REDUCING COST AND WASTE IN AMERICAN MEDICINE

A Physician-Led Roadmap to Patient-Centered Medical Care

Reducing Cost and Waste in American Medicine

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Free to Care Physician Symposium
Washington, DC
April 1, 2019

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Preface

The cost of medical care—and access to medical care itself—now sit atop the list of worries for American households.

In years past, the debate over healthcare reform centered on the **autonomy** of individual patients and their physicians. Who should control the personal and complex process of medical decision-making? The patient in consultation with the physician? The insurer? Perhaps an agency of the state government? The federal government?

However, the skyrocketing cost of healthcare has blurred this focus on patient and physician autonomy. **COST** now supplants **autonomy** as the primary worry of the patient.[1] After all, if the sick cannot pay their hospital bills, or must ration (or even forgo) essential medications because they are unaffordable, why worry about autonomy and the medical decision-making process?

Access to medications, doctors, tests, medical devices, and hospitals ***when*** they are needed will always take precedence over medical decision-making. Sadly, with this shift in the healthcare debate, Americans now better understand worries that usually characterize underdeveloped countries.

As costs soar and dollars are relentlessly wasted in countless, hidden ways, access to care is threatened. For too many, it is choked off completely. The most vulnerable? Those with pre-existing conditions.

At the heart of the matter, we have the patient and the physician. Yet, they have little control over actual costs and waste. We have even reached the absurd point where the "rules of the system" sometimes **prevent** physicians from caring for the sick, the very people they swore to protect.

America's fiscal house tilts toward collapse as waves of red ink lap against its foundation. Both American businesses and the workforce struggle to succeed under the ever increasing cost of medical care.

To state it plainly, access is an issue because of the increased costs. With no end in sight, fear pushes vulnerable Americans toward any voice or scheme that promises relief.

Meanwhile, the middle class shrinks under the crushing costs of insurance and treatment, costs which make it impossible to save and get ahead.

Those who examine the subject have become habituated to using the words "unsustainable" and "untenable."

[1] https://www.kff.org/health-reform/poll-finding/kff-election-tracking-poll-health-care-in-the-2018-midterms/

Preface

(continued)

America must understand **WHY** we pay so much for healthcare and waste so much in the process. We must pull back the curtain and expose the drivers of cost.

Americans deserve to know how healthcare is paid for in this country; they deserve to know what really drives the skyrocketing costs; they deserve to know of the simple, legislative fixes that could eliminate wasteful spending.

Who better to present these solutions to the problems besetting our nation's healthcare system than the practicing physicians who have dissected the drivers of cost?

Physicians have devoted their lives to helping those we see in the exam rooms, emergency rooms and operating rooms across this great nation. It is time we fulfilled our Hippocratic Oath in a new way. It is time that we inform our fellow Americans of the barriers to quality, affordable medical care.

This White Paper

This White Paper offers a roadmap drawn by a coalition of organizations made up of working physicians and industry experts who are unabashedly pro-patient. For decades, and with neither compensation nor conflict of interest, many of us have been advocates for patient-centered, fiscally responsible public policy as it relates to medical care. We call for freedom and individual liberty over the centralized control and excessive regulation of the practice of medicine.

On pages 35 through 38 of this document, we have provided all of our legislative "asks" in a single location. The body of the paper contains our justification for why and how those asks— a response to a call to experts for suggestions during a speech on the Senate floor by Senator Alexander (R-TN) in December 2018—will decrease cost and waste in the system for delivering medical care.

Our roadmap will facilitate (and record) a bipartisan dialog at the Free to Care Symposium, April 1-2, 2019, in the Thomas Jefferson Building's Members' Room of the Library of Congress. We have three primary goals:

1) **Lowering the cost of medical care**—not merely stabilizing it at its current levels, not merely slowing its rate of increase, but driving it down. This requires identifying, exposing, and eliminating the layers upon layers of waste, redundancy, fraud, corruption, and profiteering inherent in those multiple layers of corporate middlemen and endless government bureaucracy.
2) **Restoring autonomy** (choices) to patients and their physicians. Especially for patients with chronic diseases.
3) **Educating lawmakers and the public** about the root causes of skyrocketing costs and waste in the current American medical system.

It is our earnest hope that this proposal, and the recordings that will result from the discussions at the **Free to Care Symposium,** will be useful to legislators and to the coalition of pro-patient advocacy groups. These ideas may form a basis for productive cooperation and the restoration of sanity and decency in the nation's healthcare system.

The Nation's Dilemma and How to Address It

Spending on the healthcare sector in the United States now constitutes almost 20% of GDP—nearly one dollar in five, an amount that beggars the vocabulary for describing the absurd.

The consumption by the healthcare sector of such a large portion of the nation's financial wherewithal limits spending on other crucial items, such as infrastructure and education.

There is only one way amenable to serious debate that could reduce the cost of medical care while simultaneously restoring autonomy to people who seek that care. We must return power over spending on medical care to patients and the physicians they trust. This will give them a reason to ask two simple questions that govern the entire market-based system:

- Is this test, product, or service necessary?
- How much does it cost?

Solving the Problem:
Dismantling Complexity in Stages

Even though we have reached a point of great peril for the financial structure supporting our nation's system of medical care, hyper-partisanship has paralyzed both lawmakers and citizens. But there is one group that is never paralyzed—the special interests. They never lose sight of their objective or of the need to bend lawmakers in the direction that best advances their agenda.

In this White Paper, while steadfastly opposing "Medicare for All," we avoid the polarizing call for repeal of the Affordable Care Act in its entirety. We seek neither Scylla nor Charybdis. Instead, we begin with goals and ideas that are workable and that resonate very readily with most citizens and practitioners.

We must set aside the idea of demolishing our hopelessly complex, needlessly expensive system in one huge explosion. The best way to fix it is to do it one step at a time.

This White Paper advances individual reforms that would start to dismantle the worst parts of the American medical care system, while preserving function along rational, efficient lines. We favor explaining each reform to the public before introducing legislation in Congress.

The individual reforms fall under these five headings.

A. Drive Drug Prices Down and Increase Supply.
B. Strengthen the Safety Net for the Vulnerable.
C. Foster Fresh Models to Pay for Medical Care.
D. Reverse Our Physician Shortage.
E. Make Actual Prices Transparent.

A. Drive Drug Prices Down and Increase Supply.

Reform 1. Repeal the "safe harbor" law that drives up the prices for medications and medical devices.

In 1987, the adoption of the Medicare Anti-Kickback Safe Harbor law (as part of the Medicare and Medicaid Patient and Program Protection Act of 1987) established the conditions for the development of near-monopolies over the distribution of medical supplies and medications—monopolies now doing more than $600 billion of business ***each year***. That little-known law provided a "safe harbor" for kickbacks (euphemized as "rebates") under Section 1128B(b) of the Social Security Act (42 USC 1320a-7b(b).

The law granted indemnity from prosecution to Group Purchasing Organization (GPO) middlemen when executing pay-to-play market allocation contracts.

After significant consolidation, four behemoth GPOs now control 90% of the entire chain of hospital and nursing home supplies, and we are in the grip of an unspeakably corrupt, pay-to-play system of financial kickbacks. This adds an estimated $250 billion of unnecessary expense to the American healthcare tab ***each year*** merely on the in-patient side; it does not include outpatient medications and supplies.

Not only does the "safe harbor" significantly drive up the cost of medical supplies and medications, it is responsible for the drug shortages we see in hospitals.[2]

Most affected by this catastrophically wrongheaded statute are those with chronic illnesses, i.e., pre-existing conditions, and the elderly. Both groups are most sensitive to the high cost of drugs and of supplies in hospitals and nursing homes because they are the most likely to require drugs and hospitalization.[3]

In 2003, the Office of Inspector General (OIG) in the Department of Health and Human Services (HHS) extended the GPO Kickback Safe Harbor to the PBM industry. This created the means for the PBM industry (now consolidated into three behemoth PBMs) to control over 85% of outpatient prescriptions and to allocate market share by way of secret, kickback contracts.

