providers and entities should be required to make information about prices for common procedures or services readily available to consumers.
- Physicians should communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status of the patient (e.g., self-pay, in-network insured, out-of-network insured).
- Health plans should provide plan enrollees or their designees with complete information regarding plan benefits and real-time, cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs.
- Health plans, public and private entities, and other stakeholder groups should work together to facilitate price and quality transparency for patients and physicians.
- Entities promoting price transparency tools should have processes in place to ensure the accuracy and relevance of the information they provide.
- All-payer claims databases should be supported and strengthened.
- Electronic health records (EHR) vendors should include features that assist in facilitating price transparency for physicians and patients.
- Patient confusion and health literacy should be addressed by developing resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving.

The lack of transparency in health care pricing and costs is primarily the result of a health care financing system that depends largely on the complex arrangements between and among employers, payers, providers, and patients. These arrangements can make it difficult to identify accurate and relevant information regarding costs associated with specific medical services and procedures. For example, contracts offered by payers to providers frequently delineate contracted rates as proprietary information. Insurer payment policies, coverage rules, and cost-sharing requirements often are difficult for patients to find, let alone clearly understand. Moreover, determining whether a provider is in-network may be difficult because of outdated provider directories or confusion associated with multiple plan contracts. Price also varies depending on where the service is performed, which impacts cost and a patient's cost-sharing. The cumulative effects of each of these factors often make it difficult to provide accurate pricing information for an individual patient in the absence of an actual service claim.

The AMA believes that achieving meaningful price transparency can also empower patients to make informed decisions about where to receive certain outpatient services. The AMA supports Medicare payment policies for outpatient services that are site-neutral without lowering total Medicare payments.

However, payment policies under Medicare's Outpatient Prospective Payment System are complex and confusing, and it is difficult to translate rates under the current rules into a coherent and transparent price signal for patients. Many patients are not able to readily distinguish between sites of service (e.g., hospital-owned versus independent physician practices; on-campus versus off-campus hospital outpatient departments) and may not understand how choice of setting for certain services impacts their cost-sharing expenses. The AMA supports measures to expand the availability of health care pricing information that allows patients and their physicians to make value-based decisions when patients have a choice of provider or facility.

Prescription Drug Price and Cost Transparency

As prescription drug spending will continue to represent a larger portion of overall health spending over time, **the AMA strongly urges Congress to advance prescription drug price and cost transparency among pharmaceutical companies, PBMs, and health insurers.** The ability of patients and physicians to have the information they need to make key decisions regarding medication, and of policymakers to craft viable solutions to high and escalating pharmaceutical costs, has been hampered by the often byzantine and confidential arrangements that are driving increased medication prices without a clear and justifiable reason. Pharmaceutical manufacturers, PBMs, and health insurers contribute to the prescription drug cost equation, ultimately impacting patient cost-sharing, drug tiering decisions, prior authorization policies, and decisions whether to change formularies in the middle of a plan year. These practices and policies of pharmaceutical manufacturers, PBMs, and health insurers warrant steps by Congress and the Administration to interject much needed transparency.

As mentioned above, in 2016 the AMA launched a grassroots campaign and website, TruthinRx.org, the goal of which was to expose the opaque process that pharmaceutical companies, PBMs, and health insurers engage in when pricing prescription drugs and to rally grassroots support to call on lawmakers to demand transparency. To date, more than 335,000 individuals have signed a petition to members of Congress in support of greater drug pricing transparency, with the campaign also generating more than one million messages sent to Congress demanding drug price transparency.

The AMA strongly supports drug price transparency measures that require pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase. In addition, patients can benefit if pharmaceutical manufacturers are required to publicly disclose a variety of information, which could include research and development costs; expenditures on clinical trials; total costs incurred in production; and marketing and advertising costs.

For patients and physician prescribers, it is a moving target throughout the year as to what prescription medication will be covered under the patient's insurance plan and what restrictions around coverage will be in place. The AMA supports improved transparency so that patients are fully informed about their specific formulary, prescription drug cost-sharing, and the use of utilization management techniques (e.g., prior authorization and step therapy) at the time of health plan enrollment. It is confusing and often disruptive for patients and physicians when health plans and PBMs change their formularies at any point during a patient's plan year to remove one pharmaceutical in favor of another, or add a new utilization management technique. This means that the patient may be forced to switch to a drug that is less effective, and it also is highly unlikely the patient receives a cost discount when the change is made. This

switch may destabilize a patient or it will require additional resource expenditure by the physician and extended health care team to file an exceptions request and/or to file an appeal.

