Putting Patients First:

The Centers for Medicare & Medicaid Services' Record of Accomplishment from 2017-2020

PUTTING PATIENTS FIRST: CMS' RECORD OF SUCCESS FROM 2017-2020

Executive Summary

In 2017, under the leadership of Administrator Seema Verma, the Centers for Medicare & Medicaid Services (CMS) began a four-year transformation to ensure all Americans have access to quality and affordable healthcare, and to serve Medicare and Medicaid beneficiaries by putting patients first.

When we came into office, we inherited a quagmire of government policies that gave us a healthcare system marked by $200 billion in annual administrative costs, ever-growing insurance premiums and deductibles, and a bureaucratic system that forced doctors to spend more time on paperwork than with patients.

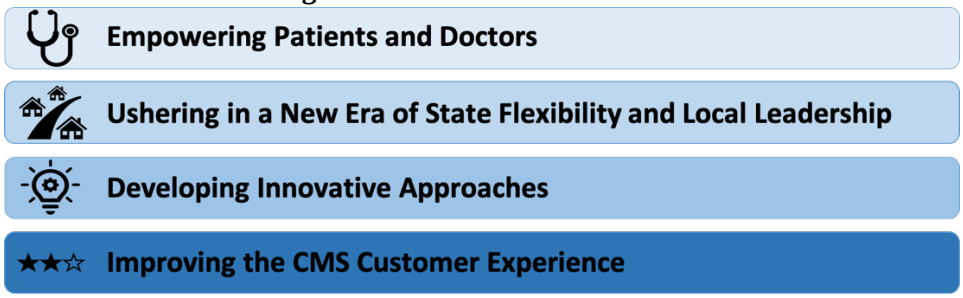
CMS reversed course and formulated a fresh agenda that would be sweeping in scope and consequential over the long term. Our goal was to give all Americans access to affordable care while improving or maintaining the world-class standard of quality they are used to receiving. We accomplished it by infusing free market principles at every turn, driving competition, empowering doctors and patients, and cutting regulation to unleash innovation. CMS devoted itself to protecting Medicare and Medicaid while making these vital safety net programs more sustainable over the long term.

These transformative accomplishments required CMS to think differently, take risks, and work together across divisions and components. CMS changed the way it does business on a day-to-day basis. We have undergone reorganizations that integrated the agency's regional offices and made us more productive and coordinated. We established new offices that helped us to stay in close contact with frontlines providers and other key stakeholders. We implemented strategic planning across the agency, leading to better alignment on our goals. These internal reforms were challenging, but they allowed CMS to lead the healthcare system, rather than to follow it – to set the agenda and drive change rather than react to it.

The result was worth the effort. CMS has reoriented the healthcare system to focus on patients and taken on long-standing problems that have festered for decades. The last four years at CMS have brought the healthcare system to a turning point.

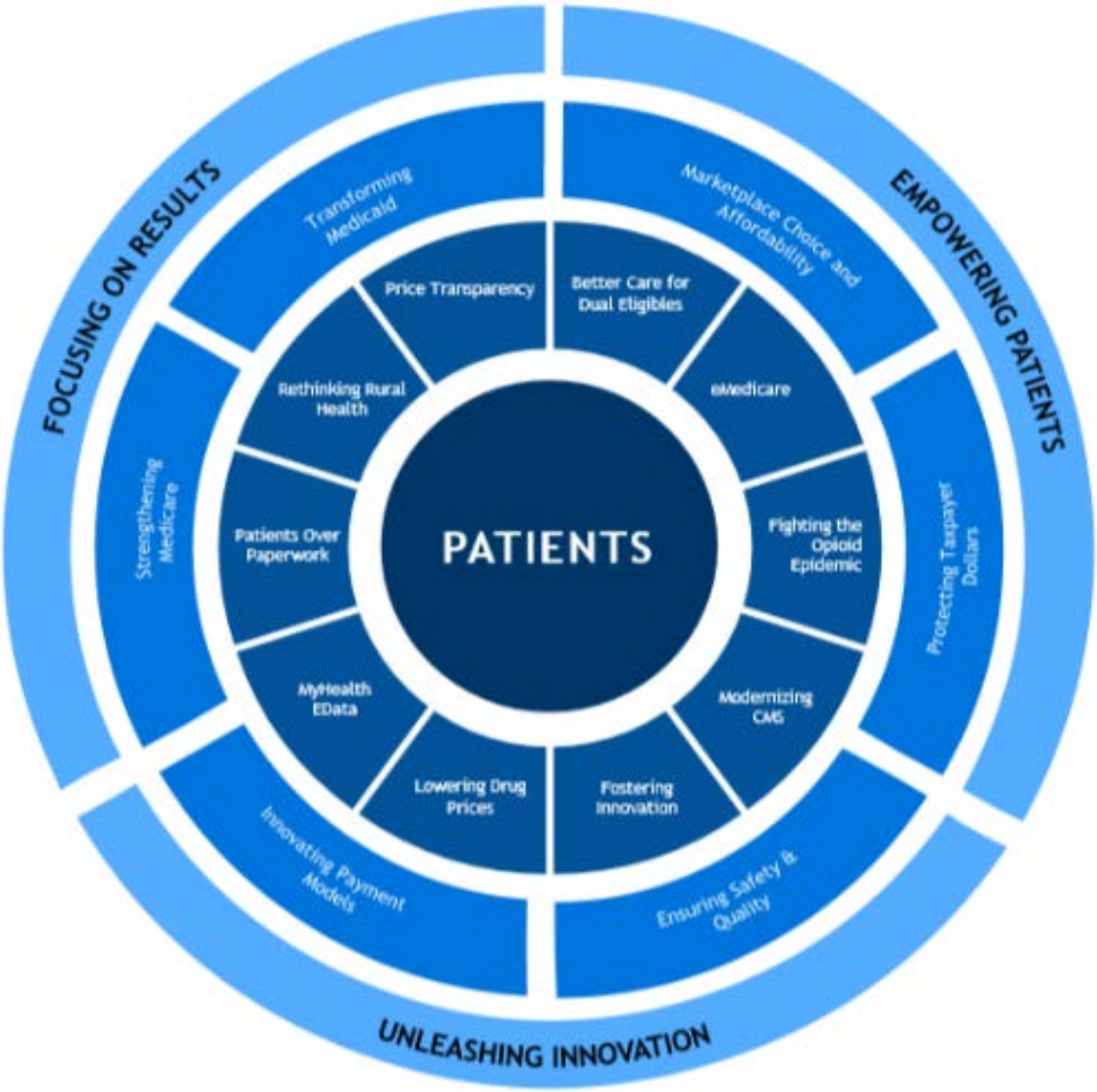
To attain our vision, CMS set out on a path to advance policies and projects that fell under four core goals:

Figure 1. CMS' Four Core Goals



To achieve these Four Core Goals, based on listening sessions with experts in the U.S. healthcare system and providers on the frontlines, CMS leadership developed a strategy to organize its work around 16 initiatives.

Figure 2. Strategic Initiatives Supporting CMS' Four Core Goals



This paper examines the accomplishments CMS achieved from March 2017 to January 2021. As discussed in this paper, "Accomplishments" means any action taken by the agency that furthered one of the Four Core Goals identified in 2017, such as major regulatory actions, changes in guidance, and streamlined processes and procedures, including the reorganization of CMS. The Executive Summary discusses the accomplishments CMS made towards the Four Core Goals, highlighting how progress with respect to those goals significantly contributed to the agency's ability to respond to the unprecedented COVID-19 PHE. The remainder of the paper is organized around the 16 strategic initiatives. At its center, this report is an evaluative document for agency staff and leadership to better understand the impacts of the policy decisions and document the changes that were made and to inform future decisions.

Core Goal: Empowering Patients and Doctors

PROBLEM: For years, providers have been faced with red tape and overly burdensome regulations, unnecessarily increasing their costs, and diverting their attention and resources away from patients. At the same time, these regulations have not improved access to information, like price transparency and quality information, patients need to make choices about their care.

VISION: Patients should be empowered to make informed decisions, without administrative red tape getting in their way or their clinician's way. To truly empower patients, CMS must unleash information so that – patients have access to quality, cost, and personal data. And as a result of this increased data availability and improved patient decision-making, there will be greater competition within the market.

Spotlight on COVID-19 Response

CMS' empowerment of doctors and patients allowed the agency to rapidly engage and respond to the needs of both clinicians and providers. Specifically, CMS:

- Reduced regulatory and reporting requirements during the PHE, allowing providers to focus on patient care and addressing the coronavirus crisis.
- Rapidly initiated stakeholder outreach to hear from providers about what they were experiencing and what they needed to best care for patients and facilitate sharing of best practices in the face of a public health emergency. This outreach included a series of weekly COVID-19-specific stakeholder calls, over 60 regular CMS Newsroom publications, and extensive outreach campaigns around regulatory actions.
- Quickly implemented and released regulations that removed barriers to COVID-19 testing in Medicare, Medicaid, CHIP, and private insurance; making COVID-19 tests free for Medicare beneficiaries and increasing funding to Medicare providers for testing of uninsured individuals.

SOLUTIONS:

To cut the red tape and put patients over paperwork, CMS:

- ✓ Finalized the Omnibus Burden Reduction Final Rule in 2019 to eliminate and reform outdated and burdensome Medicare regulations system-wide, including for hospitals, home health agencies, surgery centers, hospices, and transplant programs. In addition, the part of the rule on hospitals advances the overall quality and safety of patient care by modernizing and updating the requirements for hospitals to have active and facility-wide infection prevention and control and antibiotic stewardship programs that demonstrate adherence to nationally recognized guidelines for the surveillance, prevention, and control of hospital acquired infections and other infectious diseases, as well as best practices for the optimization of antibiotic use to reduce the development and transmission of antibiotic-resistant organisms.
- ✓ Finalized changes to modernize and clarify the regulations that interpret the Physician Self-Referral Law ("the Stark Law") by providing greater certainty for healthcare providers participating in value-based arrangements and providing coordinated care for patients. Specifically, the final rule creates new, regulatory exceptions to the Stark Law for value-based arrangements, other new exceptions, and guidance and clarification on existing requirements. It also creates new opportunities for coordinated care across the industry, while maintaining strong safeguards to protect patients and programs from fraud and abuse.

To empower patients to make choices about their care, CMS:

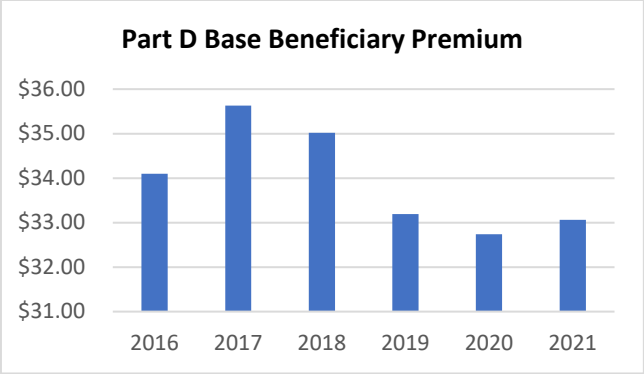
- ✓ Issued the Interoperability and Patient Access Final Rule to liberate data for 85 million beneficiaries served under Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and Qualified Health Plans in the federal marketplaces, enabling patients to access their data and share it with providers and health systems.

- ✓ Launched Blue Button 2.0, enabling beneficiaries to obtain access to their Medicare claims data and connect that data to applications, services, and research programs they trust. As a result of this improved data connectivity, over 70 organizations have created apps for beneficiaries to access information from their medical records in a portable, user-friendly manner.
- ✓ Redesigned the eight existing Compare websites and launched Care Compare, a website providing patients a single user-friendly interface to access cost, quality, volume of services, and other information to make informed decisions about their healthcare.
- ✓ Launched the Procedure Price Lookup Tool, allowing consumers to compare national average Medicare out-of-pocket costs, payments, and co-payments for procedures performed in hospital outpatient departments and ambulatory surgical centers, empowering consumers and clinicians to make an informed decision about the most appropriate care setting for a patient undergoing a given procedure.
- ✓ Implemented the Hospital Price Transparency Rule, requiring hospitals, for the first time, to share with patients easy-to-understand cost information on 300 "shoppable services," services that can be scheduled by a healthcare consumer in advance. These requirements are effective January 1, 2021.
- ✓ Required insurance companies to disclose out-of-pocket costs up front beginning in 2022. In 2023, health plans will be required to offer an online shopping tool that will allow consumers to see the negotiated rate between their provider and their plan, as well as a personalized estimate of their out-of-pocket cost for 500 of the most shoppable items and services.
- ✓ Required hospitals to post a freely available file of standard charges in a machine-readable format for all hospital services so that developers can create additional transparency tools for consumers.
- ✓ Through the Data at the Point of Care pilot, made a patient's Medicare Parts A, B and/or D claims data available to the clinician directly in his or her workflow so that the clinician can get a full snapshot of a patient's history and offer informed treatment solutions.
- ✓ Proposed requirements for the Marketplace to provide patients real-time, personalized access to cost sharing information, giving them the information they need to shop for the best deal, and to force providers to compete for their business on the basis of cost and quality.
- ✓ Made quality information available for the first time on all Exchange plans to help consumers compare their coverage choices.
- ✓ Finalized requirements for Part D plans to provide access to price estimator tools integrated into clinicians' electronic prescribing or electronic health record (EHR) system.
- ✓ Steadily increased options in Medicare Advantage (MA) and Part D plans, including by removing the requirement that certain Part D and MA plans had to "meaningfully differ" from one another.

IMPACT

- ❖ By rolling back regulations, yielded $6.6 billion and 42 million hours in savings for the medical community through 2021, allowing clinicians to engage more with patients and less with paperwork.
- ❖ Through the Meaningful Measures initiative, decreased nearly 20% of measures that were duplicative or overly burdensome to report, freeing providers to spend more time with patients.
- ❖ Increased the number of issuers participating in HealthCare.gov state marketplaces from 132 issuers in Payment Year (PY) 2018 to a total of 175 in PY 2020.
- ❖ Decreased the percent of counties with only one Federal Marketplace issuer available to consumers from 56% in PY18 to 26% in PY 2020.
- ❖ Decreased the average 2021 monthly MA premium by an estimated 34% since 2017, the lowest average since 2007.

- Decreased Part D basic plan 2020 premiums by 13.5% since 2017, saving beneficiaries about $1.9 billion in premium costs over that time, with enrollment increasing 12.2% during the same period.
- Decreased Marketplace benchmark plan premiums by 4% in 2019.



Core Goal: Ushering in a New Era of State Flexibility and Local Leadership

PROBLEM: The last several years have seen a rapid increase in Medicaid spending, from $456 billion in 2013 to an estimated $576 billion in 2016, driven by several factors, including Medicaid expansion. To maintain the financial viability and sustainability of their programs, states require increased flexibility to allow them to continue to provide innovative and fiscally responsible solutions to manage their programs.

VISION: States are in the best position to know their needs, their systems, and their residents. CMS' 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. By giving more flexibility to states, states are empowered to innovate and drive toward better health outcomes. In doing so, CMS also aims to increase states' accountability and ensure states are using funds appropriately to improve health outcomes for beneficiaries.

Spotlight on COVID-19 Response

CMS' empowerment of states to pursue COVID-19 responses tailored to their specific needs allowed the agency to prioritize federal focus on the highest-priority, cross-cutting issues during the public health emergency.
Specifically, CMS:

- Released Medicaid and CHIP Telehealth Toolkits to help states accelerate adoption of broader telehealth coverage policies.
- Created COVID-19 specific templates for 1115 waivers, 1135 waivers, 1915 Appendix K amendments, and Disaster State Plan Amendments, dramatically increasing the speed of state application and CMS processing for waivers related to the public health emergency.
- Rapidly approved:
  - 125 1135 Medicare waivers
  - 138 1915 Appendix K amendments
  - 121 Medicaid Disaster State Plan Amendments
  - 45 CHIP Disaster State Plan Amendments
  - 22 (14 of which were HCBS flexibilities that align with Appendix K) 1115 Demonstrations
  - 34 emergency information technology funding requests

SOLUTIONS:

To increase state flexibility, CMS:

- ✓ Collaborated closely with states and the National Association of Medicaid Directors to identify issues impacting Medicaid State Plan Amendment (SPA) and 1915 waiver processing, and jointly developed a number of process improvement strategies.
- ✓ Approved nine states' SPA proposals, since 2018, to negotiate supplemental rebate agreements, empowering these states to enter into value-based purchasing arrangements with drug manufacturers that link payment for prescription drugs to the value delivered to patients. These arrangements stand to reduce the use of utilization management practices that can impede patient access to drugs they need.
- ✓ Approved 31 state Medicaid demonstrations for Opioid Use Disorder (OUD)/Substance Use Disorder (SUD) treatment, approved five demonstrations for Serious Mental Illness, and awarded $48.4 million for state demonstration planning.
- ✓ Approved community engagement demonstrations to promote work and financial independence among Medicaid program beneficiaries in 13 states. Given court decisions affecting some states, and delayed implementation in others, none is active at this time.
- ✓ Issued guidance for the Healthy Adult Opportunity (HAO) which emphasized the concept of value-based care while granting states flexibility to administer and design their programs within a defined budget.
- ✓ Issued guidance on Value-Based Care (VBC), which seeks to capture the collective lessons learned from past experiences in payment reform and value-based care and provide a roadmap to states to accelerate adoption of value-based payment arrangements in Medicaid and other payers.

