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SUBCHAPTER I—IMMEDIATE ACTIONS TO PRESERVE AND EXPAND COVERAGE

§ 18001. Immediate access to insurance for uninsured individuals with a preexisting condition

(a) In general

Not later than 90 days after March 23, 2010, the Secretary shall establish a temporary high risk health insurance pool program to provide health insurance coverage for eligible individuals during the period beginning on the date on which such program is established and ending on January 1, 2014.

(b) Administration

(1) In general

The Secretary may carry out the program under this section directly or through contracts to eligible entities.

(2) Eligible entities

To be eligible for a contract under paragraph (1), an entity shall—

(A) be a State or nonprofit private entity:

(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require; and

(C) agree to utilize contract funding to establish and administer a qualified high risk pool for eligible individuals.

(3) Maintenance of effort

To be eligible to enter into a contract with the Secretary under this subsection, a State shall agree not to reduce the annual amount the State expended for the operation of one or more State high risk pools during the year preceding the year in which such contract is entered into.

(c) Qualified high risk pool

(1) In general

Amounts made available under this section shall be used to establish a qualified high risk pool that meets the requirements of paragraph (2).

(2) Requirements

A qualified high risk pool meets the requirements of this paragraph if such pool-

- (A) provides to all eligible individuals health insurance coverage that does not impose any preexisting condition exclusion with respect to such coverage;
 - (B) provides health insurance coverage—
 - (i) in which the issuer's share of the total allowed costs of benefits provided under such coverage is not less than 65 percent of such costs; and
 - (ii) that has an out of pocket limit not greater than the applicable amount described in section 223(c)(2) of title 26 for the year involved, except that the Secretary may modify such limit if necessary to ensure the pool meets the actuarial value limit under clause (i);
- (C) ensures that with respect to the premium rate charged for health insurance coverage offered to eligible individuals through the high risk pool, such rate shall—
 - (i) except as provided in clause (ii), vary only as provided for under section 300gg of this title (as amended by this Act and notwithstanding the date on which such amendments take effect);
 - (ii) vary on the basis of age by a factor of not greater than 4 to 1; and
 - (iii) be established at a standard rate for a standard population; and
- (D) meets any other requirements determined appropriate by the Secretary.

(d) Eligible individual

An individual shall be deemed to be an eligible individual for purposes of this section if such individual—

- (1) is a citizen or national of the United States or is lawfully present in the United States (as determined in accordance with section 18081 of this title):
- (2) has not been covered under creditable coverage (as defined in section 300gg(c)(1) of this title as in effect on March 23, 2010) during the 6-month period prior to the date on which such individual is applying for coverage through the high risk pool; and
- (3) has a pre-existing condition, as determined in a manner consistent with guidance issued by the Secretary.

(e) Protection against dumping risk by insurers (1) In general

The Secretary shall establish criteria for determining whether health insurance issuers and employment-based health plans have discouraged an individual from remaining enrolled in prior coverage based on that individual's health status.

(2) Sanctions

An issuer or employment-based health plan shall be responsible for reimbursing the program under this section for the medical expenses incurred by the program for an individual who, based on criteria established by the Secretary, the Secretary finds was encouraged by the issuer to disenroll from health benefits coverage prior to enrolling in coverage through the program. The criteria shall include at least the following circumstances:

(A) In the case of prior coverage obtained through an employer, the provision by the

- employer, group health plan, or the issuer of money or other financial consideration for disenselling from the coverage.
- (B) In the case of prior coverage obtained directly from an issuer or under an employment-based health plan—
 - (i) the provision by the issuer or plan of money or other financial consideration for disenrolling from the coverage; or
 - (ii) in the case of an individual whose premium for the prior coverage exceeded the premium required by the program (adjusted based on the age factors applied to the prior coverage)—
 - (I) the prior coverage is a policy that is no longer being actively marketed (as defined by the Secretary) by the issuer; or
 - (II) the prior coverage is a policy for which duration of coverage form ¹ issue or health status are factors that can be considered in determining premiums at renewal.

(3) Construction

Nothing in this subsection shall be construed as constituting exclusive remedies for violations of criteria established under paragraph (1) or as preventing States from applying or enforcing such paragraph or other provisions under law with respect to health insurance issuers.

(f) Oversight

The Secretary shall establish—

- (1) an appeals process to enable individuals to appeal a determination under this section; and
- (2) procedures to protect against waste, fraud, and abuse.

(g) Funding; termination of authority

(1) In general

There is appropriated to the Secretary, out of any moneys in the Treasury not otherwise appropriated, \$5,000,000,000 to pay claims against (and the administrative costs of) the high risk pool under this section that are in excess of the amount of premiums collected from eligible individuals enrolled in the high risk pool. Such funds shall be available without fiscal year limitation.

(2) Insufficient funds

If the Secretary estimates for any fiscal year that the aggregate amounts available for the payment of the expenses of the high risk pool will be less than the actual amount of such expenses, the Secretary shall make such adjustments as are necessary to eliminate such deficit.

(3) Termination of authority

(A) In general

Except as provided in subparagraph (B), coverage of eligible individuals under a high risk pool in a State shall terminate on January 1, 2014.

(B) Transition to Exchange

The Secretary shall develop procedures to provide for the transition of eligible individ-

¹ So in original. Probably should be "from".

uals enrolled in health insurance coverage offered through a high risk pool established under this section into qualified health plans offered through an Exchange. Such procedures shall ensure that there is no lapse in coverage with respect to the individual and may extend coverage after the termination of the risk pool involved, if the Secretary determines necessary to avoid such a lapse.