The AMA recognizes that the negative fluidity of the drug benefit is largely a result of the rebate system and the constant negotiations that take place to advance the interests of many drug benefit stakeholders—but not patients. The AMA is concerned that the rebate process results in list prices above what they would be absent rebates, as neither PBMs nor manufacturers currently have an incentive to lower list prices. As such, the rebates that are being negotiated by PBMs are not resulting in true savings. Moreover, there is little evidence that any savings associated with rebates are being passed through to patients or payers, but the major PBMs continue to reap massive profits while providing no product or service themselves. To improve transparency in this space, the disclosure of rebate and discount information, financial incentive information, and pharmacy and therapeutics committee information would constitute critical steps forward. The AMA also would support applying manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale. This policy would add much needed transparency and ensure that beneficiaries benefit from discounts. More broadly, the AMA supports the regulation of PBMs, which no longer simply negotiate drug prices on behalf of their clients, but rather fully administer the drug benefit creating formularies, making coverage decisions, and determining medical necessity using utilization management tools. Their “benefit management” now largely resembles the typical role of insurers, and they should be treated as such by regulators. Regulators must better understand and control the costs to patients and the system that are resulting from PBM practices.

Data Transparency

To better drive quality outcomes and lower costs, the health care system needs to better utilize clinical data. Data is a critical building block to achieving a better health care system. However, it is critical that data not only be accessible but also be presented as useable information. Raw data on their own do not provide insights and, more importantly, lack the context needed to make the data relevant, which makes the data potentially harmful to users misinterpreting and misunderstanding the data. Data transparency is two-fold. Data must be made available and also be presented with context that includes safeguards to help the public interpret the material. Meaningful data transparency requires not only access to data but an understanding of the scope, exclusions, and limitations of information. The AMA supports the following specific measures to expand the availability of health care data information that allows patients and their physicians to make value-based decisions:

- Promote new payment and delivery models;
- Improve care choices and decisions by providing the appropriate information with context;
- Inform physicians through development of user interfaces;
- Inform patients by encouraging them to discuss data transparency with their physicians;
- Inform consumers by facilitating more proactive use of health care data;
- Standardize through uniform formatting in electronic health records;
- Mitigate administrative burden by making collection, reporting and review of data voluntary;
- Avoid data attribution errors;
- Increase data availability and sharing among stakeholders;
- Access to the most current data; and
- Accurate data through proper oversight and public reporting safeguards.

Many payers, including the Centers for Medicare & Medicaid Services (CMS), continue to rely on administrative claims data to assess physicians' quality and cost because it does not require additional investments into new electronic systems or additional reporting on the part of a physician or practice. Measuring cost and quality based on claims data does not provide physicians with real time information about their patients which they need to establish care coordination and disease management interventions.

Achieving health care improvements with data requires a robust data framework. There is also need for standardization across data sets and avoidance of administrative burdens that may have the effect of diverting attention away from patient care. Clinical data are a richer data source because it incorporates information that cannot be documented on a claim such as family history, patient allergies, functional status, and patient-generated health data. Clinical data are also needed to appropriately risk-adjust for differences in the stages of disease and other factors. In addition, claims data do not allow physicians to utilize predictive analytics to optimize their performance, know how they are performing compared to their peers, and implement improvement strategies. In the era of EHRs, registries, and other innovative digital health tools, continuing to rely on claims data to assess performance is a step backward and discourages physicians and the greater health care system from adopting electronic tools to improve care.

Maximizing big data and realizing its full potential requires a significant investment in the underlying infrastructure. The exchange or access to big data alone is not sufficient to enable physicians and their patients to achieve better quality at lower costs. There is a strong need to give physicians access to meaningful patient data across systems and platforms. Importantly, in order for information to support patients and their care, data must be in a recognizable electronic package (data structure or syntax) and maintain a consistent meaning (data semantics). Just as the English language is built from words and grammar, interoperability can only provide knowledge when the data structure and meaning are consistent. However, interoperability varies greatly in the health care system. Almost everyone agrees that the current level of interoperability is inadequate to support the necessary changes, reforms, and innovations desired in health care.

