

STATEMENT OF

SEEMA VERMA

ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

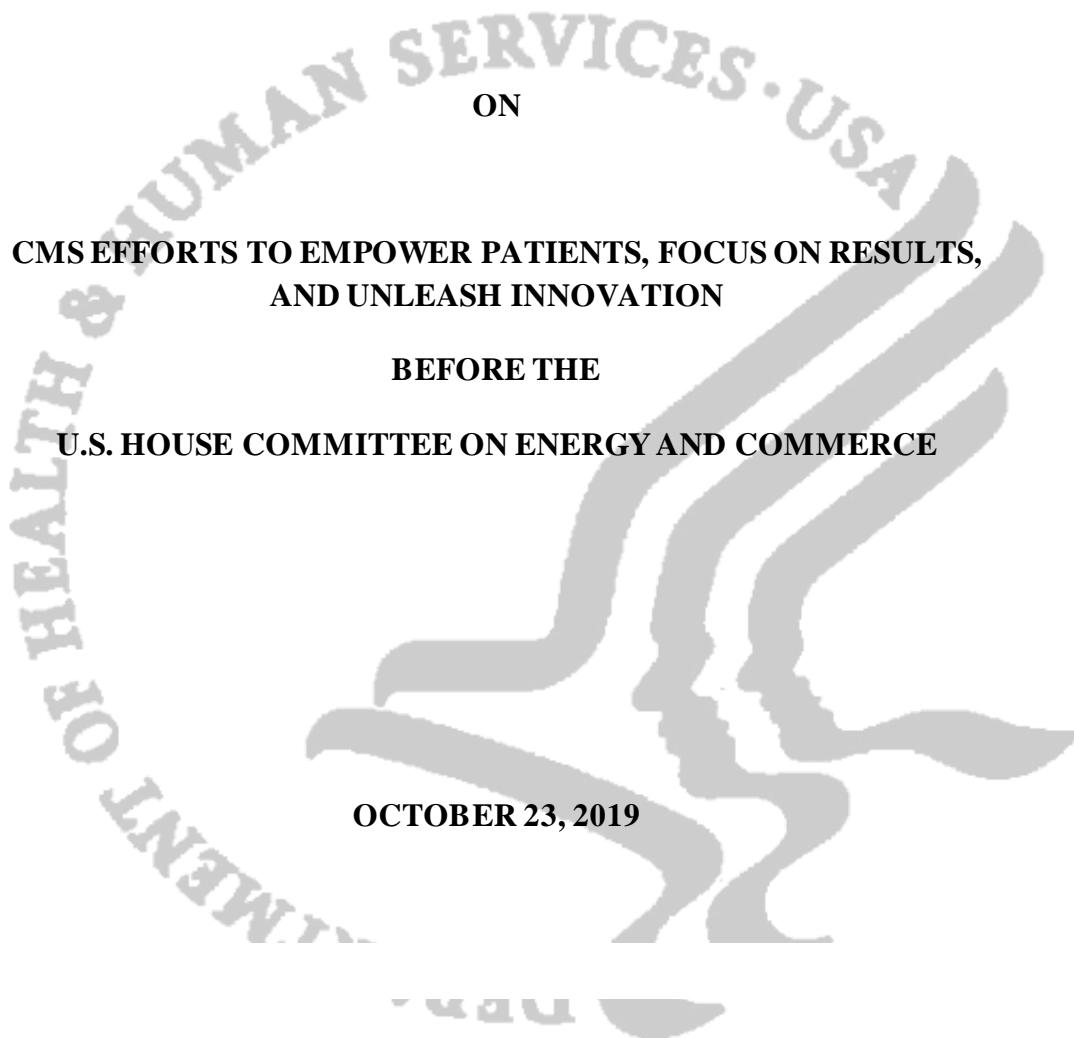
ON

**CMS EFFORTS TO EMPOWER PATIENTS, FOCUS ON RESULTS,
AND UNLEASH INNOVATION**

BEFORE THE

U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE

OCTOBER 23, 2019



Chair DeGette, Ranking Member Guthrie, and distinguished Members of the Subcommittee, thank you for the opportunity to discuss the record of success at the Centers for Medicare & Medicaid Services (CMS) under this Administration. I am excited to share with you the incredible progress we have already made and ongoing efforts to build upon this progress. At CMS, we are putting patients first. We are committed to focusing on results instead of process, empowering patients to make their own health care decisions, and unleashing innovation to tackle the unsustainable rising costs of health care.

I continue to work hand in hand with Secretary Azar, under the leadership of President Trump, to carry out the Department's top priorities. During my time at CMS, I have been able to meet with many Members of this Committee, and it is clear that we share many priorities, including bringing down the costs of prescription drugs, increasing choices for all Americans, and putting patients at the center of our health care policies. I look forward to continuing to work with you all on our shared interests.

For too long, government health insurance programs focused on regulating processes, overwhelming providers with burdensome rules and paperwork. CMS oversight plays a critical role in improving the quality of care and our requirements need to be developed and implemented in a way that streamlines regulations and allows providers to focus on their patients, not their paperwork.

Soon after I arrived at CMS, I began extensive listening sessions with experts in the U.S. health care system, along with the talented staff at CMS, on ways to transform the U.S. health care system. This resulted in a strategic vision with 16 core principles (*Figure 1*). Across our programs, we make sure our efforts are building upon this guiding vision.

Patients Over Paperwork

After becoming Administrator of CMS, one of my first actions was to launch the Patients Over Paperwork initiative, which is in accord with President Trump's Executive Order directing federal agencies to "cut the red tape" to reduce burdensome regulations.

Through Patients Over Paperwork, CMS established an internal process to evaluate and streamline regulations to reduce unnecessary burden and increase efficiencies. On a national listening tour, we gathered feedback from over 2,000 customers across 23 states and, using this

information, made common-sense changes to regulations and guidance. I have often heard that unnecessary regulations are increasing costs on providers, and they are losing time with patients as a result. Recently, CMS released the Omnibus Burden Reduction (Conditions of Participation) Final Rule, which is estimated to save providers 4.4 million hours previously spent on paperwork annually, with overall total provider savings projected to be approximately \$8 billion over the next 10 years, giving doctors more time to spend with their patients.¹

Physician Self-Referral Regulations

On October 9, CMS announced proposed changes to modernize and clarify the regulations that interpret the Physician Self-Referral Law (“the Stark Law”) by providing greater certainty for health care providers participating in value-based arrangements and providing coordinated care for patients. Specifically, the proposed rule would create new, regulatory exceptions to the Stark Law for value-based arrangements, other new exceptions, and guidance and clarification on existing requirements. This rule would create new opportunities for coordinated care across the industry, while maintaining strong safeguards to protect patients and programs from fraud and abuse.