(4) Limitations

The Secretary has the authority to stop taking applications for participation in the program under this section to comply with the funding limitation provided for in paragraph (1).

(5) Relation to State laws

The standards established under this section shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to qualified high risk pools which are established in accordance with this section.

(Pub. L. 111-148, title I, §1101, Mar. 23, 2010, 124 Stat. 141.)

Editorial Notes

References in Text

This Act, referred to in subsec. (c)(2)(C)(i), is Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 119, known as the Patient Protection and Affordable Care Act. For complete classification of this Act to the Code, see Short Title note set out below and Tables.

The date on which such amendments take effect, referred to in subsec. (c)(2)(C)(i), is the date on which the amendments by Pub. L. 111–148 to section 300gg of this title take effect, which is Jan. 1, 2014. See section 1255 of Pub. L. 111–148, set out as an Effective Date note under section 300gg of this title.

Statutory Notes and Related Subsidiaries

SHORT TITLE OF 2014 AMENDMENT

Pub. L. 113–235, div. M, §1, Dec. 16, 2014, 128 Stat. 2767, provided that: "This division [enacting section 18014 of this title] may be cited as the 'Expatriate Health Coverage Clarification Act of 2014'."

SHORT TITLE

Pub. L. 111–148, §1(a), Mar. 23, 2010, 124 Stat. 119, provided that: "This Act [see Tables for classification] may be cited as the 'Patient Protection and Affordable Care Act'."

Executive Documents

EXECUTIVE ORDER No. 13765

Ex. Ord. No. 13765, Jan. 20, 2017, 82 F.R. 8351, which related to minimizing the economic burden of the Patient Protection and Affordable Care Act (Pub. L. 111-148) pending repeal, was revoked by Ex. Ord. No. 14009, §4(a), Jan. 28, 2021, 86 F.R. 7794, set out below.

EXECUTIVE ORDER No. 13813

Ex. Ord. No. 13813, Oct. 12, 2017, 82 F.R. 48385, which related to promoting association health plans, short-term, limited-duration insurance, and health reimbursement arrangements, was revoked by Ex. Ord. No. 14009, §4(a), Jan. 28, 2021, 86 F.R. 7794, set out below.

EX. ORD. No. 13877. IMPROVING PRICE AND QUALITY TRANSPARENCY IN AMERICAN HEALTHCARE TO PUT PATIENTS FIRST

Ex. Ord. No. 13877, June 24, 2019, 84 F.R. 30849, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. Purpose. My Administration seeks to enhance the ability of patients to choose the healthcare that is best for them. To make fully informed decisions about their healthcare, patients must know the price and quality of a good or service in advance. With the predominant role that third-party payers and Government programs play in the American healthcare system, however, patients often lack both access to useful price and quality information and the incentives to find low-cost, high-quality care. Opaque pricing structures may benefit powerful special interest groups, such as large hospital systems and insurance companies, but they generally leave patients and taxpayers worse off than would a more transparent system.

Pursuant to Executive Order 13813 of October 12, 2017 (Promoting Healthcare Choice and Competition Across the United States) [formerly set out above], my Administration issued a report entitled "Reforming America's Healthcare System Through Choice and Competition." The report recommends developing price and quality transparency initiatives to ensure that healthcare patients can make well-informed decisions about their care. In particular, the report describes the characteristics of the most effective price transparency efforts: they distinguish between the charges that providers bill and the rates negotiated between payers and providers; they give patients proper incentives to seek information about the price of healthcare services; and they provide useful price comparisons for "shoppable" services (common services offered by multiple providers through the market, which patients can research and compare before making informed choices based on price and quality).

Shoppable services make up a significant share of the healthcare market, which means that increasing transparency among these services will have a broad effect on increasing competition in the healthcare system as a whole. One study, cited by the Council of Economic Advisers in its 2019 Annual Report, examined a sample of the highest-spending categories of medical cases requiring inpatient and outpatient care. Of the categories of medical cases requiring inpatient care, 73 percent of the 100 highest-spending categories were shoppable. Among the categories of medical cases requiring outpatient care, 90 percent of the 300 highest-spending categories were shoppable. Another study demonstrated that the ability of patients to price-shop imaging services, a particularly fungible and shoppable set of healthcare services, was associated with a per-service savings of up to approximately 19 percent.

Improving transparency in healthcare will also fur-

Improving transparency in healthcare will also further protect patients from harmful practices such as surprise billing, which occurs when patients receive unexpected bills at highly inflated prices from out-of-network providers they had no opportunity to select in advance. On May 9, 2019, I announced principles to guide efforts to address surprise billing. The principles outline how patients scheduling appointments to receive facility-based care should have access to pricing information related to the providers and services they may need, and the out-of-pocket costs they may incur. Having access to this type of information in advance of care can help patients avoid excessive charges.

Making meaningful price and quality information more broadly available to more Americans will protect patients and increase competition, innovation, and value in the healthcare system.

SEC. 2. Policy. It is the policy of the Federal Government to ensure that patients are engaged with their healthcare decisions and have the information requisite for choosing the healthcare they want and need. The Federal Government aims to eliminate unnecessary barriers to price and quality transparency; to increase the availability of meaningful price and quality information for patients; to enhance patients' control over their own healthcare resources, including through tax-preferred medical accounts; and to protect patients from surprise medical bills.