Value-Based Insurance Design (VBID)

To incentivize care that improves health and patient outcomes, **Congress should continue to expand the application of value-based insurance design (VBID) and strive to align clinical and financial incentives among health care stakeholders.** Innovative VBID plans designed with clinical nuance recognize that medical services may differ in the amount of health produced and that the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided. While traditional benefit designs apply standard cost-sharing rules to all services and all patients, VBID bases coverage and cost-sharing rules on the clinical value of individual health care services. Accordingly, VBID plans can reduce financial barriers to, and incentivize use of, high-value services, and they can discourage use of services that are of low value to patients. Effort should be taken to align clinical and financial incentives through innovative payment and benefit design reform programs that encourage the use of high-value services and discourage low-value services. On the supply side, financial incentives are aligned between payers and providers around quality metrics. On the demand side, financial incentives are created between patients and third-party payers that impact whether patients will pursue care, and these financial incentives can thwart high-value clinical goals. For example, some patients may not pursue evidence-based preventive care when significant patient cost-sharing is required. When the clinical and financial incentives motivating patients, providers, and payers are not aligned, it can be excessively challenging to achieve their shared goal of quality health care.

To implement these steps, **Congress and the Administration can support the creation of a legal and regulatory environment that cultivates innovation and freedom to experiment with transformational plan designs that continue to ensure adequacy of health insurance coverage and that incorporate the tenants of clinical nuance.** For example, revisions should be made to the tax laws governing health savings accounts (HSAs) associated with eligible high-deductible health plans (HDHPs). HSA-HDHPs are among the fastest-growing plan types in the United States. Current Internal Revenue Service (IRS) regulations permit a safe harbor that allows for coverage of specified preventive services prior to satisfaction of the plan deductible, but IRS regulations state that clinical services meant to treat “an existing illness, injury, or condition” cannot be included in pre-deductible coverage. When HSA-HDHP enrollees with existing conditions or risk factors are required to pay out-of-pocket for necessary services prior to meeting the plan deductible, the results can be lower utilization of care, potentially resulting in poorer health outcomes and higher costs.³ To encourage patients to access high-value preventive and/or chronic disease management services, HSA-HDHPs may want to apply VBID to reduce cost-sharing for those services before enrollees satisfy their deductibles, but they are prohibited by law from doing so. **Congress and the Administration should work to remove legal and regulatory barriers preventing VBID application. Additionally, Congress and the Administration should continue to support on-going innovations in benefit design reform.** Current initiatives include: the Medicare Advantage (MA) VBID Model, expanding flexibility around the MA uniformity requirement to allow for the implementation of VBID principles throughout the MA program, TRICARE VBID pilot programs, and the Centers for Disease Control and Prevention’s (CDC) 6|18 initiative.

Alternative Payment Models

The AMA strongly supports efforts to advance value-based care delivery and payment models. **We offer the following policy recommendations as a means of generating more successful alternative payment models (APMs) that will achieve better outcomes for patients and more savings for Medicare and other insurance programs.**

Encourage APMs Developed by Practicing Clinicians

The best ideas for improving outcomes and efficiencies come from those on the front lines of the health care delivery system. For this reason, we were extremely pleased to hear that the Administration is working to implement multiple APMs based on the many innovative proposals developed by physicians and recommended to by the Physician-Focused Payment Model Technical Advisory Committee (PTAC). **We encourage Congress to support implementation by Medicare of the models recommended by the PTAC.** Dozens of innovative APM proposals have been submitted to the PTAC. Here are just two examples of how adoption of these models could improve care for patients with Medicare:

- *Sonar MD* is a model for patients with chronic conditions that was used in the private sector to improve care for patients with Crohn’s disease. Its founder said patients are like submarines, out there submerged. Physicians cannot see them, and do not know how they are doing because they only come in when they are in trouble. By reaching out to patients in between visits, Sonar helps patients recognize that they are in trouble and get them the services they need to fix it. Importantly, patients are assigned to Sonar as soon as they are diagnosed with Crohn’s—it does

³ Center for Value Based Insurance Design University of Michigan. HSA-High Deductible Health Plans. Available at: <http://vbidcenter.org/initiatives/hsa-high-deductible-health-plans/>. Accessed 2-28-19.

not wait for them to be hospitalized for their condition as current Medicare bundled payment models do.

- *End Stage Renal Disease (ESRD) Clinical Episode* is a model focused on patients during the first six months after an ESRD diagnosis, a period of time during which patients experience extremely high mortality rates under the current payment system. This model would support improvements in: the way patients choose between home and center-based dialysis; vascular access through fistula creation instead of catheters; access to renal transplants; patient education and risk reduction for patients with chronic kidney disease who have not progressed to ESRD; advance care planning; and palliative care. Adoption of this model for Medicare patients could save many lives.