¹ Final Rule available at: <https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and>

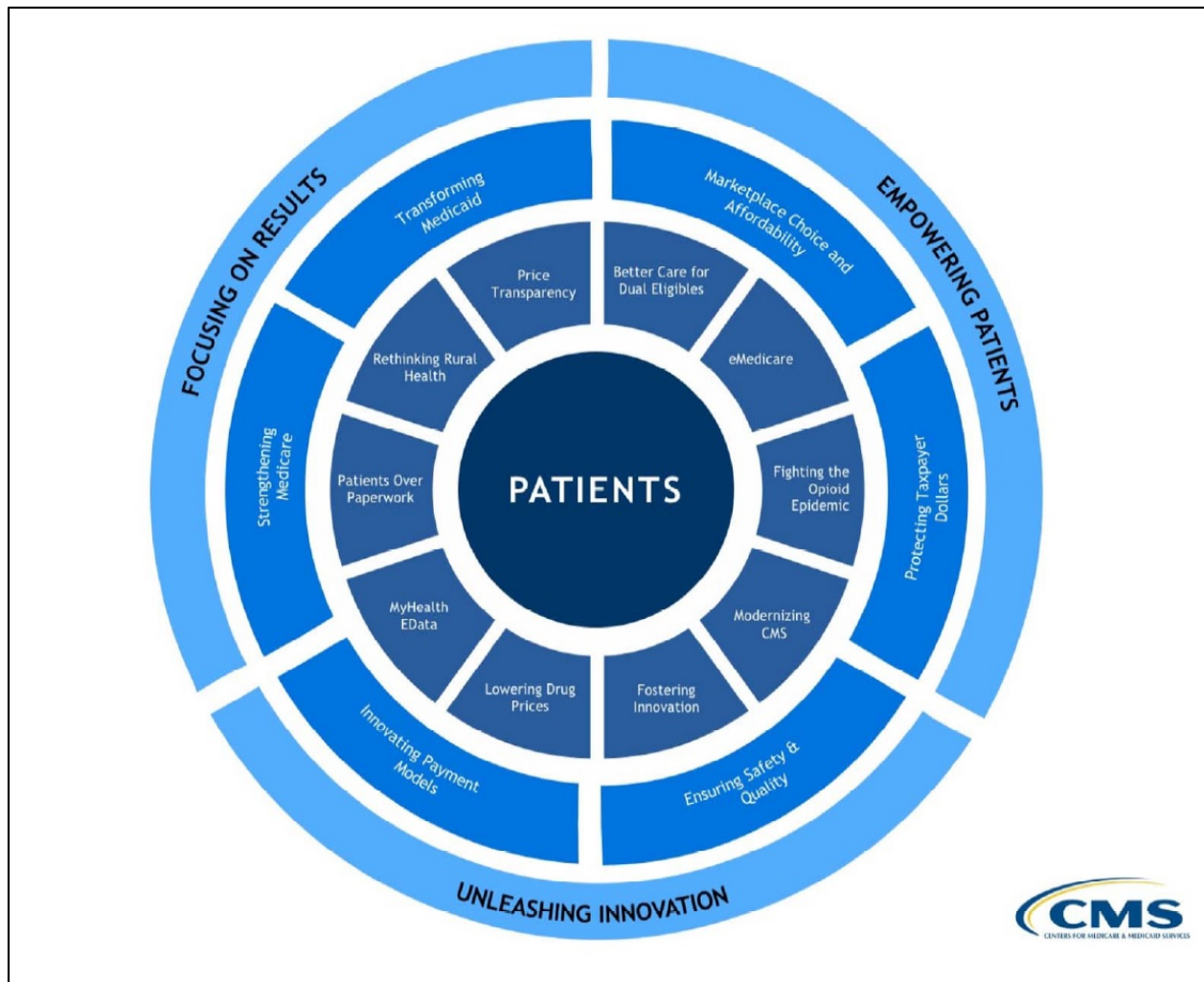


Figure 1

One of my priorities has also been to engage with our federal partners to leverage their expertise, coordinate efforts, and work together efficiently and effectively. One example is our work with the Government Accountability Office (GAO) and the Department of Health and Human Services’ Office of Inspector General (HHS-OIG). Since I arrived at the agency, I have placed a renewed focus on implementing their recommendations quickly and in a thoughtful manner, and I am proud to report that we have closed more than half of the backlog I inherited, and we look forward to continuing to work with our federal partners.

Lowering Drug Prices

This Administration has done more than any other in history to combat the rising costs of prescription drug prices, and CMS—along with our partners across the federal government—plays an important role in these efforts.

In May 2018, President Trump released the “American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,” which outlines four key strategies for addressing challenges in the American drug market: improved competition, better negotiation, incentives for lower list prices, and lower out-of-pocket costs.²

CMS is doing our part to execute that strategy, and we are already seeing results. Over the past three years, average part D basic premiums have decreased by 13.5 percent, and the projected average premium for plan year 2020 is the lowest it has been since 2013.

Improved Competition

Promoting innovation can lead to increased competition and lower costs. Many of the highest-cost medicines that Medicare pays for are biologics, and CMS is looking to increase the availability of biosimilars to encourage competition with biologics. By providing biosimilars with separate payment codes in Medicare Part B and lowering the amount of cost sharing paid for biosimilars by low-income beneficiaries in Medicare Part D, CMS has is encouraging companies to invest in bringing more biosimilars to market, which would increase competition and reduce costs.

CMS also finalized policies to increase competition among Medicare Advantage and Part D plans. Previously, when an issuer wanted to offer multiple plans in the same region, they had to prove that each plan was “meaningfully different,” in terms of enrollee out-of-pocket costs. This led to concerns that issuers were reducing the benefits of some plans to meet the meaningful difference requirements. We removed a requirement that certain Part D plans have to “meaningfully differ” from each other, increasing competition and making more plan options available for consumers.³

Strengthened Negotiation

Market-based negotiation is an important part of our efforts to lower drug prices. In May 2019, CMS finalized a policy that facilitates a Medicare Advantage plan’s ability to negotiate prices for Part B physician-administered medicines by allowing the plan to institute step therapy when

² “American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,”

<https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>

³ Final rule available at: <https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf>

beneficiaries first start on the medicines.⁴ By strengthening a plan’s ability to negotiate with prescription drug companies, plans can deliver better value for a patient’s medical needs.

Beginning in plan year 2020, plans can use indication-based formulary design and management as a new negotiation tool.⁵ Currently, when a plan covers a drug for one indication approved by the Food and Drug Administration (FDA), it has to cover all other FDA-approved indications. This can mean that a more appropriate or more affordable drug may not be covered because the plan has already been required to cover a therapeutic alternative. Allowing indication-based management will mean more tailored choices for patients and more power for Part D plans to bring down drug prices.

Incentivizing Lower List Prices through Increased Transparency

In the “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Out-of-Pocket Expenses” final rule issued in May 2019, CMS implemented a provision in the Know the Lowest Price Act of 2018 (P.L. 115-262) to codify the existing prohibition of “gag clauses.”⁶ Under the rule, Part D sponsors may not include “gag clauses” in contracts with pharmacies that prohibit or penalize pharmacists from disclosing to an enrollee if he or she would pay a lower price if they paid in cash rather than going through their insurance.

