TAXPAYERS PROTECTION ALLIANCE

Healthcare Issue Briefs

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The Taxpayers Protection Alliance (TPA) is a rapid response taxpayer group dedicated to analyzing and researching the consequences of government intervention in the economy. TPA examines public policy proposals through a non-partisan focus, identifying how government waste and overreach impacts taxpayers and consumers regardless of the political party responsible.

TPA holds government officials in the United States, and around the world, accountable through editorials, statements, coalition letters, public interest comments, and radio and television interviews. TPA recognizes the importance of reaching out to concerned citizens through traditional and new media, and utilizes blogs, videos, and social media to connect with taxpayers and government officials.

While TPA regularly publishes exposés and criticisms of politicians of all political stripes, TPA also provides constructive criticism and reform proposals based on market principles and a federalist philosophy. TPA empowers taxpayers and consumers to make their opinions known to their elected and non-elected officials and embraces bold solutions to hold an ever-growing government in check.

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Introduction

The American healthcare sector is a system of stark contradictions. The healthcare system simultaneously drives innovation through the invention of life-saving medications and operations, yet is plagued by bloat and inefficiency due to an onerous government-driven system of overregulation. It is difficult to concisely diagnose the problems plaguing the U.S. healthcare system due to these contradictions, but that has not stopped politicians, policymakers, and pundits from trying. Depending on the news sources (or Twitter feeds) consulted, America either already has socialized medicine or a Darwinian, capitalistic system that profits off of the death and suffering of patients.

In reality, neither characterization is accurate. Drug manufacturers and medical device companies find that America has strong intellectual property incentives and protected profits which foster innovation and allow for the arrival of life-saving new products to market. At the same time, regulations micromanage nearly every aspect of the care and insurance services that Americans enjoy access to. As a result, patients regularly pay for services they may not want or need, and face tax penalties for seeking alternative (and often more cost-effective) medical provider arrangements (e.g. hospice care, concierge medicine). Furthermore, repeated government interventions into the medical sector have resulted in unintended consequences such as the narrowing of insurance networks leading to the rise of “surprise medical bills.”

Despite these clear negative consequences of government meddling in medicine, politicians want to increase federal clout over the healthcare system even more by price-fixing services and having the U.S. move toward a fully socialized system. TPA regularly points out the flaws of these proposals and how “fixing” problems created by big government with even bigger government will simply make the problem worse. TPA also works to keep patients updated as to the latest regulatory developments in healthcare policy. As part of our fight for patient choice and freedom, TPA created the following healthcare policy briefs to provide patients and policymakers with a greater understanding of government policies and proposals pertaining to the medical sector. TPA explains the history and provides descriptions of current policies for five issues areas (Billing, Medicare-for-All, Tax Policy, End-of-Life, Prescriptions) and proposes market-based solutions to improve the quality of healthcare while lowering costs for patients. If members of Congress and agency officials implement these recommendations, patients can continue to enjoy the best aspects of the current system without the high costs presently paid for by consumers and taxpayers.

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Billing

Many Americans rightly fear the prospect of getting a "surprise medical bill" in the mail, days or even weeks after getting discharged from a hospital room. In the usual scenario, patients attend an "in-network" facility, but nevertheless receive an unexpected "surprise" bill from an out-of-network physician that helped to treat them. Typically, the issue is not a lack of insurance. More than 90 percent of Americans have coverage, while virtually all of the remaining 10 percent have chosen not to enroll in insurance programs despite being eligible for Medicaid or subsidized Affordable Care Act (ACA) exchanges.[1] Even if patients have health insurance, however increasingly "narrow" networks as a direct result of the ACA have resulted in a situation where insurance networks fail to cover many doctors who may interact with patients during their stay at the hospital.

Breakdowns in negotiation between doctors and insurers has resulted in some doctors (particularly in medical disciplines such as anesthesiology, and emergency medicine) not having access to insurance reimbursements, prompting physicians to send bills in the mail to patients recently discharged from the hospital. This is not a trivial issue because, according to a 2019 analysis by the Health Care Cost Institute, approximately 1 in 7 in-network hospital admissions result in at least one surprise bill. While emergency room physicians and anesthesiologists were among the top five specialties ranked by likelihood of sending patients a surprise bill (for 12 and 7.9 percent of all in-patient admissions, respectively), independent labs (i.e. for blood work) sent surprise bills for nearly a quarter of in-network admissions.[2]

Providers submitting these surprise medical bills have found that insurers have failed to offer acceptable reimbursements for their services, a problem that has only increased since the 2010 passage of the ACA. The wide-reaching law hoisted expansive requirements onto insurers, forcing them to provide "essential benefits" to beneficiaries ranging from maternity coverage to smoking cessation despite millions of patients not needing these services.[3] As a result, insurer dollars were required to cover far more services than under previous rules. This meant fewer resources left over to attract qualified medical personnel. Additionally, the ACA prompted a historic shift to high-deductible plans, as overall premium costs increased and low-deductible plans were barred by regulators if they didn't meet the stringent conditions set forth by the government.

1 Kaiser Family Foundation. "Health Insurance Coverage of the Total Population." 2018.
2 Fuglesten Biniek, Jean, Bill Johnson, Kevin Kennedy. "Surprise out-of-network medical bills during in-network hospital admissions varied by state and medical specialty, 2016." Health Care Cost Institute. March 28, 2019.
3 National Conference of State Legislatures. "State Insurance Mandates and the ACA Essential Benefits Provisions." April 12, 2018.

In 2016, Xtelligent Healthcare Media reported that out-of-pocket expenses have increased by more than 200 percent over the past decade, and "Providers only expect to collect 50 to 70 percent of a patient's balance after a visit."[4] As patients increasingly opt for high-deductible plans to cope with federal mandates (and insurers afford minimal reimbursement concessions to physicians), doctors have faced unprecedented growing costs due to rising medical services prices and additional government mandates such as those requiring the provision of electronic records.

Medical researchers Steven H. Hinrichs, MD and Patina Zarcone, MPH note that, "One important aspect of the ACA is its mandate for improvements in the way laboratory test results are exchanged and transmitted to electronic health records (EHRs), including a process for 'meaningful use' of laboratory data throughout the medical care continuum."[5] But EHRs can be cost-prohibitive, especially for smaller practices. A 2011 analysis by the Agency for Healthcare Research and Quality concluded that the "real-life" cost of implementing this technology exceeded a staggering $160,000 for a five-physician practice, with annual maintenance costs exceeding $80,000.[6] Hospitals and doctors working at larger practices may see lower per-patient costs for electronic records, but they must still grapple with rising EHR expenses on top of generally rising price levels.

Despite federal mandates causing and contributing to narrow insurance networks, rising costs and the corresponding increase in surprise medical billing, some members of Congress want to increase federal involvement in the healthcare sector even further to address the issue. In May of 2019, Sens. Lamar Alexander (R-Tenn.) and Pat Murray (D-Wash.) released a federal rate-setting proposal mandating that the federal government prohibit the practice of surprise medical billing and implement a system of national central planning and price controls. In these out-of-network cases, physicians would be reimbursed at the median in-network rate of the services rendered. A similar proposal was introduced by Sen. Alexander, Rep. Frank Pallone (D-N.J.) and Rep. Greg Walden (R-Ore.) in December of 2019.

Their approach would force physicians to accept the median in-network rate for surprise bills up to $750. Liabilities above this price point would be subject to negotiation between doctors and insurers. While this $750 benchmark was an improvement from Sens. Alexander and Murray's previous benchmark of $1,250, even the "compromise" proposal would effectively result in federal rate-setting across the country. According to a 2016 analysis by Yale University scholars Zack Cooper, Ph.D., and Fiona Scott Morton, Ph.D., the average unpaid medical balance charged to patients is $622.[7] For the doctor attending to the average patient, currently proposed federal legislation would dictate a large cut in payment for hospital services provided.

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4 Jacqueline LaPointe. "Key Ways to Boost Collection of Patient Financial Responsibility." *RevCycle Intelligence*. August 12, 2016.

5 Hinrichs, Steven H., and Patina Zarcone. "The Affordable Care Act, meaningful use, and their impact on public health laboratories." *Public Health Reports* 128, no. 2_suppl (2013): 7-9.