Limit Accountability to Costs and Outcomes Physicians Can Control

Many physicians would be comfortable taking accountability for getting complex conditions under control and preventing acute exacerbations that lead to emergency visits and hospital admissions, but they are concerned about taking risk for patients' other medical conditions that are being managed outside of their organization or costs they cannot influence, such as drug prices. Physicians should not be forced to choose between the fee-for-service system or an APM that places them at risk for costs that are beyond their control. APMs also need to better support outpatient specialty care and collaboration between primary care and specialist physicians to achieve accurate diagnosis and effective treatment for patients with challenging health problems. **We recommend modifying the APM financial risk rules to: apply them only to a percentage of a physician practice's own service revenues; account for start-up and ongoing costs practices incurred to deliver care within an APM; and establish lower risk thresholds for all small practices, not just primary care medical homes.**

Extend Medicare and CHIP Reauthorization Act (MACRA) APM Incentives

MACRA was enacted almost four years ago, but most physicians still do not have opportunities to participate in APMs that meet the criteria for the bonus payments authorized by Congress. The AMA believes that Congress authorized these payments not just as an incentive to participate in APMs, but because it recognized the time and costs physicians face in transitioning to APMs. MACRA only authorized six years of APM bonus payments, and the current 2019 performance period is halfway through the available time to earn them. **We urge Congress to extend this time period for more years so that physicians will have the opportunity to receive all of the support that Congress intended.**

Lowering Health Care Costs with Preventive Services

The burden of chronic disease in the U.S. has a devastating impact on health care costs and the health care systems that treat individuals with these diseases. According to the CDC, six out of 10 adults in the U.S. have a chronic condition, and most have more than one, especially as they age. Chronic diseases are the leading cause of death and disability in the U.S. and leading drivers of skyrocketing health care costs. Seventy-five percent of typical primary care visits are for multiple chronic illnesses. The U.S. Department of Health and Human Services (HHS) projects that by the year 2020, 81 million Americans will have multiple chronic health conditions. Managing chronic diseases takes significant time—more time than is

allotted for acute care visits. This volume of care combined with changes to health care delivery places an added burden on primary care physicians and their teams.⁴

To address the high chronic disease burden and associated rising health care costs, the AMA is leading efforts to improve hypertension control and prevent type 2 diabetes. These two conditions have an acute impact on physicians' practice of medicine and the quality of life for the patients they serve in their offices and in the communities. The total estimated direct and indirect cost of diagnosed diabetes is \$327 billion, including \$237 billion in direct medical costs and \$90 billion in reduced productivity. The indirect costs associated with high blood pressure in 2015 in the U.S. were \$68 billion in health care services and medications. The indirect costs were \$42 billion in lost productivity.⁵ People with hypertension have roughly 2.5 times more inpatient costs, almost twice the outpatient cost, and roughly triple the prescription medication cost annually. These costs increases are in part due to uncontrolled hypertension.

More than 30 million Americans have diabetes with the majority of those individuals diagnosed with type 2 diabetes.⁶ It is estimated that an additional 84 million adults in the U.S. have prediabetes. If left untreated 70 percent of these individuals will develop type 2 diabetes in their lifetime.⁷ An estimated 103 million adults in the U.S. have hypertension but only 54 percent are under control.⁸ Uncontrolled hypertension rates have declined but remain high among older adults, African Americans, and people with multiple chronic conditions. Treated and uncontrolled hypertensive adults are at increased risk of all-cause, CVD-specific, heart disease-specific or cerebrovascular disease-specific mortality.⁹

Many of the costly negative outcomes associated with type 2 diabetes and hypertension are avoidable thanks to effective and cost-saving preventive interventions. **The AMA encourages the HELP Committee and Congress to consider the following opportunities to generate cost savings by applying specific approaches to improve access to effective preventive interventions.**

Prioritize Diabetes Prevention

Scientific research has demonstrated conclusively that type 2 diabetes can be prevented or delayed in adults with prediabetes through interventions delivered in both community-based and online settings. The CDC's National Diabetes Prevention Program (National DPP) is a public-private partnership that seeks to reduce the growing problem of prediabetes and type 2 diabetes in the United States. Over a thousand organizations nationwide now offer CDC-recognized diabetes prevention lifestyle change programs, both

⁴ <https://www.medicaleconomics.com/modern-medicine-feature-articles/chronic-disease-growing-challenge-pcps>

⁵ http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491513.pdf

⁶ Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.