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[2] https://www.wsj.com/articles/where-does-the-law-against-kickbacks-not-apply-your-hospital-1525731707

[3] https://www.theintell.com/opinion/20190213/guest-opinion-kickbacks-kill-and-cost-those-with-pre-existing-conditions

A. Drive Drug Prices Down and Increase Supply. *(continued)*

Reform 1. Repeal the "safe harbor" law that drives up the prices for medication and medical devices. (continued)

Multiple Senate Antitrust Subcommittee hearings on the abuses among GPOs and Pharmacy Benefit Managers (PBMs) have exposed the "safe harbor" as the root of drug shortages.[4] The mere existence of shortages is itself adding to the medical tab for all Americans.

Another consequence of high domestic drug prices has been the temptation to seek foreign sources. The risk? Poor manufacturing standards and practices leading to contaminated drugs and patient deaths, such as occurred in 2008 from contaminated heparin imported from China.[5] More recently, there was a recall of a commonly used antihypertensive because it was discovered to have carcinogenic ingredients.

If the law that established the "safe harbor" for kickbacks to the GPOs (and extended to PBM's in 2003) was repealed, the cost for medical supplies and medications would fall by an estimated 25% to 30%. The cost of prescription medications would fall by 35-43%. Additional declines in prices are projected as true competition replaces a rigged marketplace. We estimate this reform would save Medicare and Medicaid an estimated $75 billion ***each year***. See Appendix B for more information.

The White House introduced the HHS PBM Rule on February 6, 2019. This rule rescinds the GPO/PBM Kickback Safe Harbor for PBMs as it relates to Medicare and partially as it relates to Medicaid. This proposed rule would aid in fixing the misaligned incentives in the system that currently result in insurers and PBMs favoring medicines with high list prices.

Senator Mike Braun R-Indiana recently announced S 657, the Drug Price Transparency Act. S 657 codifies the provisions of the HHS PBM Rule and extends all such protections to all patients, not just to those covered under federal benefit programs.

[4] https://www.gao.gov/products/GAO-15-13 ;https://www.gao.gov/products/GAO-14-194

[5] https://www.desmoinesregister.com/story/opinion/columnists/iowa-view/2019/01/28/growing-dependence-china-national-security-concern-drugs-pharmaceuticals-fda/2699771002/

A. Drive Drug Prices Down and Increase Supply. *(continued)*

Reform 1. Repeal the "safe harbor" law that drives up the prices for medication and medical devices. (continued)

Americans, especially those with pre-existing conditions, will not have protection of their medical treatment until the full repeal of GPO safe harbor for kickbacks is also enacted. GPO kickback safe harbor repeal is necessary to give relief to the rural hospitals, less able to stockpile than their urban counterparts. Increased supply will drive down the costs of medications and basic supplies.

We project that the HHS PBM Rule eliminates roughly 25% of the kickbacks to middlemen. Senator Braun's bill would codify and eliminate an additional 25%, approximately, of those kickbacks. The bill we propose (see Appendix B in this document for language that may be useful) would eliminate 100% of the kickbacks. It is the only comprehensive, enduring remedy for the conflicts of interest in the health care supply chain. It is the only bill written that protects both in-patient and out-patient costs for individuals with pre-existing conditions. It is the only bill that would reintroduce competition to the entire healthcare supply chain while restoring its integrity.

WE ASK for full repeal of the kickback protections afforded to PBMs and GPOs in 42 U.S.C. 1320a-7b(b)(3)(C). To that end, we have a bill already written for both the House and Senate to introduce. (See Appendix B.)

B. Strengthen the Safety Net for the Vulnerable.

Reform 2. Allow tax deductions for pro bono physician care.

The Association of Mature American Citizens (AMAC) proposed the *Pro Bono Care Act of 2019 (H.R. 856)* to help provide medical care for American citizens in financial need. Under the bill sponsored by Representative Daniel Webster (R–FL 11th District) and co-sponsored by Representative Collin Peterson, (D-MN 7th District), physicians would receive a tax deduction in return for treating indigent patients without charge. Participation would be voluntary for both the physicians and patients; the number of such patients per doctor would be capped at 20.

WE ASK that the Pro Bono Care Act of 2019 be passed.

The primary beneficiaries of this program would be the 27 million Americans currently without health insurance and those now covered under Medicaid. Based on surveys of doctors and potential patients, the program anticipates a high rate of participation. The projected savings? Between $6 and $9 billion annually ($75 billion over 10 years), some of it being realized by states, some by the federal government).

Reform 3. Allow tax deductions for nurses and physicians who engage their community via education on preventative health topics.

Prevention, nutrition, exercise, diabetic care, vaccination, sunscreen, dental care, prenatal care, parenting, care of the elderly during their twilight years—all of these are matters on which patients seek the guidance of physicians and nurses.

In its administrative overhead, our medical care system is a labyrinth in which practitioners are lost, attending to inescapable busywork that sucks up time and destroys opportunities to spend quality time with patients.

Tax-deductible, donated time for community forums would foster educational engagement between practitioners and the public. While not a substitute for the face-to-face personal encounter, the repetition provided by forums and the ability to address questions would support robust, cost-effective, public health education.

B. Strengthen the Safety Net for the Vulnerable. *(continued)*

Reform 3. Allow tax deductions for nurses and physicians who engage their community via education on preventative health topics. *(continued)*

The obvious benefits of increased engagement between practitioners and the public would foster trust—a much-needed seed for the growth of patient compliance. Poor compliance by patients with instructions received from practitioners leads directly to higher costs and waste in medical care.

As a proposed model, we offer the work done in suburban Philadelphia's Bucks County by the Bucks County Health Improvement Partnership (BCHIP).[6] BCHIP is building a coalition of community members, engaging practitioners, and having the latter give lectures on such topics as these: smoking cessation, the opioid epidemic, and the need for families and physicians to have discussions about advance directives.

We do ***not*** advocate government intrusion into end-of-life decisions; these are rightfully left to families, patients, and physicians. Yet we must stimulate national discussion about this and other important matters.

Incentivizing our younger physicians particularly to donate time to forums supporting community education can reasonably be projected to enhance public health across the country, thereby saving many public and private dollars.

Innovative incentives for voluntary efforts—true charity—should be created. Here are a couple of possibilities: a state tax credit for donations to agencies that pay medical bills for needy patients (the agencies, not the state, would decide how funds are allocated); and state assumption of the cost of malpractice liability insurance for doctors who have donated their services at charity clinics.

WE ASK for tax deductions to be extended to physicians and nurses who donate time in public settings to educate the public and to address legislative bodies on state-based incentives for true pro-bono care.

[6] https://www.bchip.org/

C. Foster Fresh Models to Pay for Medical Care.

Reform 4. Expand permitted use of Health Savings Accounts to reduce third-party interference; increase state support and patient awareness of Association Health Plans and Short-Term Limited-Duration Insurance as affordable alternatives.

The Nobel Prize-winning economist Milton Friedman (1912-2006) once observed, "Nobody spends somebody else's money as wisely as he spends his own."

When a third party is positioned between a patient and the physician for the sole purpose of controlling the over-inflated cost of health care and profit, the results are (1) the transfer of excessive administrative costs to the patient, and (2) less care delivered by the physician.

The money wasted through administrative red tape is staggering, as reported in a study published by the Commonwealth Fund regarding administrative costs in American hospitals. The data compiled in the study demonstrated that "[a]dministrative costs accounted for 25 percent of hospital spending in the United States…"[7] The most disturbing fact noted in this study was that higher administrative costs did not directly correlate with higher-quality care.

Third parties create more financial waste through pre-authorizations (PA) and denials of care. Dealing with these administrative hassles results in less time spent with patients. An AMA Sustainability Study from April 6, 2018, states that "[o]n average, a medical practice will complete 29.1 PA requests per physician per week that take 14.6 hours to process…" and physician offices are wasting "…an average of two business days a week per physician to comply with health plans' inefficient and overused prior-authorization (PA) protocols."[8] If a PA is rejected, often due to reasons or recommendations that are not helpful for the patient, physicians lose additional time that should be dedicated to patient care.

How do the corporate purveyors of health plans maintain such control? They lobby aggressively themselves, and they use the power of "adjunctive lobbies," including some physician organizations. Such groups have not contributed to any effort at lowering the cost of healthcare for patients.