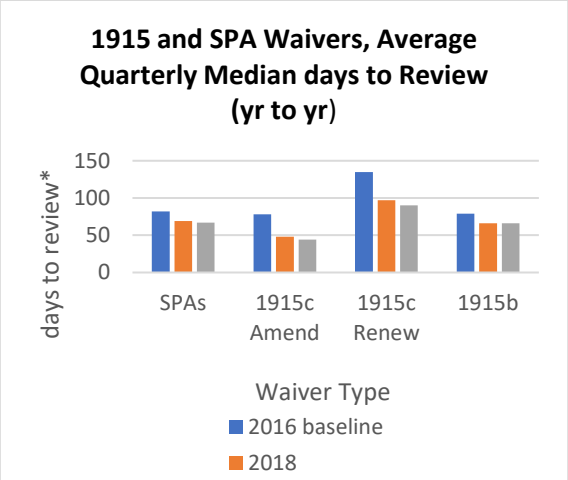
- ✓ Through the Medicaid Innovation Accelerator Program, provided direct technical assistance to help states design effective care management strategies for identifying Beneficiaries with Complex Care Needs target populations, by incorporating social determinants of health into targeting and program design activities.
- ✓ Issued guidance announcing policy changes that increase states' flexibility through Section 1332 State Relief and Empowerment Waivers on the Marketplaces to encourage innovative thinking on how states can take action to strengthen their markets.

To ensure state accountability in light of this increased flexibility, CMS:

- ✓ Implemented the Medicaid Program Integrity Strategy, which includes improved auditing and oversight strategies, optimized data reporting and collection under the Transformed Medicaid Statistical Information System (T-MSIS) and improved educational and technical assistance to reduce improper payments.
- ✓ Introduced the first-ever Medicaid and CHIP Scorecard, a public-facing federal dashboard of state health and administrative performance meant to achieve a better balance between appropriate federal oversight and state flexibility, ensure fiscal integrity, and promote accountability for the quality of care provided to program beneficiaries.

IMPACT:

- ❖ As a result of Medicaid SPA process improvements, reduced median total approval time for SPAs by 18% between 2016 and 2019, and increased the rate of SPAs approved within the first 90-day review period by 23% over the same period.
- ❖ As a result of Medicaid 1915 waiver process improvements, between 2016 and 2019 reduced: 1915(b) waiver median total approval times by 14%; 1915(c) renewal approval times by 41%; and 1915(c) amendment approval times by 37%.
- ❖ Improved the integrity of federal financial oversight of state spending by issuing over $1.1 billion in disallowances since January 2017 to begin recovery of improperly claimed federal funding.
- ❖ Recovered $9.7 billion in rate adjustments for the 2014-2016 period from the State of California.



* Days to review represents CMS days to review. State review and revision times are excluded.

Core Goal: Developing Innovative Approaches

PROBLEM: Taking innovations from the test bench to the bedside is a complex, costly, slow process; Innovators often comment about the myriad regulatory and procedural hurdles they face when bringing new technologies to healthcare. This is as true for healthcare delivery and payment as it is for medical innovation. When innovation is hampered by unnecessary regulatory hurdles, patients miss out on potentially beneficial care.

VISION: CMS set out to be a champion for innovation, fostering the development of new technologies to solve existing issues, and to foster innovative payment models. Healthcare innovation is driving better quality of care, enhanced access to care, increased efficiency, and lowered healthcare costs. CMS is embracing technology and innovation by identifying and implementing effective payment models and removing regulatory barriers.

SOLUTIONS:

To encourage innovation in healthcare delivery through value-based care, CMS:

- ✓ Redesigned the national Accountable Care Organization (ACO) program in which CMS pays for value as opposed to volume through new Pathways to Success policies that puts ACOs on a quicker path to taking on real financial risk in Medicare, resulting in a net per-beneficiary savings of $169 under the new policies in the 2019 performance year.
- ✓ Finalized the Kidney Care Choice Model, which provides incentives for kidney care providers to improve management of care for patients with late-stage chronic kidney disease to delay the onset of dialysis and encourage kidney transplant.
- ✓ Launched the Maternal Opioid Misuse Model to address care fragmentation, with a focus on value-based care tailored to the particular needs of pregnant and postpartum Medicaid beneficiaries with OUD and their infants, through state-driven transformation of the delivery system surrounding this population.
- ✓ Launched the Community Health Access and Rural Transformation Model, which aims to provide seed money to build the infrastructure rural communities need to transform their healthcare delivery systems, leveraging innovative financial arrangements and operational and regulatory flexibilities, to deliver high quality care at lower costs over the long term.

Spotlight on COVID-19 Response

During the public health emergency, CMS developed innovative approaches to care, which enhanced access, increased efficiency, and ensured availability of affordable care for beneficiaries.

Specifically, CMS:

- ❖ Expanded use of telehealth by adding 135 covered services to Medicare. Since mid-March, over 11 million beneficiaries have used telemedicine in traditional Medicare. Over 7 million of those received a common office visit via telemedicine.
- ❖ Fostered rapid sharing of best practices and accelerated adoption of telehealth in state programs, similar to what CMS provided under Medicare.
- ❖ Used existing programs, such as advanced payment programs, in innovative ways to ensure facilities had financial and other resources to care for patients.
- ❖ Employed flexibilities and innovative solutions to make sure consumers in the Marketplaces retained access to affordable care.
- ❖ Employed innovative payment discretion available during the PHE to ensure Medicare, Medicaid, and CHIP beneficiaries can receive COVID-19 tests without cost sharing, and required price transparency for test costs.
- ❖ Used administrative claims and encounter data to track changes in utilization of healthcare services related to COVID-19 in CMS programs, releasing data on COVID-19 including the Medicare Snapshot and the weekly nursing home data.
- ❖ Hospital at Home

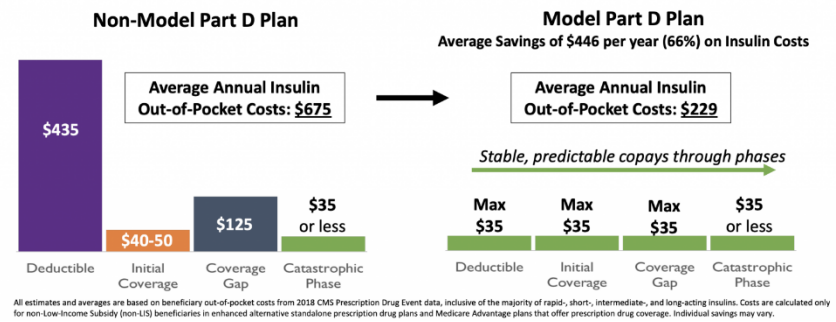
To foster innovations in care, CMS:

- ✓ Made it easier for Medicare Advantage plan sponsors to offer innovative benefits and services beyond traditional "healthcare," such as wheelchair ramps, meals, and rides to the doctor through Special Supplemental Benefits for the Chronically Ill.
- ✓ Launched the Part D Senior Savings Model to address high prescription drug costs and provide Medicare patients with new choices like Part D plans that offer insulin at an affordable and predictable cost – no more than $35 for a thirty-day supply.
- ✓ Provided additional payment incentives for new and innovative medical items and services provided in the hospital inpatient setting by increasing the New Technology Add-on Payment (NTAP) for approved technologies by 15%.
- ✓ Proposed changes to FFS Medicare to cover breakthrough technologies on the same day as FDA approval in the Medicare Coverage of Innovative Technologies Proposed Rule.
- ✓ Covered nationally innovative cancer treatments like CAR-T and diagnostic treatments like next generation sequencing for Medicare patients who need these technologies.
- ✓ Covered both on-label and off-label indications if the off-label use is supported by CMS-approved evidence for FDA-approved CAR T-cell therapies; finalized increased payment for this treatment to align with hospital outlays.
- ✓ Under the Medicare Coverage of Innovative Technology (MCIT) rule CMS will automatically cover new FDA-breakthrough devices) by creating a new coverage pathway that covers devices the same day as FDA approves the device for marketing.
- ✓ Encourage the development of safe and effective antimicrobial drug products that address unmet needs of patients with serious bacterial and fungal infections.
- ✓ Created a pilot of CMS Navigators for innovators to assist them in discussions with the Agency as part of a reorganization of the Center for Medicare to create a group focused on technology, coding and market-based pricing in original Medicare.
- ✓ Approved a record number of 24 new technology add-on payments (NTAP), which is an additional payment to hospitals for cases involving eligible new and relatively high cost technologies.

IMPACT:

- ❖ Estimated savings to Medicare totaling $2.9 billion over ten years as a result of the Pathways to Success policies for ACOs, with 37% of ACOs taking on risk.
- ❖ Starting in the 2021 plan year, beneficiaries who take insulin and enroll in a plan participating in the Part D Senior Savings Model, should save an average of $446 in annual out-of-pocket costs for insulin, or over 66%, relative to their average cost-sharing for insulin without the model. Projected federal savings of $250 million as a result of the Part D Senior Savings Model a five-year period, primarily due to pharmaceutical manufacturers paying additional coverage gap discounts under the model.

Comparison of Estimated Insulin Costs, Non-Model Part D Plan vs. Model Part D Plan


Non-Model Part D Plan
Average Annual Insulin Out-of-Pocket Costs: $675
$435
$40-50
$125
$35 or less
Deductible
Initial Coverage
Coverage Gap
Catastrophic Phase
Model Part D Plan
Average Savings of $446 per year (66%) on Insulin Costs
Average Annual Insulin Out-of-Pocket Costs: $229
Stable, predictable copays through phases
Max $35
Max $35
Max $35
$35 or less
Deductible
Initial Coverage
Coverage Gap
Catastrophic Phase
All estimates and averages are based on beneficiary out-of-pocket costs from 2018 CMS Prescription Drug Event data, inclusive of the majority of rapid-, short-, intermediate-, and long-acting insulins. Costs are calculated only for non-Low-Income Subsidy (non-LIS) beneficiaries in enhanced alternative standalone prescription drug plans and Medicare Advantage plans that offer prescription drug coverage. Individual savings may vary.

★★☆ Core Goal: Improving the CMS Customer Experience

PROBLEM: For too long, CMS operated in ways that was not always transparent or visible to beneficiaries and stakeholders. Therefore, beneficiaries were not always able actively engage with CMS on the actions that affected their ability to effectively access and understand CMS programs. As a result, the perspective of consumers, legislators, providers, and other stakeholders were missing from the policymaking process, which impacted the agency's ability to adapt programs to stakeholders needs.

VISION: CMS is committed to putting patients first. To do this, CMS should be organized to permanently embed in the CMS organizational structure a culture focused on reducing burden on providers and improving patient outcomes. CMS must prioritize the customer experience by improving communications and stakeholder feedback, modernizing customer focused tools, and removing barriers to engagement.

SOLUTIONS:

To enhance the customer experience, and realigned its structure for greater effectiveness, CMS:

- ✓ Adopted Objectives and Key Results (OKRs) as a tool to define ambitious and measureable goals that indicate progress against key strategic priorities.
- ✓ Integrated the work of CMS' 10 regional offices through alignment with the program centers to monitor and ensure consistent performance and policy guidance across the country.
- ✓ Created a unified home for all quality improvement and survey and enforcement activities, regardless of location, in the Center for Clinical Standards and Quality.
- ✓ Centralized all Medicaid & CHIP work, regardless of location, in the Center for Medicaid & CHIP Services, instituting centers of excellence focused on key programmatic and operational areas.
- ✓ Connected regional leadership directly to the Office of the Administrator by creating the Office of Program Operations and Local Engagement (OPOLE) with staff from all of CMS' regional offices. OPOLE conducts local outreach and education to strengthen customer understanding of national policy and Agency initiatives, improve customer experience by streamlining touchpoints for external partners and increases cohesion & integration within each regional location, across program areas, program centers and external partners.
- ✓ Created the Office of Strategy, Performance, and Results to support delivery of CMS' strategy from development through execution.

Spotlight on COVID-19 Response

CMS' improved customer experience across the Agency enabled CMS to effectively communicate with and inform providers in all settings to ensure they were working with the most up-to-date information. Specifically, CMS:

- ❖ Sought advice and recommendations from the Independent Coronavirus Commission on Safety and Quality in nursing homes, who CMS believes validated the actions CMS took to stem COVID impacts. CMS believes it implemented most of the commission's recommendations by the time the report was published.
- ❖ Acted upon customer feedback relayed through OPOLE about local needs and deployed the Quality Improvement Organizations (QIO) to address nursing home hotspots.
- ❖ Supported providers in the field by ensuring proper oversight and learning diffusion is occurring across the system, with a special emphasis on nursing infection control training. CMS made training readily available through the Quality, Safety & Education training portal.
- ❖ Supported the states as a partner by updating regulations to allow more flexibility for Medicaid home health services, for Medicaid lab services, and in the Basic Health Program.
- ❖ Held 100 small group listening sessions from March 2020 to December 2020 to gather feedback from stakeholders.
- ❖ Conducted over 750 stakeholder conference calls with a wide range of providers on a regular basis to hear and better understand their COVID related needs and concerns.

- ✓ Formalized CMS' burden reduction activities in the new Office of Burden Reduction and Health Informatics.
- ✓ Created a stakeholder engagement function within the Office of the Administrator to ensure better and consistent communication with external partners.

To enhance the customer experience for beneficiaries and caregivers, CMS:

- ✓ Launched the "What's Covered" app, which allows consumers to see whether Original Medicare covers a specific medical item or service, streamlining their experience.
- ✓ Redesigned the Medicare Plan Finder, including an improved, consumer-friendly front-end user interface (mobile optimized), improved data processing, improved performance and scalability, a consolidated plan preview, and expanded web chat capabilities. This redesign also includes a modern codebase and design, allowing for much faster improvement in response to user feedback.
- ✓ Adopted an online premium payment feature, far exceeding expectations, totaling 1.5 million electronic payments made (over $690 million), since its launch in February 2019. The changes to the online tools contributed to a customer satisfaction rating of over 96% on premium-related inquiries.

Case Study: COVID Response

As a result of the agency's progress the previous 3 years, CMS was ready to handle the most severe and unprecedented health crisis of our time: the COVID-19 pandemic. We turned for guidance to CMS's preexisting pandemic plan in the hopes that it might provide the broad outlines of an effective response. Unfortunately, the plan was inadequate to meet the severity of the emergency. Specifically, the plan lacked detailed records of what CMS had done and how previous public health threats, such as Ebola or the Swine flu, loomed. While those pandemics certainly never attained the scope and fury of our current one, we had hoped to draw on the experiences of our predecessors in crafting a response tailored to the unique characteristics of COVID-19. In response, CMS started from scratch and took immediate action to ensure that the healthcare system could meet the challenge of the public health emergency.

Leaning into the **new era of state flexibility and local leadership**, CMS proactively removed barriers to care so that states and local leaders could apply the best solutions for their unique situations. CMS identified and implemented temporary flexibilities through four Interim Final Rules with Comment Period (IFC), over a hundred Medicare waivers and over 600 Medicaid waivers, and scores of guidance to support the healthcare system in its response to the pandemic and ensure that beneficiaries got the care they needed.

CMS also used its enhanced data analytic capabilities to evaluate incoming data, flagging which changes to its programs might be worth keeping permanently. Finally, CMS coordinated information sharing across all areas of healthcare through weekly, and sometimes daily, communications, ensuring that healthcare providers and stakeholders had ready access to all available information in the format they needed.

Accomplishments

On January 31, 2020, the Department of Health and Human Services (HHS) declared a Public Health Emergency (PHE) in response to signals that the US would soon join other world countries in facing the novel coronavirus pandemic.[1] In February, CMS held numerous meetings, gathered critical data, and issued its first guidance on February 6, 2020, to prepare healthcare facilities for the Coronavirus threat.[2]Throughout the PHE, CMS has taken steps to increase flexibility and capacity of the healthcare system, accelerate the provision of diagnostic testing and care to those in need, expand benefits and increase funding for CMS program participants, and reduce administrative burden. Starting in the earliest days of the PHE, **CMS issued over 280 national and state-based waivers to provide relief when providers needed it most.** Throughout the PHE, CMS has joined in the front lines of the fight against COVID-19 caused by the novel coronavirus by using its many policy levers to ensure Americans continue to receive needed care and come out of this PHE stronger. Additionally, blanket waivers alleviate the need for providers to apply for individual 1135 waivers to seek relief from a CMS requirement and permit CMS to offer providers other flexibilities necessary for their community to make sure Americans continue to have access to the healthcare they need. **Since the PHE, CMS has issued over 130 nationwide Medicare waivers.** These waivers have expanded the available healthcare workforce, ensured local health systems have enough capacity to address COVID-19 patients, and increased telehealth to keep patients and providers at home.