6 U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. "Study identifies costs of implementing electronic health records in network of physician practices." October 2011.

7 Cooper, Zack, and Fiona Scott Morton. "Out-of-Network Emergency-Physician Bills—An Unwelcome Surprise." *New England Journal of Medicine* 375, no. 20 (2016): 1915-1918.

Setting artificially-low rates for physician care leads to fewer options for patients across the country, with particularly large, negative effects concentrated in rural areas. Federal policymakers have a particularly poor track-record in ensuring "correct" payment levels even when reimbursement rates are subject to regulatory guidance. For example, the Department of Health and Human Services (HHS) uses a "wage index" to reimburse providers for services rendered to Medicare-insured payments. This index is supposed to adequately account for different economic and salary conditions across the country, ideally resulting in proportionally lower reimbursement rates provided to doctors in rural areas with a lower cost-of-living.

But the Institute of Medicine (affiliated with the National Academies of Science) notes that current policies "do not produce an index that reflects the prevailing wages that hospitals face in their respective markets" resulting in a lack of funding for rural practices.[8] Due in part to lackluster federal funding relative to urban and suburban areas, more than 100 rural hospitals have closed since 2010.[9] According to a 2019 poll of more than 1,405 adults commissioned by the Robert Wood Johnson Foundation, National Public Radio, and the Harvard T.H. Chan School of Public Health, one-quarter of Americans living in rural areas cited significant difficulties in obtaining access to healthcare.[10] Due to a lack of resources in these areas, medical facilities are often hard to come by and spread far apart. Further price regulation by the federal government would likely exacerbate these issues, triggering more rural facility closures and significantly compromising access for Americans living in sparsely-populated areas.

The California Approach

California provides a real-world example of the negative consequences of adopting rate-setting as a "solution" to the surprise billing issue. In 2017, the state implemented legislation mandating that, for out-of-network billing, physicians accept either the average in-network rate for medical services rendered or 125 percent of the Medicare rate.[11]

According to a 2019 analysis of the legislation's effects published in the *American Journal of Managed Care*, physicians cited consolidation and decreased leverage as a direct consequence of the surprise billing law.[12] Study author Dr. Erin Duffy found that California's approach, "appears to be reducing physicians' leverage to negotiate higher in-network payments, and in turn is speeding the consolidation of physician groups as they seek to regain lost leverage."[13] These concerns appear to be well-founded, as patient complaints about access to care have significantly increased since the law's enactment.

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8 The National Academies of Science, Engineering, and Medicine. *Geographic Adjustment in Medicare Payment: Phase I: Improving Accuracy*. 2012.
9 Kirk Siegler. "The Struggle To Hire And Keep Doctors In Rural Areas Means Patients Go Without Care." *National Public Radio*. May 21, 2019.
10 National Public Radio, Robert Wood Johnson Foundation, Harvard T.H. Chan School of Public Health. "Life in Rural America Part II." May 2019.
11 Health Access, California Labor Federation. "AB72: Stopping Surprise Bills." July 22, 2019.
12 Duffy, Erin L. "Influence of out-of-network payment standards on insurer-provider bargaining: California's experience." *The American Journal of Managed Care* 25, no. 8 (2019): 243-246.
13 Ibid.

According to data from the California Department of Managed Health Care, consumer care access complaints increased from 415 in 2016 to 614 in 2018, a spike of nearly 50 percent.[14] While it is difficult to identify the exact cause of complaints due to the generality of the data, physician practice consolidations tend to increase patient dissatisfaction without improving the quality or efficiency of care.

Fortunately, there is an alternative approach to resolving surprise medical billing issues which protects patients without mandating artificially-low rates for doctors.

The New York and Florida Approach

In response to some of the highest out-of-network billing rates in the country, New York State and Florida adopted arbitration-based systems to address surprise medical billing in 2015 and 2016 respectively.[15] [16] In both states, patients are not held responsible for out-of-network bills; the patient need only pay the median in-network rate for the services they benefited from. The remaining expenses are subject to a negotiation process between attending doctors and the patient's insurers and arbitrated by a third-party entity via an online portal.

In these cases, independent unbiased arbiters determine proper physician compensation based on the circumstances of the case, doctor experience, typical rates paid for services rendered, and the physician's previous billing practices. The dispute resolution staff typically consists of doctors with relevant experience in the field and awareness of local medical market conditions, rendering their judgments more reasonable than state or federal agency staff who are typically many years – and thousands of miles – removed from private medical practice (if they are even a doctor in the first place). [17]

In both states, this process has provided satisfactory outcomes for both doctors and insurers as decisions have regularly benefited both sides and "split decisions" – where neither the insurer nor the physician achieves their preferred outcome – occur in approximately one-third of arbitration decisions. According to 2017 and 2018 data from the New York Department of Financial Services, health insurers won a modest majority (59 percent) of cases, allaying concerns by insurers and trade organizations that an arbitration system would systematically favor physicians.[18] Patients benefit the most from arbitration; out-of-network billing rates have declined 34 percent post-enactment of legislation.[19] Data on arbitration is far more limited in Florida, but annual statistics on the medical sector suggest significant benefits statewide. In 2017 (the first full year of the law's enactment), the num-

14 California Department of Managed Health Care. "DMHC Protects Consumers' Health Care Rights (Dashboard)." Accessed January 20, 2020.
15 NY Health Access. "2015 NYS Law Gives Protection from Surprise Bills and Emergency Services."
16 Julio Ochoa. "Florida's Surprise Bill Law Could Be Template For Federal Legislation." *WUSF News.* August 19, 2019.
17 Medical Society of the State of New York. "New Out of Network Emergency/Surprise Bill Rules Go into Effect March 31." 2015.
18 New York State Department of Financial Services. "Report on the Independent Dispute Resolution Process." September 2019.
19 Cooper, Zack, Fiona Scott Morton, and Nathan Shekita. "Surprise! Out-of-network billing for emergency care in the United States." National Bureau of Economic Research. No. w23623. 2017.

ber of practicing physicians in Florida jumped 12 percent, a significant increase compared to previous years.[20] Greater available medical resources have led to doctors' and hospitals' increased ability to provide care for low-income residents. The percentage of Florida doctors accepting Medicaid patients jumped from 62.7 percent in 2016 to 76.3 percent in 2019, according to Florida Department of Health data.[21]

Members of Congress have cited the success of Florida and New York State's approach in advocating for a nationwide arbitration model to curb surprise medical billing. In May 2019, Sens. Bill Cassidy (R-La.) and Michael Bennet (D-Colo.) introduced a pro-arbitration proposal at the federal level which would allow doctors and insurers to negotiate payment disputes via third-party examiners.[22] The following month, Reps. Phil Roe, M.D. (R-Tenn.) and Raul Ruiz, M.D. (D-Calif.) unveiled similar legislation in the House of Representatives.[23] As the proposal's wording is similar to legislation enacted in New York State and Florida, similar benefits would almost certainly result from the legislation's passage.

Recommendations

Oppose any attempts to introduce rate-setting

Proposals to "fix" healthcare prices would lead to the widespread consolidation of doctor's offices across the country, compromising care for millions of patients. Lawmakers must resist any attempt to increase federal interference in the American healthcare system.

Support a nationwide arbitration system

Wherever tried, arbitration has allowed doctors and insurers to successfully negotiate billing claims while absolving patients of unwanted medical liabilities. Members of Congress should support the creation of a market-based negotiation process, while ensuring that arbitration proposals remain free of overregulation and rampant rulemaking.

Increase competition and choice in the healthcare sector

While lawmakers debate various "solutions" to the issue of surprise medical billing, they must remain mindful of the underlying reasons for out-of-network billing. Insurance networks remain "narrow" due to failed federal interventions in healthcare such as the ACA. Until this regulatory overreach is repealed, patients will continue to see unintended consequences such as surprise bills.

20 Florida Department of Health. "2019 Physician Workforce Annual Report." November 2019.
21 Ibid.
22 Webpage of Bill Cassidy, M.D., U.S. Senator for Louisiana. "Bipartisan Senate Working Group Introduces Surprise Medical Billing Legislation." May 16, 2019.
23 Webpage of U.S. Representative Phil Roe, M.D., 1st District of Tennessee. "Reps. Roe and Ruiz Introduce the Bipartisan Protecting People from Surprise Medical Bills Act." June 26, 2019.