[7] http://www.commonwealthfund.org/publications/in-the-literature/2014/sep/hospital-administrative-costs

[8] https://www.ama-assn.org/practice-management/sustainability/prior-authorization-major-practice-burden-how-do-you-compare

C. Foster Fresh Models to Pay for Medical Care. *(continued)*

Reform 4. Expand permitted use of Health Savings Accounts to reduce third-party interference; increase state support and patient awareness of Association Health Plans and Short-Term Limited-Duration Insurance as affordable alternatives *(continued)*

Within the existing system and with the current debate over the issues in Congress, how well are physicians able to care for patients with pre-existing conditions and chronic illness?

How can the interference of the third parties and the "middlemen" be reduced?

We recommend giving more control to patients over their own healthcare dollars.

States need to be encouraged or incentivized to advance this administration's expansion of less-costly health insurance alternatives, such as Association Health Plans (AHPs) and Short-Term Limited-Duration Insurance (STLDI). These plans have high deductibles which can be combined with Health Savings Accounts (HSAs). If an HSA is used for medical services with an AHP or STLDI, patients will ultimately have greater control over their healthcare dollars. Americans will also have and more choices[9] and control over medical decision-making, which can improve wellness, preventative care, and management of chronic disease(s) and pre-existing conditions. HSA dollars are used most effectively in these ways when medical fees are not inflated by red tape.

Alongside AHPs and STLDI, Direct Primary Care (DPC) or other direct-care models provide affordable, third-party-free medical services, which optimize HSA dollars for medical services, particularly in caring for those with pre-existing conditions. Regulatory and/or legislative reform of the tax treatment of HSAs in relation to DPC/direct-care is much-needed reform and must be free of unnecessary regulatory burden for independent DPC practices. The continuation of regulatory/administrative burdens would impede the delivery of affordable and attentive care to patients with HSAs in conjunction with either AHPs or STLDI. Those burdens undermine the concept of consumer-driven use of HSAs with either AHPs or STLDI. We second the current administration's support for logical and affordable choices for Americans when they seek medical care.[10]

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9 http://www.aei.org/events/health-care-that-matters-real-choices-for-real-competition/

10 https://www.hhs.gov/about/news/2018/12/03/reforming-americas-healthcare-system-through-choice-and-competition.htm (see page 73 in document)

C. Foster Fresh Models to Pay for Medical Care. *(continued)*

Reform 4. Expand permitted use of Health Savings Accounts to reduce third-party interference; increase state support and patient awareness of Association Health Plans and Short-Term Limited-Duration Insurance as affordable alternatives *(continued)*

WE ASK that states be encouraged to implement, and the American public be educated about, AHPs and STLDI, which increase choices for affordable options in health coverage.

WE ASK that HSAs be redefined so that in a context featuring the high deductibles of AHPs and STDLI, HSA dollars can be used for affordable Direct Primary Care/direct-care specialty services that are free of third-party interference.

Reform 5. Allow unobstructed expansion of Direct Patient Care in its pure form to increase patient choice.

Despite the unfavorable conditions, entrepreneurial physicians who engage in primary care and use the fixed-fee model of Direct Primary Care (DPC) have begun to blossom across the landscape of American medical care. Specialists, too, are beginning to provide care directly to patients for fixed fees paid to the specialist directly. Because these physicians can operate with much greater efficiency and lower overhead than traditional institutions, they can offer the same or better care for all medical conditions—including pre-existing ones—at a substantially lower price. **DPC is an innovative, grassroots, physician-led movement focused on consumer-driven, value-based patient care.**

Physicians who have adopted the DPC model are able to serve all patients, but especially the chronically ill, providing expanded access, while realizing huge cost savings through fewer visits to emergency rooms by their patients and lower rates of hospitalization.[11] The DPC model also enhances the comprehensive management of pre-existing conditions.

[11] https://www.johnlocke.org/press-release/direct-primary-care-could-help-patients-with-chronic-diseases-disabilities/

C. Foster Fresh Models to Pay for Medical Care. *(continued)*

Reform 5. Allow unobstructed expansion of Direct Patient Care in its pure form to increase patient choice. *(continued)*

Other advantages of the DPC model, specifically independent DPC offices, include transparently priced, value-added services delivered to patients through generic prescriptions dispensed from the office at near-wholesale prices, along with negotiated, discounted cash prices for radiology and imaging services. **This effectively removes the overhead of the middleman from the picture, resulting in *tremendous* savings for patients.**

One DPC office in Pennsylvania self-reports the following office data averaged over a 3-year period. Cost per:

- 30-day supply of medication, **$3.58**;
- Lab test, **$5.87**;
- Radiology study, **$148.49**.

Moreover, there were no price increases for these ancillary services from 2016 through 2018, a characteristic in the vast majority of independent DPC practices. These numbers stand in drastic contrast to the incredible, annual cost increases of insurance-based care.

It should be permissible under the relevant law to pay the periodic medical fees incurred under DPC arrangements from monies in Health Reimbursement Arrangements (HRAs) for employees, from the HSAs of individuals and families, and from the MSAs of Medicare beneficiaries.

To ensure this result, legislative fixes must ***not*** incorrectly define DPC as an insurance plan, for instance under Internal Revenue Code Section 223 (d)(2)(C). Instead, DPC arrangements **should** be properly defined as a medical expense under Sec. 213 (d).

DPC will also work independently, but seamlessly, with AHPs and STLDI as they expand, and with certain employer or health-sharing plans.

Why should payment of periodic DPC fees be acceptable only if they are made from after-tax funds of employers/employees in HRA arrangements or for families or individuals with HSAs? And why are patients in a DPC practice prohibited from making contributions to their HSAs?

C. Foster Fresh Models to Pay for Medical Care. *(continued)*

Reform 5. Allow unobstructed expansion of Direct Patient Care in its pure form to increase patient choice. *(continued)*

Regrettably, direct-care physicians are largely, although not completely, off limits for patients who have been forced into relying on these programs.

Under the current system, patients who must participate in Medicare and Medicaid cannot use their benefits to seek care from physicians who are outside the government-run program or who do not participate in the corporate health plans under contract with these programs. Instead, these patients must rely upon contracted practitioners and facilities that cost the system vastly more. This is an obvious barrier for Medicare and Medicaid patients who may wish to choose a DPC practice and benefit from the care the DPC model provides.

Medicare patients are permitted to find an "opted-out physician" and pay out of pocket. But shouldn't Medicare patients be allowed to use the benefits they've paid for over their lifetimes to pay for the services of physicians of their own choosing?

WE ASK that monies from HSAs, HRAs, and MSAs be usable for payment of periodic DPC medical service fees to increase choice and competition and lower health care costs. This will benefit American families, individuals, and employers/employees.

WE ASK that any potential legislation regarding use of pre-tax HSA dollars for DPC services not restrict the innovation of independent DPC practices or restrict the services brought to their patients, including those with chronic illness and/or pre-existing conditions.

WE ASK that Medicare and Medicaid patients be able to use monies provided as a voucher to purchase DPC services. Medicare patients should be able to do so and to opt out of traditional Medicare Part A without fear of losing their earned Social Security benefits.

D. Reverse Our Physician Shortage.

Reform 6. Eliminate expensive federal mandates.

The Health Information Technology for Economic and Clinical and Health Act (HITECH, 2009), the Medicare Access and CHIP Reauthorization Act (MACRA, 2015) and the Affordable Care Act (ACA, 2010) imposed numerous and expensive mandates on physicians, hospitals, and insurance plans. These include the government-certified electronic health record technology (CEHRT), penalties for failure to use EHRs meaningfully, MACRA's onerous reporting requirements (MIPS), ACA data-intensive Accountable Care Organizations, population-healthcare tracking, value-based payment models, and required reporting of compliance with numerous protocols imposed by those outside the medical examination room.

The result?

The cost of running small medical practices has skyrocketed, forcing physicians to "sell out" and consolidate under the umbrellas of big hospitals.

Another result?

Epic levels of burnout among physicians, some 78% of whom (according to the most-recent survey by the Physician's Foundation[12]) report experiencing that unhappy combination of physical and emotional exhaustion from stress in the workplace that leads people to seek other lines of work. That can do nothing but deepen the existing shortage of physicians.

The unhappy side effect of mandates for patients is less time with their physicians.