To complement the immediate relief CMS offered with the blanket waivers, CMS issued several IFCs to suspend requirements that were deemed impediments to care during the unprecedented demands of the PHE. CMS continued to put patients over paperwork by giving providers, healthcare facilities, MA and Part D plans, and state Medicaid plans temporary relief from many reporting and audit requirements during the health emergency. **Rulemaking usually takes a full year from proposal to finalization for just one rule. In under a year since the PHE was declared on January 31, 2020, CMS has issued *four* IFCs with sweeping regulatory changes to ensure hospital capacity and access to care for beneficiaries and consumers.**

Additionally, through the 146 newly added services available via telehealth in Medicare, CMS ensured patients continued to receive critical care in the safest manner possible during the PHE.[3] Based on successes observed during this period, CMS is now proposing to permanently allow some of those services to be offered through telehealth, including home visits for the evaluation and management of a patient, while others will temporarily be extended, such as emergency department visits.[4]

Capturing Agency Actions in Improved Pandemic Plan and Document Repository

- The previous Agency Pandemic Plan was too simplistic, utilizing a template operational planning model, and did not consider the complex and tightly coupled systems in which CMS operations and policy decisions are made. A concerted effort was made to capture decisions, data, processes, partner engagements, and key actions that accurately reflect the nimbleness needed to successfully respond to the ongoing Pandemic and to ensure guidance is available for future public health emergencies. These decisions, data, processes, engagements, and key actions were combined into an actionable CMS Pandemic Plan.
- The COVID-19 Public Health Emergency Response Document Repository was developed to archive COVID-19 actions and artifacts, such as report templates and component processes, as a robust companion to the CMS Pandemic Plan.

Putting Patients First During the Public Health Emergency

- During the Public Health Emergency (PHE), CMS chose to put patients first by:
    - Temporarily eliminating certain paperwork requirements such as signature and proof of delivery for Part B drugs and durable medical equipment, and submission of certain forms for home oxygen therapy and infusion pumps.
    - Adjusting audit schedules for Medicare Advantage, Part D plans, and Programs of All-Inclusive Care for the Elderly (PACE) organizations to reflect how the pandemic has changed healthcare delivery.
    - Paused prior authorization for certain items and services, including durable medical equipment, during the public health emergency so providers can act quickly to provide time-sensitive care to beneficiaries.
    - Extending some current providers' certification to bill Medicare and Medicaid, waiving certain screening requirements for new providers, and expediting new applications to accelerate the process for new providers joining the Medicare program to ensure beneficiaries have access to treatment.
    - Waiving certain provisions in the physician self-referral law (also known as the "Stark Law") to permit activities such as allowing healthcare providers to support each other financially to avoid issues with continuity of operations, such as loss of staff or clinic closures, related to the COVID-19 emergency.

Augmenting the Healthcare Workforce

- Through the removal of certain barriers, health professionals, such as physicians, nurses, and other clinicians, can practice at the top of their licensure, allowing the healthcare system to effectively employ resources, such as through quick hiring from the local community or other states.[5] As a result of CMS' actions:
    - Nurse practitioners, in addition to physicians, may now perform some medical exams for Medicare patients at skilled nursing facilities.

- Occupational therapists from home health agencies can now perform initial assessments on certain homebound patients, allowing home health services to start sooner and freeing home-health nurses to do more direct patient care.
- Nurses are not required to conduct an onsite visit every two weeks for home health and hospice unless needed, and requirements for hospice nurses and nursing home aides to perform hospice aide in-service training are relaxed so they can spend more time with patients.
- Medical residents now have more flexibility to provide services under the direction of the teaching physician. Teaching physicians have the option of providing supervision virtually using audio/video communication technology.

- Nurse practitioners, clinical nurse specialists, and physician assistants can now provide home health services, as mandated by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. These practitioners can: (1) order home health services; (2) establish and periodically review a plan of care for home health patients; and (3) certify and re-certify that the patient is eligible for home health services. Previously, Medicare and Medicaid home health beneficiaries could only receive home health services with the certification of a physician. CMS issued waivers so that hospitals can use other practitioners, such as physician assistants and nurse practitioners, to the fullest extent possible, in accordance with a state's emergency preparedness or pandemic plan. These clinicians can perform services such as order tests and medications that may have previously required a physician's order where this is permitted under state law.
- CMS waived the requirements that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician. This allows CRNAs to function to the fullest extent allowed by the state, and frees up physicians from the supervisory requirement and expand the capacity of both CRNAs and physicians.
- CMS issued a blanket waiver to allow hospitals to provide benefits and support to their medical staffs, such as multiple daily meals, laundry service for personal clothing, or child care services while the physicians and other staff are at the hospital and engaging in activities that benefit the hospital and its patients.
- CMS allowed healthcare providers (clinicians, hospitals and other institutional providers, and suppliers) to enroll in Medicare temporarily to provide care during the public health emergency.
- CMS further expanded the types of clinical practitioners who may provide telehealth services to include physical therapists, occupational therapists, and speech language pathologists.[6]

Ensuring Access to Testing

- Americans now have access to testing for COVID-19, while ensuring they are not burdened by the costs of testing services. CMS has:
  - Mandated testing of nursing home staff for COVID 19 and required facilities to offer testing to residents, including when there is an indication that skilled nursing facilities may be experiencing new outbreaks.[7] Facilities that do not meet the testing requirement will be cited for non-compliance, including civil money penalties where the consequences of noncompliance affected residents.
  - Worked with HHS to provide point-of-care testing devices and test kits to every Medicare- and Medicaid-certified nursing homes allowed to conduct low-complexity testing.

- Provided relief to hospitals and other facilities in terms of reporting of quality measures to keep the focus on patient care.
- Adopted a policy to pay hospitals and practitioners to assess beneficiaries and collect laboratory samples for COVID-19 testing, including when it is the sole service rendered, during the PHE.
- Announced several additional Medicare coverage policies to expand testing, such as covering certain FDA approved serology (antibody) tests that beneficiaries may self-collect at home.
- Required all hospitals, laboratories, and nursing homes to report cases of infection to HHS. This reporting is needed to support broader surveillance of COVID-19.[8]
- Specified that each beneficiary may receive one COVID-19 test without the order of a physician or other health practitioner, but Medicare will require such an order for all further COVID-19 tests. This change helps ensure that beneficiaries receive appropriate medical attention if they need multiple tests, while also preventing billing for unnecessary tests.

Expanding Telehealth in Medicare

- Prior to the PHE, Medicare coverage for telehealth was limited to beneficiaries living in a rural area and generally traveling to a local medical facility to get telehealth services from a doctor in a remote location. **CMS announced additional temporary rules and waivers to expand the scope of Medicare telehealth services so that all beneficiaries living in both rural and urban settings can get care from their homes rather than unnecessarily traveling to their doctor's office. This led to immediate, dramatic increases in telehealth services.**
  - As a result of this policy response, CMS added 135 services where **emergency department visits, initial nursing facility and discharge visits, home visits, and physical, occupational, and speech therapy services could all be performed via telehealth,** maintaining the same Medicare payment rate as they would receive for in-person services.[9] CMS also:
    - Allowed telecommunications technologies to fulfill many face-to-face requirements for clinicians to see their patients in inpatient rehabilitation facilities, hospice and home health.
    - Expanded the types of healthcare providers that can provide Medicare telehealth services to include rural health clinics, federally qualified health clinics, physical therapists, occupational therapists, and others.
    - Expanded the scope of separately billable services that allow Medicare physicians to speak with patients virtually, by phone or video, rather than in person in order to prevent risk of infection.
    - Added payment for services of physicians and practitioners who treat patients over the phone to meet the needs of Medicare beneficiaries who may not have access to interactive audio/video technology.
    - Authorized Medicare Advantage plans to offer expanded telehealth coverage in urban and rural areas to meet the needs of their enrollees.

- In May, CMS published a comprehensive informational toolkit containing recommendations and best practices from a variety of resources including front-line healthcare providers, governors'

COVID-19 task forces, associations, and other organizations and experts **to facilitate the rapid sharing of best practices and accelerate adoption of telehealth in the states programs, similar to what CMS provided under Medicare**.[10]

- Since coverage and payment policies vary by state, the toolkit helped states identify policies that deter utilization of telehealth, so that states could make sure patients could receive needed care from the safety of their homes.
    - Additionally, **CMS authorized 89 of the newly covered visits to be furnished without meeting the video technology requirement**, allowing providers to reach patients on landline phones when audio-visual technology is unavailable.

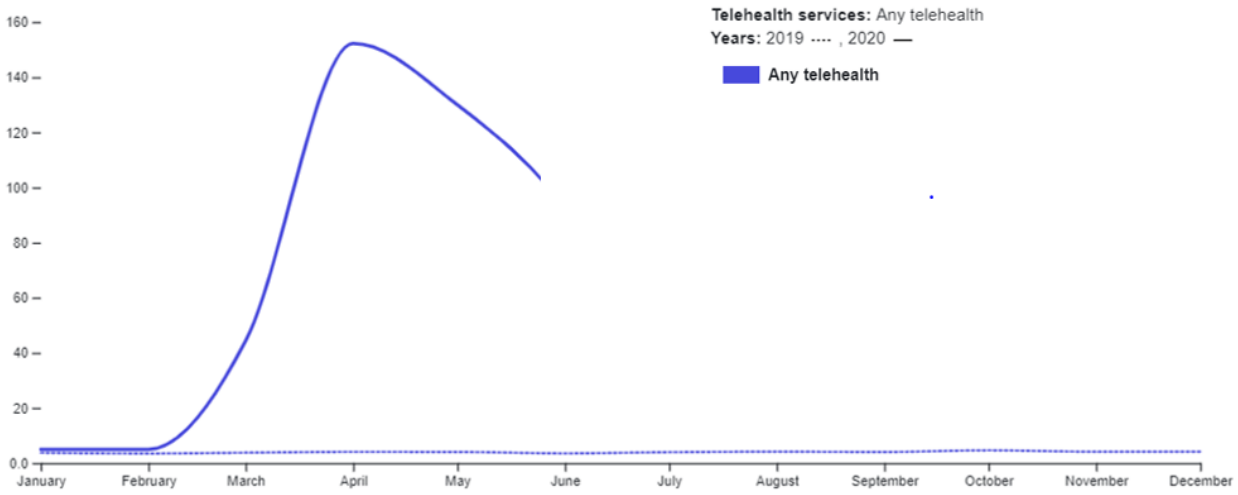
Figure 2. Counts of FFS Medicare Beneficiary Telemedicine Use, by Week

Time Period	Weekly Beneficiary Counts by Telemedicine Category				Weekly Telemedicine Totals		Weekly Evaluation and Management (E&M) beneficiaries	
	Telehealth	Audio-Only	Virtual Check-in	E-Visit	Telehealth or Audio-Only Total	All Telemedicine Total	Total	Via Telehealth
Weeks 1 - 11 (01/01 - 03/14) Weekly Average	**14,805**	**439**	**569**	**795**	**15,147**	**16,561**	**4,231,337**	**7,046**
Weeks 12 and after (03/15 - 09/12) Weekly Average	**877,971**	**268,101**	**28,870**	**7,816**	**1,106,218**	**1,139,152**	**3,384,294**	**585,026**
Week 12 - ending 03/21	198,915	93,463	40,760	6,444	283,770	325,441	2,647,125	128,831
Week 13 - ending 03/28	660,046	251,415	124,164	17,686	881,958	1,003,577	1,907,875	482,161
Week 14 - ending 04/04	1,013,855	361,723	121,525	21,813	1,328,654	1,450,686	1,917,244	739,628
Week 15 - ending 04/11	1,212,518	455,740	95,025	21,079	1,606,856	1,705,115	1,982,732	899,465
Week 16 - ending 04/18	1,322,131	497,558	80,306	19,935	1,751,858	1,836,806	2,158,741	978,608
Week 17 - ending 04/25	1,359,613	492,713	66,264	17,288	1,785,464	1,856,248	2,367,884	1,004,613
Week 18 - ending 05/02	1,355,844	458,998	50,219	14,234	1,751,270	1,806,612	2,548,524	971,185
Week 19 - ending 05/09	1,321,134	450,287	36,055	11,490	1,707,582	1,749,505	2,993,649	950,357
Week 20 - ending 05/16	1,260,463	432,130	29,061	10,026	1,630,975	1,665,911	3,217,746	893,127
Week 21 - ending 05/23	1,191,600	400,861	24,239	9,224	1,535,616	1,566,009	3,463,575	829,451
Week 22 - ending 05/30	933,456	295,240	17,551	6,992	1,186,529	1,209,471	2,987,280	618,989
Week 23 - ending 06/06	1,018,046	320,300	18,303	7,006	1,287,617	1,311,119	3,799,222	660,290
Week 24 - ending 06/13	941,953	295,075	15,970	6,261	1,189,861	1,210,974	3,981,381	617,487
Week 25 - ending 06/20	883,303	268,239	13,972	5,432	1,107,830	1,126,945	4,041,340	570,305
Week 26 - ending 06/27	847,511	244,972	13,270	5,360	1,051,974	1,070,277	3,937,769	542,913
Week 27 - ending 07/04	760,136	201,111	10,968	4,794	928,977	944,635	3,395,485	462,363
Week 28 - ending 07/11	834,675	226,984	11,748	5,004	1,024,795	1,041,199	3,903,234	529,224
Week 29 - ending 07/18	853,168	229,550	11,747	5,114	1,045,116	1,061,565	3,970,494	542,229
Week 30 - ending 07/25	831,539	220,129	11,401	4,677	1,016,033	1,031,787	3,856,048	524,800
Week 31 - ending 08/01	810,680	208,178	10,640	4,493	984,440	999,577	3,743,172	497,256
Week 32 - ending 08/08	783,058	202,540	10,551	4,119	952,083	966,560	3,737,009	492,162
Week 33 - ending 08/15	780,977	200,018	10,139	4,125	948,649	963,140	3,894,286	491,026
Week 34 - ending 08/22	765,774	194,397	9,764	3,937	929,063	943,060	3,936,564	477,303
Week 35 - ending 08/29	742,714	187,406	9,496	3,829	899,872	913,390	3,890,226	460,295
Week 36 - ending 09/05	724,351	178,933	8,740	3,675	873,667	886,446	3,880,800	439,252
Week 37 - ending 09/12	602,623	147,258	7,054	3,140	726,531	737,497	3,389,516	361,780
Week 38 - ending 09/19	703,658	175,468	8,290	3,600	849,990	862,427	4,106,937	431,780
Week 39 - ending 09/26	672,541	167,270	7,665	3,213	812,161	823,685	3,983,326	410,570
Week 40 - ending 10/03	637,581	155,442	7,082	2,984	768,322	779,094	3,813,660	383,451
Week 41 - ending 10/10	611,084	153,962	6,761	2,852	741,142	751,363	3,798,576	381,300
Week 42 - ending 10/17	582,150	143,761	6,250	2,478	704,101	713,577	3,661,693	363,612
TOTAL: 2020 through 2020-10-17	10,373,997	5,154,583	716,226	168,415	12,978,793	13,288,105	27,061,286	8,694,709
TOTAL: Before March 17	126,478	12,457	8,483	3,835	138,116	150,449	20,393,752	71,923
TOTAL: March 17 or after	10,345,713	5,149,172	709,635	165,723	12,953,782	13,260,994	24,915,844	8,675,154

Notes: Data are sourced from the CMS Integrated Data Repository using claims received by 11/13/2020. For recent dates of service, there has been very little for claims runout, and we expect to see changes in figures reported after each weekly data load.

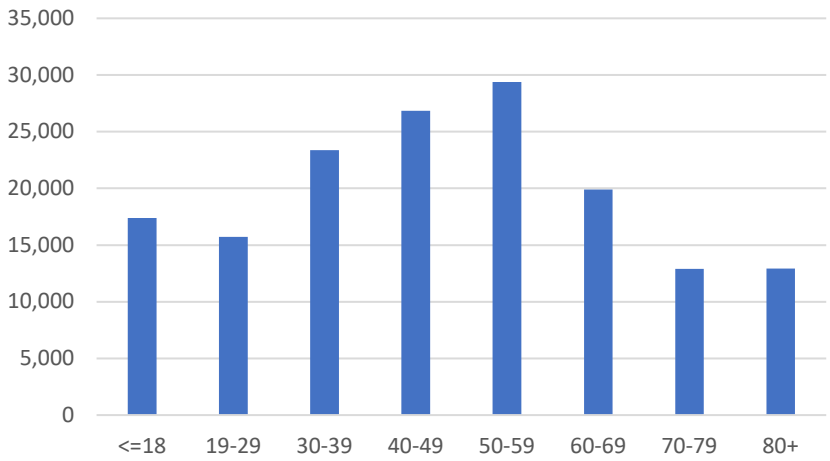
- As demonstrated in Figure 2, early CMS data have shown telehealth to be an effective way for patients to access healthcare safely during the COVID-19 pandemic, whether it is getting a prescription refilled, managing chronic conditions, or obtaining mental health counseling.[11]
    - **Before the PHE, approximately 15,000 beneficiaries in fee-for-service (FFS) Medicare received telemedicine in a week. Between mid-March and mid-August 2020, over 12.1 million Medicare beneficiaries (over 36 percent) of people with Medicare Fee-For-Service have received a telemedicine service. (Additional analyses on the types of telehealth services provided can be found in Appendix B.)**

Figure 3. Number of Telehealth visits in Medicaid and CHIP per 1,000 beneficiaries, by year[12]



Notes: These data are preliminary. Data are sourced from the T-MSIS Analytic Files v4 in AREMAC, using final action claims. They are based on August T-MSIS submissions with services through the end of July. Recent dates of service have very little time for claims runout and we expect large changes in the results after each monthly update. Data for recent months are likely to be adjusted upward due to claims lag. Because data for July are mostly incomplete, results are only presented through June.