SEC. 3. Informing Patients About Actual Prices. (a) Within 60 days of the date of this order [June 24, 2019], the Secretary of Health and Human Services shall propose a regulation, consistent with applicable law, to require hospitals to publicly post standard charge information, including charges and information based on negotiated rates and for common or shoppable items and services, in an easy-to-understand, consumer-friendly, and machine-readable format using consensus-based data standards that will meaningfully inform patients' decision making and allow patients to compare prices across hospitals. The regulation should require the posting of standard charge information for services, supplies, or fees billed by the hospital or provided by employees of the hospital. The regulation should also require hospitals to regularly update the posted information and establish a monitoring mechanism for the Secretary to ensure compliance with the posting requirement, as needed.

(b) Within 90 days of the date of this order, the Secretaries of Health and Human Services, the Treasury, and Labor shall issue an advance notice of proposed rule-making, consistent with applicable law, soliciting comment on a proposal to require healthcare providers, health insurance issuers, and self-insured group health plans to provide or facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive care

to patients before they receive care.

(c) Within 180 days of the date of this order, the Secretary of Health and Human Services, in consultation with the Attorney General and the Federal Trade Commission, shall issue a report describing the manners in which the Federal Government or the private sector are impeding healthcare price and quality transparency for patients, and providing recommendations for eliminating these impediments in a way that promotes competition. The report should describe why, under current conditions, lower-cost providers generally avoid healthcare advertising.

SEC. 4. Establishing a Health Quality Roadmap. Within 180 days of the date of this order, the Secretaries of Health and Human Services, Defense, and Veterans Affairs shall develop a Health Quality Roadmap (Roadmap) that aims to align and improve reporting on data and quality measures across Medicare, Medicaid, the Children's Health Insurance Program, the Health Insurance Marketplace, the Military Health System, and the Veterans Affairs Health System. The Roadmap shall include a strategy for establishing, adopting, and publishing common quality measurements; aligning inpatient and outpatient measures; and eliminating low-value or counterproductive measures.

SEC. 5. Increasing Access to Data to Make Healthcare Information More Transparent and Useful to Patients. Within 180 days of the date of this order, the Secretary of Health and Human Services, in consultation with the Secretaries of the Treasury, Defense, Labor, and Veterans Affairs, and the Director of the Office of Personnel Management, shall increase access to de-identified claims data from taxpayer-funded healthcare programs and group health plans for researchers, innovators, providers, and entrepreneurs, in a manner that is consistent with applicable law and that ensures patient privacy and security. Providing access to this data will facilitate the development of tools that empower patients to be better informed as they make decisions related to healthcare goods and services. Access to this data will also enable researchers and entrepreneurs to locate inefficiencies and opportunities for improvement, such as patterns of performance of medical procedures that are outside the recommended standards of care. Such data may be derived from the Transformed Medicaid Statistical Information System (T-MSIS) and other sources. As part of this process, the Secretary of Health and Human Services shall make a list of priority datasets that, if de-identified, could advance the policies set forth by this order, and shall report to the President on proposed plans for future release of these priority datasets and on any barriers to their release.

SEC. 6. Empowering Patients by Enhancing Control Over Their Healthcare Resources. (a) Within 120 days of the date of this order, the Secretary of the Treasury, to the extent consistent with law, shall issue guidance to expand the ability of patients to select high-deductible health plans that can be used alongside a health savings account, and that cover low-cost preventive care, before the deductible, for medical care that helps maintain health status for individuals with chronic conditions.

(b) Within 180 days of the date of this order, the Secretary of the Treasury, to the extent consistent with law, shall propose regulations to treat expenses related to certain types of arrangements, potentially including direct primary care arrangements and healthcare sharing ministries, as eligible medical expenses under section 213(d) of title 26, United States Code.

(c) Within 180 days of the date of this order, the Secretary of the Treasury, to the extent consistent with law, shall issue guidance to increase the amount of funds that can carry over without penalty at the end of the year for flexible spending arrangements.

SEC. 7. Addressing Surprise Medical Billing. Within 180 days of the date of this order, the Secretary of Health and Human Services shall submit a report to the President on additional steps my Administration may take to implement the principles on surprise medical billing announced on May 9, 2019.

SEC. 8. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

 Donald J. Trump.

Ex. Ord. No. 13951. An America-First Healthcare $$\operatorname{PLan}$$

Ex. Ord. No. 13951, Sept. 24, 2020, 85 F.R. 62179, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. Purpose. Since January 20, 2017, my Administration has been committed to the goal of bringing great healthcare to the American people and putting patients first. To that end, my Administration has taken monumental steps to improve the efficiency and quality of healthcare in the United States.

(a) My Administration has been committed to restoring choice and control to the American patient.

On December 22, 2017, I signed into law the repeal of the burdensome individual-mandate penalty, liberating millions of low-income Americans from a tax that penalized them for not purchasing health-insurance coverage they did not want or could not afford. Through Executive Order 13813 of October 12, 2017 (Promoting Healthcare Choice and Competition Across the United States) [formerly set out above], my Administration has expanded coverage options for millions of Americans in several ways. My Administration increased the availability of renewable short-term, limited-duration healthcare plans, providing options that are up to 60 percent cheaper than the least expensive alternatives under the Patient Protection and Affordable Care Act (ACA) [Pub. L. 111-148] and are projected to cover 500,000 individuals who would otherwise be uninsured. My Administration expanded health reimbursement arrangements, which have been projected by the Department of the Treasury to reach 800,000 businesses and

over 11 million employees and to expand coverage to more than 800,000 individuals who would otherwise be uninsured. My Administration also issued a rule to increase the availability of association health plans for small businesses, which, upon implementation of the rule, are projected to cover up to 400,000 previously uninsured individuals for on average 30 percent less cost.