Government-Run Healthcare

Since the start of the 2020 Democratic presidential nomination process, candidates have released and debated various proposals to replace the current American healthcare system with a one-size-fits-all socialized "Medicare for All" system. Various iterations of these proposals have been adopted into legislative proposals in the Democratic-controlled House of Representatives, though the current likelihood of passage and enactment remains low in the Trump administration. While each of these plans share a common belief that the federal government can manage and set healthcare prices for hundreds of millions of Americans, the proposals differ significantly on coverage and funding details. **Table 1** compares current, popular proposals for "Medicare for All" in the U.S.

Table 1. *Major Proposals for Government-Sponsored Medical Care in the U.S.*[24] [25] [26]

	"Traditional Single-Payer" (Sen. Bernie Sanders)	**"Single-Payer with Public Option"** (Sen. Elizabeth Warren)	**"Obamacare Plus"** (former VP Joe Biden)
Description/Coverage	Abolishes private insurance, replaces with federal compulsory plan to cover primary, specialist care, prescriptions, home-based care, vision, dental, etc. No copays except for drugs (up to $200 in prescription copays per year).	Same as traditional single-payer (wholly taxpayer-financed) system, but with transitional "public option" system existing alongside current insurance system for first 2-3 years which would cover children, adults within 200% of Federal Poverty Line.	Keeps basic, existing Obamacare structure in place, but supplements with new Medicare buy-in open to all (likely would cover primary, specialist care, partial prescription coverage). Increases ACA exchange subsidies, lifts subsidy eligibility cap.
Implementation	Four-year transition by increasing Medicare coverage and successively lowering eligibility age.	Automatic enrollment of eligible individuals to "public option" immediately, ratcheting down Medicare age to fifty, followed by eventual, complete "Medicare for All" within a few years.	Immediate, "could" eventually lead to true single-payer system along lines of "Medicare for All."

24 Sarah Kliff. "Bernie Sanders's Medicare-for-all plan, explained." *Vox*. April 10, 2019.
25 Dylan Scott. "Elizabeth Warren's new Medicare-for-all plan starts out with a public option." *Vox*. November 15, 2019.
26 Matthew Yglesias. "Joe Biden's health care plan, explained." *Vox*. July 16, 2019.

	"Traditional Single-Payer" (Sen. Bernie Sanders)	**"Single-Payer with Public Option"** (Sen. Elizabeth Warren)	**"Obamacare Plus"** (former VP Joe Biden)
Financing	7.5 percent payroll tax paid by employers, 4 percent tax paid by households.	Companies would pay 98 percent of current, private insurance premiums to a government contribution fund. Payments would be adjusted up or down to reflect national averages.	Trump tax cuts would be reversed, capital gains taxes would be doubled.
Cost	**$32.6 trillion** over ten years.[27]	**$52 trillion** over ten years.[28]	**$750 billion** over ten years (likely conservative estimate).[29]

Despite different coverage guidelines and funding mechanisms, virtually all of the proposals by the current Democratic presidential field would likely cost taxpayers more than $1 trillion, or roughly $8,000 per household over the next decade. Former Vice President Biden's plan is the least expensive option presented, but only because it retains private insurance plans for consumers alongside a "public option." Plans that involve a single-payer (completely taxpayer-financed) system have costs running into the tens of trillions of dollars per decade. These "headline" costs are likely a small fraction of overall economic costs as reimbursement rates for physicians decrease and healthcare becomes correspondingly difficult to find.

Presidential candidates such as Sen. Sanders advocate for a significant reduction in physician reimbursement rates as the Medicare system is offered to a steadily-increasing share of the U.S. population. According to a 2019 analysis by RAND Corporation scholars Chapin White and Christopher Whaley, average reimbursement rates from private insurers are significantly higher than from the Medicare program (which currently covers America's senior population). They find, "Relative prices, including all hospitals and states in the analysis, rose from 236 percent of Medicare prices in 2015 to 241 percent of Medicare prices in 2017."[30]

Given that government payments to providers are significantly lower than private payments, physicians and hospitals rely on recouping this lost revenue through cross-subsidization and charging private patients even more than they would otherwise (e.g. cost-shifting). But if single-payer/ "Medicare for All" policies result in the outlawing of private insurance, providers will cease to have privately insured patients and face significant, unavoidable – and unaffordable – decreases in revenue. According to 2019 analysis published in *The Journal of the American Medical Association*, America's approximately 7,200 hospitals would shoulder losses amounting to a staggering $150 billion every single year.[31]

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27 Charles Blahous. "The Costs of a National Single-Payer Healthcare System." Mercatus Working Paper, Mercatus Working Paper. July 2018.
28 Jacob Pramuk. "Elizabeth Warren says she would not raise middle-class taxes for $52 trillion health-care plan." *CNBC*. November 1, 2019.
29 Dan Diamond. "Biden unveils health care plan: Affordable Care Act 2.0." *Politico*. July 15, 2019.
30 White, Chapin, and Christopher Whaley. "Prices Paid to Hospitals by Private Health Plans Are High Relative to Medicare and Vary Widely." RAND Corporation. 2019.
31 Schulman, Kevin A., and Arnold Milstein. "The implications of 'Medicare for All' for US hospitals." *JAMA* 321, no. 17 (2019): 1661-1662.

This revenue contraction would disproportionately harm rural hospitals, which already account for a disproportionate share of all hospital closures.[32] The sudden closure of medical facilities has significant, negative economic implications, resulting in large decreases in community welfare and diminished revenue for governments at all levels. When a hospital closes, the unemployment rate in the surrounding community increases by 1.6 percentage points and per-capita income contracts by 4 percent on average.[33] The closure of hospitals also results in reduced access for patients, triggering an array of adverse medical outcomes such as a greater likelihood of dangerous preterm births.[34] These consequences would inevitably put strain on communities already struggling economically, and lead to greater taxpayer resources being expended on unemployment claims, emergency services, and counseling centers in addition to the inevitable costs to human health.

Other versions of government-provided healthcare (envisioned along the lines of the National Health Service in the United Kingdom) would have federal agencies directly take charge of the management of healthcare operations. The U.S. government already administers healthcare to certain populations such as Native Americans and veterans of the Armed Forces. These attempts, however, have often ended tragically with inadequate services and systemic inefficiencies. The Indian Health Service (IHS) operates in Native American reservations across 36 states and manages medical facilities while directly employing physicians. IHS is responsible for the care of more than 2 million patients, but these tribal members face significant difficulties in obtaining the care they need. Inspectors regularly find severe deficiencies in the level and quality of care at IHS institutions, including babies being born in bathrooms and 90-minute wait times for heart-attack patients.[35]

Systematic problems compromise the quality of care, including, "emergency room nurses who do not know how to administer such basic drugs as dopamine; employees who did not know how to call a Code Blue; an emergency room where defibrillators could not be found or utilized when a human life was at stake…"[36] These problems are exacerbated by a lack of skilled, qualified personnel, as the systemwide vacancy rate for physicians, nurses, and other healthcare professionals is around 25 percent.[37] This is not simply a matter of under-compensation, though lawmakers face a difficult task in securing appropriate funding levels from successive Congresses that fail to prioritize Native American healthcare needs.

Agency staff attempting to recruit qualified personnel must go through a lengthy HHS approval process, resulting in potential applicants accepting other offers elsewhere. In 2018, the Government Accountability Office (GAO) noted, "While IHS may seek approval from HHS to exceed the maximum salary of certain pay tables, IHS officials said the approval process can be lengthy, which has resulted in the loss of promising candidates—including emergency medicine, general surgery, radiology, and anesthesiologist providers."[38]

32 Samantha Scotti. "Tackling Rural Hospital Closures." National Conference of State Legislatures. June 2017.
33 Austin Frakt. "A Sense of Alarm as Rural Hospitals Keep Closing." *The New York Times*. October 29, 2018.
34 Ibid.
35 Andrew Siddons. "The Never-Ending Crisis at the Indian Health Service." *Roll Call*. March 5, 2018.
36 Maggie Fox. "Care at Native American Health Facilities Called 'Horrifying and Unacceptable' in Senate Hearing." *NBC News*. February 3, 2016.
37 U.S. Government Accountability Office. "Indian Health Service: Agency Faces Ongoing Challenges Filling Provider Vacancies." GAO-18-580. August 2018.
38 Ibid.