CMS has also advanced price transparency through the release of interactive, online dashboards that show spending per dosage unit on prescription drugs for the Medicare Part B and Part D programs as well as Medicaid.⁷ In March 2019, we updated these dashboards to include data through 2017. By 2021, we are requiring Part D plans to implement one or more real-time benefit tools that can provide prescribers with information through the prescriber’s electronic health record or e-prescribing system on a patient’s out-of-pocket costs for different prescription drugs, so they can discuss this information with patients at the time a prescription is written. Also effective January 1, 2021, CMS will require the Explanation of Benefits that Part D plans send to beneficiaries to include drug price increases and lower cost therapeutic alternatives. By

⁴ <https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf>

⁵ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf>

⁶ Final rule available at <https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>

⁷ CMS Dashboards available at: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/information-on-prescription-drugs/index.html>

empowering patients with more information on the cost of their prescription drugs at the point of prescribing, our rule will help ensure that pharmaceutical companies have to compete on the basis of price.

Modernizing Part D

Part D plans are the primary source of outpatient prescription drug coverage for 43.9 million Medicare beneficiaries, and in May 2019, CMS finalized policies that will give enrollees greater information on the cost of prescription drugs.

Earlier this year, we announced the testing of a new payment model and transformative updates to an existing model tested by the CMS Center for Medicare and Medicaid Innovation. Under the Medicare Part D Modernization Model—which begins in 2020—participating plans take a higher risk for spending once a beneficiary hits the catastrophic phase of Part D, creating new incentives for plans, patients, and providers to choose drugs with lower list prices.

More work must be done to lower prescription drug prices, and CMS is committed to doing our part. As the largest payer for health care in the U.S., Medicare policies can have a wide-reaching impact on health care spending, including prescription drug costs. That is why we are continuing to take steps to reduce prescription drug prices by unleashing innovation and empowering patients through increased transparency across the program.

Choice and Affordability on the Exchanges

We are empowering patients by addressing choice and affordability on the Exchanges. When I began my tenure as CMS Administrator, it was clear that the status quo was not working for far too many Americans, and the individual market was in a state of crisis because of the Patient Protection and Affordable Care Act (PPACA). In 2017, the average premium for plans offered through the Federally-facilitated Exchanges was more than double the average overall individual market premium recorded in 2013; issuers were dropping out of the individual market and rates were rapidly increasing.⁸

Under President Trump’s direction, the Administration acted to promote market stability, increase competition, and provide states additional tools and flexibility to meet the needs of their

⁸ <https://aspe.hhs.gov/system/files/pdf/256751/IndividualMarketPremiumChanges.pdf>

residents and promote more affordable coverage. For example, we finalized the Market Stabilization Rule in 2017 and later went on to finalize other rulemaking to give states new tools and flexibility in regulating their insurance markets. And as a result of increased efficiency, the Administration was able to reduce the user fee charged to issuers on the Federally-facilitated Exchanges and State-based Exchanges using the Federal Platform, a reduction that will be passed on to consumers in the form of lower premiums. But we know we still have more to do—premiums are too high, and unsubsidized consumers are fleeing the individual market—so we have not stopped focusing on encouraging innovation.

Promoting State Innovation

Section 1332 of the PPACA permits states to request waivers of certain rules under federal law to pursue innovative strategies for providing their residents with access to high quality, affordable health insurance.

Last October, the Administration issued new guidance to provide states with significant opportunities to chart a different course for their markets by expanding state flexibility through State Relief and Empowerment Waivers.⁹ Previous guidance significantly restricted the innovative approaches states could pursue and made it difficult for states to address the specific needs of their residents. The October 2018 guidance works within the existing law to empower states to address problems with their health insurance markets and increase coverage options for their residents while at the same time encouraging states to adopt innovative strategies to reduce future overall health care spending.

As of September 30, 2019, we have approved waivers in 13 states, and all but one of these waivers have been for states to create their own reinsurance programs. While some states are still working to implement their waiver, other states have estimated that these reinsurance programs have reduced average premiums 6 to 30 percent.

To be approved, waiver plans must meet the four statutory guardrails relating to comprehensiveness, affordability, coverage, and federal deficit neutrality. Importantly, the October 2018 guidance maintains the same strong protections for people with pre-existing conditions, and the law does not permit states to waive these protections, among other certain

⁹ <https://www.federalregister.gov/documents/2018/10/24/2018-23182/state-relief-and-empowerment-waivers>

PPACA requirements. This Administration remains firmly committed to maintaining protections for all Americans with pre-existing conditions, and we believe that states can develop waiver plans that improve upon the status quo while also providing necessary support for people with pre-existing or chronic conditions.

CMS has worked closely with states to unleash the potential of 1332 waivers. We have published numerous resources to help states design and submit applications for waivers that use the new flexibilities in the October 2018 guidance, including waiver concepts, application templates, and checklists.¹⁰ In May 2019, we issued a request for information to gather further feedback and ideas on how states could use the flexibilities provided by the new guidance to provide their residents with a variety of choices for affordable health insurance.¹¹

Marketplace Choice and Affordability

In Plan Year 2018, more than half of the counties across America had only one issuer offering individual market coverage on the Federal-facilitated Exchanges. For Plan Year 2019, this dropped to 35.3 percent, and we expect this trend to continue for Plan Year 2020.¹² While we work to increase consumer choice, we are committed to increasing transparency and empowering consumers to make informed health care decisions. Our initiatives put patients at the center of our policies and are aimed toward better serving those Americans who have been left behind and priced out of health insurance under the PPACA.

Short-Term, Limited-Duration Insurance

This Administration's efforts to expand access to affordable coverage, including short-term, limited-duration insurance, provide needed options, particularly for many middle-class Americans without employer-sponsored coverage who are not eligible for subsidies under the PPACA. Average individual market Exchange premiums in the 39 states that used HealthCare.gov increased by 105 percent from 2013 to 2017.¹³ Recent reports show a decline of

¹⁰ State application tools and resources available at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_state_Innovation_Waivers-.html#Application%20Tools%20and%20Resources

¹¹ <https://www.federalregister.gov/documents/2019/05/03/2019-09121/request-for-information-regarding-state-relief-and-empowerment-waivers>

¹² <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Final-2019-County-Coverage-Map.pdf>

¹³ CMS, "Individual Market Premium Changes: 2013 - 2017," May 23, 2017. <https://aspe.hhs.gov/system/files/pdf/256751/IndividualMarketPremiumChanges.pdf>

1.3 million unsubsidized people covered by individual market health insurance plans in 2017, and another 1.2 million fewer unsubsidized people in 2018.¹⁴ Many state individual markets experienced far more dramatic declines, with unsubsidized enrollment dropping by more than 40 percent in six states, including a 73 percent decline in Arizona.¹⁵

Short-term, limited-duration insurance has existed for decades—including after the enactment of the PPACA under the previous Administration—offering flexible and affordable coverage for American individuals and families. This Administration has expanded the availability of such insurance by extending its maximum initial contract term from less than 3 months to less than 12 months, and by permitting renewal of coverage under a policy for up to 36 months. At the same time, we instituted more robust notice requirements for informing consumers about the potential limits of this insurance than the previous Administration.¹⁶ Short-term, limited-duration options are more affordable, in part because they generally do not have to cover all the mandated benefits and meet all of the requirements imposed under the PPACA. The Congressional Budget Office predicted that, for consumers with low expected health care costs who are ineligible for a subsidy to purchase PPACA-compliant insurance on the Exchange, premiums may be as much as 60 percent lower than the lowest cost bronze plans, depending on an individual’s health characteristics.¹⁷

These plans are not for everyone, but for many Americans, access to short-term, limited-duration insurance may mean the difference between some insurance and no insurance at all. Ultimately,

¹⁴ CMS, “Trends in Subsidized and Unsubsidized Enrollment,” August 12, 2019, <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Trends-Subsidized-Unsubsidized-Enrollment-BY17-18.pdf>

¹⁵ Id.