Figure 4. Number of Telehealth visits in Medicaid and CHIP per 100,00 beneficiaries, by age, 2020[13]



Ensuring Healthcare Facilities Have Capacity and Financial Resources

- Given the strain placed on our healthcare system by an increase in hospitalizations, CMS ensured that local hospitals and health systems had the capacity to handle and safely provide care to patients, including outside a traditional hospital setting.
    - CMS addressed the urgent need to increase facility capacity to handle COVID-19 patients through an initiative called "Hospital Without Walls." Through Hospitals Without Walls, CMS is permitting non-hospital buildings and spaces to be used for patient care and quarantine sites, provided that the location is approved by the State; waiving the distance, market share, and bed requirements for the classification of Critical Access Hospitals; and waiving enforcement of some of the longstanding regulations for emergency departments to set up off-site screening locations for potentially COVID-positive patients.[14]
        - Additionally, CMS temporarily suspended enforcement on certain requirements, such as timing for providing medical records, as well as requirements that hospitals develop and maintain written policies for patients in isolation and other emergency procedures.
        - CMS' Hospitals Without Walls strategy also expanded access to care during the PHE. In Texas, when COVID-19 infection rates started to exponentially increase, access to hospital-based care was rapidly expanded through a rule change allowing ASCs and freestanding emergency centers to enroll as hospitals.
        - **As a result, 116 facilities were enrolled as hospitals, greatly expanding the capacity for Texas to respond to its burgeoning healthcare needs.**
    - In November 2020, CMS announced an update to add more regulatory flexibility, clarifying that participating ambulatory surgical centers (ASCs) need only provide 24-hour nursing services when there is actually one or more patient receiving care onsite. The program change provides ASCs enrolled as hospitals the ability to flex up their staffing when needed and provide an important relief valve in communities experiencing hospital capacity constraints, while not mandating nurses be present when no patients are in the ASC. CMS expects this flexibility will allow these and additional ASCs enrolled as hospitals to serve as an added access point that will allow communities to maintain surgical capacity and other life-saving non-COVID-19, like cancer surgeries. Allowing these types of treatments to occur in designated ASCs enrolled as hospitals while hospitals are managing any surges of COVID-19 would allow vulnerable patients to receive this needed care in settings without known COVID-19 cases.[15]
        - Additionally, building upon the **Hospital without Walls initiative**, CMS launched the **Acute Hospital Care at Home** program, which expanded flexibility for hospitals to provide certain healthcare services outside of the traditional hospital setting. Specifically, this program gives hospitals the ability to treat eligible patients in their own homes. Hospitals that participate will be required to implement appropriate screening protocols to determine if patients are eligible and a registered nurse will evaluate each patient daily, with two in-person visits either by a registered nurse or mobile integrated health paramedics based on the patient's care plan. Importantly, to ensure patient safety, this is not a blanket waiver – it must be requested and granted following a thorough review. Facilities interested in participating will also having certain reporting requirements that will assure patients we are closely monitoring this program. **As**

of January 7, 2021, CMS has approved 63 hospitals to participate in the program in 21 states across the nation.

- The COVID-19 PHE has required many healthcare facilities, most notably hospitals, to suspend normal operations and realign resources to fight the ongoing pandemic. Some states issued specific orders affecting the type of care that could be provided under stay-at-home orders, which forced hospitals to cease income-generating services upon which hospitals rely.
- CMS recognized the difficulties these facilities were facing and took action:
    - In late March 2020, CMS expanded the Accelerated and Advance Payment Program to a broader group of Medicare Part A providers and Part B suppliers, providing an immediate avenue for financial relief.
    - CMS further adjusted the Accelerated and Advanced Payment programs to align with additional funding sources provided through the CARES Act.[16]
    - To ensure hospitals had funds to keep up the fight, **CMS delivered over $107 billion to healthcare providers** through the Accelerated and Advance Payments Program.[17]
    - When it became evident that providers and suppliers would need more time to repay these loans, CMS worked with Congress to establish new repayment terms. The Continuing Appropriations Act of 2021 extended the period before repayment begins and the period before the balance must be repaid in full, reduced the recoupment percentage, and lowered the interest rate on any remaining balance.

Figure 5. CMS Accelerated and Advanced Payments Programs Payments During the PHE

Payment Type	Providers/Suppliers Paid	Dollars Paid	Trust Fund Impact
Accelerated Payments – Part A	22,757	$98.8 billion	$67.2 billion
Advance Payments – Part B	28, 336	$8.5 billion	$40.1 billion
TOTAL	**51,093**	**$107.3 billion**	**$107.3 billion**

Providing State Flexibility to Medicaid

- The President's declaration of a National Emergency on March 13, 2020, enabled CMS to grant state and territorial Medicaid agencies a wide range of flexibilities under multiple authorities to best meet their populations' needs locally.
    - States can request approval to allow providers to give care in alternative settings and waive prior authorization requirements. States could also enhance provider payment rates, waiver cost sharing, enhance or add critical benefits and adopt a number of other flexibilities so that the state could effectively respond to the pandemic. To streamline the process, CMS developed tools and checklists to speed state applications and approvals. Since the beginning of the PHE, and as of September 30, CMS received over 620 such requests and provided decisions on greater than 90% (~570) of states' requests.
    - Additionally, CMS has:

- Approved Medicaid emergency waivers (section 1135 waivers) for all 50 states as well as the District of Columbia, Puerto Rico, U.S. Virgin Islands and the Commonwealth of the Northern Mariana Islands.
- Permitted state Medicaid programs to pay providers from other states for care delivered during the public health emergency, increasing the number of practitioners available to serve beneficiaries.
- Allowed states to enroll eligible beneficiaries more quickly in programs that care for the elderly and people with disabilities, and to make changes to state rules to enhance access and delivery of services for vulnerable populations in home and community-based settings.
- Approved emergency information technology funding for certain states to enhance the systems that support Medicaid healthcare providers, patients, and state staff to ensure they have the resources they need to address the crisis.
- Fostered acceleration of broader telehealth coverage policies and payment by issuing new guidance on telehealth opportunities, outlining ways that states can remove barriers to telehealth, and rapidly approving state requests for emergency waivers and funding.
- Developed a toolkit to expedite the application and approval of Medicaid waivers and State Plan Amendments in order to approve new state requests in record time.
- Updated regulations to allow more flexibility for Medicaid home health services, for Medicaid lab services, and in the Basic Health Program.
- Provided guidance to states on flexibilities available to increase reimbursement for nursing facilities that implement specific infection control practices, such as designating a quarantine or isolation wing for COVID-19 patients.
- Issued a call to action for states, providers, and communities to address the urgent need of children on Medicaid forgoing important preventative care and screenings during the public health emergency.

Quickly Deploying Resources to Address Outbreaks in Nursing Homes

- From the beginning of the pandemic, CMS has made data-driven decisions to protect nursing home residents and employees from COVID-19. CMS has:

- Provided guidance, recommendations and training:
    - Provided infection control 46 new guidance documents to help the nation's healthcare facilities prepare for the COVID-19 threat, including procedures for screening and the use of personal protective equipment (PPE), with 9 specific to nursing homes.
    - Hosted biweekly calls and office hours with nursing homes, home health/hospice, nurses, and dialysis facilities, to provide ongoing direct assistance.
    - Released a toolkit with recommendations and best practices to address the specific challenges facing nursing homes as they combat COVID-19. CMS updates the toolkit regularly.
    - Created and published a video as part of the Department of Health and Human Services' (HHS) "5 Things to Know" series, which described the actions nursing homes can take to protect their staff and residents while also highlighting the steps the agency has taken to improve health and safety of residents during the pandemic.
    - Launched an unprecedented, scenario-based, national training curriculum featuring the most recent lessons learned and best practices to equip both frontline caregivers and their

management with the knowledge they need to stop the spread of COVID-19 in their nursing homes.

- Issued guidance on limiting visitors and nonessential healthcare personnel at nursing homes, except in compassionate care and end of life situations, to prevent transmission of the 2019 novel coronavirus.
- Issued an informational bulletin on Medicaid reimbursement strategies to prevent spread of COVID-19 in nursing facilities.
- CMS created the Independent Coronavirus Commission on Safety and Quality in nursing homes and deployed the Quality Improvement Organizations (QIO) to address nursing home hotspots.

- Increased surveys:
  - Conducted more than 15,000 investigations of patient health and safety in nursing homes through surveys nationwide since March, prioritizing infection control and situations in which residents are at risk for serious injury or death, and imposed more than $15 million in civil monetary penalties (CMPs) for noncompliance and failure to report COVID-19 data.
  - Required all 15,417 Medicare and Medicaid nursing homes to report cases of COVID-19 to all residents, their families, and the CDC.
  - Published data showing the incidence of COVID-19 in nursing homes, as well as the results of the agency's targeted infection control inspections, including individual facility survey results. Failure to report this data could result in enforcement action.
  - Began releasing a list of nursing homes with an increase in cases that will be sent to states each week as part of the weekly Governor's report to help ensure that states have the information needed to target their support to the highest risk nursing homes.
  - Implemented an enhanced survey/inspection process tailored to meet the specific concerns of hotspot areas, and coordinated Federal, state and local efforts to leverage all available resources for these facilities.
  - Created the CMS COVID-19 Nursing Home Website and Dataset, which provides to the public COVID-19 data reported to NHSN by nursing homes.
  - Completed the transition to the New Care Compare website and announced that results from the focused infection control surveys will be used to calculate each nursing home's inspection rating

- Directly aided Nursing Homes to better fight the pandemic:
  - Allowed facilities to transfer or discharge residents in order to group residents based on their COVID-19 status.
  - Made it easier for nursing homes to staff up by extending training requirement deadlines.
  - Deployed Quality Improvement Organizations (QIOs) to provide immediate assistance to 1,212 nursing homes in hotspot areas, as identified by the White House Coronavirus Task Force.
  - CMS, along with partners in the CDC and the Office of the Assistant Secretary for Health (OASH), formed federal Task Force Strike Teams to provide on-site technical assistance

and education to nursing homes experiencing outbreaks among residents. To date, 96 facilities in 30 states have been provided this direct on-site assistance.

- COVID Scenario-based training has occurred in 68% of nursing homes nationwide with 10,556 facilities and 232,432 individuals.

- Launched the Nursing Home Resource Center to serve as a centralized hub bringing together the latest information, guidance, and data on nursing homes that is important to facilities, frontline providers, residents and their families.

- Enhanced testing in Nursing Homes:
  - Required that all nursing homes in states with a 5% positivity rate or greater test all nursing home staff each week, enhancing efforts to keep the virus from entering and spreading through nursing homes by identifying asymptomatic carriers.
  - Along with HHS, worked to ensure the availability of point of care testing in every certified nursing home across the country.
  - Revised infection-control regulations for long-term care facilities to require nursing homes to test their staff for COVID-19 to safeguard nursing home residents from the ongoing threat of the virus.
  - Required nursing homes to offer COVID-19 tests to residents when there is an outbreak, or when residents show symptoms, to help nursing homes control the spread of the virus.
- Increased enforcement:
  - Increased enforcement (e.g., civil monetary penalties) for facilities with persistent infection control violations, and imposed enforcement actions on lesser infection control deficiencies to ensure they're addressed properly and in a timely manner.

Ensuring Access to Vaccines and Therapeutics

- As new therapeutics have come to market, CMS ensured that beneficiaries would have access to these lifesaving treatments without the burden of cost. CMS has:
  - Issued a rule to ensure that Medicare Part B will cover the COVID-19 vaccine, and its administration, without coinsurance or deductible.
  - Required plans and issuers to cover COVID-19 immunizations that have in effect a recommendation of the Advisory Committee on Immunization Practices with respect to the individual involved, even if not listed for routine use on the Immunization Schedules of the CDC.
  - Required plans and issuers to cover, without cost sharing, qualifying coronavirus preventive services, regardless of whether an in-network or out-of-network provider delivers such services during the public health emergency.
  - Required every provider of a COVID-19 diagnostic test to make the cash price of the test public on its website or for those providers without their own website, in writing within two business days upon request. Failure to comply with this requirement may lead to a civil monetary penalty.

- Updated the policy for maintaining Medicaid enrollment during the COVID-19 public health emergency to ensure that states have the flexibility to implement certain changes to effectively manage their programs.
- Implemented a policy to provide an enhanced payment for eligible inpatient cases that involve the use of certain new, innovative products authorized or approved to treat COVID-19.
- Announced that Medicare beneficiaries can receive coverage of monoclonal antibodies to treat coronavirus disease 2019 (COVID-19) with no cost-sharing during the public health emergency (PHE).[18] This would allow for a broad range of providers and suppliers, including freestanding and hospital-based infusion centers, home health agencies, nursing homes, and entities with whom nursing homes contract, to administer this treatment in accordance with the EUA, and bill Medicare to administer these infusions.

Supporting Innovative Approaches to Care - Maximizing Use of CMS Data

- CMS has developed an internal dashboard that uses administrative claims and encounter data to track changes in utilization of healthcare services related to COVID-19 in CMS programs. This dashboard includes data on COVID-19 testing, telehealth services, and elective/preventative services and procedures.
- CMS is also making Medicare COVID-19 data available publicly, releasing monthly COVID-19 cases and hospitalizations information via the Medicare COVID-19 Snapshot.[19]
- CMS is also collaborating with the Centers for Disease Control and Prevention (CDC) to collect and release data on nursing home COVID-19 cases and mortality to improve public health responses and inform the public.
- To ensure sufficient program oversight without burdening providers, CMS is using its data to identify bad actors and develop quick and effective ways to address unscrupulous behavior.
    - CMS is using data, such as 1-800-MEDICARE complaints, to look for signals of emerging fraud schemes, and using its real-time claims and payment data analytic and surveillance capabilities to expose unexpected spikes and outliers that may indicate fraudulent behavior.

Providing Relief for Consumers in the Marketplace

- In August 2020, CMS announced a policy allowing issuers to offer temporary premium reductions for individuals with 2020 coverage in the individual and small group markets.
- CMS is providing this additional flexibility to help ensure consumers struggling to pay their premiums can maintain coverage and receive the care they may need during this time.
- In addition to premium reductions, CMS also extended issuers offering coverage through HealthCare.gov permission to extend premium payment deadlines and delay cancellation for non-payment of premiums.

  CMS also adopted a non-enforcement policy permitting issuers to prepay to enrollees a portion or all the estimated Medical Loss Ratio (MLR) rebate for the 2019 MLR reporting year.[20]

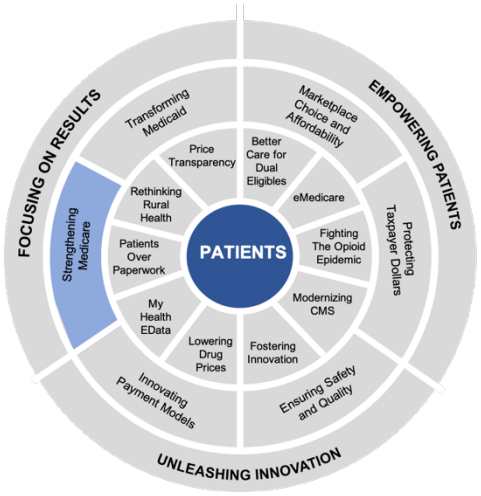
Enhancing Customer Experience through Communications

- CMS devised an effective communication and training strategy to ensure providers in all settings were working with the most up-to-date information.
- Throughout the PHE, **CMS has held numerous nationwide calls, including weekly COVID-19 care site-specific calls, office hours calls, and lessons from the front lines calls,** to give providers and experts—nurses, home health and hospice workers, hospital groups, and physicians—a space to share experiences, ideas, strategies, and insights related to the COVID-19 response.
    - These calls have become a ready avenue for providers to ask questions and learn from experts across the federal healthcare space, proliferating best practices across the healthcare system.
- In addition to the above, CMS developed a **series of trainings** to ensure proper oversight and learning diffusion is occurring across the system, placing a special emphasis on nursing infection control training. CMS made this training readily available through the QSEP training portal.[21]
- In addition to training, CMS has provided **direct assistance to states, including weekly calls with state Medicaid agencies,** to ensure Medicaid and CHIP enrollees receive the care they need. By providing rapid technical assistance, expanding flexibilities with disaster state plan amendments, and providing guidance on other available flexibilities, CMS is ensuring patients are protected across the programs.
- CMS also used its considerable expertise to engage stakeholders across the healthcare system to share best practices, disseminate important information and provide a forum to get questions answered.
    - CMS conducted 53 stakeholder calls in addition to the 23 weekly care site specific calls, 23 lessons from the front lines calls and 30 office hour calls held since the beginning of March 2020 (These calls are described in Appendix B.2).
    - The care site specific calls have moved to a biweekly cadence, while the office hours calls continue weekly, with other stakeholder calls added as needed.
- As an example of the importance of these calls, in the Lessons from the Front Lines calls, between 4,000-8,000 physicians and other clinicians join biweekly to share their experience, ideas, strategies, and insights with one another related to their COVID-19 response

Key Accomplishments by CMS Strategic Initiative

Strengthening Medicare

CMS welcomes approximately 10,000 enrollees a day to the Medicare program and the agency is modernizing and strengthening the program to make it sustainable for future generations through increased choices, private sector competition, and innovation.