Conditions are similarly desperate at the U.S. Department of Veterans Affairs (VA) which attends to approximately 6 million patients and employs more than 11,000 physicians.[39] A 2014 report by the Inspector General (IG) of the Veterans Health Administration (a component of the VA) found that (as of September 2014) more than 300,000 veterans who applied for access to care had died before their applications were processed. Furthermore, "employees incorrectly marked unprocessed applications as completed and possibly deleted 10,000 or more transactions from the Workload Reporting and Productivity (WRAP) tool over the past 5 years."[40]

Examinations of regional VA operations find widespread lapses of care and diagnosis standards, resulting in unnecessary issues for patients. A 2019 review by the Veterans Health Care System of the Ozarks of 33,902 of their own pathology results from 2005 to 2017 found 3,029 errors, resulting in an error rate of 8.9 percent (significantly higher than the national pathology average error rate of .7 percent).[41] Taxpayers regularly pay for the VA's compromised care standards, and cost control remains a significant issue. The VA budget has increased approximately four-fold over the past twenty years, from $47 billion in FY 2000 to $217 billion in FY 2020.[42] Over this time period, inflation-adjusted spending per veteran patient climbed from $17,900 to $36,200, an increase of more than 100 percent.[43] These spending increases have not resulted in better quality-of-care, however, and the VA continues to fail patients and punish whistleblowers who identify deficiencies in the system. An IG report released in October 2019 found that the VA has "floundered in its mission to protect whistleblowers" and failed "to consistently conduct investigations that were procedurally sound, accurate, thorough, and unbiased."[44] The issue at the VA isn't a lack of money, it's a lack of leadership, proper care incentives, and management expertise.

Government-run healthcare systems such as the IHS and the VA fail to adequately provide care to patients and are unresponsive to calls for improvement. In addition, current proposals to retain private physicians and reimburse them through a single-payer system are cost-prohibitive and would likely lead to widespread closures of medical facilities across the country. Leading presidential candidates and members of Congress fail to consider alternative approaches that would use market forces to lower costs and increase the quality of care for patients.

39 U.S. Government Accountability Office. "Veterans Health Administration: Better Data and Evaluation Could Help Improve Physician Staffing, Recruitment, and Retention Strategies." GAO-18-124. October 2017.
40 Patricia Kime. "Report: VA lost 10,000 applications for health care." *USA Today*. September 2, 2015.
41 Doug Thompson. "VA finishes lab-test review, finds 30 serious errors." *Arkansas Democrat Gazette*. June 2, 2019.
42 Statista. "Outlays of the U.S. Department of Veterans Affairs in fiscal years 2000 to 2024." Accessed January 20, 2020.
43 Based on data from: Erin Bagalman. "The Number of Veterans That Use VA Health Care Services: A Fact Sheet." U.S. Congressional Research Service. June 3, 2014.
44 U.S. Department of Veterans Affairs, Office of the Inspector General. "Failures Implementing Aspects of the VA Accountability and Whistleblower Protection Act of 2017." Report #18-04968-249. October 24, 2019.

Market-Based Approaches

Current problems with healthcare costs and quality of care are almost certainly due to excessive federal involvement in the healthcare sector, not too little federal involvement as is often supposed by single-payer advocates. The U.S. healthcare market is the most-heavily regulated sector of the American economy and widespread interference by federal and state agencies leads to the dictation of care – even when such "standards" don't accord with what patients want or need. Repealing these standards would lead to a better-functioning healthcare market and give patients increased choices as to which providers they can see and which services they have access to. Members of Congress could kickstart the reform process by repealing "essential benefits" dictated by the ACA. Current federal law requires that individual insurance plans cover – and patients pay for – services including smoking cessation and maternity care, even if plan-holders do not require them and fail to benefit from these provisions.[45]

Additionally, Congress continues to overpay for state-level healthcare services, even when the services are compromised by state laws that decrease competition and artificially inflate costs. For example, certificate-of-need (CON) laws require medical facilities to obtain permissions from bureaucrats to increase offerings and make capital investments such as adding new hospital wings. In a 2018 report, HHS found that CON laws, "suppress supply, misallocate resources, and shield incumbent healthcare providers from competition from new entrants. In addition, incumbent firms may use CON laws to thwart or delay entry or expansion by new or existing competitors… in 2006, a hospital in Charleston, West Virginia, used the threat of objection during the CON process to keep a potentially competitive hospital from expanding."[46] Tying federal healthcare funding to state-level healthcare reforms would be a welcome step toward increasing competition and lowering medical costs for patients.

45 *Managed Healthcare Executive*. "Essential Benefits drive premiums up 47%." May 1, 2013.
46 U.S. Department of Health and Human Services. "Reforming America's Healthcare System Through Choice and Competition." 2018.

Recommendations

Allow for increased insurance plan flexibility

Congress should allow patients to purchase medical plans that are right for them, even when benefits may not be deemed "acceptable" by federal agency officials. The elimination of "essential benefits" would legalize low-cost plans that exclude unnecessary benefits such as smoking cessation.

Condition federal healthcare funding to states on state-level reforms

The federal government spends nearly $400 billion annually to subsidize state-level government insurance plans through Medicaid. But these disbursements are likely far higher than necessary, due to cost-inflating CON provisions. Congress should use its funding leverage to incentivize states to reform these restrictions.

Allow patients an alternative to government-managed care

Patients receiving care from the IHS or VA face long waiting-lists and a lack of access to qualified personnel. Congress could give these enrollees more options by offering vouchers that could be applied to private facilities and healthcare plans. The VA currently has a "Veterans Choice Option" that allows for private choices, but eligibility remains limited and depends on arbitrary criteria such as current driving distance to a VA facility. Bolder reforms would give all VA patients the choice of private care.

Healthcare and the Tax Code

Despite significant progress in reforming the tax code via The Tax Cuts and Jobs Act (signed into law by President Trump on December 22, 2017), federal tax law remains complex with excessive compliance costs. *Claims Journal* contributor Gary Wickert notes that, "The federal tax rules and resources within the CCH Standard Federal Tax Reporter exceed 75,000 pages, enough to fill a small library."[47] According to the National Taxpayers Union's analysis of Office of Information and Regulatory Affairs data, Americans spent more than 8 billion hours complying with tax law in 2018. They estimate an annual compliance burden of more than $360 billion, a yearly total of nearly $3,000 per family.[48]

A significant component of the federal (and state) tax code addresses the healthcare sector, rewarding and penalizing consumers for their coverage and purchasing decisions. The tax code provision with the single largest impact on the healthcare sector is the tax exclusion for employer-provided coverage, which came out of a WWII wartime measure designed to aid employers in recruiting new employees after the imposition of wage ceilings.[49] Yet, even after the end of the war, these tax policies remained law and the healthcare premiums paid by businesses on behalf of their employees continued to be exempt from federal taxation. In addition, federal tax law instructs employers to exclude health insurance premiums from employees' wages for payroll tax calculations.

These tax exclusions lower federal tax collections by approximately $300 billion per year. But, maintaining the employer tax exclusion while taxing other forms of health benefits creates wider-reaching consequences for taxpayers and consumers.[50] Since employer-provided health plans are tax-preferred by the federal government, relatively few medical expenses are paid for out-of-pocket by patients. Insurance plans have increased in generosity, offering coverage for routine and expected services such as annual physicals as employers use increased benefits to attract talented personnel.