As set forth in the Economic Report of the President (February 2020), my Administration's expansion of health savings accounts will further help millions of Americans pay for health expenditures by allowing them to save more of their own money free from Federal taxation, and will especially help Americans with chronic conditions who now have more flexibility to enroll in plans that fit their complicated care needs and can be paired with a tax-advantaged account.

At the beginning of the current COVID-19 pandemic, my Administration acted to dramatically increase the accessibility and availability of telehealth services for Medicare beneficiaries, enabling millions of individuals to use these services. Pursuant to Executive Order 13941 of August 3, 2020 (Improving Rural Health and Telehealth Access) [42 U.S.C. 254c note], the Secretary of Health and Human Services will make permanent many of the new policies that improve the accessibility and availability of telehealth services. In addition, pursuant to that order, the Secretary of Health and Human Services and the Secretary of Agriculture will develop and implement a strategy to improve the physical and communications healthcare infrastructure available to rural Americans.

Through our State Relief and Empowerment Waivers, my Administration has given States additional health-insurance flexibility, which has expanded health-insurance coverage options for consumers and lowered costs for patients. These waivers allow States to move away from the ACA's rigid structure and are estimated to have lowered premiums by approximately 11 percent in Wisconsin, 20 percent in Minnesota, and 43 percent in Maryland. Due to actions my Administration took, like the State Relief and Empowerment Waivers, after years of dwindling choices and escalating prices, plan options for consumers increased and for 2019, for the first time ever, benchmark premiums actually decreased on Healthcare.gov. For 2020, the average benchmark premium dropped by nearly 4 percent.

After the prior Administration spent tens of billions of dollars creating electronic health records systems unable to accurately or effectively record and communicate patient data, my Administration has paved the way for a new wave of innovation to allow patients to safely send their own medical records to care providers of their choosing. My Patients over Paperwork initiative has cut red tape for doctors and nurses so they can spend more time with their patients, which the Centers for Medicare and Medicaid Services (CMS) within the Department of Health and Human Services (HHS) has estimated to save over 40 million hours of wasted time for providers and suppliers between 2017 and 2021.

(b) My Administration has been ceaseless in its efforts to lower costs to make healthcare more affordable for American patients

Under my tenure, prescription drugs saw their largest annual price decrease in nearly half a century. For three consecutive years, we have approved a record number of generic drugs. The Council of Economic Advisers has estimated that these approvals saved patients \$26 billion in the first 18 months of my Administration alone. As part of the Further Consolidated Appropriations Act, 2020 [Pub. L. 116-94], I signed into law the Creating and Restoring Equal Access to Equivalent Samples Act [see 21 U.S.C. 355-2], which will pave the way for even more generic drugs and is projected to save taxpayers \$3.3 billion from 2019 to 2029.

CMS has acted to offer Medicare beneficiaries prescription drug plans with the option of insulin capped at \$35 in out-of-pocket expenses for a 30-day supply. We are also reducing Government payments to overcharging hospitals participating in the 340B Drug Pricing Program by instead paying rates that more accurately reflect the hospitals' acquisition costs, which CMS estimated would save Medicare beneficiaries \$320 million on copayments for drugs alone.

As a result of Executive Order 13937 of July 24, 2020 (Access to Affordable Life-Saving Medications) [42 U.S.C. 254b note], low-income Americans who receive care from a federally qualified health center will have access to insulin and injectable epinephrine at prices lower than ever before. Under Executive Order 13938 of July 24, 2020 (Increasing Drug Importation to Lower Prices for American Patients) [21 U.S.C. 384 note], my Administration will be the first to complete a rulemaking to authorize the safe importation of certain lower-cost prescription drugs from Canada. Pursuant to Executive Order 13939 of July 24, 2020 (Lowering Prices for Patients by Eliminating Kickbacks to Middlemen) [42 U.S.C. 1320a-7b note], my Administration is taking action to eliminate wasteful payments to middlemen by passing drug discounts through to patients at the pharmacy counter without increasing premiums for beneficiaries or cost to Federal taxpayers. And my Administration is taking action to ensure that Medicare patients receive the lowest price that drug companies offer comparable foreign nations through Executive Order 13948 of September 13, 2020 (Lowering Drug Prices by Putting America First) [42 U.S.C. 1395u note].
As part of the Further Consolidated Appropriations

As part of the Further Consolidated Appropriations Act, 2020, I also signed into law the repeal of the medical device tax, the annual fee on health-insurance providers, and the "Cadillac" tax on certain employersponsored health insurance, which threatened to dramatically increase the cost of healthcare for working families.

My Administration is transforming the black-box hospital and insurance pricing systems to be transparent about price and quality. Regardless of health-insurance coverage, two-thirds of adults in America still worry about the threat of unexpected medical bills. This fear is the result of a system under which individuals and employers are unable to see how insurance companies, pharmacy benefit managers, insurance brokers, and providers are or will be paid. One major culprit is the practice of "surprise billing," in which a patient receives unexpected bills at highly inflated prices from providers who are not part of the patient's insurance network, even if the patient was treated at a hospital that was part of the patient's network. Patients can receive these bills despite having no opportunity to select around an out-of-network provider in advance.

On May 9, 2019, I announced four principles to guide congressional efforts to prohibit exorbitant bills resulting from patients' accidentally or unknowingly receiving services from out-of-network physicians. Unfortunately, the Congress has failed to act, and patients remain vulnerable to surprise billing.