The result of mandates for insurance companies and the plans they offer? Premiums and deductibles skyrocketed. The dramatic increase created a new group of uninsured—working-class Americans who have ***no*** affordable alternative.

WE ASK that the restoration of small physician practices be encouraged and that, as a first step, the mandates associated with the Electronic Health Record (EHR) and Merit-Based Incentive Payment System (MIPS) be removed for practices having fewer than 50 physicians.

[12] https://physiciansfoundation.org/press-releases/the-physicians-foundations-sixth-biennial-survey-finds-physicians-are-pessimistic-about-the-future-of-the-profession-as-burnout-rates-continue-to-rise/

D. Reverse Our Physician Shortage.

Reform 7. Prevent Prior Authorizations from impeding patient-care and increasing the administrative burden on the physician's office.

When seriously misused or overused, prior authorizations can be harmful to patients, even life-threatening. While not a new complaint, physicians across the nation have noted in recent years that requirements for prior authorizations have been increasingly imposed by many insurers to the detriment of patients. When used to create inappropriate barriers to care, prior authorizations can lead to difficulty in accessing care, denial of medically necessary care, and even disease progression and death. It is also troubling that increased requirements for prior authorization significantly increase the administrative burden on physicians and their staff, greatly inhibiting their ability to spend time caring for their patients.

The requirement for prior authorization should be subjected to annual review to see whether it is being used appropriately, and whether it should be eliminated entirely for some therapies. It should never delay care, and the providers of medical care who are subject to it should know the rules for its use.

WE ASK that for physicians whose performance in and adherence to evidence-based medical practices, or participation in a value-based agreement with a health insurance provider warrants the removal of the requirement for prior authorization, the requirement be removed.

WE ASK that services and medications which require prior authorization be regularly reviewed and that the requirements for therapies that no longer warrant prior authorization be lifted.

WE ASK that channels of communication be improved between health insurance providers, medical care professionals, and patients to minimize delays in access to care and to ensure clarity on prior authorization requirements, rationale, and changes.

WE ASK that continuity of care be protected for patients who are on an ongoing, active treatment or a stable treatment regimen when there are changes to coverage, in health insurance providers, or in in requirements for prior authorization.

WE ASK that the health insurance industry adopt national electronic standards for prior authorization and accelerate and improve transparency of formulary information and coverage restrictions at the point of care.

D. Reverse Our Physician Shortage. *(continued)*

Reform 8. Stimulate state-based reform of our broken medical malpractice system.

A lawsuit is one of the most emotionally traumatic experiences a physician experiences. In fact, a lawsuit, even a frivolous one, has driven many fine physicians from the practice of medicine.

Defensive medicine is a rarely discussed, but significant, driver of skyrocketing healthcare costs. All too often, physicians order tests they do not think will likely be helpful, but they do so guard against a possible lawsuit, and to demonstrate that they "have done everything." During hearings at the Senate HELP committee in 2018, Dr. Brent James of the National Academy of Medicine stated that at least 30% and as much as 50% of all money spent on health care may be unnecessary.[13]

There is no lobby harder to escape in the politics of healthcare than that of the trial lawyers. However, this reform may save at least $45 billion ***each year*** the money squandered through the widespread practice of hyper-defensive medicine.[14]

In May 2017, the House passed a malpractice reform bill.[15]

WE ASK that the Senate reform our broken malpractice system by passing companion legislation to that bill (H. R. 1215).

[13] https://www.help.senate.gov/imo/media/doc/James3.pdf

[14] https://www.policymed.com/2010/09/defensive-medicine-adds-45-billion-to-the-cost-of-healthcare.html

[15] https://www.congress.gov/bill/115th-congress/house-bill/1215

D. Reverse Our Physician Shortage. *(continued)*

Reform 9. Train more physicians and make the training of all practitioners transparent.

In its "2018 Update: The Complexities of Physician Supply and Demand: Projections from 2016 to 2030," the Association of American Medical Colleges (AAMC) projected a national shortage of physicians by 2030 that could range from a low of 42,600 to a high of 121,300.[16] This projection assumes that barriers faced by patients when seeking affordable, equitable, and timely care will have been removed.

Heading off this development should be a top priority. However, the conditions governing the practice of medicine in America threaten only to deepen the projected shortage.

We advance five measures in this White Paper to keep talented people in the field of medicine and to draw more people to it. Increasing the supply of physicians will improve patient access to affordable, equitable, safe, and timely physician-led care.

(i) *Addressing the shortage of Primary Care Physicians (PCPs)*. PCPs—i.e., those in Family Medicine/General Practice— are the first-line coordinators of care for the American people. But as indicated by the AAMC's update for 2018 and by an AAMC-generated profile of the physician workforce, they are vastly outnumbered by physicians in other specialties.[17]

The incentive to become a PCP is comparatively weak. It is essential to strengthen that incentive to the point where it exceeds the incentives attached to other choices. It simply ***must*** happen.

[16] https://aamc-black.global.ssl.fastly.net/production/media/filer_public/85/d7/85d7b689-f417-4ef0-97fb-ecc129836829/aamc_2018_workforce_projections_update_april_11_2018.pdf

[17] https://www.aamc.org/data/workforce/reports/492558/1-2-chart.html

D. Reverse Our Physician Shortage. *(continued)*

Reform 9. Train more physicians and make the training of all practitioners transparent. *(continued)*

(ii) *Removing barriers to the practice of telehealth.* Telehealth (sometimes called "telemedicine") allows patients to engage physicians in many specialties remotely. This is true for not only the PCP, but for psychiatrists, radiologists, and even dermatologists, among others. Physicians who are willing to work with patients by these means can offer expert medical care to a widely dispersed clientele, and they themselves are not tied to a single location. They can even reap significant savings of their own in childcare, travel, and other expenses.

According to the National Board of Medical Examiners (NBME), rates of graduation from medical schools are often misaligned with the number of available residency positions in the geographic areas where the schools are located and where the greatest need exists. Even so, the AAMC's *2017 Physician Specialty Data Report* indicates that 47% of all graduates—and 51% to 56% of graduates in primary care—remain in the state where they trained.[18] The expanded practice of telehealth would be a useful step toward overcoming this tendency toward the misalignment mentioned above.

iii) *Addressing the challenges of reductions in Residency Programs.* Medical Doctors (MDs) or Doctors of Osteopathy (DOs) who have completed four-year medical school programs and passed all but the final step of either the United State Medical Licensing Examination (USMLE) or Comprehensive Osteopathic Medical Licensing Examination (COMLEX) are just short of practicing on their own. While not completing a residency program, they are prepared to practice primary care because of their extensive educations and training in medical school. Having them work under the close supervision of fully licensed physicians is one way to increase the number of PCPs.

[18] https://www.aamc.org/data/workforce/reports/492570/1-8-chart.html

D. Reverse Our Physician Shortage. *(continued)*

Reform 9. Train more physicians and make the training of all practitioners transparent. (continued)

(iv) *Encouraging integrated medical care teams.* Other practitioners—non-physicians, such as Physician Assistants (PAs) and Advanced Practice Registered Nurses (APRNs)—have traditionally been prominent parts of medical care communities of all types and indispensable members of physician-led teams. Their presence has helped greatly in the care of patients. The website of the American Association of Nurse Practitioners (AANP) offers informative statistics.[19]

However, in 2010, acceding to a recommendation from the Institute of Medicine, the writers of the ACA included a measure to encourage the use of APRNs as *substitutes for* physicians. The aim was to reduce shortages of medical care professionals. APRN graduation rates increased dramatically; the AANP reported on its website these results from a 2018 NP Sample Survey: the number of NP certificates doubled from 2016 to 2017, and still grew by another 9% from 2017 to 2018. As of this writing, 23 states and the Veteran's Administration now allow APRNs to care for patients without supervision by or under a collaboration agreement with a licensed physician.