Increased flexibility in the FFS Medicare program and increased competition in the MA program not only empowers beneficiaries by allowing them to choose the care that is best for them, but also decreases costs across the system. CMS ensures true competition rather than a "race to the bottom" by using quality standards to drive continuous improvement while increasing competition and efficiencies in both programs. Thus, to strengthen Medicare by increasing quality while lowering costs and empowering beneficiaries, CMS has focused on creating more competition, choice, flexibility, and benefits, while keeping high standards of care.

Accomplishments

Valuing Clinician Time Spent with Patients

- CMS has brought needed choice to patients under Medicare FFS while reducing burden on the clinicians who treat them. The Executive Order on Protecting and Improving Medicare for Our Nation's Seniors signed in October 2019, directs the HHS Secretary to "identify and remove unnecessary barriers to private contracts."[22]
    - CMS has repeatedly heard that the major source of physician burnout is the documentation burden associated with evaluation and management (E/M) coding.[i]
    - Since the implementation of the E/M framework, the nature of clinical care has evolved with a greater emphasis on collaborative models and having to care for patients with increased complexities. After receiving over 15,000 public comments in response to its proposals, CMS updated documentation requirements to alleviate documentation burden on clinicians.[23]
        - As further discussed in the *Patients Over Paperwork* section of this paper, CMS also established policies to simplify documentation and remove potentially duplicative requirements.[24] By making these updates to the most-used codes in medicine, CMS is **reducing burden on physicians while making sure that clinician time is appropriately compensated**.
    - For 2020, CMS also increased payment for several types of care management services reflecting the importance of these services for the Medicare population. These changes help CMS **promote the evidence-based interventions proven to improve health outcomes**, especially for Medicare beneficiaries with multiple chronic conditions.[25]

[i] For more discussion of E/M coding changes, see "Patients over Paperwork".

- CMS increased payment for Transitional Care Management (TCM) services. TCM services are provided to patients requiring medical and/or psychosocial care and involve a transition of care from one setting to another.
- CMS created a code for additional time providers spent with patients beyond the initial 20 minutes allowed in the current coding for Chronic Care Management (CCM) services.
- CMS established a Principle Care Management (PCM) service code for the management of a single serious and high-risk chronic condition.[26]

Providing Flexibility to Increase the Provider Workforce and Access to Care

- In the CY 2021 Physician Fee Schedule Final Rule, CMS made additional changes so that practitioners can practice at the top of their license, including permanently extending many COVID-19 flexibilities.[27] CMS is finalizing the following changes:
  - Certain non-physician practitioners such as nurse practitioners and physician assistants can supervise the performance of diagnostic tests within their scope of practice and state law, as they maintain required statutory relationships with supervising or collaborating physicians.
  - Physical and occupational therapists will be able to delegate "maintenance therapy" – the ongoing care after a therapy program is established – to a therapy assistant.
  - Physical and occupational therapists, speech-language pathologists, and other clinicians who directly bill Medicare can review and verify, rather than re-document, information already entered by other members of the clinical team into a patient's medical record. As a result, practitioners have the flexibility to delegate certain types of care, reduce duplicative documentation, and supervise certain services they could not before, increasing access to care for Medicare beneficiaries.
- In the CY 2020 Physician Fee Schedule Final Rule, CMS **removed regulatory barriers so that Physician Assistants (PA) have greater flexibility to practice at the top of their license**, within state scope of practice guidelines. Accordingly, physician supervision for PA services is now required to align with State scope of practice rules.[28]
- These changes, taken together, afford greater flexibility in the practice of medicine, as clinicians are given more control over the time they spend with patients, and can focus efforts on the interventions, like care management, that make patients healthier.[29]

Providing Care Choices in FFS Medicare

- CMS made significant changes in its payment rules in 2019 to remove payment disparities and achieve site neutrality for certain services, increasing market competition and giving patients more choices and lowering out of pocket costs.[30]
- In the CY 2020 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rule, CMS continued a two-year phase-in of the method to reduce unnecessary utilization of outpatient services by reducing payments for clinic visits furnished in the off-campus hospital outpatient setting.
  - These visits are the most common service billed under the OPPS.
  - This change would result in lower copayments for beneficiaries and savings for the Medicare program and taxpayers estimated to be $800 million for 2020.

- Beginning January 1, 2021, we are adding eleven procedures to the ASC covered procedures list (CPL), including total hip arthroplasty (CPT 27130), under our standard review process.[31] Additionally, CMS is revising the criteria we use to add surgical procedures to the ASC CPL, providing that certain criteria we used to add surgical procedures to the ASC CPL in the past will now be factors for physicians to consider in deciding whether a specific beneficiary should receive a covered surgical procedure in an ASC.
    - Using our revised criteria, we are adding an additional 267 surgical procedures to the ASC CPL beginning January 1, 2021.
    - CMS is adopting a notification process for surgical procedures the public believes can be added to the ASC CPL under the criteria we are retaining.
    - In the final rule, CMS will begin eliminating the Inpatient Only (IPO) list of 1,700 procedures for which Medicare will only pay when performed in the hospital inpatient setting over a three-year transitional period, beginning with some 300 primarily musculoskeletal-related services.[32] The IPO list will be completely phased out by CY 2024. This will make these procedures eligible to be paid by Medicare when furnished in the hospital outpatient setting when outpatient care is appropriate, as well as continuing to be payable when furnished in the hospital inpatient setting when inpatient care is appropriate, as determined by the physician.
    - **CMS is giving Medicare beneficiaries and doctors more choices around how to deliver care, often at a lower cost,** by making sure that beneficiaries and their clinicians have flexibility to choose the most appropriate site of care for various surgical procedures that would not be expected to pose a significant risk to beneficiary safety.
    - While the data available is limited, a utilization review of Medicare Part B claims for Q1 2020 shows ASCs are taking advantage of these flexibilities. For additional data on recently added procedures, Appendix B.3 shows change in utilization of procedures newly added to ASC list by year.
- Section 340B of the Public Health Service Act (340B) allows participating hospitals and other providers to purchase certain covered outpatient drugs at discounted prices from manufacturers. In the CY 2018 OPPS/ASC final rule, CMS reexamined the appropriateness of the prior Average Sale Price (ASP) plus 6 percent payment methodology for drugs acquired through the 340B Program, given that 340B hospitals acquire these drugs at steep discounts.
    - Beginning January 1, 2018, Medicare adopted a policy to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals that are acquired through the 340B Program by a hospital paid under the OPPS that is not excepted from the payment adjustment policy.
    - The payment policy helps beneficiaries save on coinsurance for drugs that were administered at hospital outpatient departments and acquired through the 340B program, which allows certain hospitals to buy outpatient drugs at lower costs. Since this policy went into effect in 2018, Medicare beneficiaries have saved nearly $1 billion on drug costs, with expected Medicare beneficiary drug cost savings of over $300 million in CY 2021.

Figure 9. Unique Beneficiary Counts for Selected New HCPCS Codes Approved in the ASC Setting, Q1 2020

	93458 - L hrt artery/ventricle angio	27447 - Total knee arthroplasty	C9600 - Perc drug-el cor stent sing

Total	**108,525**	**81,213**	**22,654**
Outpatient	58,694	34,293	22,271
ASC	1,097	1,448	383
Inpatient	48,734	45,472	-

- **Fiscal Year Medicare Hospital Inpatient Prospective Payment System (IPPS) Final Rules**
    - The primary focal points for the FY 2018 IPPS final rule press release were changes to quality reporting and EHR incentive programs, which included changes to the Medicare uncompensated care payments.
    - As a part of CMS' priority of "Rethinking Rural Health," **CMS finalized historic changes to the way many low wage index hospitals, which tend to be rural, are paid.** By improving the accuracy of the Medicare payments to these low wage hospitals, they will be able to increase what they pay their workers, and this will help ensure that patients, including those living in rural areas, continue to have access to high-quality, affordable healthcare.[33]
    - CMS **ensured patients have access to potentially life-saving diagnostics and therapies by approving 24 total technologies applications for add on payments for FY 2021.**
    - CMS is spending additional money to promote innovation in the IPPS setting, estimating **spending approximately $874 million on this technology in FY 2021, nearly a 120% increase over the FY 2020 spending.**[34]
- **Calendar Year Medicare End Stage Renal Disease (ESRD) Final Rules**
    - CMS has **modernized its payment policies to encourage much needed innovation in the treatment of kidney disease**, and, more specifically end stage renal disease.
    - In the CY 2020 ESRD Final Rule, CMS established a **new transitional add-on payment adjustment** to support the use of certain new and innovative renal dialysis equipment or supplies furnished by ESRD facilities, called the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). Technology that meet certain criteria, including demonstrating substantial clinical improvement, will receive TPNIES for 2 calendar years, after which the equipment or supply will qualify as an outlier service and no change to the ESRD PPS base rate will be made.[35]
    - Beginning in 2021, CMS will **allow transitional add-on payments to ESRD facilities for purchasing new and innovative home dialysis machines.**[36] Specifically, ESRD facilities that purchase new and innovative home dialysis machines for use by an individual patient in their home may receive an additional payment for two years to offset the cost of acquiring and integrating innovative equipment into their operations to support home dialysis.
        - Studies indicate frequent nocturnal hemodialysis can improve certain cardiac measures, reduce the need for blood pressure medications, and improve selected measures of a patient's quality of life. [37]
        - CMS' initiative to **increase Medicare ESRD beneficiaries' access to home dialysis services** builds on the Transitional Payment for New and Innovative

Equipment and Supplies policy that was finalized in the CY 2020 ESRD Prospective Payment System final rule to support ESRD facilities in acquiring, testing, and implementing innovative care solutions.[38]

- In the CY 2021 ESRD PPS Final Rule, CMS **increased the monthly capitated payment for physicians managing ESRD patients**. Increasing the resources provided to clinicians managing the care of ESRD patients will improve access to and quality of care for Medicare ESRD beneficiaries.[i]

- **Calendar Year Home Health Rules**
  - CMS implemented a new home infusion therapy benefit beginning January 1, 2021, which includes professional services, including nursing; patient education and training; and patient monitoring for the provision of home infusion therapy.
  - CMS modified its regulations to allow therapist assistants—rather than only therapists—to perform maintenance therapy under the Medicare home health benefit, in accordance with individual state practice requirements. This change allows therapist assistants to utilize all of the skills under their license and gives HHAs the opportunity to use both therapists and therapist assistants to perform maintenance therapy. This ensures that HHAs have enough staff available to provide the appropriate amount of therapy to their patients, improving beneficiary access to these services.
  - CMS finalized regulatory changes related to the use of telecommunications technology in providing care under the Medicare home health benefit. These finalized policies will ensure patient access to the latest technology and give HHAs predictability that they can continue to use telecommunications technology as part of patient care.
    - Beginning January 1, 2021, home health agencies (HHAs) can utilize telecommunications technologies in providing care to beneficiaries under the Medicare home health benefit, as long as any provision of remote patient monitoring or other services furnished via a telecommunications system or audio-only technology are included on the plan of care.
    - CMS also expanded the definition of telecommunications technology, in addition to remote patient monitoring, that HHAs are allowed to report as allowable administrative costs on the HHA cost report.
  - Beginning in 2019, CMS allowed the cost of remote patient monitoring to be reported by home health agencies as allowable costs on the Medicare cost report form. This is expected to help foster the adoption of emerging technologies by home health agencies and result in more effective care planning, as data are shared among patients, their caregivers and their providers.

- **Calendar Year Durable Medical Equipment (DME) Rules**
  - Because of CMS' subregulatory changes in 2019, the process of Medicare billing code establishment was shortened to an average of six months for completion, instead of the usual 18 months. In the CY 2020 DME Rule Final Rule, CMS further **streamlined DMEPOS requirements** so that practitioners and suppliers could focus their attention on caring for Medicare beneficiaries.

        - CMS created one Master List of DMEPOS items that could potentially be subject to face-to-face encounter and written order prior to delivery and/or prior authorization requirements to provide clarification for providers.[39]
        - CMS streamlined the requirements for ordering DMEPOS items by creating one standardized set of required elements for all DMEPOS orders.[40]
    - Round 2021 of the DMEPOS CBP will be implemented in 127 competitive bidding areas (CBAs) on January 1, 2021, for the OTS Back Braces and OTS Knee Braces product categories only, and will extend through December 31, 2023.[41] CMS estimates Medicare benefit savings of over $600 million over three years for these product categories because of their inclusion in the CBP. Beneficiaries are generally responsible for a 20 percent co-payment for DMEPOS items and services, so many beneficiaries will receive considerable savings from this action
    - For CY 2021, CMS has proposed **expanding Medicare coverage and payment for continuous glucose monitors**. Currently, CMS only covers therapeutic CGMs, those approved by the Food and Drug Administration (FDA) for use in making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM.
    - For CY 2021, CMS has proposed a number of actions that will **further increase beneficiary access to DMEPOS and prevent delays in coverage** of these items. For example:
        - CMS proposed to expand the interpretation of the appropriate for use in the home requirement within the definition of DME, specifically for external infusion pumps with the goal of increasing access to home infusion drugs.
        - CMS proposed processes for making benefit category and payment determinations for new DMEPOS technology that considers consultation from the public.

- **Calendar Year Outpatient Prospective Payment System (OPPS) Rules**
    - The CY 2018 OPPS final rule provided relief to rural hospitals and rural clinicians by placing a two-year moratorium on the direct physician supervision requirements for rural hospitals and critical access hospitals. Subsequently, in the CY 2020 final rule, CMS finalized a change to the generally applicable minimum required level of supervision for hospital outpatient therapeutic services furnished by all hospitals and CAHs from direct supervision to general supervision. General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. This change ensures a standard minimum level of supervision for each hospital outpatient therapeutic service furnished incident to a physician's service.
    - In the CY 2019 OPPS final rule, CMS gave patients more options on where to obtain care by increasing the services that can be furnished in Ambulatory Surgical Centers (ASCs). These policies:
        - Expand the number of surgical procedures payable at ASCs to include additional procedures that can safely be performed in that setting;

        - Ensure ASC payment for procedures involving certain high-cost devices generally parallels the payment amount provided to hospital outpatient departments for these devices; and
        - Help ensure that ASCs remain competitive by addressing the differential between how ASC payment rates and hospital outpatient department payment rates are updated for inflation.

- **Calendar Year Physician Fee Schedule (PFS) Final Rules**
    - For 2020, CMS increased payment for several types of care management services to appropriately reflect the resources necessary to provide these services for the Medicare population. These changes help CMS **promote evidence-based interventions proven to improve health outcomes**, especially for Medicare beneficiaries with multiple chronic conditions.[42]
        - CMS increased payment for Transitional Care Management (TCM) services.
        - CMS created a code for additional time providers spent with patients beyond the initial 20 minutes allowed in the current coding for Chronic Care Management (CCM) services.
        - CMS established a Principle Care Management (PCM) service code for the management of a single serious and high-risk chronic condition.[43]
    - CMS has finalized a number of documentation, coding, and payment changes to reduce administrative burden and improve payment accuracy for office/outpatient evaluation and management (E/M) visits over several years. These changes **allow practitioners greater flexibility to exercise clinical judgment in documentation**, so they can focus on what is clinically relevant and medically necessary for the beneficiary.[44] For example:
        - For CY 2019 and beyond, CMS eliminated the requirement to document the medical necessity of a home visit in lieu of an office visit.
        - For established patient office/outpatient visits, when relevant information is already contained in the medical record, CMS **gave practitioners the flexibility to focus their documentation on what has changed** since the last visit, or on pertinent items that have not changed, and not spend their time re-recording the defined list of required elements if there is evidence that the practitioner reviewed the previous information and updated it as needed.
        - CMS **removed potentially duplicative requirements for notations** in medical records that may have previously been included in the medical records by other members of the medical team for E/M visits furnished by teaching physicians.
    - **CMS modernized Medicare physician payment by recognizing communication technology-based services in our payment policies.** Beginning in CY 2019, CMS began to pay physicians separately for two services furnished using communication technology: brief communication technology-based services, like virtual check-ins, and the remote evaluation of recorded video or images that a patient sends to the physician.[45]
    - **CMS recognized technology-based and remote evaluation services for rural health clinics and federally qualified health centers** by finalizing payment for these services when there is no associated billable visit. This way, RHC or FQHC practitioners are paid when they have medical discussions or perform remote evaluations of conditions not related to an RHC or FQHC service provided within a certain timeframe.[46]

- In the CY 2018 PFS Final Rule, CMS worked to tackle and prevent the onset of diabetes by **implementing the Medicare Diabetes Prevention Program expanded model** starting in 2018. Through the final rule, CMS finalized policies necessary for suppliers to begin furnishing MDPP services nationally in 2018, including the MDPP payment structure, as well as additional supplier enrollment requirements and supplier compliance standards aimed to enhance program integrity.[47]
- CMS has **pioneered and promoted the uptake of telehealth in Medicare** by adding additional codes to the list of Medicare telehealth services through the years. For example, in the CY 2020 PFS Rule, CMS added 3 HCPCS codes which describe a bundled episode of care for treatment of opioid use disorders through telehealth.[48] In the CY 2021 PFS Rule, CMS finalized adding more than 60 services to the Medicare telehealth list that will continue to be covered beyond the end of the COVID-19 PHE, and we will continue to gather more data and evaluate whether more services should be added in the future. These additions allow beneficiaries in rural areas who are in a medical facility (like a nursing home) to continue to have access to telehealth services such as certain types of emergency department visits, therapy services, and critical care services.