¹⁶ 83 FR 38212 at 38224 (Aug. 3, 2018). Specifically, issuers of short-term, limited-duration insurance must prominently display the following notice in the contract and in any application materials provided in connection with enrollment in short-term, limited-duration insurance:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage.

¹⁷ https://www.cbo.gov/system/files/2019-01/54915-New_Rules_for_AHPs_STPs.pdf

we believe Americans should be allowed to make their own decisions when buying coverage that works for them and their families.

Expanding Health Coverage Options for Businesses

CMS, together with the Departments of Labor and the Treasury, issued a new policy that will provide employers, and American workers with more options for health insurance coverage. The Departments issued a final regulation that will expand the use of health reimbursement arrangements (HRAs). When employers have fully adjusted to the rule, it is estimated this expansion of HRAs will benefit approximately 800,000 employers, including small businesses, and more than 11 million employees and family members, including an estimated 800,000 Americans who were previously uninsured.

Under the rule, starting in January 2020, employers will be able to use individual coverage HRAs to provide their workers with tax-preferred funds to pay for the cost of health insurance coverage that workers purchase in the individual market, subject to certain conditions. These conditions include employer flexibility and guardrails meant to protect the individual market against adverse selection and include a notice requirement to ensure employees understand the benefit. Individual coverage HRAs are designed to give working Americans and their families greater control over their health care by providing an additional way for employers to finance health insurance for their employees.

Improving the Consumer Experience

Quality Rating System for Qualified Health Plans on Exchanges

In August 2019, we announced that—for the first time—CMS will require the display of the five-star Quality Rating System (or star ratings) nationwide for health plans offered on the Health Insurance Exchanges. Consumers will be able to compare health coverage choices using a five-star quality rating of each plan on Exchange websites, including HealthCare.gov, similar to other CMS star rating programs, such as the Hospital Compare and Nursing Home Compare websites and Medicare Advantage.

Enhanced Direct Enrollment

In November 2017, CMS launched a new enhanced direct enrollment pathway for consumers to enroll in health insurance coverage through the Federally-facilitated Exchanges. This pathway allows CMS to partner with the private sector to provide a more user-friendly and seamless

enrollment experience for consumers by allowing them to apply for and enroll in an Exchange plan directly through an approved issuer or web-broker without the need to be redirected to HealthCare.gov or contact the Exchange Call Center.

Our primary goal for Open Enrollment is to provide a seamless experience for HealthCare.gov consumers, ensuring that those who want Exchange coverage can enroll in a plan. For the last two Open Enrollment Periods, the Exchange Call Center has maintained a consumer satisfaction rating of over 90 percent, and we are committed to maintaining this success.

Strengthening Medicare

We welcome thousands of enrollees a day to the Medicare program, and we have to protect Medicare to make it sustainable for future generations. CMS is modernizing the program to increase choices and unleash private sector competition and innovation. This includes bringing Medicare into the 21st century by empowering beneficiaries with tools to meet modern consumer expectations and new types of benefits from private plans.

We have also worked to strengthen the Medicare program through our proposed rulemaking, including our efforts to increase patient choice and lower beneficiary out-of-pocket costs by making sure Medicare does not pay substantially more for visits at a hospital outpatient department than a clinic visit and expanding the services that can be paid for at ambulatory surgery centers; requiring hospitals to publish price information so beneficiaries are able to do an apples-to-apples comparison on the price of procedures across hospitals; adding new values for evaluation and management coding to increase Medicare payments to reward the time that doctors spend with patients; and implementing a new home infusion benefit for beneficiaries, increasing home-based care.

Enhancing Access to Value-Based Care and Payment Models

We are proud of our ongoing work to test innovative payment and service delivery models at the Center for Medicare and Medicaid Innovation (Innovation Center), which has introduced or updated 15 models and solicited comments on a potential Part B drug payment model.

Primary Care Transformation

Building on knowledge gained from previous models, I announced new CMS Center for Medicare and Medicaid Innovation payment models that aim to transform primary care and deliver better value for patients throughout the health care system. The CMS Primary Care Initiative will reduce administrative burdens and overall health care costs by providing primary care practices and other providers with five new payment options under two paths: Primary Care First and the Direct Contracting Model.

Kidney Care Transformation

Delivering on President Trump's Advancing American Kidney Health Executive Order, I announced new CMS Center for Medicare and Medicaid Innovation payment models that aim to transform kidney care so that patients with chronic kidney disease have access to high quality, coordinated care.¹⁸ And we released a proposed rule that would encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with End-Stage Renal Disease (ESRD) through the required ESRD Treatment Choices Model. These historic initiatives aim to improve the quality of life for kidney disease patients by preventing disease progression, encouraging transplants over dialysis, and, if dialysis is needed, promoting more convenient home-based dialysis to improve health outcomes.

Medicare Advantage Value-Based Insurance Design

Since January 2017, the Medicare Advantage Value-Based Insurance Design model has been testing innovative delivery approaches by allowing eligible Medicare Advantage plans to offer reduced cost sharing or additional supplemental benefits to enrollees with select chronic conditions. We have enhanced this model over the years, increasing both the number of participating plans and the number of chronic conditions they are allowed to focus on. In 2020, the model will be further expanded, to include the ability for plans to offer increased access to “non-primarily health related” items and services for enrollees, based on chronic condition or socioeconomic status. In 2021, the model will test allowing Medicare Advantage plans to offer Medicare's hospice benefit.

¹⁸ Advancing American Kidney Health Executive Order available at: <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>

Better Care for Dually Eligible Beneficiaries

Approximately 12 million Americans are simultaneously enrolled in both Medicaid and Medicare, relying on the state and federal governments to separately administer their health coverage. A lack of coordination can lead to fragmented care for individuals, misaligned incentives for payers and providers, and administrative inefficiencies and programmatic burdens for all. CMS and states spend over \$300 billion per year on the care of dually eligible individuals, yet still have room for improving health outcomes.¹⁹

In the 2020 Medicare Advantage and Part D final rule, we implemented provisions of the Bipartisan Budget Act of 2018, including policies that would create standards to better integrate Medicare Advantage dual eligible special needs plans, as well as a new Medicare-Medicaid integrated appeals process for beneficiaries in fully integrated plans.²⁰

We are also driving innovation in integrated care through CMS models and demonstrations. In December 2018, we sent a letter to state Medicaid directors highlighting ten opportunities to improve care for dually eligible individuals, and in April 2019, CMS opened up models to all states to participate in our Medicare-Medicaid Financial Alignment Initiative.