<https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.

⁷ Tabak AG, Herder C, Rathmann W, Brunner EJ, Kivimaki M. Prediabetes: A high-risk state for developing diabetes. *Lancet*. 2012;379:2279-2290.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3891203/pdf/nihms535847.pdf>.

⁸ Matthew Ritchey, Cathleen Gillespie, Gregory Wozniak, Christina Shay, Angela M. Thompson-Paul, Fleetwood Loustalot, Yuling Hong, Potential need for expanded pharmacologic treatment and lifestyle modification services under the 2017 ACC/AHA Hypertension Guideline. *J Clin Hypertens*. 2018;20:1377-1391.

<https://onlinelibrary.wiley.com/doi/full/10.1111/jch.13364>.

⁹ Zhou D, Xi B, Zhao M, Wang L, Veeranki SP. Uncontrolled hypertension increases risk of all-cause and cardiovascular disease mortality in US adults: the NHANES III Linked Mortality Study. *Sci Rep*. 2018;8:9418.

in-person and virtually, to individuals at risk for type 2 diabetes. In addition, Medicare began covering CDC-recognized in-person diabetes prevention programs beginning April 1, 2018 through the expansion of a CMMI demonstration that found an average cost savings to Medicare of \$2,650 over 15 months.

The AMA recommends continuing and expanding federal funding for the important work of the National DPP housed in the CDC's Division of Diabetes Translation. The National DPP is working to improve access to preventive services across the country. In addition, **the AMA recommends that Congress consider the following steps to improve access to the Medicare DPP which has demonstrated cost savings.**

Align MDPP Services and CDC National DPP

Eligibility for a CDC-recognized lifestyle change program differs from the Medicare DPP which creates confusion for physicians and for program providers who are enrolling participants. The two programs have inconsistent blood-based screening requirements with a higher value of fasting plasma glucose (FPG) needed in MDPP compared to the National DPP. This misalignment potentially results in fewer people being identified and referred to the cost-effective intervention.

Remove the Once-per-lifetime Limit on the Medicare DPP Benefit

The AMA is seriously concerned about the once-per-lifetime limit for MDPP. The once-per-lifetime limit punitively denies some beneficiaries the benefits of a program that reduces Medicare expenditures while also improving health outcomes and quality of life for those at risk for diabetes.

To take full advantage of the demonstrated savings to CMS, **the AMA recommends CMS rescind the once-per-lifetime limit, and similarly to Medicare coverage of obesity counseling and tobacco cessation, provide beneficiaries additional opportunities to participate in and benefit from MDPP.** This will also better align Medicare coverage with the commercial market.

Allow Virtual Programs to Participate in MDPP

MDPP has the potential to be transformative to the Medicare program but limited coverage to in-person programs does not take advantage of the growing number of virtual DPP providers and increases in telehealth opportunities for health care. Congress and the Administration can take steps now to improve accessibility and uptake of this benefit which will help prevent diabetes and thus reduce spending on the disease. **The AMA recommends that CMS allow virtual programs to participate in MDPP.** Virtual diabetes prevention programs have similar outcomes to in-person programs and are essential for beneficiary choice as well as access (particularly for vulnerable populations, individuals with transportation needs or those in rural areas with no access to an in-person program).

Improve Screening and Early Detection

Screening is the entry point for prevention and treatment. Improving access and coverage for diabetes screening will help reduce the number of people with undiagnosed prediabetes, type 2 diabetes, and gestational diabetes. The United States Preventive Services Task Force (USPSTF) diabetes screening guideline requires private health plans to cover prediabetes/diabetes screening with no co-pay for

individuals age 40 to 70 who are overweight or obese. The guidelines also allow for screening at younger ages if clinical risk factors are present or if the patient is a member of certain racial/ethnic groups.

To encourage more consistent screening and use of the guideline, clarification of the USPSTF diabetes screening guideline, including publication of a FAQ by the Departments of Labor, Treasury, and HHS, would provide valuable guidance to health plans and others who are unclear on coverage requirements. This step would help identify more individuals with undiagnosed diabetes and prediabetes and get them into the care or prevention program they need thus reducing health care spending on this devastating disease. Congress may also consider what additional actions it may take to clarify with payers that USPSTF guidelines must be implemented as intended.