- **Fiscal Year Hospice Final Rules**
  - CMS has revised its payment policies as part of the agency's continued commitment to **better align the hospice payment rates with the costs of providing care and increasing transparency so patients can make more informed decisions**.
    - In FY 2020, CMS finalized the rebasing of the continuous home care (CHC), general inpatient care (GIP), and the inpatient respite care (IRC) per diem payment rates in a budget-neutral manner through a small reduction to the routine home care (RHC) rates **to more accurately align Medicare payments with the costs of providing care**.[49]
    - Additionally, **to promote high quality care and adherence to quality requirements**, CMS has finalized a policy for FY 2021 that if hospices fail to meet the quality reporting requirements, they will receive a 2 percentage point reduction to the annual market basket percentage increase for the year.[50]
      - CMS also finalized starting in 2021 modifications to the existing hospice election statement content requirements to increase coverage transparency for patients that elect hospice.
      - Hospices will be required to provide, upon request, an election statement addendum with a list and rationale for items, drugs, and services that the hospice has determined to be unrelated to the terminal illness and related conditions to the beneficiary (or representative), other providers that are treating such conditions, and to Medicare contractors.[51]

- **Fiscal Year Skilled Nursing Facilities (SNF) Final Rules**
  - CMS created a new case-mix model, the Patient-Driven Payment Model (PDPM), which **focuses on the patient's condition** and resulting care needs rather than on the amount of care provided in order to determine Medicare payment.[52]
  - CMS continued to tweak payment under the SNF Value Based Purchasing (VBP) Program to reflect **our commitment to shifting Medicare payments from volume to value**, with the continued implementation of the PDPM and SNF VBP.[53]

  - CMS began rewarding SNFs with **incentive payments based on their quality measure performance** on October 1, 2018. The program scores SNFs on an all-cause measure of hospital readmissions and will transition to a measure of potentially preventable hospital readmissions.[54]

- **Fiscal Year Medicare Inpatient Psychiatric Facilities PPS Final Rules**
  - CMS is **removing unnecessary regulatory burden** on psychiatric hospitals by allowing advanced practice providers, including physician assistants, nurse practitioners, psychologists, and clinical nurse specialists, to operate within the scope of practice allowed by state law by documenting progress notes in the medical record of patients, for whom they are responsible, receiving services in psychiatric hospitals. [55]

- **Fiscal Year Medicare Inpatient Rehabilitation Facility (IRF) PPS Final Rules**
  - In the FY 2020 IRF PPS Final Rule, CMS continued to make progress towards the eventual transition to a unified post-acute care system, through updates to the data used for IRF payments, including revising the case-mix groups (CMGs), updating the CMG relative weights and average length of stay values, and using concurrent inpatient prospective payment system (IPPS) wage index data for the IRF PPS to align wage index data across settings of care.[56]
  - In FY 2021, in finalizing a flexibility that was provided during the COVID-19 PHE, CMS eliminated the requirement for physicians to conduct a post-admission visit since the post-admission evaluation covers much of the same information as continues to be included in the pre-admission screening of the patient and the patient's plan of care.[57]
  - CMS gave providers flexibility on a requirement mandating that physicians perform a visit to each patient three times per week to ensure that the patient's care plan is working as intended. CMS recognizes that non-physician practitioners (NPPs) are an important part of the interdisciplinary care of patients and often support physicians during their visits. Therefore, CMS finalized that a NPP may perform one of these three required visits in lieu of the physician in the second and later weeks of a patient's care, when consistent with the NPP's state scope of practice.[58]

Providing More Meaningful Choices in Medicare Advantage and Part D

- **Part D plans basic premiums have decreased by 12% since 2017, saving beneficiaries about $1.9 billion in premium costs over that time, with enrollment increasing 12.2%** during the same period.[59]
- Even though most seniors receive coverage of their prescription drugs through Part D, over 75% of seniors believe the price of their drugs is "unreasonable," with over 25% saying it is "difficult" or "very difficult" for them to afford their medications.[60]Since 2017, CMS has steadily increased options for people in MA, thereby increasing competition. Removing these requirements made more options available for beneficiaries when seeking plans and providers to meet their individual needs.[ii] **These plans often come with benefits that would not be available within Medicare FFS**. This increase in choice is good for both beneficiaries and plans, driving competition and lower cost while still putting a premium on quality.
- In the CY 2019 Medicare Advantage and Part D Final Rule:
  - CMS removed the requirement that certain Part D and MA plans had to "meaningfully differ" from one another.[61,62]

[ii] For more discussion of these accomplishments, see "eMedicare".

  - CMS increased competition among pharmacies by clarifying the "any willing provider" requirement, to increase the number of pharmacy options that beneficiaries have.[63]

- The average monthly MA premiums decreased by an estimated 34% since 2017, the lowest average since 2007.[64]
  - Beneficiaries have more plan choices, with about 2,100 more Medicare Advantage plans operating in 2021 than in 2017, a 76.6 percent increase. Overall, beneficiaries could choose from more than 4,800 Medicare Advantage plans during 2021 open enrollment. The average number of MA plan choices per county increased from about 39 plans in 2020 to 47 plans in 2021.[65]

Increasing Negotiating Power

- In the CY 2019 Medicare Advantage and Part D Final Rule, CMS directly impacted prescription drug costs by allowing for certain low-cost generic drugs to be substituted onto plan formularies at any point during the year, so beneficiaries immediately benefit and have lower cost sharing.[66]
- CMS implemented a provision to further encourage the use of lower-cost alternatives by applying generic cost-sharing to biosimilar and interchangeable biological products for LIS Part D enrollees throughout all phases of the benefit, at an estimated savings to the Medicare program of $10 million in 2019
- In the CY 2020 Medicare Advantage and Part D final rule, CMS **required Part D plans to adopt tools that provide clinicians with information that they can discuss with patients on out-of-pocket costs for prescription drugs** at the time a prescription is written,[iii] which Part D plans will be required to integrate into EHR systems.[67,68]
  - In addition, this rule requires "the Explanation of Benefits document that Part D enrollees receive each month to include information on drug price increases and lower-cost therapeutic alternatives" so that beneficiaries are kept informed and can alert their clinician if a drug is no longer within reach.[69]

Demanding High-Quality Beneficiary Care

While increasing competition and choice, CMS has continued to also demand high quality in its MA and Part D plans.

- Year-over-year, CMS made changes to our star ratings methodology to make it more predictable and transparent, ensuring the most accurate and up-to-date information for MA and Part D plans and consumers, with an increase in quality in these plans.[70]
  - As part of the Administration's effort to increase transparency and seek public comment on the Part C and D Star Ratings program, CMS codified the methodology for the Part C and D Star Ratings program in the CY 2019 Medicare Part C and D Final Rule, published in April 2018 for the 2021 Star Ratings. CMS historically had announced changes to the Star Ratings framework, measures, and methodology through the annual Medicare Parts C and D Call Letter.
  - CMS codified key aspects of the Part C and D Star Ratings methodology, including the principles for adding, updating, and removing measures, and the methodology for calculating and weighting measures.

[iii] For more discussion of these accomplishments, see "Price Transparency"

- CMS set new rules related to how Star Ratings are assigned when contracts consolidate to more accurately reflect the performance of all contracts (surviving and consumed) involved in the consolidations.
- CMS increased the predictability and stability in the Star Ratings by reducing the influence of plans with outlier performance on the thresholds that determine the star rating for each plan.
- We've seen plan quality improve over time through Star Ratings with majority of plans having 4 stars or higher and the average star rating has gone up. (The average star rating for all Medicare Advantage plans with prescription drug coverage has improved to 4.16 out of 5 stars in 2020, increasing from 4.02 in 2017.)
- We continue to look at how we can improve the program and make it meaningful for our beneficiaries. For example, earlier this year, we finalized increased emphasis on patient experience in our Star Ratings methodology. The goal here is to improve incentives for plans to focus on what patient's value and feel is important.
- Another area is how to align incentives to encourage availability of lower cost drugs. For example, we recently sought feedback on developing measures of generic and biosimilar utilization in Medicare Part D as part of a plan's star rating. This would reward plans based on the rate at which they encourage market adoption of these competitor products and lower costs for patients.
- Also, under the Part D program, plans currently do not have to disclose to CMS the measures they use to evaluate pharmacy performance in their network agreements. CMS has heard concerns from pharmacies that the measures plans use to assess their performance are unattainable or otherwise unfair. The measures used by plans potentially impact pharmacy reimbursements. We've proposed to require Part D plans to disclose such information so we can track how plans are measuring and applying pharmacy performance measures. CMS will also be able to report this information publicly to increase transparency on the process and to inform the industry in its new efforts to develop a standard set of pharmacy performance measures. CMS also sought comment on Part D pharmacy performance measures more broadly, including stakeholders' recommendations for potential Part D Star Ratings metrics that could incentivize the uptake of a standard set of measures once the industry establishes one.
- Finally, we've also sought feedback on other areas for measure development. With ESRD patients able to join MA plans starting in 2021, we've sought feedback on ESRD measures to include in Star Ratings. We've also sought feedback on prior authorization measures, as part of our efforts to ensure that this utilization management isn't burdensome.

Capturing Encounter Data

- As beneficiaries increasingly choose MA, with enrollment more than one-third of total Medicare enrollment in 2019 and surpassing 40% of total enrollment in six states, data is important for evaluating use trends for these beneficiaries.[71] Because MA organizations pay claims for beneficiaries directly using payment received from CMS on a per capita basis, historically little was known about the healthcare use patterns and behaviors of the MA patient experience.
- In the past, CMS has used diagnoses submitted into CMS' Risk Adjustment Processing System (RAPS) by MA organizations for the purpose of calculating risk scores for payment. In recent years, CMS has collected encounter data, which capture the details of a MA beneficiary's health and treatment based on "encounters" with clinicians.

- The data are useful for CMS from a programmatic standpoint, as well as being valuable to researchers who may find **MA encounter data more useful than other data sets for understanding program costs**, quality of MA relative to fee-for-service Medicare, and for gaining insight into provider behavior and use patterns.[72]
    - Encounter data offers more information, over more provider types with more frequent reporting than RAPS.
- Researchers are more able than ever to produce important findings, such as the 2018 Avalere research report, which found MA beneficiaries with high cholesterol, high blood pressure, and diabetes experienced fewer inpatient hospital stays and fewer emergency room visits than their Medicare FFS counterparts.[73]
- For CY 2021, CMS finalized the proposal to calculate risk scores for payment to MA organizations and certain demonstrations as the sum of 75% of the encounter data-based risk score and 25% of the RAPS-based risk score which will further ensure appropriate expenditures.[74]

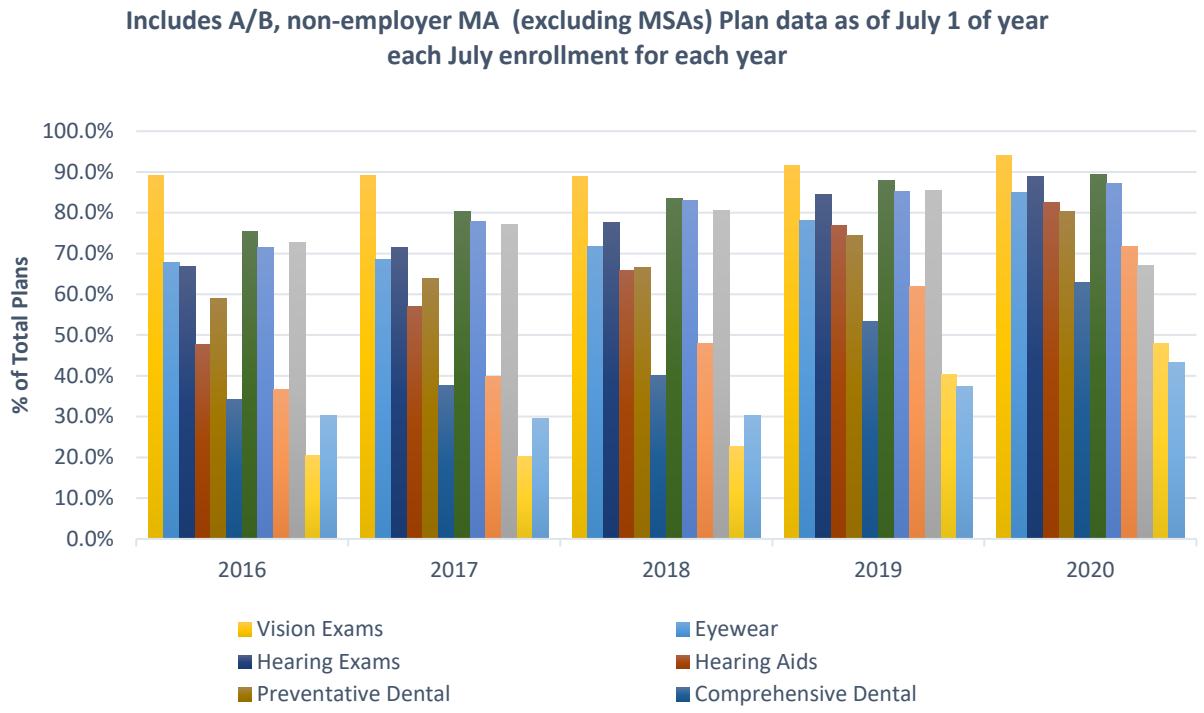
Offering Innovative Benefits

- CMS has also raised the bar in the MA plans by offering additional benefits. When given the choice of lower cost, high quality care that is flexible and comparable, beneficiaries increasingly choose what is right for them.
- CMS expanded access to reduced cost sharing to benefits for enrollees with certain conditions, such as diabetes and congestive heart failure, due to the agency's reinterpretation of the uniformity requirement in 2018.
- CMS expanded opportunities for chronically ill patients to choose Medicare Advantage plans that offer a broader range of supplemental benefits that are not necessarily health-related but may help to improve or maintain their health. For example, chronically ill beneficiaries enrolled in a Medicare Advantage plan can now receive meal delivery in more circumstances, transportation for non-medical needs like grocery shopping, and home environment services in order to improve their health or overall function as it relates to their chronic illness. About 250 plans in 2020 offered access to these types of supplemental benefits reaching an estimated 1.2 million enrollees.
- In the CY 2020 Medicare Advantage and Part D final rule:
    - CMS implemented legislation **giving seniors access to additional telehealth benefits in MA plans, reaching up to 13.7 million MA enrollees in 2020**.[75]
    - CMS has made it easier for plan sponsors to **offer innovative supplemental benefits or extra benefits beyond traditional "healthcare" like wheelchair ramps, meals, and rides to the doctor**, which help seniors maintain their health, keeping them out of the hospital and overall healthcare costs down.[76]

Figure 10. Medicare Advantage Enrollment (in millions),[iv] 2016-2021

[iv] Source: https://www.cms.gov/newsroom/press-releases/trump-administration-announces-historically-low-medicare-advantage-premiums-and-new-payment-model

Figure 11. Supplemental Benefits,[v] 2016-2020



[v] Includes Medicare Parts A and B, non-employer MA (excluding MSAs). Plan data as of July 1 of each enrollment year.

Transforming Medicaid

Medicaid is the provider for health insurance coverage for 75.5 million or about one in five Americans, and the largest payer for long-term care services in the community and nursing homes. There has been a rapid increase in Medicaid spending recently, from $456 billion in 2013 to an estimated $576 billion in 2016. The increase has been driven by several factors, including Medicaid expansion.

With this historic growth comes an equally growing and urgent responsibility to ensure sound stewardship and oversight of Medicaid program resources. To this end, CMS put forth three pillars to guide work in the Medicaid program: Flexibility, Accountability, and Integrity.[77]

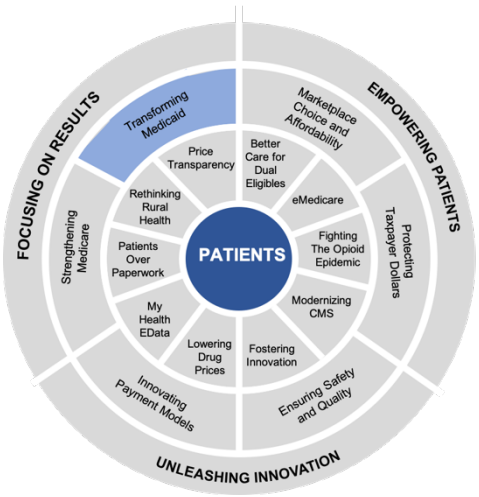


Figure 12. Medicaid and CHIP Enrollment Snapshot, July 2020

TOTAL ENROLLMENT JULY 2020, MEDICAID AND CHIP	75,521,263
By Program:	
Medicaid	**68,826,573**
CHIP	**6,694,690**
children in either Medicaid or CHIP	36,666,093

Accomplishments

Aligning all Medicaid and CHIP work into CMCS

- We centralized all Medicaid and CHIP work, regardless of location, into CMCS, creating *centers of excellence* in key programmatic and operational areas including financial management, managed care, and home and community based services.
- This change has resulted in more consistent, accurate, and timely guidance and 'one voice' on policy and operational matters related to Medicaid and provided greater flexibility to align work based on relative risks and demands.
- Being align in this way greatly accelerated our ability to rapidly respond during the Public Health Emergency as one team, with one voice.