This expansion has increased the numbers of these practitioners per capita. Ironically, it has ***not*** decreased wait times, nor has it improved affordability or the delivery of care. Previous workforce studies concluded that it would take **10 NPs to equal the contribution of one resident in family medicine**.[20] AAMC workforce projections combined with the American Medical Association's (AMA's) mapping of practice locations show that unsupervised APRNs are saturating health care markets ***already*** populated by physicians.[21] Given this demographic oddity, it is easy to understand why patients wonder aloud about who is really treating them. The American Council on Science and Health has raised thought-provoking concerns on the trend.[22]

Bipartisan legislation has been introduced to get at the problem.[23]

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19 https://www.aanp.org/

20 Bowman, R. C., "Measuring primary care: The standard primary care year." Rural Remote Health. 2008 Jul-Sep;8(3):1009

21 https://www.ama-assn.org/system/files/corp/media-browser/premium/arc/ama-issue-brief-independent-nursing-practice.pdf

22 https://www.acsh.org/news/2017/10/25/first-they-came-my-white-coat-america%E2%80%99s-war-doctors-12027

23 https://bucshon.house.gov/news/documentsingle.aspx?DocumentID=490

D. Reverse Our Physician Shortage. *(continued)*

Reform 9. Train more physicians and make the training of all practitioners transparent. *(continued)*

In any case, calls for pay parity with physicians from the AANP and the APRN work against the original objectives of reducing the cost of care and of speeding up the delivery of care to patients.

In light of such data, the licensing of GAPs to expand the physician workforce and provide safe, economical, and equitable medical care appears to have greater promise of effectiveness than granting non-physicians the right to practice *without* supervision.

Therefore, encouraging *integrated* medical care teams ***led by*** physicians is the best solution for improving the quality of care that is available to patients.

(v) *Increasing Attention to Rural Areas.* Allocation of funds for physician training should be focused on primary-care residency, particularly in rural and underserved areas.

Rural areas provide the food, fuel, and fiber for the entire country. Every American should be concerned about public health in those areas and the documented shortages of physicians there. Since 2013, Texas, a glaring example, leads the nation with 21 closures of rural hospitals. Of the 300 rural hospitals that served Texas in the 1960s, 161 are left today to serve 3.1 million Texans.

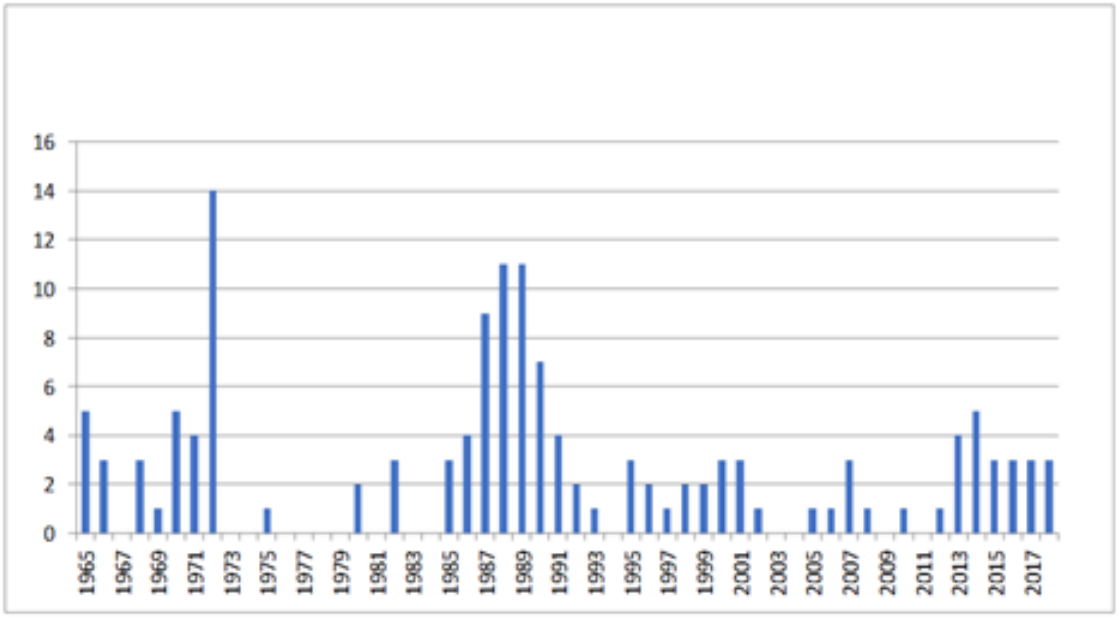
Rural hospitals see higher percentages of Medicaid and Medicare patients also, accentuating the devastating effects of Medicare and Medicaid cuts and mandates. A declining rural population and the choices of some patients to bypass their rural hospital to seek care in urban centers have contributed to the trend line for closures. So, too, has the problem of increased numbers of Medicaid patients, a phenomenon that is attributable to the way that state and federal governments calculate payments in light of onerous regulation designed for larger, urban hospitals. While some blame the rejection of Medicaid expansion by certain states for the closures, we must remember that expansion itself imposes an economic burden on states.[24]

[24] *https://www.governing.com/topics/health-human-services/gov-medicaid-expansion-funding-states.html*

D. Reverse Our Physician Shortage. *(continued)*

Reform 9. Train more physicians and make the training of all practitioners transparent. *(continued)*

The bar chart below, developed by the Texas Organization of Rural & Community Hospitals (TORCH), shows closures of rural hospitals (defined as "critical access hospitals, sole community hospitals, rural referral centers in a non-MSA, or any other acute care hospital in a county of 60,000 or less) in that state from 1965 through 2017, with an update in December 2018. Note that waves of closures have tended to follow government regulatory changes. Many small hospitals in urban settings were similarly affected. Osteopathic hospitals closed because they were small, private operations. Corporate hospitals would often buy and close them to eliminate competition.



Access to a medical care is severely limited in the 32 counties in Texas that have ***no*** physician. It is alarming to consider that for women of childbearing age, 157 of the 254 counties in Texas have ***no*** obstetrician.

D. Reverse Our Physician Shortage. *(continued)*

Reform 9. Train more physicians and make the training of all practitioners transparent. *(continued)*

Addressing these shortages requires an honest look at root causes. An inescapable factor is the deepening shortages of time, which degrade the productivity of the existing population of physicians. **A physician's time for seeing patients has decreased, but regulatory mandates with the EHR and payer demands have tripled the time that must be spent on the administrative side of seeing a single patient. Because of regulatory intrusion (for example, MIPS compliance, prior authorizations, and the onerous EHR), there is simply not enough time to serve the same volume of patients as previously.**

Also chipping away at the physician population is the cost of doing business in the current regulatory climate. The upfront cost for buying an EHR system can approach $170,000.[25] Nationwide, over 60% of physicians have had to switch their EHR systems, shelling out non-trivial fees for consultants, subscriptions for new software, ongoing tech support, and more. This financial burden has devastated small practices, striking rural communities the hardest, shutting them down at alarming rates nationwide, and creating physician shortages and critical deficiencies of access to care.[26]

Rural areas have the best chance of recruiting young doctors who have a connection to those areas. The Primary Care Pathway Program is an effort to reduce the time needed to train primary-care physicians adequately through an intensive, highly focused three-year, pre-med program that begins in the rural areas served by community colleges. Such a pilot program in Midland, Texas, seeks to reduce the cost of training a medical student through graduation. The program has been operating only a few years, but there is hope that it will succeed in developing primary-care doctors who will practice in the rural settings where they grew up, and to which they have personal connections.

Because many rural areas have high numbers of uninsured patients, innovative payment models—DPC for one—and incentives for physicians via the tax code to care for the uninsured should go some distance toward reviving the practice of medicine in places where it is most-sorely needed.

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[25] https://www.americanactionforum.org/research/are-electronic-medical-records-worth-the-costs-of-implementation/

[26] https://www.medicaleconomics.com/business/true-cost-switching-ehrs

D. Reverse Our Physician Shortage. *(continued)*

Reform 9. Train more physicians and make the training of all practitioners transparent. *(continued)*

To review, these are the measures discussed under this heading on the training of physicians and dealing with shortages:

- Encouraging health systems to increase the incentives to become PCPs.
- Responsibly removing barriers—medical license restrictions, insurance networks, and the Stark Law, among others—to the delivery of care via remote methods (telehealth).
- Encouraging the licensing of GAPs so that they can become part of physician-led medical care teams.
- Encouraging the proliferation of integrated, physician-led medical care teams comprised of members whose level of training is transparent to the patient in each case.
- Reducing the administrative burden that consumes hours upon hours of physicians' time and drives them from the profession.
- Reducing the cost of doing business (particularly technology costs related to administrative burdens) which drives physicians from the profession
- Experimenting with accelerated pathways to completing medical education
- Incentivizing physicians to care for the uninsured.