In the absence of congressional action, my Administration has already taken strong and decisive action to make healthcare prices more transparent. On June 24, 2019, I signed Executive Order 13877 (Improving Price and Quality Transparency in American Healthcare to Put Patients First) [set out above], directing certain agencies—for the first time ever—to make sure patients have access to meaningful price and quality information prior to the delivery of care. Beginning January 1, 2021, hospitals will be required to publish their real price for every service, and publicly display in a consumer-friendly, easy-to-understand format the prices of at least 300 different common services that are able to be shopped for in advance.

We have also taken some concrete steps to eliminate

We have also taken some concrete steps to eliminate surprise out-of-network bills. For example, on April 10, 2020, my Administration required providers to certify, as a condition of receiving supplemental COVID-19 funding, that they would not seek to collect out-of-pocket expenses from a patient for treatment related to COVID-19 in an amount greater than what the patient would have otherwise been required to pay for care by an in-network provider. These initiatives have made important progress, although additional efforts are necessary.

Not all hospitals allow for surprise bills. But many do. Unfortunately, surprise billing has become sufficiently pervasive that the fear of receiving a surprise bill may dissuade patients from seeking appropriate care. And research suggests a correlation between hospitals that frequently allow surprise billing and increases in hospital admissions and imaging procedures, putting patients at risk of receiving unnecessary services, which can lead to physical harm and threatens the long-term financial sustainability of Medicare.

Efforts to limit surprise billing and increase the number of providers participating in the same insurance network as the hospital in which they work would correspondingly streamline the ability of patients to receive care and reduce time spent on billing disputes.

On May 15, 2020, HHS released the Health Quality Roadmap to empower patients to make fully informed decisions about their healthcare by facilitating the availability of appropriate and meaningful price and quality information. These transformative actions will arm patients with the tools to be active and effective shoppers for healthcare services, enabling them to identify high-value providers and services, and ultimately place downward pressure on prices.

My Administration has cracked down on waste, fraud, and abuse that direct valuable taxpayer resources away from those who need them most. My Administration implemented a "site neutral" payment system between hospital outpatient departments and physicians' offices, to ensure Medicare beneficiaries are charged the same price for the same service regardless of where it takes place, which CMS estimates will save them approximately \$160 million in co-payments for 2020. We also changed the rules to enable Government watchdogs to proactively identify and stop perpetrators of fraud before money goes out the door.

(c) My Administration has been dedicated to providing better care for all Americans.

This includes a steadfast commitment to always protecting individuals with pre-existing conditions and ensuring they have access to the high-quality healthcare they deserve. No American should have to risk going without health insurance based on a health history that he or she cannot change.

In an attempt to justify the ACA, the previous Administration claimed that, absent action by the Congress, up to 129 million (later updated to 133 million) non-elderly people with what it described as pre-existing conditions were in danger of being denied health-insurance coverage. According to the previous Administration, however, only 2.7 percent of such individuals actually gained access to health insurance through the ACA, given existing laws and programs already in place to cover them. For example, the Health Insurance Portability and Accountability Act of 1996 [Pub. L. 104–191] has long protected individuals with pre-existing conditions, including individuals covered by group health plans and individuals who had such coverage but lost it.

The ACA produced multiple other failures. The average insurance premium in the individual market more than doubled from 2013 to 2017, and those who have not received generous Federal subsidies have struggled to maintain coverage. For those who have managed to maintain coverage, many have experienced a substantial rise in deductibles, limited choice of insurers, and limited provider networks that exclude their doctors and the facilities best suited to care for them.

Additionally, approximately 30 million Americans remain uninsured, notwithstanding the previous Administration's promises that the ACA would address this intractable problem. On top of these disappointing results, Federal taxpayers and, unfortunately, future generations of American workers, have been left with an enormous bill. The ACA's Medicaid expansion and subsidies for the individual market are projected by the Congressional Budget Office to cost more than \$1.8 trillion over the next decade.

The ACA is neither the best nor the only way to ensure that Americans who suffer from pre-existing con-

ditions have access to health-insurance coverage. I have agreed with the States challenging the ACA, who have won in the Federal district court and court of appeals, that the ACA, as amended, exceeds the power of the Congress. The ACA was flawed from its inception and should be struck down. However, access to health insurance despite underlying health conditions should be maintained, even if the Supreme Court invalidates the unconstitutional, and largely harmful, ACA.

My Administration has always been committed to ensuring that patients with pre-existing conditions can obtain affordable healthcare, to lowering healthcare costs, to improving quality of care, and to enabling individuals to choose the healthcare that meets their needs. For example, when the COVID-19 pandemic hit, my Administration implemented a program to provide any individual without health-insurance coverage access to necessary COVID-19-related testing and treatment.

My commitment to improving care across our country expands vastly beyond the rules governing health insurance. On July 10, 2019, I signed Executive Order 13879 (Advancing American Kidney Health) [42 U.S.C. 280g-6 note] to improve care for the hundreds of thousands of Americans suffering from end-stage renal disease. Pursuant to that order, my Administration launched a program to encourage home dialysis and promote transplants for patients, and expects to enroll approximately 120,000 Medicare beneficiaries with endstage renal disease in the program. We also have removed financial barriers to living organ donation by adding additional financial support for living donors, such as by reimbursing expenses for lost wages, child care, and elder care. HHS, together with the American Society of Nephrology, issued two phases of awards through KidneyX's Redesign Dialysis Price Competition to work toward the creation of an artificial kid-

ney. My Administration has taken unprecedented action to improve the quality of and access to care for individuals with HIV, as part of our goal of ending the epidemic of HIV in the United States by 2030. HHS has awarded at least \$226 million to expand access to HIV care, treatment, medication, and prevention services, focused on 48 counties, Washington, DC, and San Juan, Puerto Rico, where more than 50 percent of new HIV diagnoses occurred in 2016 and 2017, as well as seven States with a substantial rural HIV rate. We secured a historic donation of a groundbreaking HIV preventive medication that is available at no cost to eligible patients