Providing States Flexibility to Design Their Medicaid Programs

- Because states know their residents best, CMS is offering states unprecedented flexibility to design health programs that meet the unique needs of their residents. **CMS has accelerated the review of Section 1115 Medicaid demonstrations and other waivers**, enabling states and territories to test new approaches in Medicaid not otherwise allowed under current law, provided the demonstration meets the objectives of the program.

- For 1115 Demonstrations

    - In November 2017, CMCS issued guidance to improve its internal controls and provided guidance to states on public notice and transparency rules for Section 1115 demonstrations, strengthening consistency in its review of applications and oversight of approved demonstrations.

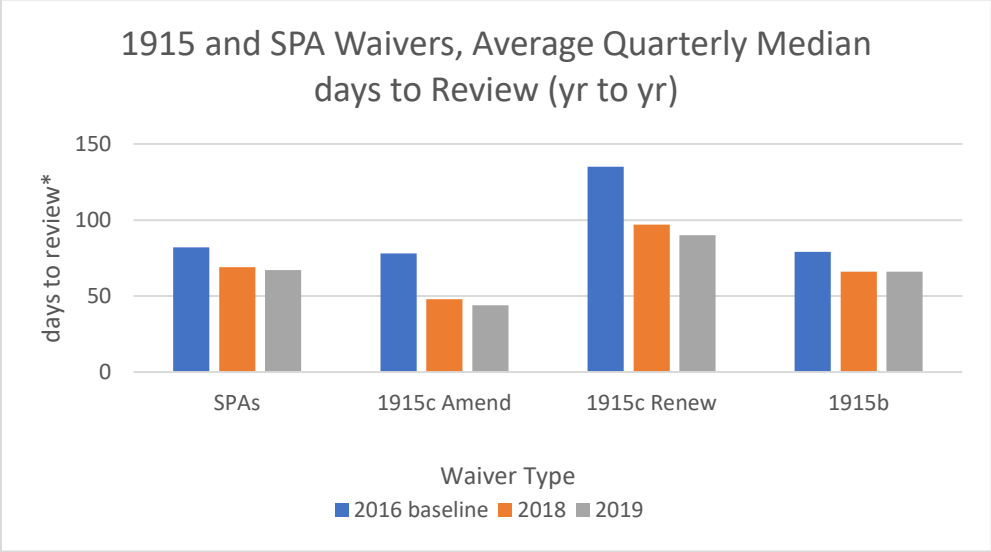
- CMS released comprehensive monitoring and evaluation guidance and tools, conducted eight state webinars, and published four technical white papers on planning evaluations and beneficiary surveys.[78]
- CMS also has issued guidance that supports states' efforts to incentivize community engagement among non-elderly, non-pregnant adult Medicaid beneficiaries who are eligible for Medicaid on a basis other than disability to help improve Medicaid enrollee health and well-being through Medicaid section 1115 demonstrations. [79]
- **CMCS also increased state accountability for results** through its support of robust and structured state monitoring and evaluation efforts for 1115 demonstrations.
- To date, CMCS has approved 14 community engagement demonstrations in 13 states, and 7 SMI demonstrations, giving states the flexibility to provide better care for beneficiaries while also giving them the tools to lift themselves out of poverty.
- CMS increased by seven fold the number of approved state Medicaid demonstrations for Opioid Use Disorder (OUD)/Substance Use Disorder (SUD) treatment, going from four approved demonstrations in 2017 to 31 approved demonstrations as of December, 2020. These demonstrations significantly increase access to high quality, evidence-based treatment options for Medicaid beneficiaries with SUD to improve health outcomes.
- Starting in November 2017, CMS issued guidance and has been approving demonstrations to allow states to use Medicaid funds to provide short-term inpatient and residential treatment for enrollees with substance use disorder (SUD).
  - In November 2018, CMS **waived a longstanding federal rule that prohibited reimbursing behavioral healthcare and substance use disorder services for Medicaid enrollees** with SMI or serious emotional disturbance (SED) in "institutions for mental disease" (IMD) by initiating a call for demonstration proposals.
  - As of November 2020, 31 and the District of Columbia have approval for such demonstrations for SUD services, and seven states have approval for SMI/SED services. Without these demonstrations, states have limited authority to finance these services for nonelderly adults in IMDs.
- CMS approved a new 1115 demonstration in Tennessee which uses a budget neutrality structure with an aggregate cap and risk corridor. The demonstration gives the state a range of autonomy within which it can make decisions about its Medicaid program with less administrative burden, as well as significant flexibility in the provision of coverage of pharmacy benefits.
- Median months to approval for non-COVID 1115 demonstrations has been consistently declining over the last 12 months, and is now at 7.5 months, declining an average of 60 days compared to September 2019.[80]

- <u>For 1915 (b) and (c) Waivers and State Plan Amendments (SPAs)</u>:
  - As a result of Medicaid 1915 waiver process improvements, between 2016 and 2019 reduced:
    - **1915(b) waiver median approval times by 14%;**
    - **1915(c) renewal approval times by 41%; and**
    - **1915(c) amendment approval times by 37%.**[81]

- CMS approved more than 80% of SPAs and 1915 waivers on the first clock according to 2020 Q3 results.[82]
- As a result of process improvements, reduced median approval time for SPAs by 23% between 2016 and 2019, and increased the rate of SPA approval within the first 90-day review clock by 20% over the same period.[83]

- In addition to maintaining the improved review times, CMS also received more than 620 state submissions related to COVID-19, and have disposed of greater than 90% of them at an incredibly quick pace.
  - The median Medicaid Disaster SPA processing time for April through June 2020 was 17 days from receipt to approval, with all being approved on the first clock. CMS processed 1915(c) Home and Community Based Service (HBCS) waiver amendments in just seven days on average.
  - Alongside Disaster Relief SPAs, CMS also continued to process nearly 200 regular SPAs in the second quarter of 2020. CMS had a median processing time of 64 days, which bested the prior year's average. Similarly, HCBS amendments were processed in 43 days, down from days in the same quarter in 2019.[84]

Figure 13. Improvement in 1915 and SPA Waiver Reviews, Medicaid Scorecard

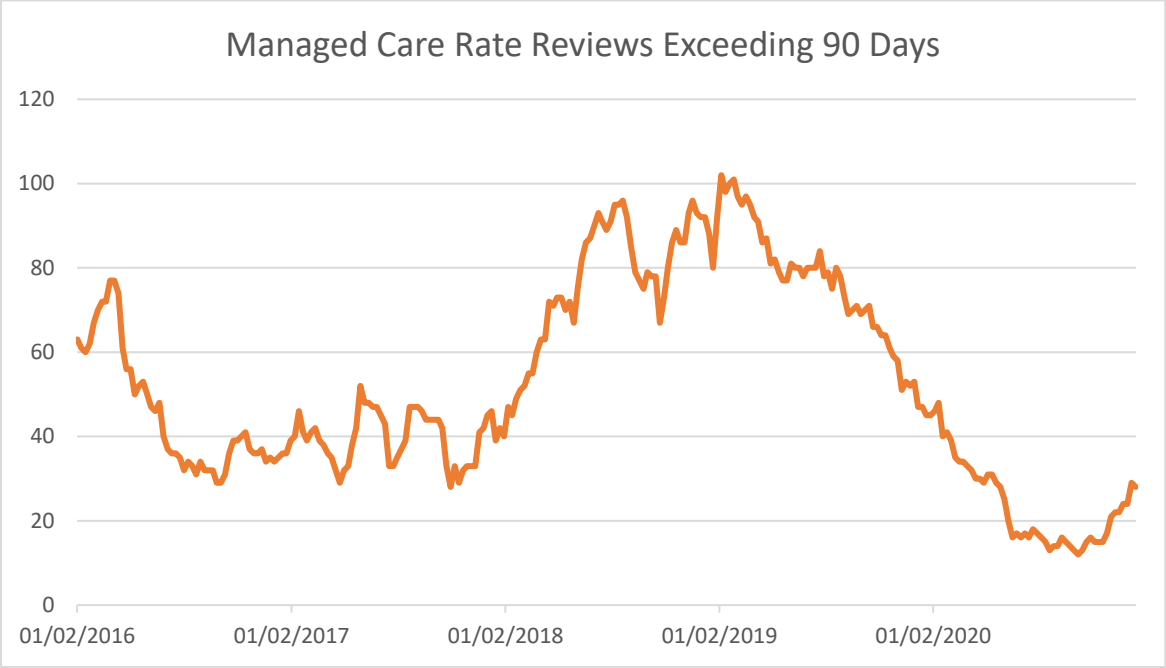


* Days to review represents CMS days to review. State review and revision times are excluded.

- Figure 14 shows the improvement in timeliness of review of managed care rate certifications from a 2016 baseline to July 2020. Similarly, the percentage of rate reviews completed within 90 days has increased from 23 percent in the first quarter of 2018 to 85 percent in the first quarter of 2020.
- Due to a separate but related process improvement effort, CMS also continues to reduce overall managed care contract review time compared to 2019. As of 2020 Quarter 3 (not shown), CMS

has achieved a 19% reduction in the review time compared to 2019, going from an average processing time of 316 days (based on a sample) to 255 days.[85]

Figure 14.Improvement in Timeliness of Managed Care Rate Reviews, Medicaid Scorecard



- On November 13, 2020, CMS published the Medicaid managed care final rule.[86]
    - This final rule streamlines the Medicaid and CHIP managed care regulatory framework, reduces unnecessary and duplicative administrative burdens, and further reduces federal regulatory barriers to help ensure that states are able to work efficiently and effectively to design, develop, and implement Medicaid and CHIP managed care programs that best meet each state's local needs.
    - The rule fosters accountability by ensuring CMS issues guidance to help states more quickly complete the federal rate review process, while preserving the requirement for states to implement a Quality Rating System (QRS) for the managed care plans they contract with, so beneficiaries can have information about their plan and make informed decisions about their healthcare. It also reinforces CMS' commitment to providing access and quality care to beneficiaries living in rural America by changing the minimum standards states must use in developing network adequacy requirements in a way that supports state facilitation for telehealth options. For additional details on the provisions that were finalized, visit: https://www.medicaid.gov/medicaid/managed-care/guidance/medicaid-and-chip-managed-care-final-rules/index.html.

Empowering State Innovation Through Value-Based Purchasing Agreements

- As part of its effort to incentivize states to pursue innovative approaches to address rising drug prices, CMS has approved eight state plan amendment proposals to negotiate supplemental rebate agreements.[87] These supplemental rebate agreements are value-based purchasing arrangements with drug manufacturers that allow states to link payment for prescription drugs to the value delivered to patients.

  - Increasing states' flexibility empowers them to develop policies that are effective and responsive to local conditions and price "hot spots" that lower costs, increase the predictability of expenses, and improve access for patients.

Using Medicaid Waivers and Technical Assistance to Innovate in Medicaid

- On September 15, 2020 CMS released a Value Based Care State Medical Director Letter (SMDL) that provides guidance to states on how to advance value-based care in their Medicaid populations and share pathways for adoption of the various strategies.[88]
  - The SMDL highlights alternative payment and delivery models that use value-based payment that are applicable across multiple payer types, including Medicare.
  - The letter references Alternative Payment Methodologies (APM) described in the Health Care Payment Learning and Action Network (HCP-LAN) APM Framework and clarifies how state Medicaid agencies can adopt them.
  - CMS set a 2020 target of 4 states submitting new VBP proposals, and as of 2020 Q3 CMS has met double that goal with eight states submitting proposals.
- On January 30, 2020, CMS issued a SMDL conveying guidance for the Healthy Adult Opportunity (HAO) demonstration which emphasized the concept of value-based care while granting states flexibility to administer and design their programs within a defined budget.[89]
  - HAO is available to all states, subject to CMS approval, with a focus on a limited population – adults under age 65 who are not eligible for Medicaid on the basis of disability or their need for long term care services and supports, and who are not eligible under the state plan. The HAO was designed to give states a broad suite of flexibilities in exchange for meeting certain performance and spending targets.
  - With the significant flexibility afforded under this demonstration opportunity, states will be held to a high standard of accountability for producing positive health outcomes. To the extent states achieve savings and demonstrate no declines in access or quality, CMS will share back a portion of the federal savings for reinvestment into Medicaid.
- Through the Medicaid Innovation Accelerator Program (IAP), CMS is providing direct technical assistance to participants in its program to identify Beneficiaries with Complex Care Needs (BCN) target populations, incorporating social determinants of health into targeting and program design activities. **The IAP helps programs design effective care management strategies and APM**. Learnings from the IAP are also shared in national webinars to all Medicaid agencies.

Making Transformed Medicaid Statistical Information System (T-MSIS) Data Available

- T-MSIS data is the most current and complete Medicaid and CHIP data resource available and builds upon years of CMS' work toward strengthening data availability. The T-MSIS Analytic Files (TAF) RIF files are a research-optimized version of T-MSIS data and serve as a data source tailored to meet the broad research needs of the Medicaid and CHIP data user community. These files include data on Medicaid and CHIP enrollment, demographics, service utilization and payments.
  - The T-MSIS SUD Data Book is an example of how T-MSIS data can be used to better understand the complex needs of the Medicaid population. The SUD data book is found at: https://www.medicaid.gov/medicaid/data-and-systems/downloads/macbis/sud-data-book.pdf.
- CMS is working with states to enhance their Adult and Child Core Set reporting, helping states to use their data to drive quality improvement for Medicaid and CHIP beneficiaries.

  - Through the third quarter of 2020, more than half the states participated in Core Set learning diffusion opportunity focused on improving measure performance and health outcomes.[90]
  - CMS worked closely with the states to optimize data reporting and collection under T-MSIS to ensure CMS and oversight bodies of access to the best, most complete and accurate Medicaid data.[91]

- For the first time, CMS used data from T-MSIS data in real time to analyze and report out on the COVID-19 experience in the Medicaid and CHIP beneficiaries (COVID data analysis, foregone care, telehealth utilization). This was a milestone accomplishment in CMS' ongoing commitment to data driven decision-making.[vi]
- CMS launched the Data Quality (DQ) Atlas tool in August 2020. This tool allows anyone to review the quality and usability of the T-MSIS research files for all years of published T-MSIS data.
  - The DQ Atlas is an interactive, web-based tool to help policymakers, analysts, researchers, and other stakeholders explore the quality and usability of the T-MSIS data for their analytic needs, such as enrollment, claims, expenditure, and service use.
- On September 16, 2020, CMS released T-MSIS data for calendar years 2017-2018. The 2017 and 2018 data releases mark a watershed in the timeliness and quality of Medicaid & CHIP data available to the public.
  - Later in 2020, the published files for 2014, 2015, and 2016 will be refreshed to reflect the substantial data quality improvements undertaken by state partners.

Improving Accountability through the Medicaid & CHIP Scorecard

- On June 4, 2018, CMS released the Medicaid and CHIP Scorecard, a central component of the Administration's **commitment to modernize the Medicaid and CHIP program through greater transparency and accountability for the program's outcomes**.[92]
- Using a combination of federally reported and state-level voluntarily reported measures, the Scorecard is a public-facing federal dashboard of state health and administrative performance in the Medicaid and CHIP programs.
  - The 2020 MAC Scorecard includes healthcare quality measures of asthma medication management for children and adults as well as a measure of follow-up care for adults after an emergency department visit for mental illness. The 2020 MAC Scorecard also contains new administrative accountability measures including CMS and state approval times for managed care contract reviews; and CMS approval times for enhanced federal funding to support states' eligibility, enrollment and information technology systems
- The Scorecard reflects a three-pillared Medicaid strategy to achieve a better balance between appropriate federal oversight and state flexibility, ensure fiscal integrity, and promote accountability for the quality of care provided to Medicaid beneficiaries.[93]
- CMS has also updated the dashboard to improve user experience and navigation across the Scorecard, further demonstrating the Administration's desire to ensure the dashboard is optimized for use by beneficiaries.
  - CMS is using TMSIS data to calculate the per capita expenditures for enrollees using 5 eligibility groups for the MAC Score Card. In the recently released data update, CMS

[vi] For more discussion of CMS' response to the COVID-19 PHE, see "Case Study: COVID Response".

displayed per capita expenditure data for all states for children, adults, the aged, people with disabilities, and the ACA expansion population, stratified by the quality of their data.

Improving Integrity of Medicaid Spending

- While the responsibility for making proper payments in Medicaid primarily lies with the states, CMS plays a significant role in supporting state efforts and increasing state oversight, accountability, and transparency.
- In June 2018, CMS announced a set of new and enhanced initiatives designed to improve Medicaid program integrity through greater transparency and accountability, strengthened data, and innovative and robust analytic tools.[94]
- CMS implemented improved audits and oversight activities. These audit processes include targeted audits of some states' managed care organization financial reporting and audits of state beneficiary eligibility determination in states previously reviewed by the Office of the Inspector General,[95] as well as revisions to the Medicaid Eligibility Quality Control (MEQC) program, which conducts continuous oversight of states' eligibility determinations.[96]
    - CMS leadership committed to reducing a backlog of potential disallowances totaling $1.37 billion FFP that existed prior to January 2017. As of December 7, 2020, CMCS has resolved almost $1.12 billion FFP of $1.37 billion FFP by issuing disallowances or otherwise resolving 40 backlog items. In addition, CMCS is working to resolve up to an additional 22 potential disallowances totaling $250 million.
        - CMS also recovered $9.7 billion in rate adjustments for the 2014-2016 period from the State of California.
        - CMS also anticipates recovering $2.5 billion from other states over this same time period.
        - Time spent on administrative requirements associated with state innovation efforts has also decreased over the past three years, enabling states to act more quickly on interventions.
- CMS built upon its existing education and technical assistance support to focus on providing effective provider education to reduce aberrant billing.[97]
- On November 12, 2019, CMS issued the proposed Medicaid Fiscal Accountability proposed rule to strengthen the fiscal integrity of the Medicaid program and help ensure state supplemental payments and financing arrangements are transparent and value driven.[98]
    - This rule proposes to improve reporting on supplemental payments, clarify Medicaid financing definitions, and reduce questionable financing mechanisms.
    - Through these policy changes, CMS will gain access to the timely and adequate State Medicaid payment and financing data necessary[vii] to enable more effective oversight of the Medicaid program.