"Health insurance" no longer conforms to the traditional definition of insurance as a backstop against a catastrophic expense that could not be foreseen (i.e. a heart attack or fall down the stairs). As a result, the continued tax preference toward employer-provided care reduces incentives for patients to shop around and find the healthcare services best suited for them. According to a 2019 survey by the Kaiser Family Foundation, 90 percent of work-

47 Gary L. Wickert. "Subrogation Settlements and the IRS." *Claims Journal*. January 10, 2020.
48 Demian Brady. "Tax Reform Bill Made Modest Progress Toward Simplification, But Significant Hurdles Remain." National Taxpayers Union Foundation. April 15, 2019
49 Stephen Mihm. "Employer-based health care was a wartime accident." *Chicago Tribune*. February 24, 2017.
50 Tax Policy Center. "Briefing Book: Key Elements of the U.S. Tax System." Accessed January 20, 2020.

ers were employed by firms that offer health insurance benefits.[51]

Roughly 60 percent of insured Americans are covered by their employer, a figure that rises to 82 percent excluding government insurance beneficiaries (i.e. Medicare, Medicaid, VA, IHS).[52] The predominance of employer-provided care offering a wide array of benefits explains America's low out-of-pocket health care spending percentage of 11 percent, even lower than countries with "universal" taxpayer-funded insurance such as Canada and Germany (14.6 and 12.4 percent respectively).[53]

The resulting lack of "skin in the game" for consumers, however, leads to the overutilization of healthcare resources resulting in sustained, significant increases in medical prices over time. While the prices of all goods across the U.S. economy have averaged 2.2 percent growth over the past twenty years, healthcare prices increased at an average rate of 3.5 percent over the same time-period.[54] These trends have persisted over the past several decades, leading to excess cost growth even as patients report a high degree of satisfaction overall with the U.S. healthcare system. Americans spent approximately 5 percent of Gross Domestic Product on medical services in 1960, a figure that increased to nearly 18 percent in 2019.[55]

Bridging the Tax Preference for Employer Care

Despite the large preference for employer-provided care, an increasing chorus of lawmakers and economists in the 1980s and 1990s called for policies to help individuals purchase medical care tax-free. The result was the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 which created tax-free Health Savings Accounts (HSAs).[56] Individuals could use these tax-free dollars on eligible expenses such as prescription medications, physical therapy, psychological counseling, and hearing aids. But HSAs are subject to strict annual contribution limits ($3,550 for individuals and $7,100 for families in 2020).[57] In addition, accounts must be paired with a high-deductible health plan defined by the Internal Revenue Service (IRS) as an insurance plan with an annual deductible of at least $1,400 for an individual and $2,800 for a family (2020 figures).[58]

This pairing is designed to allow consumers exposure to prices for routine medical expenses and allow for competition and "shopping around," while reserving the use of health insurance for significant, unpredictable medical events. This exposure to competition and market forces has led to controlled costs for healthcare services used by more than 25 million Americans who own HSAs. Employee Benefit Research Institute scholar Paul Fronstin, Ph.D. and RxEconomics analyst M. Christopher Roebuck, Ph.D find in a 2019 analysis that,

51 Kaiser Family Foundation. "2019 Employer Health Benefits Survey." September 25, 2019
52 Ibid.
53 The World Bank. "Out-of-pocket expenditure (% of current health expenditure)." Accessed January 20, 2020.
54 Peter G. Peterson Foundation. "Why are Americans Paying More for Healthcare?" March 15, 2019.
55 The Commonwealth Fund. "National Health Expenditures as a Percentage of Gross Domestic Product, 1960–2020." Accessed January 20, 2020.
56 Feldman, Roger, Stephen T. Parente, Jean Abraham, Jon B. Christianson, and Ruth Taylor. "Health savings accounts: early estimates of national take-up." *Health Affairs* 24, no. 6 (2005): 1582-1591.
57 SHRM. "2020 HSA Limits Rise Modestly, IRS Says." May 28, 2019.
58 Ibid.

although "higher HSA balances resulted in increased use of health care services and higher spending…magnitudes were quite small."[59]

Even as average balances in HSAs more than doubled over the course of the period studied (2014 to 2016), account holders realized that they could keep any unspent funds since HSA balances roll over from year to year and resources can be used for non-medical purposes upon retirement. Tax-free individual savings accounts offer incentives for cost-control whereas individual plans encourage beneficiaries to use more medical services than they otherwise would.

Although most employer-provided plans require co-pays that result in some cost exposure for patients, the majority of expenses are paid by employees and employers in monthly premiums which stay the same (within each year) regardless of utilization. Moreover, employer-provided plans will likely remain the dominant form of health insurance provision absent reforms expanding HSA eligibility and coverage. Currently, these tax-free accounts face arbitrary restrictions as to which products and services are "qualified," and current restrictions seem to correspond little to medical/health efficacy. **Table 2** illustrates the limits of current HSA eligibility.

Table 2. *HSA Eligibility by Product/Service Category*[60]

	HSA Dollars Can be Used for….	But Not For….
Smoking Cessation	Nicotine patches, gum, nasal sprays, prescription medications, as part of a stop-smoking program	Electronic-cigarettes, heat-not-burn products
Dietary Supplements	Prenatal vitamins, calcium supplements	Daily multivitamins, fiber supplement (unless for specific illness)
Medical Service Fees	Co-pays for doctor's office visits, eye examinations	Membership fees for concierge medicine, high-deductible insurance plan premiums

Most smoking cessation products are eligible HSA purchases (with a prescription or as part of a stop-smoking program) with the notable exception of e-cigarettes. But this exclusion makes little sense because, according to a 2019 analysis published in the *New England Journal of Medicine*, vaping products are nearly doubly as effective as conventional nicotine replacement therapies for quitting smoking.[61] For dietary supplements, current law only accepts products as eligible if they confer a medical benefit for a specific condition such as a vitamin deficiency or a specific occurrence such as pregnancy. These legal stipulations are

59 Fronstin, Paul, Ph. D, M. Christopher Roebuck, Ph.D. "Do Accumulating HSA Balances Affect Use of Health Care Services and Spending?" *Employee Benefit Research Institute*. No. 482. May 23, 2019.
60 Source: Connect Your Care. "HSA, Health FSA, and HRA Eligible Expenses." Accessed January 20, 2020.
61 Hajek, Peter, Anna Phillips-Waller, Dunja Przulj, Francesca Pesola, Katie Myers Smith, Natalie Bisal, Jinshuo Li et al. "A randomized trial of e-cigarettes versus nicotine-replacement therapy." *New England Journal of Medicine* 380, no. 7 (2019): 629-637.

inconsistent with medical literature, which finds benefits for taking routine vitamins and various supplements. One of the few large-scale, randomized trials on the efficacy of multivitamins, conducted from 1997 to 2011 by Brigham and Women's Hospital and Harvard Medical School researchers, found that routine recipients were 8 percent less likely to develop various cancers than non-infrequent takers.[62]

HSA eligibility is subject to even more limitations for patients making an appointment with a medical provider. Co-pays for seeing a primary care doctor or specialist are typically covered, but alternative arrangements with physicians are heavily discouraged by the tax code. For example, many doctors have formed "concierge medicine" practices, where patients can enjoy more intensive access to their physicians for a membership fee. Providers in these practices typically see fewer patients than doctors in ordinary practices, allowing for more regular access for individuals with pressing medical issues. Despite the benefits of this approach centered on patient access, the IRS forces patients to pay for these services with their after-tax income.[63]

Additionally, HSA holders are barred from using their balances to pay for the high-deductible insurance plans that are a precondition for having an HSA in the first place.[64] This discourages young adults from opening tax-free accounts as this age group typically has fewer miscellaneous healthcare expenses in addition to their high-deductible plans. For existing account holders, this limitation makes contributions more difficult by disallowing the most predictable aspects of healthcare spending (e.g. monthly insurance premiums). Pro-patient reforms would increase the purchasing power of HSAs and allow consumers more choices as to how to use their pre-tax dollars.

62 Gaziano, J. Michael, Howard D. Sesso, William G. Christen, Vadim Bubes, Joanne P. Smith, Jean MacFadyen, Miriam Schvartz, JoAnn E. Manson, Robert J. Glynn, and Julie E. Buring. "Multivitamins in the prevention of cancer in men: the Physicians' Health Study II randomized controlled trial." *JAMA* 308, no. 18 (2012): 1871-1880.
63 Joe Lasher. "How to Use Your HSA or FSA for Concierge Medicine." Partner MD. October 15, 2019.
64 Ryan Kennelly. "What are Qualified Medical Expenses I Can Pay for With My HSA Account?" Independent Health Agents. January 17, 2020.