My Administration has started a transformation in healthcare in rural America. This includes a new effort, pursuant to my directive in Executive Order 13941, to support small hospitals and health clinics in rural communities in transitioning from volume-based Medicare and Medicaid reimbursement, which has failed rural communities that struggle with a lack of patient volume, and toward value-based payment mechanisms that are tailored to meet the needs of their communities. We updated Medicare payment policies to address a problem in the program's payment calculation that has historically disadvantaged rural hospitals, and released a Rural Action Plan to incorporate recommendations from experts and leaders across the Federal Government. We have also dedicated a special focus on improving care offered through the Indian Health Service (IHS) within HHS, including by creating the Office of Quality, implementing an increase in annual funding for IHS by \$243 million from 2019 to 2020, and expanding nationwide IHS's successful Alaska Community Health Aide Program.

My Administration has additionally demonstrated an incredible dedication to protecting and improving care for those most in need, including senior citizens, those with substance use disorders, and those to whom our Nation owes the greatest debt: our veterans.

I have protected the viability of the Medicare program. For example, on February 9, 2018, I signed into law the repeal of the Independent Payment Advisory

Board, which would have been a group of unelected bureaucrats created by the ACA, designed to be insulated from the will of America's elected leaders for the purpose of cutting the spending of this important program. On October 3, 2019, I signed Executive Order 13890 (Protecting and Improving Medicare for Our Nation's Seniors) [42 U.S.C. 1395 note prec.], to modernize the Medicare program and continue its viability. According to CMS estimates, seniors have saved \$2.65 billion in lower Medicare premiums under my Administration while benefiting from more choices. For example, the average monthly Medicare Advantage premium has declined an estimated 28 percent since 2017, and Medicare Advantage has included about 1,200 more plan options since 2018. New Medicare Advantage supplemental benefits have helped seniors stay safe in their homes, improved respite care for caregivers, and provided transportation, more in-home support services and assistance, and non-opioid pain management alternatives like therapeutic massages. Medicare Part D premiums are at their lowest level in their history, with the average basic premium declining 13.5 percent since 2016.

My Administration has directed unprecedented attention on the substance use disorder epidemic, with a focus on reducing overdose deaths from prescription opioids and the deadly synthetic opioid fentanyl. On October 24, 2018, I signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act [Pub. L. 115-2711, enabling the expenditure of billions of dollars of funding for important programs to support prevention and recovery. My Administration has provided approximately \$22.5 billion from 2017 to 2020 to address the opioid crisis and improve access to prevention, treatment, and recovery services. We saw a 34 percent decrease in total opioids dispensed monthly by pharmacies between 2017 and 2019, an approximate increase of 64 percent in the number of Americans who receive medication-assisted treatment for opioid use disorder since 2016, and a 484 percent increase in naloxone prescriptions since 2017. Data show that drug overdose deaths fell nationwide for the first time in decades between 2017 and 2018, with many of the hardest-hit States leading the way.

Improving care for our Nation's veterans has been a priority since the beginning of my Administration. On June 6, 2018, I signed the [John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson] VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 [Pub. L. 115-182], which authorized billions of dollars to improve options for veterans to receive care outside of Department of Veterans Affairs (VA) healthcare providers. Since taking effect, the VA estimates that more than 2.4 million veterans have benefited from more than 6.5 million referrals to the 725,000 private healthcare providers with which the VA is now working. On June 23, 2017, I signed the Department of Veterans Affairs Accountability and Whistleblower Protection Act of 2017 [Pub. L. 115-41] to hold our civil servants accountable for maintaining the best quality of care possible for our Nation's veterans by giving the Secretary of Veterans Affairs more power to discipline employees and shorten an appeals process that can last years. On March 5, 2019, I signed Executive Order 13861 (National Roadmap to Empower Veterans and End Suicide) [Mar. 5, 2019, 84 F.R. 8585] to ensure that the Federal Government leads a collective effort to prevent suicide among our veterans

I have used scientific research to focus on areas most pressing for the health of Americans. On September 19, 2019, I signed Executive Order 13887 (Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health) [42 U.S.C. 247d-7enote], recognizing the threat that pandemic influenza continues to represent and putting forward a plan to prepare for future influenza pandemics. To modernize influenza vaccines and promote national security and public health, HHS issued a 6-year, \$226 million contract to retain and increase capacity to produce recombinant influenza vaccine domestically, and the Na-

tional Institute of Allergy and Infectious Diseases, part of the National Institutes of Health within HHS, initiated the Collaborative Influenza Vaccine Innovation Centers program.

Investments my Administration has made in scientific research will help tackle some of our most pressing medical challenges and pay dividends for generations to come. This includes working to increase funding for Alzheimer's disease research by billions of dollars since 2017 and a plan to invest more than \$500 million over the next decade to improve pediatric cancer research. On December 18, 2018, I signed the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2018 [Pub. L. 115–327, see 42 U.S.C. 300b–5] to provide support for research into sickle cell disease, which disproportionately impacts African Americans and Hispanics, and to authorize programs relating to sickle cell disease surveillance, prevention, and treatment.

cell disease surveillance, prevention, and treatment.
On May 30, 2018, I signed the Trickett Wendler, Frank
Mongiello, Jordan McLinn, and Matthew Bellina Right
to Try Act of 2017 [Pub. L. 115-176, see 21 U.S.C.
360bbb-0a], which gives terminally ill patients the right
to access certain treatments without being blocked by
onerous Federal regulations.