For the purpose of this White Paper, firstly addressed to legislators:

WE ASK for the reintroduction and passage of the bipartisan legislation (the "Truth in Healthcare Marketing Act," H.R. 1427) prepared by Representatives Larry Bucshon (R-IN 8th District) and David Scott (D-GA 13th District), to ensure that patients are informed about the level of training their medical care provider has undergone.

WE ASK that caps on funding that supports the education of medical residents be lifted by passing the bipartisan "Resident Physician Shortage Reduction Act of 2019" (S.348) introduced by Senator Robert Menendez (D-NJ).

WE ASK for discussion of legislation removing barriers to responsible telehealth. (NOTE: We do NOT consider the Interstate Medical Licensing Compact to be responsible as written.)

E. Make Actual Prices Transparent.

Under this heading, we develop suggestions to promote the empowerment for those who finance and consume medical care services.

Reform 10. Provide true price transparency for patients.

On January 1, 2019, the Centers for Medicare & Medicaid services (CMS) implemented a new rule mandating that hospitals post their charges online. The aims were to increase price transparency (reduce opacity) and empower patients with information.

This is a good first step, but pricing in medical care is highly convoluted, and the prices that have been posted are almost never the prices that are actually paid.[27] Multiple middlemen cause charges to be hyper-inflated. This, in turn, increases what patients pay in co-insurance and contributes to sticker shock when the services of an out-of-network provider are engaged.

The weakening of the patient's (the medical care consumer's) position in the marketplace from not knowing what things really cost is a glaring problem, the implications of which cannot be underestimated.

It is believed that Sir Francis Bacon (1561-1626) said, "*ipsa scientia potestas est*" ("knowledge itself is power"). Empowering consumers with information that is indispensable to the rational operation of any marketplace will enable both patients and employers to make informed decisions in a complex system.

WE ASK that there be continued legislative pressure toward making actual prices fully transparent.

WE ASK that all providers of medical care be required to provide an itemized bill for services within 30 days of discharge from a hospital, and that the bill must include the full name of each billed medical care item (abbreviations are unacceptable), accompanied by its five-digit Common Procedural Technology medical billing code, and the charge (retail amount). Furthermore, if such an itemized bill is not provided, the consumer cannot be compelled to court and/or reported to any of the existing credit bureaus.

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[27] https://www.buckscountycouriertimes.com/news/20190208/experts-hospital-charges-can-be-confusing-but-necessary
https://www.buckscountycouriertimes.com/opinion/20190214/editorial-on-hospital-charges-murky-transparency-is-start

E. Make Actual Prices Transparent. *(continued)*

Reform 10. Provide true price transparency for patients. *(continued)*

WE ASK that all health insurance organizations and third-party administrators be required to provide, without charge, to fully insured and self-insured employers all medical and pharmaceutical claims data by line item, accompanied by all information contained within existing and utilized claim forms, twice per year <u>or</u> within days of receiving a written request by those employers. A failure to comply with the Claims Review Law (such as already exists in Texas) should result in a fine of $10,000 per day made payable to the employer requesting its data.

Reform 11. Revoke the tax-exempt status of non-profit hospitals.

The opacity of hospital billing affects tax revenues.

An estimated 62% of America's hospitals and health systems are tax-exempt because they have "non-profit" status.

The non-profits claim that the free care they provide to the indigent (reflected on their 990 tax forms, not at the actual price, but at inflated chargemaster prices (see footnote 29 on the preceding page). This allows them to write off millions of dollars more.

In the 2016 Florida Bar Journal, it was reported that the common diagnosis of chest pain can carry a chargemaster price of over $25,000. But the amount that Medicare will pay is set at just over $3,500.

WE ASK that abuse of tax-exempt status by non-profit hospitals be stopped either by removing that status altogether or by requiring that they provide true charitable-care figures calculated at Medicare-allowable prices, and that they not be allowed to request taxpayer-funded Disproportionate Share (DSH) reimbursements from the federal government for the cost of charity care. Such "double dipping" (a tax-exemption <u>and</u> tax-payer funding for charity care) should be prohibited.

E. Make Actual Prices Transparent. *(continued)*

Reform 12. Repeal the moratorium on physicians owning hospitals.

There are models of physician-owned surgery centers already operating and saving money for American patients.[28]

It is claimed, and not without reason, that there is a strong correlation between the quality of care provided by hospitals and whether they are owned and led by physicians.[29]

In fact, surgeries performed in physician-owned hospitals or in independent surgery centers cost 30% less than the same surgeries in hospitals under different ownership arrangements.[30]

An estimated $500 billion in savings ***each year*** could be realized by increasing the number of physician-owned facilities across the landscape. Standing in the way are state-based "Certificate of Need" laws and a clause in the ACA that prevents the proliferation of independent surgery centers.

Legislation has been drafted to allow what the ACA prohibits.[31]

WE ASK for renewed discussion of H.R. 1156, the "Patient Access to Higher Quality Health Care Act of 2017,"[32] which attracted significant bipartisan co-sponsorship, toward the objectives of extending to physicians the freedom to own and operate their own hospitals, and expanding the competitive forces that would drive down the cost of medical treatment.

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28 https://monticellosurgery.com/transparent-surgery-pricing/

29 https://www.ncbi.nlm.nih.gov/pubmed/21802184

30 https://opinionator.blogs.nytimes.com/2013/07/31/a-new-health-care-approach-dont-hide-the-price/

31 https://www.physicianhospitals.org/news/333368/

32 https://www.congress.gov/bill/115th-congress/house-bill/1156/cosponsors?overview=closed

E. Make Actual Prices Transparent. *(continued)*

Reform 13. Adopt a strengthened "Sunshine for All" Act.

In May 2018, Senators Chuck Grassley (R-IA), Sherrod Brown (D-OH), and Richard Blumenthal (D-CT) introduced the *Fighting the Opioid Epidemic with Sunshine Act* to shed light on how our opioid crisis developed and what is driving it.

As noted earlier in this White paper, there is now some limited light shining on costs via the Open Payments database and website created by the CMS, as required under Senator Grassley's *Physician Payments Sunshine Act*.[33]

A bipartisan bill of May 2018 would extend transparency to include Nurse Practitioners (NPs) and the Physicians Assistants (PAs), who can write prescriptions in 23 states.

While expressly designed to shine light on prescriptions for opioids, this legislation should include ***all*** prescriptions. Interestingly, according to CMS data, NPs account for a significant number of opioid prescriptions. In fact, they are the main prescribers of opioids in some states.[34]

Senator Claire McCaskill (D-MO) added (then retracted) a provision that would have included transparency for the money passing between pharmaceutical manufacturers and physician advocacy groups. She amended this to include transparency ONLY for opioid manufacturers. Her initial idea had great merit, and we suggest expanding it to include funding provided by pharmaceutical manufacturers or pharmaceutical channeling companies (including PBMs, GPOs, and the distributors Cardinal Health, McKesson Corporation, and AmerisourceBergen). There is a welter of conflicts of interest in these relationships, with their payments made to and sponsorships provided for:

- Physician advocacy groups;
- Think tanks;
- Patient advocacy groups.

This transparency should be ***retroactive*** in the interest of establishing the histories of potential conflicts of interest.

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[33] https://www.cms.gov/OpenPayments/Program-Participants/Physicians-and-Teaching-Hospitals/Physicians-and-Teaching-Hospitals.html

[34] https://projects.propublica.org/checkup/drugs/2954/states/new-hampshire

E. Make Actual Prices and Conflicts of Interest Transparent. *(continued)*

Reform 13. Adopt a strengthened "Sunshine for All" Act. *(continued)*

WE ASK that hospitals post cash prices, and that all entities in the medical care revenue stream disclose the flow of dollars. The sum of collected revenues and who receives those revenues must become public knowledge.

WE ASK that the abuse by non-profit hospitals of their tax-exempt status be stopped. These hospitals should either pay taxes, like the rest of America, <u>or</u> calculate their charitable care honestly via Medicare-allowable prices.