Recommendations

Level the Tax Playing Field by Increasing HSA Contribution Limits

Despite the creation of HSAs, strict limits on annual contributions make it difficult for many individuals to rely on account savings for their medical care. These limitations, coupled with the unlimited tax benefits of employer-provided care, prevent a level tax playing field and discourage patients shopping around to find the right care for them. To remedy this, annual contribution limits should at least be doubled to $7,100 for individuals and $14,200 for families.

Increase the Breadth of HSA-Eligible Goods and Services

HSA account holders are limited by arbitrary restrictions on medical goods and services they can purchase with pre-tax dollars, resulting in access and affordability issues. Members of Congress should reexamine HSA eligibility guidelines and consider the benefits of products such as e-cigarettes and services such as "concierge medicine." Additionally, lawmakers should allow patients to use their HSAs to pay for high-deductible insurance plan premiums.

Resist Attempts to Use Tax Policy to Influence Healthcare Decisions

Economists and healthcare scholars often remark that the WWII-era tax exclusion for employer-provided care was the "original sin" of the U.S. healthcare system, setting the healthcare sector on a course toward higher prices and decreased choice. This history lesson should be informative for lawmakers intent on influencing patient decisions through the already-complex tax code. Congress and the Trump administration have already taken important steps to ease the burden of tax policy on healthcare by repealing the individual mandate and eliminating the "Cadillac tax" on high-end insurance plans. Further vigilance is needed to keep harmful proposals in check.

Hospice Care

End-of-life care is one of the most costly aspects of the American healthcare system, accounting for roughly one-quarter of all Medicare spending.[65] Individuals with multiple chronic illnesses spend around $60,000 on medical services per year, an expense paid for primarily by taxpayers since America's elderly population receives government-provided insurance.[66] Countries with greater government control over healthcare management and spending sometimes respond to this disproportionate utilization of care by rationing services and denying ailing patients necessary care and treatments.

A 2018 report by Cancer Research U.K. found that older British patients were less likely to have tumor-removing surgeries than non-seniors, even after adjusting for co-morbidities that might impact their ability to undergo surgery.[67] In the United Kingdom, elderly patients with poor vision must wait six months to have their cataracts removed.[68] In nations such as Germany, state-backed insurers are "exporting" the elderly to other, low-cost nations for treatment and housing.[69]

The U.S. incurs larger medical costs than these nations in large part due to prompt delivery of healthcare to seniors in their last few years of life. As America's senior population approaches one-fifth of the general population, reliance on end-of-life services, nursing homes, and home healthcare will increase with corresponding burdens on the U.S taxpayer. Providers and families must also address the growing number of patients who are terminally ill and will not benefit from full-course treatment. For these ailing Americans, hospices can provide comfort and service without unnecessary procedures.

One hospice professional described the benefits of palliative care to a team of VA researchers: "When you're able to say you're still able to do palliative treatments, you know, we're not going to cure but we're going to help … it's like you're not … not just slamming the door and saying, 'We're giving up on you.' It's saying, as far as aggressive treatment, there's nothing else we can do but we do realize the pain level, (and) we're going to shrink this tumor. … And as long as the quality of life is there I think that it (concurrent care) should be done."[70] The transition from conventional care to palliative care can be eased with the assurance

65 Riley, Gerald F., and James D. Lubitz. "Long-term trends in Medicare payments in the last year of life." *Health Services Research* 45, no. 2 (2010): 565-576.
66 Ashish K. Jha, MD, MPH. "JAMA Forum: End-of-Life Care, Not End-of-Life Spending." *News@JAMA*. July 13, 2018.
67 Cancer Research U.K. "Advancing Care, Advancing Years: Improving Cancer Treatment and Care for an Ageing Population." June 2018.
68 Campbell, Denis, Pamela Duncan. "Long delays to NHS cataract operations leave elderly at risk." *The Guardian*. July 20, 2019.
69 Kate Connolly. "Germany 'exporting' old and sick to foreign care homes." *The Guardian*. December 26, 2012.
70 Haverhals, Leah M., Chelsea E. Manheim, Vincent Mor, Mary Ersek, Bruce Kinosian, Karl A. Lorenz, Katherine E. Faricy-Anderson, Risha A. Gidwani-Marszowski, and Cari Levy. "The experience of providing hospice care concurrent with cancer treatment in the VA." *Supportive Care in Cancer* 27, no. 4 (2019): 1263-1270.

that patients can still receive ordinary treatment even in a hospice setting. Under the concurrent care model, services such as chemotherapy can be provided alongside the pain management of hospice care. Simultaneously addressing the patient's disease and symptoms ensures increased comfort for the patient, while familiarizing the patient with services they can later solely rely on.

Currently, the VA provides funding for concurrent care, resulting in patients making less-intensive use of costly treatments as they transition to palliative care. In a 2018 *Health Affairs* study, researchers from the Stanford University School of Medicine and Veterans Affairs Palo Alto Health Care System found veterans receiving concurrent care received higher-quality, lower-intensity care at end-of-life than patients relying on hospital care until their deaths.[71]

In contrast, Medicare does not reimburse concurrent care arrangements, resulting in patients' reluctance to transition from hospital to hospice care despite benefits to their well-being. Additionally, patients must have six months or less to live (as determined by a physician) before being eligible for Medicare hospice reimbursements.[72] But as National Hospice and Palliative Care Organization Edo Banach notes, "Limiting hospice to six months really never made sense to begin with; it was a budgetary measure designed to constrain costs, but arguably it does the opposite because what you have is programs that are fixated on low or high lengths of stay compared to an arbitrary number, which is six months."[73] Medicare could stand to realize significant savings by granting terminal cancer patients earlier access to hospice services, instead of incentivizing them to undergo costly and counterproductive chemotherapy services.

According to a 2014 study published in the *Journal of the American Medical Association*, Medicare fee-for-service patients with poor cancer prognoses who utilized hospice benefits in their last year of life saved taxpayers approximately $8,700 compared to traditional hospital patients.[74] These savings could be far larger but are limited by the current underutilization of Medicare hospice benefits. Of 1.5 million Medicare beneficiaries who died in 2017 while enrolled in hospice, only 30 percent were cancer patients.[75] Yet cancer patients are commonly considered the ideal candidates for hospice care, since terminal diagnoses often proceed death by many months. Overall, fewer than half of all Medicare decedents each year make use of hospice services.[76]

Fortunately, Medicare is experimenting with expanding its hospice reimbursements to beneficiaries. In January 2016, the federal government launched a five-year trial program called the Medicare Care Choices Model (MCCM) to provide concurrent care to Medicare beneficiaries.[77] Under the model, hospices are paid a monthly reimbursement of $200 to $400

71 Gidwani-Marszowski, Risha, Jack Needleman, Vincent Mor, Katherine Faricy-Anderson, Derek B. Boothroyd, Gary Hsin, Todd H. Wagner et al. "Quality of end-of-life care is higher in the VA compared to care paid for by traditional Medicare." *Health Affairs* 37, no. 1 (2018): 95-103.
72 U.S. Department of Health and Human Services, Medicare. "Hospice Care." Accessed January 20, 2020.
73 Jim Parker. "Modernizing the Medicare Hospice Benefit." Hospice News. September 24, 2019.
74 Obermeyer, Ziad, Maggie Makar, Samer Abujaber, Francesca Dominici, Susan Block, and David M. Cutler. "Association between the Medicare hospice benefit and health care utilization and costs for patients with poor-prognosis cancer." *JAMA* 312, no. 18 (2014): 1888-1896.
75 Jim Parker. "Modernizing the Medicare Hospice Benefit." *Hospice News*. September 24, 2019.
76 Ibid.
77 Michael Brady. "New hospice trial shows promise, but questions remain." *Modern Healthcare*. September 28, 2019.

per patient to provide palliative services while beneficiaries also undergo standard procedures. But this pilot program has disappointed expectations; hospice and patient participation remains low due to low reimbursement rates combined with overly-narrow eligibility criteria.[78]

A September 2018 report prepared by research firm Abt Associates for the Centers for Medicare & Medicaid Services found that, at the time of the report's release, "One quarter (26.2 percent) of hospices have withdrawn from MCCM…Hospices that withdrew from the model said their main reason for doing so was the difficulty of enrolling beneficiaries due to MCCM eligibility criteria. Others decided that the $400 PBPM [per-beneficiary per-month] payment was insufficient to cover the costs of model implementation and services for beneficiaries."[79] The involvement of roughly 1,100 Medicare enrollees that participated in MCCM from January 1, 2016 through June 30, 2017 paled in comparison to initial estimates that more than 150,000 patients would participate. Despite issues with reimbursement and enrollment, the providers and patients expressed a high degree of satisfaction with the program. Government policies have served to limit what appears to be a promising program for Medicare beneficiaries that can save taxpayers significant money.[80]

Recommendations

Make the MCCM Pilot Program Permanent

Notwithstanding reimbursement difficulties, the Medicare Care Choices Model has saved taxpayers money and improved patient satisfaction in their last years of life. Members of Congress and HHS agency officials should transition this pilot to a permanent program and enshrine concurrent care in Medicare guidelines.