Controlling Hypertension Relies on Building Patient/Physician Partnerships

Promote Self-Monitoring Blood Pressure and Expand Coverage of Home Blood Pressure Devices

Treating hypertension does not solely take place in a clinical setting. Blood pressure management combines physician monitoring, medication management, medication adherence and lifestyle behavior change. It is important for physicians to be able to partner with their patients and provide opportunities for patients to feel in control of their disease. Utilizing home blood pressure devices has been found to improve control of blood pressure and has a positive effect on medication adherence. Home measurement of blood pressure allows patients to feel more engaged in their care and while providing valuable data to the clinical team to optimize their management. Patients who self-monitor and provide readings to their physician can adjust medications in real time and achieve lower systolic blood pressure over a 12-month period than those relying on medication and office visit blood pressures alone.¹⁰

Currently, the cost of home blood pressure devices is not covered by Medicare and many Medicaid programs despite evidence to indicate that coverage of these devices would generate cost savings. The potential cost savings associated with covering blood pressure devices has been estimated using commercial and Medicare Advantage payer data from 2008 to 2011. Cost savings was expected in all adult beneficiary age groups from both the commercial payer and Medicare Advantage perspectives. Specifically, the estimated cost savings for beneficiaries ≥ 65 years was \$166.17 net savings per beneficiary in the first year, and \$1364.27 net savings by year 10.¹¹ Because of the potential health benefits and cost savings associated with use of home blood pressure devices, **the AMA recommends considering approaches to expand CMS coverage.**

Expand Coverage of Ambulatory Blood Pressure Monitoring

A growing body of evidence supports a national coverage determination (NCD) for ambulatory blood pressure monitoring (ABPM) to better diagnose and control hypertension. CMS covers ABPM for cases of suspected white-coat hypertension with minor modification made in 2003 specifying that a physician must review the ABPM data. In the nearly fifteen years since, researchers have devoted considerable

¹⁰ <https://discover.dc.nih.ac.uk/content/signal-000615/control-of-high-blood-pressure-can-be-improved-by-self-monitoring-compared-with-gp-monitoring-alone>.

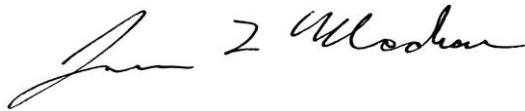
¹¹ Arrieta A, Woods JR, Qiao N, Jay SJ. Cost-Benefit Analysis of Home Blood Pressure Monitoring in Hypertension Diagnosis and Treatment: An Insurer Perspective. *Hypertension*. 2014;64:891-896.

research to ascertaining the diagnostic value of ABPM and found it to be an effective, evidence-based tool in circumstances beyond suspected white-coat hypertension as defined in the current NCD. Many organizations have issued recommendations supporting the use of ABPM as a diagnostic tool, including the American Heart Association and American College of Cardiology.¹² The most notable recent recommendation was issued by the USPSTF in 2015. The USPSTF “recommends screening for high blood pressure in adults aged 18 years or older” and “obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment.”¹³

ABPM helps prevent overtreatment for hypertension. This is especially important among older adults who may be at risk of hypotension. Researchers found approximately one-third of very elderly hypertensive patients receiving treatment for hypertension were, in fact, at risk for hypotension and more than half of patients could not be identified as hypotensive with office blood pressure monitoring alone.¹⁴ ABPM is recognized as the gold standard for out of office blood pressure measurements used to confirm a diagnosis of hypertension. **We are aware that CMS is reviewing the ABPM national coverage policy and urge Congress to encourage CMS to expand the current NCD to include other uses of ABPM.**

The AMA appreciates your leadership on this important issue and we look forward to working with you to further identify and seek solutions to the rising cost of health care in our nation.

Sincerely,



James L. Madara, MD

¹² Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*.

¹³ U.S. Preventive Services Task Force. (2017). Final Recommendation Statement: High Blood Pressure in Adults. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/high-blood-pressure-in-adults-screening>.

¹⁴ Divisón-Garrote, Juan A, et al. Magnitude of Hypotension Based on Office and Ambulatory Blood Pressure Monitoring: Results From a Cohort of 5066 Treated Hypertensive Patients Aged 80 Years and Older. *J Am Med Dir Assoc*. 2017 May; 18(5):452.e1-452.e6.