In response to the COVID-19 pandemic, my Adminislaunched Operation Warp groundbreaking effort of the Federal Government to engage with the private sector to quickly develop and deliver safe and effective vaccines, therapeutics, and diagnostics for COVID-19. On August 6, 2020, I signed Executive Order 13944 (Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States) [42 U.S.C. 247d-6b note], to protect Americans through reduced dependence on foreign manufacturers for essential medicines and other items and to strengthen the Nation's Public Health Industrial Base.

Taken together, these extraordinary reforms constitute an ongoing effort to improve American healthcare by putting patients first and delivering continuous innovation. And this effort will continue to succeed because of my Administration's commitment to delivering great healthcare with more choices, better care, and lower costs for all Americans.

SEC. 2. Policy. It has been and will continue to be the policy of the United States to give Americans seeking healthcare more choice, lower costs, and better care and to ensure that Americans with pre-existing conditions can obtain the insurance of their choice at affordable rates.

SEC. 3. Giving Americans More Choice in Healthcare. The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall maintain and build upon existing actions to expand access to and options for affordable healthcare.

SEC. 4. Lowering Healthcare Costs for Americans. (a) The Secretary of Health and Human Services, in coordination with the Commissioner of Food and Drugs, shall maintain and build upon existing actions to expand access to affordable medicines, including accelerating the approvals of new generic and biosimilar drugs and facilitating the safe importation of affordable prescription drugs from abroad.

(b) The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall maintain and build upon existing actions to ensure consumers have access to meaningful price and quality information prior to the delivery of care.

(i) Recognizing that both chambers of the Congress have made substantial progress towards a solution to end surprise billing, the Secretary of Health and Human Services shall work with the Congress to reach a legislative solution by December 31, 2020.

(ii) In the event a legislative solution is not reached by December 31, 2020, the Secretary of Health and Human Services shall take administrative action to prevent a patient from receiving a bill for out-of-pocket expenses that the patient could not have reasonably foreseen

- (iii) Within 180 days of the date of this order [Sept. 24, 2020], the Secretary of Health and Human Services shall update the Medicare.gov Hospital Compare website to inform beneficiaries of hospital billing quality, including:
 - (A) whether the hospital is in compliance with the Hospital Price Transparency Final Rule, as amended (84 Fed. Reg. 65524), effective January 1, 2021;
 - (B) whether, upon discharge, the hospital provides patients with a receipt that includes a list of itemized services received during a hospital stay; and
- (C) how often the hospital pursues legal action against patients, including to garnish wages, to place a lien on a patient's home, or to withdraw money from a patient's income tax refund.
- (c) The Secretary of Health and Human Services, in coordination with the Administrator of CMS, shall maintain and build upon existing actions to reduce waste, fraud, and abuse in the healthcare system.
- SEC. 5. Providing Better Care to Americans. (a) The Secretary of Health and Human Services and the Secretary of Veterans Affairs shall maintain and build upon existing actions to improve quality in the delivery of care for veterans.
- (b) The Secretary of Health and Human Services shall continue to promote medical innovations to find novel and improved treatments for COVID-19, Alzheimer's disease, sickle cell disease, pediatric cancer, and other conditions threatening the well-being of Americans.
- SEC. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:
- (i) the authority granted by law to an executive department or agency, or the head thereof; or
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

 DONALD J. TRUMP.

Ex. Ord. No. 14009. Strengthening Medicaid and the Affordable Care Act

Ex. Ord. No. 14009, Jan. 28, 2021, 86 F.R. 7793, provided: By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. Policy. In the 10 years since its enactment, the [Patient Protection and] Affordable Care Act (ACA) [Pub. L. 111-148] has reduced the number of uninsured Americans by more than 20 million, extended critical consumer protections to more than 100 million people, and strengthened and improved the Nation's healthcare system. At the same time, millions of people who are potentially eligible for coverage under the ACA or other laws remain uninsured, and obtaining insurance benefits is more difficult than necessary. For these reasons, it is the policy of my Administration to protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American.

SEC. 2. Special Enrollment Period. The coronavirus disease 2019 (COVID-19) pandemic has triggered a historic public health and economic crisis. In January of 2020, as the COVID-19 pandemic was spreading, the Secretary of Health and Human Services declared a public health emergency. In March of 2020, the President declared a national emergency. Although almost a year has passed, the emergency continues—over 5 million Americans have contracted the disease in January 2021, and thousands are dying every week. Over 30 million Americans remain uninsured, preventing many from obtaining necessary health services and treatment. Black, Latino, and Native American persons are more

likely to be uninsured, and communities of color have been especially hard hit by both the COVID-19 pandemic and the economic downturn. In light of the exceptional circumstances caused by the ongoing COVID-19 pandemic, the Secretary of Health and Human Services shall consider establishing a Special Enrollment Period for uninsured and under-insured Americans to seek coverage through the Federally Facilitated Marketplace, pursuant to existing authorities, including sections 18031 and 18041 of title 42, United States Code, and section 155.420(d)(9) of title 45, Code of Federal Regulations, and consistent with applicable law.