WE ASK that there be Sunshine for All. The following should be made fully transparent—funding that flows <u>from</u> pharmaceutical companies and pharmacy channel companies (such as PBMs and GPOs, which include the nation's three big distributors) <u>to</u> physician advocacy groups, such as professional societies of medical care providers, consumer advocacy organizations, patient-education organizations, providers of continuing education, co-pay assistance organizations, and think tanks. This transparency should be retroactive, so as to establish histories of possible conflicts of interest.

APPENDIX A

WE ASK…

In this appendix, all of this White Paper's direct "asks" of legislators are assembled in one place for convenience.

WE ASK for full repeal of the kickback protections afforded to PBMs and GPOs in 42 U.S.C. 1320a-7b(b)(3)(C). To that end, we have a bill already written for both the House and Senate to introduce. (See page 12.)

WE ASK that the Pro Bono Care Act of 2019 be passed. (See page 13.)

WE ASK for tax deductions to be extended to physicians and nurses who donate time in public settings to educate the public and to address legislative bodies on state-based incentives for true pro-bono care. (See page 14.)

WE ASK that states be encouraged to implement, and the American public be educated about, AHPs and STLDI, which increase choices for affordable options in health coverage. (See page 17.)

WE ASK that HSAs be redefined so that in a context featuring the high deductibles of AHPs and STDLI, HSA dollars can be used for affordable Direct Primary Care/direct-care specialty services that are free of third-party interference. (See page 17.)

WE ASK that monies from HSAs, HRAs, MSAs be usable for payment of periodic DPC medical service fees to increase choice and competition and lower health care costs. This will benefit American families, individuals, and employers/employees. (See page 19.)

WE ASK that any potential legislation regarding use of pre-tax HSA dollars for DPC services not restrict the innovation of independent DPC practices or restrict the services brought to their patients, including those with chronic illness and/or pre-existing conditions. (See page 19.)

WE ASK that Medicare and Medicaid patients be able to use monies provided as a voucher to purchase DPC services. Medicare patients should be able to do so and to opt out of traditional Medicare Part A without fear of losing their earned Social Security benefits. (See page 19.)

APPENDIX A

WE ASK…

(continued)

WE ASK that the restoration of small physician practices be encouraged and that, as a first step, the mandates associated with the Electronic Health Record (EHR) and Merit-Based Incentive Payment System (MIPS) be removed for practices having fewer than 50 physicians. (See page 20.)

WE ASK that for physicians whose performance in and adherence to evidence-based medical practices, or participation in a value-based agreement with a health insurance provider warrants the removal of the requirement for prior authorization, the requirement be removed. (See page 21.)

WE ASK that services and medications which require prior authorization be regularly reviewed and that the requirements for therapies that no longer warrant prior authorization be lifted. (See page 21.)

WE ASK that channels of communication be improved between health insurance providers, medical care professionals, and patients to minimize delays in access to care and to ensure clarity on prior authorization requirements, rationale, and changes. (See page 21.)

WE ASK that continuity of care be protected for patients who are on an ongoing, active treatment or a stable treatment regimen when there are changes to coverage, in health insurance providers, or in in requirements for prior authorization. (See page 21.)

WE ASK that the health insurance industry adopt national electronic standards for prior authorization and accelerate and improve transparency of formulary information and coverage restrictions at the point of care. (See page 21.)

WE ASK that the Senate reform our broken malpractice system by passing companion legislation to that bill (H. R. 1215). (See page 22.)

APPENDIX A

WE ASK…

(continued)

WE ASK for the reintroduction and passage of the bipartisan legislation (the "Truth in Healthcare Marketing Act," H.R. 1427) prepared by Representatives Larry Bucshon (R-IN 8th District) and David Scott (D-GA 13th District), to ensure that patients are informed about the level of training their medical care provider has undergone. (See page 29.)

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WE ASK that all health insurance organizations and third-party administrators be required to provide, without charge, to fully insured and self-insured employers all medical and pharmaceutical claims data by line item, accompanied by all information contained within existing and utilized claim forms, twice per year <u>or</u> within days of receiving a written request by those employers. A failure to comply with the Claims Review Law (such as already exists in Texas) should result in a fine of $10,000 per day made payable to the employer requesting its data. (See page 31.)

APPENDIX A

WE ASK…

(continued)

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WE ASK for renewed discussion of H.R. 1156, the "Patient Access to Higher Quality Health Care Act of 2017," which attracted significant bipartisan co-sponsorship, toward the objectives of extending to physicians the freedom to own and operate their own hospitals, and expanding the competitive forces that would drive down the cost of medical treatment. (See page 32.)

WE ASK that hospitals post cash prices, and that all entities in the medical care revenue stream disclose the flow of dollars. The sum of collected revenues and who receives those revenues must become public knowledge. (See page 34.)

WE ASK that the abuse by non-profit hospitals of their tax-exempt status be stopped. These hospitals should either pay taxes, like the rest of America, or calculate their charitable care honestly via Medicare-allowable prices. (See page 34.)

WE ASK that there be Sunshine for All. The following should be made fully transparent—funding that flows from pharmaceutical companies and pharmacy channel companies (such as PBMs and GPOs, which include the nation's three big distributors) to physician advocacy groups, such as professional societies of medical care providers, consumer advocacy organizations, patient-education organizations, providers of continuing education, co-pay assistance organizations, and think tanks. This transparency should be retroactive, so as to establish histories of possible conflicts of interest. (See page 34.)

APPENDIX B

Repeal the Safe Harbor for GPO/PBM Kickbacks: Save Billions, Save Lives

Robert Campbell, M.D.
Marion Mass, M.D.

We urge the repeal of the Group Purchasing Organization (GPO)/ Pharmacy Benefit Manager (PBM) Kickback Safe Harbor {42 CFR § 1001.952}.

The GPO/PBM cartel of middlemen bears a heavy share of the responsibility for spiraling healthcare costs, for the unprecedented spikes in drug prices, and for dangerous, even fatal, shortages of drugs that began to appear in 2006.

The GPO/PBM executives and their enablers grow immeasurably rich.

Meanwhile, the American people face escalating hospital and drug costs.

Americans can no longer afford health insurance or medications.

Seventy percent of the $30 billion insulin market funds the cartel's haul in kickbacks. While Americans can afford their insulin, they can no longer afford insulin kickbacks.

The PBM Rule published by HHS on February 6, 2019 removed kickbacks for PBMs in the Medicare market only.

But so far, the DOJ and FTC have failed to intervene against the cartel for the wider American public. Congress has not yet confronted the powerful businessmen who have turned the healthcare supply chain into a *de facto* criminal enterprise operating under a thin cover of law. The FDA has failed to take regulatory action. Only Congressional action will be permanent, but it **MUST** include the repeal of legitimized kickbacks to GPOs also.

Eliminating kickbacks in the healthcare supply chain will save an estimated $250 billion per year, according to empiric, published analyses.

Congressional repeal of the Safe Harbor for kickbacks to GPOs and PBMs will be the only enduring solution to the calamity of exorbitant prices and the associated, dangerous shortages.

APPENDIX B

Repeal the Safe Harbor for GPO/PBM Kickbacks: Save Billions, Save Lives

(continued)

That repeal can be expected to:

1. Restore a rational drug marketplace in which inexpensive generic medications are once again available to patients.
2. Revive the moribund American generic-drug manufacturing industry, creating tens of thousands of new, high-paying jobs for American workers.
3. Restore integrity in and reintroduce competition to the healthcare supply chain.
4. End dangerous drug shortages that sometimes hurt patients and even kill them.
5. Reinvigorate innovation and quality in the pharmaceutical industry by strengthening incentives.
6. Reduce hospitalization costs by an estimated 35% and drug costs by an estimated 43%, in aggregate.

The anticompetitive healthcare supply chain must be replaced by one that is not encumbered by the market allocation fees and kickbacks needed to secure access to vendors.

The intersection of sound law, sound economics, and a vibrant medicine whose practitioners are free to care is where the next chapter in improving patient safety and extending high-quality health care to all citizens will begin.

BUT THERE IS NO PATH TO HIGH-QUALITY, AFFORDABLE HEALTHCARE WHILE THIS EXECRABLE AND CORRUPT "SAFE HARBOR" FOR GPO/PBM KICKBACKS BARS THE WAY.