Expand Medicare Eligibility for Hospices

Currently, Medicare recipients must be given six months (or less) to live by a physician in order to qualify for hospice care. This requirement makes little sense, particularly for cancer patients with poor prognoses but median survival times exceeding six months. For instance – a majority of non-small cell lung cancer sufferers are alive six months after diagnoses, but only about 1 percent survive five years.[81] Many of these individuals who could benefit from hospice care are not yet eligible.

Increase Medicare Reimbursement Rates for Hospices

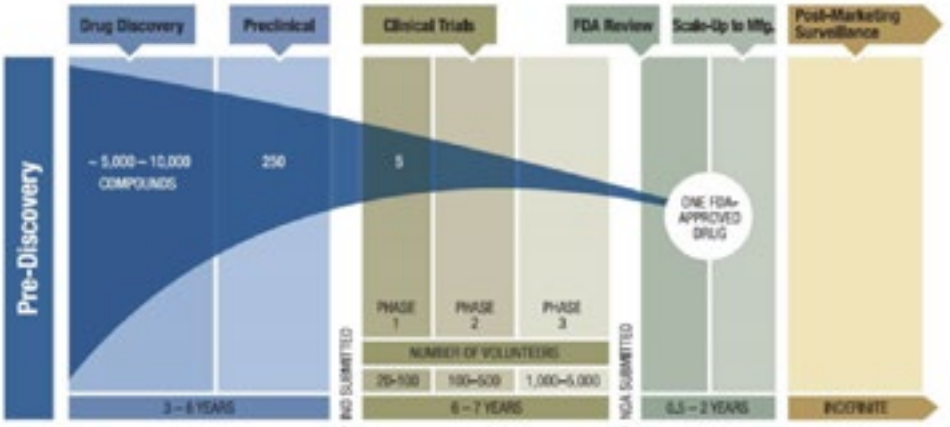
Palliative care facilities commonly cite low reimbursement rates as a rationale for dropping out of the MCCM, a program which saves significant taxpayer resources when patients successfully enroll in hospices. Doubling monthly reimbursements for patients from the $200-$400 range to the $400-$800 range would likely expand net-savings for taxpayers by increasing hospice participation in the Medicare system.

78 Ibid.
79 Abt Associates. "Evaluation of the Medicare Care Choices Model, Annual Report #1." September 2018
80 Ibid.
81 Schad, Friedemann, Anja Thronicke, Megan L. Steele, Antje Merkle, Burkhard Matthes, Christian Grah, and Harald Matthes. "Overall survival of stage IV non-small cell lung cancer patients treated with Viscum album L. in addition to chemotherapy, a real-world observational multicenter analysis." *PloS one* 13, no. 8 (2018): e0203058.

Pharmaceuticals

With the average time from pre-clinical trial to FDA approval spanning 12 years and development costs exceeding $2 billion per medication, few drugs make the leap from concept to reality. The below graph demonstrates the tedious process of drug approval through the FDA.

Figure 1. *Drug Discovery and Development Timeline*[82]



In order for a pharmaceutical product to be offered to the public, the manufacturer must subject its product to a multi-stage clinical process trial which must then be submitted to the FDA. Only after the drug is investigated, and an approval by the FDA is issued, the manufacturer is permitted to sell the product and promote medical claims.

Few products examined by the FDA are completely free of risks such as significant (even if rare) side effects or harmful interactions with commonly-used medications. Even if an experimental treatment is accompanied by a New Drug Application (NDA) thoroughly demonstrating efficacy in counteracting illness, agency evaluators are often reluctant to approve "risky" products. Medical researcher Dr. Henry I. Miller, MS, MD described his experience working at the FDA in the 1980s: "In the early 1980s, when I headed the team at the FDA that was reviewing the NDA for recombinant human insulin,...we were ready to recommend approval a mere four months after the application was submitted (at a time when the average time for NDA review was more than two and a half years). With quintessential bureaucratic reasoning, my supervisor refused to sign off on the approval - even though he agreed that the data provided compelling evidence of the drug's safety and effectiveness. 'If

82 Adopted from: *American Association of Cancer Research*. "Cancer Progress Report 2011: Transforming Patient Care through Innovation." 2011.

anything goes wrong,' he argued, 'Think how bad it will look that we approved the drug so quickly.'"[83]

Due to these concerns, which have been acknowledged by FDA officials, the agency has promulgated strict standards over the past few decades as to what constitutes acceptable evidence of safety and efficacy. In 1998, the FDA released guidance titled, "Statistical Principles for Clinical Trials" codifying stringent, across-the-board measures of statistical significance into its decision-making practices. In the document, the agency noted, "Conventionally, the probability of Type I error is set at 5 percent or less or as dictated by any adjustments made necessary for multiplicity considerations; the precise choice may be influenced by the prior plausibility of the hypothesis under test and the desired impact of the results. The probability of a Type II error is conventionally set at 10 percent to 20 percent. It is in the sponsor's interest to keep this figure as low as feasible, especially in the case of trials that are difficult or impossible to repeat."[84]

The problems inherent in the formalization of a "statistical significance" test however became clear as medications were rejected even after sponsors submitted comprehensive evidence that strongly suggested efficacy. In 2006, drug maker Dendreon submitted the results of two trials pertaining to the effectiveness of its prostate cancer immunotherapy drug, Provenge. The decline of overall mortality due to the medication was statistically significant at the 95 percent confidence interval, but the FDA reviewer rejected this result because Dendreon did not pre-specify what a statistically significant result for "overall mortality" would be sufficient to deem the studies successful.[85]

Rather, Dendreon was specifically testing for outcomes immediately related to prostate cancer disease progression and set the pre-trial threshold at the 95 percent confidence interval ($p<=.05$).[86] In other words, if Dendreon found that Provenge resulted in the halting and/or reversal of prostate cancer, and there was at least a 95 percent level of confidence that this finding was not due to chance, the drug manufacturer would have passed its test and the FDA would have likely approved the medication in the subsequent evaluation process. Instead, Dendreon narrowly failed its threshold; one of two trials had disease progression results below the 95 percent confidence level (at 94.8 percent).

Despite the closeness of this result to the statistical significance marker, the success of the second study in obtaining statistical significance, and results across both studies demonstrating statistically significant declines in overall mortality, the FDA reviewer wrote that, "the evidence is not substantial from a statistical perspective" and the agency rejected Dendreon's drug application. The medication was approved in April 2010, but only after Dendreon conducted another, large study and specified beforehand that mortality was a variable of significant interest.[87]

83 *Independent Institute*, FDA Review. "Why the FDA Has an Incentive to Delay the Introduction of New Drugs."
84 United States Food and Drug Administration. "Guidance Document: E9 Statistical Principles for Clinical Trials." September 1998.
85 Lee, Kennedy-Shaffer. "When the Alpha is the Omega: P-Values, 'Substantial Evidence,' and the 0.05 Standard at FDA." *Food and Drug Law Journal* 72, no. 4 (2017): 595-635.
86 A "confidence interval" refers to a range of values that includes the "true value" of the effect being investigated. A 95 percent confidence interval (p=.05) indicates a 95 percent chance that the actual value lies within the stated range.
87 Ibid.