Fostering Innovation

CMS is committed to strengthening the Medicare program by ensuring that beneficiaries have access to new and potentially lifesaving treatments. In August of this year, CMS finalized an alternative new technology add-on payment pathway for medical devices that receive FDA marketing authorization and are part of the Breakthrough Devices Program. The FDA's Breakthrough Devices Program can help expedite the development and review of transformative new devices that meet the program criteria (e.g., provide for more effective treatment of serious or irreversibly debilitating diseases or conditions for which there are unmet medical needs). Under an expedited timeframe, it can be challenging for innovators to gather evidence demonstrating the device's "substantial clinical improvement," which is required to qualify for Medicare new technology add-on payments. To address this issue, CMS finalized an alternative new technology add-on payment pathway in which Breakthrough Devices would no longer be

¹⁹ https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NationalProfile_2012.pdf

²⁰ Final Rule available at: <https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>

required to demonstrate evidence of “substantial clinical improvement” to qualify for new technology add-on payments.

CMS also finalized an alternative new technology add-on payment pathway to improve access to new antimicrobial therapies specifically designed with the intent of addressing resistant infections. Drug-resistant infections are a public health crisis, affecting more than 2 million Americans each year and resulting in thousands of deaths annually.²¹ To help secure beneficiary access to antimicrobials, CMS will no longer require new antimicrobial drugs to meet the “substantial clinical improvement” criterion and will increase the maximum add-on payment from 50 percent to 75 percent.

Innovators are taking notice of the Trump Administration’s commitment to unleashing innovation and creating transparency for innovators to navigate complex government processes. We have seen the number of new technology add-on payment applications nearly double since 2016. Starting this October, we will be paying for a record-breaking 18 new technologies in total. These new technologies include some used in treatment for many types of cancer, including prostate and bladder cancers, and leukemia.

Chimeric Antigen Receptor T-cell Therapy

In August, CMS finalized a national coverage determination on coverage of FDA-approved Chimeric Antigen Receptor T-cell, or “CAR T-cell” therapy, which is a form of cancer treatment that uses a patient’s own genetically-modified immune cells to fight disease. As the first type of FDA-approved gene therapy, CAR T-cell therapies are an important scientific advancement in this promising new area of medicine and provide treatment options for some patients who had nowhere else to turn.

Protecting Taxpayer Dollars through Enhanced Medicare Program Integrity

CMS’s goal is to make sure our programs pay the right amount, to the right party, for the right beneficiary. The Trump Administration’s program integrity activities saved Medicare an estimated \$15.5 billion in FY2017, for an annual return on investment of \$10.8 to \$1. The 2018 Medicare fee-for-service improper payment rate was 8.12 percent, the lowest since 2010.

²¹ <https://www.cdc.gov/drugresistance/about.html>

New Medicare Cards

Our effort to issue new, more secure Medicare cards was an important step to protect beneficiaries from becoming victims of identity theft. For the first time, CMS now has the ability to terminate a Medicare number and issue a new number to a beneficiary if their Medicare number has been compromised, without impeding access to care. Beneficiaries have received a new card featuring a unique, randomly assigned Medicare number known as a Medicare Beneficiary Identifier to help protect against personal identity theft and fraud. While beneficiaries can continue to use their old card through the end of 2019, most Medicare patients are already successfully using their new cards.

Provider Screening and Enrollment

As the gateway to the Medicare program, provider screening and enrollment is the key to preventing fraudulent providers and suppliers from entering the program. In September 2019, CMS issued a final rule, “Program Integrity Enhancements to the Provider Enrollment Process,” that creates several new revocation and denial authorities to bolster CMS’s fraud-fighting capabilities. ²² Importantly, a new “affiliations” authority in the rule allows CMS to identify individuals and organizations that pose an undue risk of fraud, waste or abuse based on their relationships with other previously sanctioned entities.

Fraud Prevention System

One of the most important improvements CMS has made in its approach to program integrity over the last several years is our enhanced focus on prevention. CMS is using a variety of tools, including innovative data analytics, to keep fraudsters out of our programs and to uncover fraudulent schemes and trends before they drain the Trust Funds. In 2018, we announced a new version of the Fraud Prevention System (FPS) that runs predictive algorithms nationwide against Medicare fee-for-service claims on a continuous basis prior to payment in order to identify, prevent, and stop potentially fraudulent claims. The updated version modernizes system and user interface, improves model development time and performance measurement, and aggressively expands CMS’s program integrity capabilities. Based on the leads generated by the FPS during FY2017, HHS took administrative action against 949 providers and suppliers.

²² Final Rule available at: <https://federalregister.gov/d/2019-19208>

Coordination with Law Enforcement

We are committed to working with our partners in law enforcement to ensure the safety of beneficiaries and the protection of taxpayer dollars. CMS has begun a Major Case Coordination initiative that includes HHS-OIG and the Department of Justice. This initiative provides an opportunity for Medicare and Medicaid policy experts, law enforcement officials, clinicians, and CMS fraud investigators to collaborate before, during, and after the development of fraud leads.

CMS provides support to law enforcement as they take coordinated actions. In April 2019, the Department of Justice charged 24 defendants—including executives associated with five telemedicine companies, the owners of dozens of durable medical equipment companies, and three licensed medical professionals—for their alleged participation in health care fraud schemes involving more than \$1.2 billion in losses, as well as the execution of over 80 search warrants in 17 federal districts. CMS took swift action to suspend payments to 130 providers, likely preventing millions of additional dollars in losses. Every dollar saved is critical to the sustainability of our Medicare program and the needs of our beneficiaries. We look forward to continuing to work collaboratively with our partners at the Department of Justice and HHS-OIG to identify, investigate, and eliminate waste, fraud and abuse in our federal health care programs.

Transforming Medicaid

CMS is determined to continue our work ushering in a new era of state flexibility in the administration of the Medicaid program. Our vision for the future of Medicaid is to reset and restore the federal-state relationship, while modernizing the program to deliver better outcomes for the people it serves. I believe that fostering state innovation and pairing it with enhanced accountability and integrity will improve health outcomes for beneficiaries. This commitment will help states achieve the flexibility they need to promote the health and well-being of their most vulnerable citizens and help them rise out of poverty.

Providing States Flexibility to Design Their Medicaid Programs

CMS is offering states unprecedented flexibility to design health programs that meet the needs of their residents. We have taken action through a number of changes that make it easier than ever before for states to design innovative approaches to improving quality, lowering costs, and delivering value to our beneficiaries.

Empowering states to advance the next wave of innovative solutions to Medicaid's challenges is a key part of our vision for the future of the program. To make changes to their Medicaid program, a state must apply to CMS for either a state plan amendment (SPA) or one of several waivers authorized by statute. Changes can also be tested under a demonstration project.

Improving the State Plan Amendment and Section 1915 Waiver Review Process

Under my leadership, CMS adopted new strategies for more efficient processes for approval of SPAs and waiver and adjudication under Section 1915 of the Social Security Act, as well as implementing other long term process improvements.²³ CMS also introduced new procedures to prevent formation of a backlog of pending SPAs in instances where CMS has not received a state response to a formal request for additional information within 90 days of issuance.