THAT SAFE HARBOR MUST BE DESTROYED BY CONGRESSIONAL REPEAL.

See the next page for language we commend to the attention of legislators.

APPENDIX B

Repeal the Safe Harbor for GPO/PBM Kickbacks: Save Billions, Save Lives

(continued)

PROPOSED LANGUAGE

ENSURING COMPETITION IN HEALTHCARE PURCHASING ACT

To amend title XI of the Social Security Act to repeal a safe harbor with respect to vendors in order to ensure full and free competition in the medical device and hospital supply industries.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. ENSURING COMPETITION IN HEALTHCARE PURCHASING ACT.

This Act may be cited as the ‘‘Ensuring Competition in Healthcare Purchasing Act’’.

SECTION 2. ENSURING FULL AND FREE COMPETITION.

(a) IN GENERAL—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—
  (1) by striking subparagraph (C); and
  (2) by redesignating subparagraphs (D) through (J) as subparagraphs (C) through (I), respectively.

(b) CONFORMING AMENDMENT—Section 1860D–31(g)(4)(A) of the Social Security Act (42 U.S.C. 1395w–141(g)(4)(A)) is amended by striking ‘‘section 1128B(b)(3)(G)’’ and inserting ‘‘section 1128B(b)(3)(F)’’.

(c) EFFECTIVE DATE—The amendments made by this section shall take effect one (1) year after the date of enactment of this Act.

APPENDIX C

AUTHORS

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Dr. Marion Mass, graduated from Duke University Medical School, and trained in pediatrics at Northwestern University. She has practiced in suburban Philly for almost 20 years in hospital, outpatient and urgent care settings. She is the co-founder of Practicing Physicians of America and serves on the board of the Bucks County Health Improvement Partnership, and the editorial board of Bucks County Courier Times, Doylestown Intel, she is a Pennsylvania Medical Society delegate.

DAVID BALAT *@DavidBalatHC*

David Balat is currently the Director of the Right on Healthcare initiative with Texas Public Policy Foundation. He has a broad base of experience throughout the healthcare spectrum with special expertise in healthcare finance. He is a former Congressional Candidate in Texas'2nd Congressional District and a seasoned hospital executive with more than 20 years of healthcare industry leadership and executive management experience. Much of his background in leading multifaceted organizations and revitalizing complex facilities in financial distress has given him the reputation as an industry expert. David uses his unique perspective to counsel members of U.S. Congress and the State of Texas House of Representatives as their healthcare advisor. He is a published Op-Ed columnist and an active speaker and commentator on matters of health policy.

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TWILA BRASE, RN *@twilabrase*

Twila Brase is president and co-founder of the Citizens' Council for Health Freedom (CCHF), a national patient-centered organization supporting health care choices, individualized patient care and medical and genetic privacy. She is author of the book Big Brother in the Exam Room: The Dangerous Truth About Electronic Health Records, which was released in July 2018—with nearly 1,000 copies already sold. Modern Healthcarenamed her #75 on their 2009 "100 Most Powerful People in Healthcare" list. Her efforts led to a federal law requiring parental consent for research using newborn DNA, a viral CCHF refusetoenroll.org billboard campaign, a national "Refuse to Sign the HIPAA Form" privacy campaign, successful parent lawsuits against government storage, use, and sharing of "Baby DNA" without consent, and a free-market initiative called The Wedge of Health Freedom, found at JoinTheWedge.com. She received the "Freedom of Informed Choice" award at the 2014 Sacred Fire of Liberty Gala in Maryland, and the 2013 Eagle Forum's Eagle Award for Minnesota.

ROBERT CAMPBELL, MD

Dr. Bob Campbell graduated from the University of Maryland with a degree in Biochemistry in 1984. He attended University of Maryland School of Medicine and completed a residency in Anesthesiology at Penn State University Medical Center in Hershey PA.. He is ABMS certified in both Anesthesiology and Pain Management. Dr. Campbell practices in Lebanon, Pennsylvania. In 2011 he founded Physicians Against Drug Shortages (PADS) which advocates for reform of the healthcare supply chain. PADS currently has bills prepared for introduction in both the House and the Senate bills that will repeal the safe harbor for kickbacks in the healthcare supply chain. In addition to his involvement with Physicians for Reform, Dr. Campbell is Past President of the Pennsylvania Society of Anesthesiologists and is currently Pennsylvania Delegate to the American Society of Anesthesiologists.

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KIMBERLY LEGG CORBA, DO, CHCO

Dr. Corba is a board-certified family physician and the owner of Green Hills Direct Family Care. Dr. Corba attended Muhlenberg College where she earned her B.S. in Biology/Natural Sciences in 1985. In 1993 she graduated from the Philadelphia College of Osteopathic Medicine where she also completed her residency in 1997. In January 2016, Dr. Corba successfully transitioned her thirteen year-old well-established, solo, independent, insurance-based office to DPC. She is an early innovator and national leader in Direct Primary Care. She has been a national speaker and has testified publicly at the state level on behalf of DPC. She has participated in numerous meetings about innovation in health care delivery with state and federal lawmakers and leaders of federal government agencies.

CAREN GALLAHER, MD

Caren E. Gallaher, MD is a retired surgeon in Knoxville, TN. Upon completion of a combined BA/MD degree at University of Missouri-Kansas City, a surgical residency also through UMKC and a liver transplant fellowship at Baylor University in Dallas, Dr. Gallaher joined the academic faculty of BUMC as an assistant professor and ultimately as the Trauma Medical Director for the John Peter Smith Hospital in Ft Worth, TX. Dr. Gallaher is a co-founder of the not for profit group, Physicians for Patients, that works to educate physicians, patients and legislators regarding the significance of medical training and how education influences may alter the level of care available to patients.

C.L. GRAY

Dr. C. L. Gray is a nationally known writer, speaker, and board certified physician who continues to practice hospital medicine and critical care in western North Carolina. Now in its second printing, his book, The Battle for America's Soul,explores the underpinnings of the culture war that savages our great nation. In the book's foreward, Reid Buckley, brother of William F. Buckley, notes Gray's book was one of the most important books written in the past 25 years. In 2006 Dr. Gray founded Physicians for Reform, a non-profit dedicated to preserving patient-centered healthcare.

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Kristin Story Held, M.D. is a board-certified ophthalmologist and ophthalmic surgeon. Following her internship in internal medicine and residency in ophthalmology, Dr. Held joined the faculty at the University of Texas Health Science Center at San Antonio where she taught residents and medical students and served as Director of the County Ophthalmology Clinic. She maintains an academic affiliation as a Clinical Professor in the Department of Ophthalmology. For the past 20 years she has been in private practice in San Antonio. On October 1, 2015 her practice became completely third party free, including opting out of Medicare, and she has developed a direct surgery and patient care model.

NICOLE M. JOHNSON, MD

Dr. Nicole M. Johnson, M.D. is a practicing pediatrician in Cleveland, Ohio. She received her medical degree from Case Western Reserve University School of Medicine and is certified by the American board of Pediatrics and the National Board of Physicians and Surgeons in General Pediatrics and Pediatric Critical Care Medicine. Dr. Johnson is the President and Co-founder of PHYSICIANS FOR PATIENTS, a grassroots organization that champions physician-led care and fights against the unsupervised practice of medicine by non-physicians. She is passionate about lowering the cost of medical care for all Americans, solving the physician shortage, and ending mandatory Maintenance of Certification®.

CRAIG M. WAX, DO *@IP4PI*

Craig M. Wax, DO, is a family physician that practices family medicine and health through prevention. He is a tireless advocate for the patient-physician relationship and free-market health care. Dr. Wax serves on the U. S. congressional subcommittee National Physicians Council for Health Care Policy at NPCHCP.org. He served on Medical Economics journal editorial board and frequently published articles on topics of free market medicine. He is the health talk show host and executive producer for "Your Health Matters," on Rowan Radio 89.7 WGLS – FM RowanRadio.com since 2002. Dr. Wax was honored by the Society of Professional Journalists of Philadelphia with an SPJ award for his ability to make complicated matters simple to understand. He began HealthIsNumberOne.com, a free public information source on health in 1999. Dr. Wax frequently blogs at Independent Physicians for Patient Independence on Facebook and Twitter.