The agency's strict adherence to pre-set statistical standards set the stage for the rejection of medications that attained 93 to 94 percent confidence levels of significance across multiple studies of several hundred applicants. This led to an increasing number of drug manufacturers to withdraw from the clinical trial process after borderline "significant" results, rather than invest an additional year and hundreds of thousands of dollars into the FDA drug approval process. As a result, a declining percentage of drug manufacturers that first filed Investigational New Drug applications (INDs) and introduced drugs for clinical testing went on to submit NDAs for review.

As experimental drugs' probability of approval declined, companies that did see the process through and collected enough statistically-significant evidence to submit an NDA to the FDA were more likely to have their NDAs approved than in previous years. In 2018, a team of researchers from the Massachusetts Institute of Technology (MIT) used data from the FDA, National Institutes of Health (NIH), and Informa Pharma Intelligence's Trialtrove and Pharmaprojects databases to estimate the probability of success for drugs by phase and FDA final approval by year, for the 2005-2015 period. The research team found that, even though FDA approval rates from NDA submission were either maintained or increased over the decade period, overall probability of success declined except for the final year.[88]

But strict FDA guidelines are far from the only barrier that drug manufacturers face in bringing their life-savings products to market. Repeated federal proposals to fix medication prices and tamper with intellectual property protections make it difficult for innovators to continue multi-billion-dollar investments into research and development. Current proposed rules by the Trump administration would tie Medicare Part B drugs to an International Pricing Index (IPI), which would be an average of pharmaceutical prices set by governments around the world.[89]

A further-reaching proposal by House Speaker Nancy Pelosi (D-Calif.) would have the federal government "negotiate" drug prices with producers. Failure to come to an agreement would result in an up-to 95 percent tax on the relevant drug's prior year sales.[90] These policy proposals would attempt to have the U.S. replicate the low medication prices seen in most industrialized nations, but lawmakers and agency officials fail to see the unintended consequences that would accompany these price controls.

For instance, cardiovascular disease remains the leading cause of mortality across virtually all healthcare systems.[91] Yet in America, statins are plentiful, readily prescribed to high-cholesterol patients, and easily obtainable at nearby pharmacies nationwide.[92] Most European nations do not have such ready access; approximately 40 percent of surveyed European

88 Wong, Chi Heem, Kien Wei Siah, and Andrew W. Lo. "Estimation of clinical trial success rates and related parameters." *Biostatistics* 20, no. 2 (2019): 273-286.
89 Dan Best. "Answering Your Questions about the IPI Drug Pricing Model." U.S. Department of Health and Human Services. October 30, 2018.
90 *Kaiser Health News*. "The House Approved H.R. 3, The Pelosi Drug Bill. What Does That Mean?" December 13, 2019.
91 World Health Organization. "Cardiovascular Diseases." May 17, 2017.
92 Salami, Joseph A., Haider Warraich, Javier Valero-Elizondo, Erica S. Spatz, Nihar R. Desai, Jamal S. Rana, Salim S. Virani et al. "National trends in statin use and expenditures in the US adult population from 2002 to 2013: insights from the Medical Expenditure Panel Survey." *JAMA Cardiology* 2, no. 1 (2017): 56-65.

pharmacists cited heart medication shortages as a significant issue in 2018.[93] In countries with price-fixing systems, many new life-saving drugs are never approved due to countries' inability to "negotiate" down prices. Access to life-saving pharmaceuticals in other countries is sharply limited as a direct result of these policies. For instance, only 41 percent of new medicines launched in the U.S. since 2011 are available in Australia.[94]

In an environment with mandated, artificially-low pricing, producers have little incentive to bring life-saving medications to market.

Recommendations

Reevaluate medication safety and efficacy statistical standards

FDA statistical standards are far too strict which results in promising and experimental medications being denied by the agency even if there is more than a 90 percent probability that the drug will be effective against an illness. Congress should mandate that the FDA consider different standards based on the diseases being targeted by medications and allow clinical trials to adopt alternative statistical standards.

Tighten advisory committee standards

The FDA often relies on outside experts to assess the applications of drugs and medical devices. Unfortunately, positions on these committees are often vacant, resulting in remaining members having outsized influence. Additionally, regular conflicts of interest require routine waivers to be issued by the FDA. Vacancies and conflicts of interest should be strictly limited by the FDA via Congressional mandate.

Resist executive and legislative attempts to impose price controls

Whether via HHS rulemaking or new legislation, using the power of the federal government to impose price controls on medications would curtail innovation and lead to less life-saving drugs entering the U.S. market. In addition, improvements on existing drugs would be more limited as less revenue results in less research and development.

93 European Association of Hospital Pharmacists. "EAHP's 2018 Survey on Medicines Shortages to improve patient outcomes." November 7, 2018.
94 Tim to provide footnote.

Conclusion

Delivering healthcare may seem complicated but fixing healthcare policy is not. Successive federal failures in the financing and management of healthcare have cost U.S. taxpayers trillions of dollars without improving quality of care for patients. Since its inception, Medicare has systematically underpriced reimbursements for rural hospitals, jeopardizing the financial condition of these facilities and resulting in hundreds of closures. The Affordable Care Act, signed into law by former President Obama in 2010, made healthcare even worse in underserved areas and significantly narrowed insurance networks.

And since the 1940s, the dysfunctional U.S. tax code has led to price hikes across the medical sector by discouraging patients to shop around for quality, affordable care. Despite hospitals regularly going out of business, millions of patients per year receiving surprise medical bills, and terminally-ill patients facing barriers to access due to cumulative government interventions, some lawmakers and agency officials want to further expand the federal reach into the healthcare sector.

Most of the proposals currently being discussed at the national political level envision bureaucrats imposing price-fixing on doctors and drug producers and further stymying the drug approval process. These ideas are counterproductive and would lead to worse quality-of-care for patients and higher expenses for taxpayers. Leading presidential candidates look across the Atlantic to the supposedly “successive” healthcare systems of Western European nations, when in reality, such systems practice widespread rationing and reduced access to life-saving products for patients. Patients in nations with socialized medicine (i.e. Sweden) are increasingly turning to private clinics and hospitals for care, while policymakers in the U.K. are increasingly mulling the partial privatization of NHS services. Choice and competition are key to cost-control and cutting-edge medical treatments for patients.

As Congress and President Trump look to improve healthcare and reduce rapidly-rising medical debts across the country, they should look to market-based solutions and a sounder, fairer tax system. Top-down government interference in medical decision-making has failed hundreds of millions of Americans, and market-based medicine can do far more to meet the needs of patients.

Recommendations

- Oppose any attempt to mandate rate-setting for physicians' services, which would lead to the widespread closure of medical facilities.
- Support a nationwide arbitration system for responding to "surprise medical bills" that would allow insurers and doctors – not patients – to go through a fair, thorough process to resolve billing disputes.
- Reevaluate medication safety and efficacy statistical standards which prevent life-saving drugs from coming to market.
- Tighten FDA advisory committee standards to ensure robust checks and balances in the FDA drug approvals process.
- Resist executive and legislative attempts to impose price controls on medications which would lead to medication shortages and decreased innovation.
- Increase Medicare reimbursement rates for hospices to encourage the use of less-costly end-of-life care.
- Expand Medicare eligibility for hospice care, which currently excludes millions of patients with terminal illnesses.
- Make permanent Medicare's "concurrent care" pilot program for terminal patients interested in hospice care.
- Level the tax playing field by doubling HSA contribution limits, which would incentivize greater "shopping around" and cost control.
- Increase the scope of goods and services that HSAs cover, including e-cigarettes and multivitamins. These products are proven to increase patient well-being yet are tax disadvantaged.
- Resist any further attempts to influence healthcare decisions via targeted breaks or penalties in the tax code.
- Increase choice and competition in the healthcare sector, so that "narrow networks" are a thing of the past for patients.
- Allow for increased insurance plan flexibility, enabling patients to purchase plans without "essential benefits" they may not want or need.
- Condition federal Medicaid funding to states on important state-level reforms, such as limiting certificate-of-need laws which drive up costs and reduce the availability of medical services.
- Allow patients to opt out of government-managed healthcare systems such as the VA and IHS. The current VA "Veterans Choice Program" should be reformed to allow for increased access and eligibility.

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