A key goal of this initiative was to develop a process improvement strategy that enhanced the efficiency of the SPA and 1915 waiver review process by reducing the administrative burden and processing times for states. We collaborated closely with states and the National Association of Medicaid Directors to identify the issues that impact SPA and 1915 waiver processing and jointly developed a number of process improvement strategies, and this effort is resulting in more efficient and timely processing of SPA and 1915 waiver actions:

- Between calendar year 2016 and the first quarter of 2018, there was a 23 percent decrease in the median approval time for Medicaid SPAs.
- Eighty-four percent of Medicaid SPAs were approved within the first 90 day review period in the first quarter of 2018, a 20 percent increase over calendar year 2016.
- Between calendar year 2016 and the first quarter of 2018, median approval times for 1915(b) waivers decreased by 5 percent, 1915(c) renewal approval times decreased by 38 percent, and 1915(c) amendment approval times decreased by 54 percent.

Waivers and State Plan Amendments

Section 1115 of the Social Security Act gives the Secretary authority to approve experimental, pilot or demonstration projects that the Secretary finds are likely to assist in promoting the objectives of the Medicaid program. These demonstrations are intended to evaluate state-specific policy approaches to better serve Medicaid populations. I have invited states to bring forward their best, most innovative ideas, and this Administration has been responsive to state priorities

²³ See: <https://www.medicaid.gov/federal-policy-guidance/downloads/cib081618.pdf>

in a way that previous Administrations have not been, approving more than 30 groundbreaking Medicaid demonstration projects.

In 10 states, CMS approved reforms to test how Medicaid can be designed to improve health outcomes and lift individuals from poverty by connecting coverage to community engagement. On January 11, 2018, CMS sent a letter to state Medicaid directors designed to help states test whether Medicaid beneficiary health and well-being is improved through section 1115 demonstration projects that incentivize work and community engagement among adult Medicaid beneficiaries who are not elderly, pregnant, or eligible for Medicaid because of a disability.²⁴ Well-designed community engagement incentives have great potential to promote better mental, physical, and emotional health in furtherance of Medicaid program objectives, and we believe targeting certain health determinants, including productive work and community engagement, may improve health outcomes.

CMS has approved community engagement requirements only when a state's demonstration design includes important exemptions for people who are eligible for Medicaid disability or pregnancy. These demonstrations also include protections and exemptions for individuals determined by the state to be medically frail and individuals with acute medical conditions validated by a medical professional that would prevent them from complying with the requirements.

Under this Administration, CMS also took the historic step of approving the first ever 10-year extension under the Medicaid program demonstration extension to provide further coverage of family planning services in Mississippi, allowing the state to administer this longstanding Medicaid program without the need for routine approvals from CMS. Since then, CMS has approved a 10-year extension of waivers in three states. This action is one in a series of improvements CMS has instituted to reduce regulatory burdens, increase efficiency and promote transparency in the review and approval of waivers and SPAs.

Amplifying and Spurring Innovation on Maternal Mortality

Maternal mortality is a critical issue for Americans across the country, including those in rural areas. While rural communities share a disproportionate share of the negative outcomes, we have

²⁴ Letter available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf>

seen some rural communities find ways to improve outcomes. Since CMS pays for nearly half of the births in this country, we are working on ways to amplify the existing solutions that are working and exploring every lever at our disposal to improve maternal health outcomes. On June 12 of this year, CMS co-hosted a forum in collaboration with other federal and private partners looking at ways to improve maternal health access, quality, and outcomes for rural communities.

Protecting Taxpayer Dollars through Enhanced Medicaid Program Integrity

CMS takes seriously our responsibility to protect the fiscal health of our programs to ensure their sustainability for the future. We have seen a rapid increase in Medicaid spending in recent years, and with this growth comes an increasing and urgent responsibility to ensure sound stewardship and oversight of our program resources. While it is critical for states to have the necessary flexibility to design health programs that meet the needs of their residents, this groundbreaking new flexibility must be balanced with appropriate accountability.

Enhanced Medicaid Program Integrity Strategy

In June 2018, we released a Medicaid Program Integrity Strategy²⁵ to protect taxpayer dollars while enhancing the financial and programmatic integrity of the Medicaid program.²⁶ The strategy includes enhanced initiatives that will create greater transparency and accountability for Medicaid program integrity performance, including increased beneficiary eligibility oversight, stronger audit functions, and enhanced enforcement of state compliance with federal rules.

Since 2014, the Medicaid program has added more than 15 million new working-age, adult enrollees who primarily qualify as part of the PPACA's Medicaid expansion. Earlier this year, CMS released renewed guidance addressing concerns raised by recent audits conducted by the HHS-OIG and others that found that some states did not always determine Medicaid eligibility for the expansion population in accordance with federal and state requirements.²⁷ The guidance emphasizes CMS's expectations for states that may be considering or that have implemented the Medicaid expansion.

²⁵ Medicaid Program Integrity Strategy available here: <https://www.medicaid.gov/state-resource-center/downloads/program-integrity-strategy-factsheet.pdf>

²⁶ Medicaid Program Integrity Strategy available here: <https://www.medicaid.gov/state-resource-center/downloads/program-integrity-strategy-factsheet.pdf>

²⁷ <https://www.medicaid.gov/federal-policy-guidance/downloads/cib062019.pdf>

Medicaid and CHIP Scorecard

Ultimately, states and the federal government share mutual obligations and accountability for the integrity of the Medicaid program and the development, application, and improvement of program safeguards necessary to ensure proper and appropriate use of both federal and state dollars. In June 2018, CMS released the first ever CMS Medicaid and CHIP Scorecard, a central component of the Trump Administration's commitment to modernizing and strengthening transparency of the Medicaid and CHIP programs by allowing every American to evaluate how the Medicaid and CHIP programs are improving the lives of beneficiaries.²⁸

As part of CMS's overall commitment to robust and transparent public reporting of quality and administrative metrics that drive performance improvement, the agency is also working to enhance the functionality of the Scorecard as part of a comprehensive annual update expected to be published later this year.

Medicaid Provider Screening and Enrollment

While states are responsible for screening and enrolling Medicaid and CHIP providers, we have taken numerous steps to support and streamline state efforts. Several states already use CMS's data compare service, whereby the state can submit their provider enrollment file to CMS and CMS will match the state's file with Medicare's provider enrollment file. For providers that were already screened by Medicare, the state can rely on Medicare's screening results. CMS is working to expand this service to additional states, as well as looking at ways to screen Medicaid-only providers on behalf of states.

Unleashing Innovation

Health care innovation is driving better quality of care, enhanced access to care, increased efficiency, and lower healthcare costs. CMS is embracing technology and innovation by identifying and implementing effective payment models and removing regulatory barriers.

Modernizing Medicare

CMS is improving our online Medicare tools to meet the needs of a growing number of tech savvy beneficiaries. However, Medicare's traditional customer service options remain, and

²⁸ <https://www.medicaid.gov/state-overviews/scorecard/index.html>

beneficiaries will continue to have access to paper copies of the Medicare & You handbook and can access help over the phone using 1-800-MEDICARE.

eMedicare Initiative

CMS launched the eMedicare initiative in 2018 to deliver simple tools and information to current and future Medicare beneficiaries. Since I started this initiative, CMS has moved quickly to develop and implement numerous new tools to deliver personalized and customized information that Medicare beneficiaries prefer. Our “What’s Covered” app—available for download on most smart phones—gives users coverage information at their fingertips. To help beneficiaries make informed decisions about providers, we developed a price transparency tool that lets consumers compare Medicare payments and copayments of certain procedures performed in both hospital outpatient departments and ambulatory surgical centers, as well as an online service available on our website that lets people quickly see how different coverage choices will affect their estimated out-of-pocket costs. CMS also redesigned the Medicare.gov homepage and refreshed the personalized MyMedicare.gov portal to create a more seamless, easy to navigate, personalized online experience.