- SEC. 3. Immediate Review of Agency Actions. (a) The Secretary of the Treasury, the Secretary of Labor, the Secretary of Health and Human Services, and the heads of all other executive departments and agencies with authorities and responsibilities related to Medicaid and the ACA (collectively, heads of agencies) shall, as soon as practicable, review all existing regulations, orders, guidance documents, policies, and any other similar agency actions (collectively, agency actions) to determine whether such agency actions are inconsistent with the policy set forth in section 1 of this order. As part of this review, the heads of agencies shall examine the following:
 - (i) policies or practices that may undermine protections for people with pre-existing conditions, including complications related to COVID-19, under the ACA:
 - (ii) demonstrations and waivers, as well as demonstration and waiver policies, that may reduce coverage under or otherwise undermine Medicaid or the ACA;
 - (iii) policies or practices that may undermine the Health Insurance Marketplace or the individual, small group, or large group markets for health insurance in the United States:
- ance in the United States; (iv) policies or practices that may present unnecessary barriers to individuals and families attempting to access Medicaid or ACA coverage, including for mid-year enrollment; and
- (v) policies or practices that may reduce the affordability of coverage or financial assistance for coverage, including for dependents.
- (b) Heads of agencies shall, as soon as practicable and as appropriate and consistent with applicable law, consider whether to suspend, revise, or rescind—and, as applicable, publish for notice and comment proposed rules suspending, revising, or rescinding—those agency actions identified as inconsistent with the policy set forth in section 1 of this order.
- (c) Heads of agencies shall, as soon as practicable and as appropriate and consistent with applicable law, consider whether to take any additional agency actions to more fully enforce the policy set forth in section 1 of this order.
- SEC. 4. Revocation of Certain Presidential Actions and Review of Associated Agency Actions. (a) Executive Order 13765 of January 20, 2017 (Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal) [formerly set out above], and Executive Order 13813 of October 12, 2017 (Promoting Healthcare Choice and Competition Across the United States) [formerly set out above], are revoked.
- (b) As part of the review required under section 3 of this order, heads of agencies shall identify existing agency actions related to or arising from Executive Orders 13765 and 13813. Heads of agencies shall, as soon as practicable, consider whether to suspend, revise, or rescind—and, as applicable, publish for notice and comment proposed rules suspending, revising, or rescinding—any such agency actions, as appropriate and consistent with applicable law and the policy set forth in section 1 of this order.
- SEC. 5. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:
- (i) the authority granted by law to an executive department or agency, or the head thereof; or (ii) the functions of the Director of the Office of
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

 J.R. BIDEN, JR.

§ 18002. Reinsurance for early retirees

(a) Administration

(1) In general

Not later than 90 days after March 23, 2010, the Secretary shall establish a temporary reinsurance program to provide reimbursement to participating employment-based plans for a portion of the cost of providing health insurance coverage to early retires (and to the eligible spouses, surviving spouses, and dependents of such retirees) during the period beginning on the date on which such program is established and ending on January 1, 2014.

(2) Reference

In this section:

(A) Health benefits

The term "health benefits" means medical, surgical, hospital, prescription drug, and such other benefits as shall be determined by the Secretary, whether self-funded, or delivered through the purchase of insurance or otherwise.

(B) Employment-based plan

The term "employment-based plan" means a group benefits plan providing health benefits that—

(i) is—

- (I) maintained by one or more current or former employers (including without limitation any State or local government or political subdivision thereof or any agency or instrumentality of any of the foregoing), employee organization, a voluntary employees' beneficiary association, or a committee or board of individuals appointed to administer such plan; or
- (II) a multiemployer plan (as defined in section 1002(37) of title 29); and
- (ii) provides health benefits to early retirees.

(C) Early retirees

The term "early retirees" means individuals who are age 55 and older but are not eligible for coverage under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], and who are not active employees of an employer maintaining, or currently contributing to, the employment-based plan or of any employer that has made substantial contributions to fund such plan.

(b) Participation

(1) Employment-based plan eligibility

A participating employment-based plan is an employment-based plan that—

(A) meets the requirements of paragraph (2) with respect to health benefits provided under the plan; and

(B) submits to the Secretary an application for participation in the program, at such time, in such manner, and containing such information as the Secretary shall require.

(2) Employment-based health benefits

An employment-based plan meets the requirements of this paragraph if the plan—

- (A) implements programs and procedures to generate cost-savings with respect to participants with chronic and high-cost conditions:
- (B) provides documentation of the actual cost of medical claims involved; and
 - (C) is certified by the Secretary.

(c) Payments

(1) Submission of claims

(A) In general

A participating employment-based plan shall submit claims for reimbursement to the Secretary which shall contain documentation of the actual costs of the items and services for which each claim is being submitted.

(B) Basis for claims

Claims submitted under subparagraph (A) shall be based on the actual amount expended by the participating employmentbased plan involved within the plan year for the health benefits provided to an early retiree or the spouse, surviving spouse, or dependent of such retiree. In determining the amount of a claim for purposes of this subsection, the participating employment-based plan shall take into account any negotiated price concessions (such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations) obtained by such plan with respect to such health benefit. For purposes of determining the amount of any such claim, the costs paid by the early retiree or the retiree's spouse, surviving spouse, or dependent in the form of deductibles, co-payments, or co-insurance shall be included in the amounts paid by the participating employment-based plan.

(2) Program payments

If the Secretary determines that a participating employment-based plan has submitted a valid claim under paragraph (1), the Secretary shall reimburse such plan for 80 percent of that portion of the costs attributable to such claim that exceed \$15,000, subject to the limits contained in paragraph (3).

(3) Limit

To be eligible for reimbursement under the program, a claim submitted by a participating employment-based plan shall not be less than \$15,000 nor greater than \$90,000. Such amounts shall be adjusted each fiscal year based on the percentage increase in the Medical Care Component of the Consumer Price Index for all urban consumers (rounded to the nearest multiple of \$1,000) for the year involved.

(4) Use of payments

Amounts paid to a participating employment-based plan under this subsection shall be