Medicare Plan Finder

As part of the eMedicare initiative, in August 2019 CMS released a modernized and redesigned Medicare Plan Finder for the first time in a decade. This tool allows users to shop and compare Medicare Advantage and Part D plans.²⁹ In 2018, approximately 25 percent of Medicare beneficiaries accessed Medicare Plan Finder on mobile devices, an increase of 40 percent from 2017.

The updated Medicare Plan Finder provides a personalized experience through an easy-to-read design that will help beneficiaries and caregivers learn about different options and select coverage that best meets their health needs. It includes new features that will make it easy for consumers to build a personal drug list to find Part D coverage that best meets their needs and compare coverage options on their smartphones and tablets. The new Plan Finder walks users through the Medicare Advantage and Part D enrollment process from start to finish and allows

²⁹ Medicare Plan Finder available at: <https://www.medicare.gov/plan-compare/>

people to view and compare many of the supplemental benefits that Medicare Advantage plans offer.

MyHealthEData

Last year, the Administration launched the MyHealthEData Initiative, a government-wide initiative spearheaded by the White House Office of American Innovation with participation from CMS and other federal agencies. A key goal of this initiative is to empower patients by giving them the ability to move from health plan to health plan and from provider to provider while having both their clinical and administrative information follow them. Patient data belongs to the patient; every American should be able, without special effort or advanced technical skills, to see, obtain, and use all electronically available information that is relevant to their health, care, and choice—of plans, providers, and specific treatment options.

Medicare Blue Button 2.0

In support of the MyHealthEData initiative, last year, CMS announced the launch of Blue Button 2.0, our first secure, standards-based Application Programming Interface (API) that allows Medicare beneficiaries to access and share their Medicare Part A, B and D claims data with applications and services that help them manage their health, in addition to sharing this information with their doctors or caregivers.

Through Blue Button 2.0, Medicare beneficiaries can select third party applications to access their data and use their electronic health information. There are now 30 Blue Button apps available, which are posted on Medicare.gov, and 2,000 developers are currently working on many more.

Ensuring the privacy and security of beneficiary data in Blue Button 2.0 is a top priority for CMS. Blue Button 2.0 applications use existing CMS standards for beneficiary authorization, and the applications must use clear and plain language to alert beneficiaries that they are sharing their data. Additionally, CMS offers a user-friendly dashboard on MyMedicare.gov that allows beneficiaries to turn off data access for any application at any time.

Interoperability and Patient Access Proposed Rule

On March 4, 2019, CMS issued a proposed rule on Interoperability and Patient Access to help move the health care market toward interoperability.³⁰ This proposed rule demonstrates our commitment to, the vision set out in the 21st Century Cures Act and Executive Order 13813 to improve access to and the quality of information for Americans to make informed health care decisions. The proposed rule would enable more patients to access their health information electronically by requiring the payers subject to this proposed rule to share health claims and clinical information electronically with their enrollees starting in 2020, much like CMS is already doing for Medicare beneficiaries through Blue Button 2.0. The proposed rule would also facilitate data exchange to allow greater access to patient health information—like event notifications at the moment of hospital admission, discharge or transfer—for health care providers and suppliers, including doctors and hospitals, regardless of where the patient may have previously received care. We are reviewing comments from the stakeholder community on these proposals as we prepare the final rule.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) included a requirement that eligible clinicians and hospitals demonstrate that they have not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of certified electronic health record technology. CMS implemented these policies through attestation requirements in our Promoting Interoperability Programs. We believe it would benefit patients and caregivers, to know if individual clinicians, hospitals, and critical access hospitals have submitted a “no” response to any of the three attestation statements regarding the prevention of information blocking. In our proposed rule, we propose including an indicator on the Physician Compare website for eligible clinicians participating in the Quality Payment Program, and to post information on a CMS website available to the public for eligible hospitals and critical access hospitals participating in the Medicare Promoting Interoperability Program, who submitted a “no” response to any of the three attestation statements regarding the prevention of information blocking.

³⁰ Proposed rule available at: <https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

Expanding Telehealth and Virtual Services

Telehealth services enable patients to become active members of the care continuum outside of a hospital setting and promotes long-term engagement between patients and practitioners.

Expanding telehealth services would improve care for patients across the country, particularly for those in rural areas that are characterized by great distances and a limited number of healthcare providers and specialty services. CMS is committed to supporting and furthering the use of telehealth services, and under policies finalized in 2018, Medicare patients receiving home dialysis are now able to receive their monthly clinical assessments via telehealth, and patients experiencing symptoms of an acute stroke will be able to receive telehealth services from mobile stroke units. In April 2019, CMS issued a final rule bringing an innovative telehealth benefit to Medicare Advantage, allowing private Medicare Advantage plans to include additional telehealth benefits for enrollees in bids for basic benefits starting in plan year 2020.³¹ We have also taken historic steps to expand vital services through the use of telecommunications technology. For the very first time, starting last January, Medicare now pays for virtual check-ins, remote evaluation of pre-recorded images and video, and virtual consultations between physicians to determine whether an office visit is warranted. For example, a patient could now connect with their doctor by phone or video chat to ask questions, or text a picture of a mole on their skin to a dermatologist for examination, and decide together whether an office visit is needed.

Rethinking Rural Health

Approximately 60 million Americans live in rural areas—including millions of Medicare and Medicaid beneficiaries. CMS recognizes the many obstacles that rural Americans face, including living in communities with disproportionately higher poverty rates, having more chronic conditions, being uninsured or underinsured, as well as experiencing a fragmented healthcare delivery system with an overworked and shrinking health workforce, and lacking access to specialty services. The Trump Administration has placed an unprecedented priority on improving the health of Americans living in rural areas, and last year, CMS furthered this commitment by introducing the agency's first Rural Health Strategy.

³¹ Final rule available at: <https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf>

Leveling the Playing Field for Rural Hospitals

Because of financial pressures and changing demographics, rural hospitals across the country have been closing, eliminating essential services, reorganizing, or transitioning to new types of facilities. In an effort to ensure that rural Americans have access to needed care, CMS finalized changes to the way we calculate the hospital wage index, which adjusts inpatient payment rates to account for local differences in hospital labor markets. Our new policy, issued in August of this year, temporarily addresses distortions in the wage index that may benefit struggling rural hospitals by better positioning them to attract and maintain a highly skilled workforce, strengthen competition, and lead to greater choice for patients in rural areas.

Developing a long-term sustainable strategy for improving rural health is a key priority for CMS. We are pushing ourselves to think more creatively about how to provide rural areas with the flexibility, resources, and innovative tools they need to transform their health care systems to deliver better quality and more accessible services.

Ensuring Safety and Quality in Nursing Homes

CMS is charged with ensuring that every nursing home serving Medicare and Medicaid beneficiaries is meeting federal requirements to keep its residents safe and provide high quality care, and we take this responsibility seriously. In April 2019, I announced a five-part approach that CMS is using to guide our work, including: strengthening oversight; enhancing enforcement; increasing transparency; improving quality; and putting patients over paperwork.

Strengthening Oversight

CMS works in partnership with State Survey Agencies (SSAs) to oversee nursing homes, since these agencies are generally also responsible for state licensure. The SSAs visit and survey every Medicare and Medicaid participating nursing home in the nation at least annually to ensure they are meeting CMS's health and safety requirements as well as state licensure requirements. To be effective, SSAs must be fair and consistent in applying CMS rules.

In recent years, we have found wide variation across SSAs in the identification of issues and the application of penalties. Residents deserve consistent nursing home quality, regardless of location, so CMS is revising our oversight of SSA performance. For example, CMS recently

streamlined the guidelines for determining Immediate Jeopardy used by surveyors.³² Information about these kinds of findings and associated enforcement actions are available on Nursing Home Compare.

Enhancing Enforcement

CMS is strengthening our enforcement of facility compliance with basic health and safety standards to ensure patient safety and quality care. As part of this effort, we're developing new ways to root out bad actors and repeat offenders.

CMS has long identified staffing as essential for quality care. CMS collects staffing data from nursing facilities through the payroll-based journal system based on payroll and other verifiable and auditable data, as required by law.

We are also taking steps to curb the inappropriate use of antipsychotic drugs in nursing homes through our work with the National Partnership to Improve Dementia Care in Nursing Homes (National Partnership). Between 2011 and the third quarter of 2018, our work with the National Partnership helped decrease the national prevalence of antipsychotic medication use among long-stay nursing home residents by 38.9 percent to a national prevalence of 14.6 percent. Additionally, in March, we announced enhanced oversight and began imposing stricter sanctions on the 1,500 nursing homes that have not improved their antipsychotic medication utilization rates for long-stay nursing home residents since 2011, or “late adopters.”³³

We are also committed to working with Congress to strengthen nursing home enforcement. In President Trump's FY2020 budget, we have asked Congress to provide us the authority to adjust the frequency of mandatory nursing home surveys so we can focus more time and resources on nursing homes that are poor performers and respond to complaints. The FY2020 Budget also requests a \$45 million increase from the previous year for Survey and Certification, which would enable CMS to continue to meet the statutory survey requirements while dealing with the increase in volume and severity of complaints, and rising survey costs.

³² CMS, QSO-19-109-ALL Revisions to Appendix Q, Guidance on Immediate Jeopardy, March 5, 2019. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-09-ALL.pdf>

³³ Announcement available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-07-Enhanced-Oversight-and-Enforcement-of-Non-Improving-Late-Adopters.pdf>

Increasing Transparency

CMS is empowering consumers, their families, and their caregivers by giving them the resources they need to make informed decisions, and key to our effort is our Nursing Home Compare website. In April 2019, we made improvements to the Nursing Home Compare website to strengthen this tool for consumers to compare quality between nursing homes. These improvements include revisions to the inspection process, enhancement of new staffing information, and implementation of new quality measures. Beginning on October 23, Nursing Home Compare will feature a new alert icon to identify nursing homes that have been cited for incidents of abuse, neglect, or exploitation.

Special Focus Facilities

When a survey finds a nursing home deficient in any way, the public has a right to know. That is why we have taken steps to empower residents and their families with more information on underperforming nursing homes that are participants or candidates of our Special Focus Facility (SFF) program. Nursing homes designated as an SFF are inspected by survey teams twice as frequently as other nursing homes.

Apart from providing increased oversight, CMS is making information regarding SFF participants and candidates available to consumers. We have published information on our methodology for selecting SFF participants and candidates online so consumers can know more about why a particular facility made the list. Each month, CMS provides a full list of SFF program participants on our website. In May 2019, we began publishing a list of candidates for the SFF program alongside the participants list. Consumers can easily identify an SFF participant on Nursing Home Compare because they are marked with a yellow caution symbol under a facility's "overall rating."

Improving Quality

CMS is actively keeping patients safe by helping nursing homes improve. We are unleashing our expertise in quality measurement to address serious quality issues like healthcare-associated infections, and we are looking at how we can better spend civil money penalty dollars on the most critical quality issues.

In addition to other enforcement remedies, CMS can fine nursing homes that do not comply with our requirements, and we recently launched an initiative to reinvest these civil money penalty

dollars in efforts to reduce adverse events, improve staffing quality and improve quality of care for residents with dementia.

Reducing Provider Burden and Placing Patients Over Paperwork

Ensuring access to high quality nursing home care is our priority, and we strive to hold facilities accountable for resident outcomes without overburdening providers with unnecessary paperwork. More regulation is not necessarily better regulation, nor does it always translate into better care or outcomes. High administrative costs can make it difficult for facilities to operate, and in rural America, a shuttered nursing home can present serious access to care problems. We want to make sure providers spend time caring for residents instead of completing unnecessary paperwork.

Our work will never stop. We are focused on ensuring America's nursing homes are keeping residents safe by rewarding quality and value, making outcomes transparent, and reducing unnecessary paperwork that detracts from patient care, and we will not hesitate to use every tool at our disposal to complete our mission.

Working with Congress

CMS greatly appreciates the important work of Congress as it endeavors to pass legislation that will support us in our mission to improve access, increase competition and unleash innovation

Legislative Proposals in the President's FY2020 Budget

President Trump's FY2020 Budget proposal includes numerous legislative ideas that would give CMS additional flexibility and resources that would complement administrative actions.

Protecting the health and safety of nursing home residents is one of the most important responsibilities CMS has. Today, there are over 15,000 nursing homes in America, but the allocated funds from which CMS funds all of our survey and certification activities, including oversight of state survey agencies, has remained flat for over five years. As mentioned above the President's FY2020 Budget requests an increase in funds for survey and certification activities and to allow CMS to more efficiently use these resources by adjusting statutorily required survey frequencies for top performing nursing homes.

A range of proposals for lowering drug prices are also included in the President's FY2020 Budget, including proposed reforms to CMS programs. These proposals are consistent with the four key strategies for addressing challenges in the American drug market outlined in the "American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," released in May 2018 including improved competition, better negotiation, incentives for lower list prices, and lower out-of-pocket costs.

The President's FY2020 Budget also includes a proposal that would strengthen CMS's ability to recoup Medicaid improper payments related to states' inaccurate beneficiary eligibility determinations. The proposal would give CMS authority to recover overpayments from states that receive federal resources for ineligible or misclassified beneficiaries. Specifically, for incorrect eligibility determinations, it would permit CMS to issue disallowances outside of the current improper payment rate measurement process and allow CMS and HHS-OIG to extrapolate findings on beneficiary eligibility to ensure federal recovery of overpayments.

CMS stands ready to work with Congress as it considers these and other proposals in the President's Budget.

Moving Forward

At CMS, we are putting patients first as we move forward with the strategic initiatives described in this testimony. This transformative vision for the agency drives our decision making every day, and we look forward to continuing to share updates on our progress with Congress.