Increasing Beneficiary Access to Medications by Promoting Value-Based Purchasing

- **On December 21, 2020, CMS published the Establishing Minimum Standards in Medicaid State Drug utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug rebate and Third Party Liability**

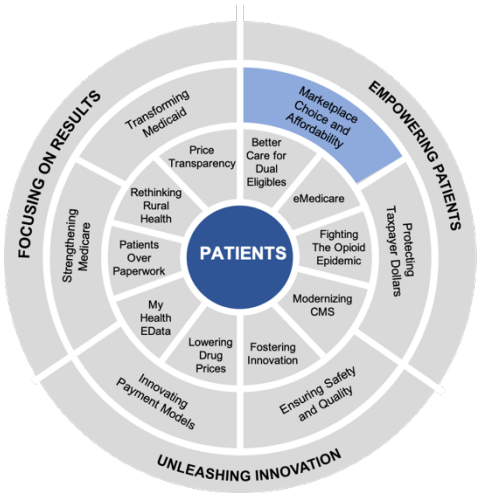
[vii] As stated in the GAO's 2015 report, "Oversight of Medicaid payments to individual hospitals and other institutional providers . . . is limited in part by insufficient information on payments and also the lack of a policy and process for assessing payments to individual providers." https://www.gao.gov/assets/670/669561.pdf

(TPL) Requirements final rule. These policy changes would begin removing barriers to value-based agreements between drug manufacturers and payers.[99] Value-based payment for pharmaceuticals has the potential to increase patient access to new medicines by holding pharmaceutical manufacturers accountable for outcomes their drug achieves, as well as creating alternatives to traditional cost controls that impede patient access.[100]

- Regulatory changes seek to remove these barriers by allowing manufacturers to report multiple best prices for a drug under the Medicaid drug rebate program when part of value-based arrangement among other new flexibilities.
- Value-based payment for pharmaceuticals has the potential to increase patient access to new medicines by holding pharmaceutical manufacturers accountable for outcomes their drug achieves, as well as creating alternatives to traditional cost controls that impede patient access.[101]

Marketplace Choice and Affordability

Individual health insurance markets across the country have experienced ongoing disruption in recent years. Premiums increased substantially in some states—more specifically, average premiums more than doubled between 2013 and 2017, and increased another 27% in 2018.[102] At the same time, insurer participation also dropped – by 2018, over 50% of U.S. counties had only one marketplace insurer option available in their county.[103] Rising premiums and fewer choices in insurers on the federal and state marketplaces resulted in a large portion of unsubsidized people dropping out of the market. Between 2016 and 2018, 2.5 million unsubsidized people left the individual market, representing a 40% drop.[104]



CMS moved quickly to address these issues, and has continued to stabilize the market and drive improvement in the federal healthcare marketplace while also increasing state flexibility to address unique Marketplace challenges.

Accomplishments

CMS' engagement in the marketplace has advanced the Administration's goals for increasing flexibility, improving affordability, strengthening program integrity, empowering consumers, promoting stability, and reducing unnecessary regulatory burdens. **After years of double-digit increases, CMS announced in October 2020 the third straight year of lower benchmark plan premiums[viii] for plans sold on HealthCare.gov for plan year (PY) 2021. In addition, for PY 2021, four states[ix] have an average benchmark plan premium decrease of 10% or more over the previous year.**[105]

Figure 15. Average Benchmark Plan Premiums, PY 2017 – PY 2021[106]

	PY17	PY18	PY19	PY20	PY21	PY19-PY20 Change	PY20-PY21 Change	PY17-PY21 Change
27-Year-Old	$300	$411	$406	$389	$379	-4%	-3%	26%
Family of Four	$1,092	$1,590	$1,591	$1,524	$1,484	-4%	-3%	36%

Increasing Marketplace Stability

- In April 2017, CMS took immediate steps to address instability in the individual health insurance market by finalizing the Market Stabilization Rule. This rule improved risk pools by encouraging individuals to maintain continuous coverage by tightening the rules around enrollment periods.[107] For instance, the rule instituted pre-enrollment verification for eligibility for special enrollment periods and shortened the open enrollment period to align with Medicare and employer market standards.

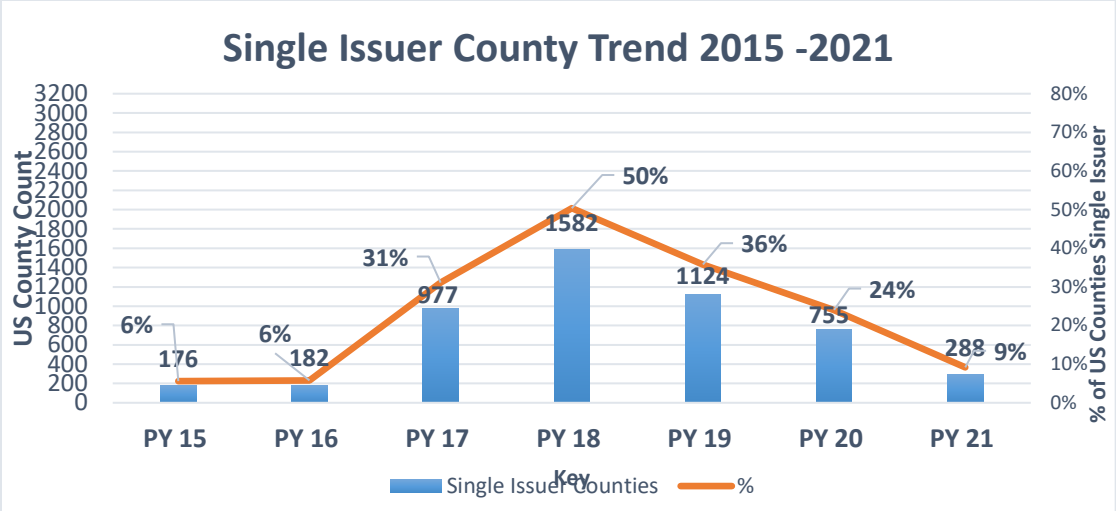
[viii] The "benchmark plan premium" is the average HealthCare.gov state second lowest cost silver plan premium attributable to essential health benefits.
[ix] These four states are: (1) Iowa; (2) Maine; (3) New Hampshire; and (4) Wyoming.

  - Approximately 8.3 million people selected or were automatically re-enrolled in plans using the HealthCare.gov platform during the 2020 Open Enrollment Period providing an ongoing stable base of plan participants.[108]

- CMS finalized the 2019, 2020, and 2021 Payment Notice rules which provided states new tools to stabilize their health insurance markets and delivered a more predictable regulatory framework to facilitate a more efficient and competitive market, including:
  - Additional flexibility in what states can select as an Essential Health Benefits-benchmark plan, including building their own customized set of benefits;
  - Opportunity for states to request reasonable adjustments to the MLR standard for the individual market if the state shows a lower MLR standard could help stabilize its individual insurance market; and
  - Returning oversight authority to states regarding state review of network adequacy.[109,110,111]

Bringing Insurers Back Into the Marketplace

- CMS implemented an outreach and marketing program in 2017 to encourage insurers back into the individual health insurance market. Initially established to prevent counties from having no insurance coverage at all, once that risk was mitigated the programs goals were expanded and revised to focus on increasing competition and to bring insurance companies back to the marketplace that had exited in previous years. Over the past three and a half years we've conducted over 200 in person or conference meetings with over 60 different companies.
- Specifically in response to these efforts, we've seen United expand from 4 to 11 states for PY 2021, and issuers like Centene, Bright, and Molina more than double their participation year over year for the past three years. Similarly, brand name plans like Cigna and Anthem have continued steady growth which has helped to send a message of stability for PY 2021 and beyond.[112]
- **Overall, CMS has seen the percent of counties with only one issuer available to consumers drop to 9% for PY 2021[113], down from over 50% in PY 2018[114].** Additionally, the number of states that only had one option for a consumer statewide has dropped from 8 states in 2018, down to only 1 for PY 2021 (Delaware) and competition on the marketplace is now nearly identical to where it was during its most competitive year of PY 2015.[115]
- These successful efforts to increase competition are working to bring down premiums. CMS research shows that counties where there was any increase in the number of issuers from 2018 to 2019 were associated with a nearly 8 percent reduction in the benchmark premium.



Increasing Alternative Coverage Options

- CMS, in collaboration with the Departments of Labor and the Treasury (collectively, the Departments), published a final rule that expanded access to short-term, limited duration insurance, primarily designed to fill gaps in coverage that may occur when an individual is transitioning from one plan to another (e.g., individuals in-between jobs) or where no affordable alternative is available. While short-term limited duration insurance plans have existed for decades, this Administration 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. These plans are not for everyone and the rule ensures that consumers are informed about the limitations of these plans.
    - This action helped increase cost-effective insurance options for Americans faced with escalating premiums and dwindling options in the individual insurance market. **According to a Congressional Budget Office analysis, for healthy individuals who are ineligible for premium tax credits, these plans can be as much as 60% lower than premiums for the lowest-cost bronze plan**.[116]
- In 2019, the Departments finalized a rule expanding health reimbursement arrangements (HRAs), giving businesses additional ways to offer health insurance coverage for their employees.[117] HRAs enable employers to provide their employees with tax-preferred funds to pay for the cost of health insurance coverage purchased in the individual market. HRAs will significantly benefit small businesses, which face significant costs in offering a traditional group health plan and businesses that do not currently offer coverage.[118] **CMS expects 800,000 employers will offer these new HRAs to more than 11 million employees and family members once employers fully adjust to this new coverage option, extending coverage to 800,000 Americans who would otherwise be uninsured.**[119]
- CMS increased outreach on individual coverage HRAs (ICHRAs), which are projected to stabilize the health pool and incentivize insurers to compete on the individual market. **CMS held over 140 stakeholder meetings and webinars regarding ICHRAs, including kicking off the year with an ICHRA Industry Day with more than 200 attendees.**

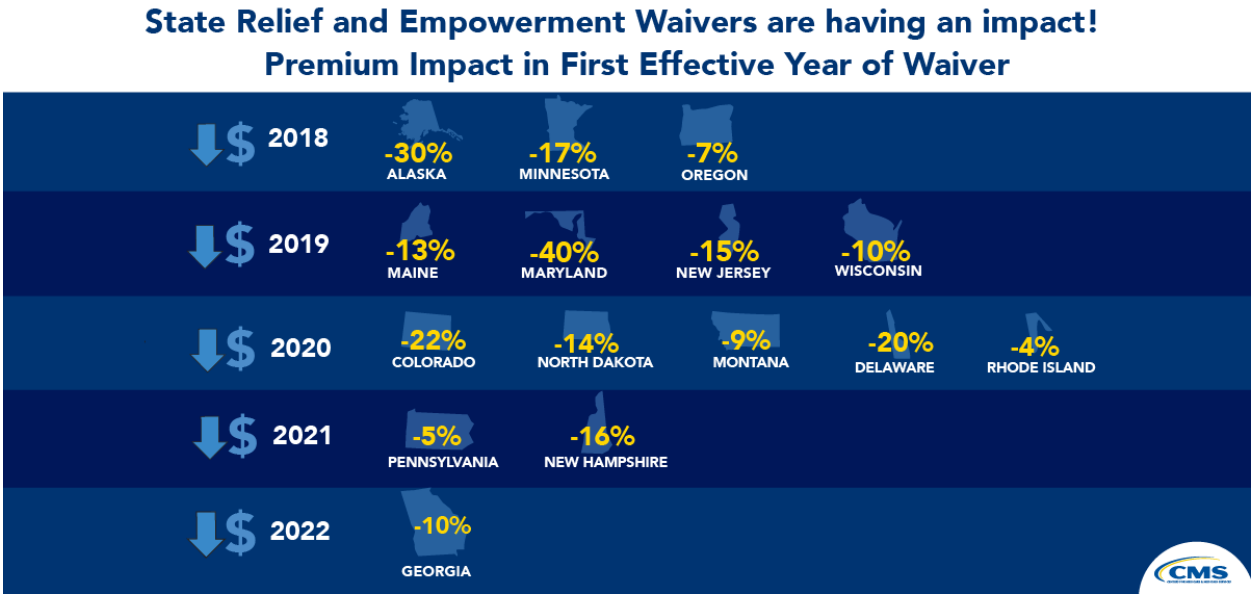
- This increased engagement is showing results – by midyear 2020, roughly 2,000 enrollees had joined the marketplace through ICHRAs.[120] CMS projects a significant increase in ICHRAs going into FY 2021.

Providing States Flexibility to Address Unique Challenges Through 1332 Waivers

- In response to an Executive Order on Minimizing the Economic Burden of the ACA,[121] CMS and the Department of the Treasury issued new guidance in October 2018 announcing policy changes that increase states' flexibility through Section 1332 State Relief and Empowerment Waivers and allow states to pursue innovative strategies for providing their residents with access to high quality, affordable health insurance.[122] The guidance also call these waivers "State Relief and Empowerment Waivers" to reflect the new direction and opportunity for states. The proposed 2022 Payment Notice proposes to incorporate this guidance into existing regulations to give states greater certainty over how the federal government will evaluate and monitor section 1332 waivers in the future.
- CMS also released four waiver concepts that illustrate how states might take advantage of this flexibility in order to encourage innovative thinking on how states can take action to strengthen their markets.[123] CMS also published more detailed concept papers and accompanying application templates for each waiver concept.
- These reinsurance programs help fund people with high claims costs and remove these costs from the individual market risk pool. By removing these costs, reinsurance lowers premiums for everyone in the market. As shown in Figure 16, premium savings range from 4 percent in Rhode Island to 40 percent in Maryland.
    - States have used section 1332 waivers to waive the single risk pool requirement under section 1312(c)(1) of the ACA to the extent that it would otherwise require excluding total expected state reinsurance payments when establishing the market-wide index rate which allow the states to implement state-based reinsurance programs. Through section 1332 waivers, states have designed and implemented different models of state-based reinsurance programs, including: a claims cost-based model, where issuers are reimbursed for a portion of the costs of enrollees whose claims exceed an attachment point (e.g., CO, DE, GA, MD, MN, MT, NH, ND, NJ, OR, PA, RI, WI); a conditions-based model, where insurers are reimbursed for costs of individuals with one or more of pre-determined high-cost conditions (e.g., AK); or a hybrid conditions and claims cost-based model (e.g., ME).[124]
- **Georgia Section 1332 Waiver:** So far, **CMS and the Department of the Treasury have approved 15 state reinsurance waivers, which drove insurance premiums down—in most cases by double digits**.[125,126]
    - In October 2020, CMS and the Department of the Treasury approved Georgia's State Relief and Empowerment waiver, a two-phased approach to address growing healthcare access and affordability challenges facing many residents across the state.[127]
    - The first phase seeks to implement a reinsurance program starting in PY 2022, which is estimated to reduce premiums for all enrollees in the individual market by an average of 10%, targeting savings to rural areas hardest hit by lack of competition and choice. The second phase seeks to transition the state's individual market to a private sector platform calls the Georgia Access Model in PY 2023.

- The Georgia Access Model leverages the innovation and expertise of the private sector to improve the enrollee shopping experience by allowing enrollees to shop for and compare available plans through private sector partners, including web brokers, health insurance companies, and traditional agents and brokers.
    - Increasing traffic to these private sector companies will not only incentivize these partners to increase their marketing and outreach to the uninsured, but will also drive improvements in the consumer shopping experience as the market innovates to meet consumer preferences.

Figure 16. Impact of 1332 Waivers on Premiums



Improving Operational Efficiency

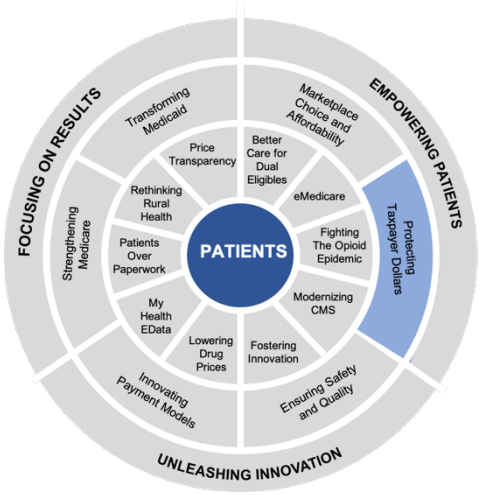
- CMS made changes to ensure individuals have a seamless enrollment experience by upgrading the system's IT functionality. Specifically, CMS increased the integrity of the federal Marketplace by closing out 50% of outstanding GAO recommendations related to IT security in 2018, and established plans to address the remaining recommendations.[128]
    - User feedback confirms CMS efforts have improved user experience with the system; HealthCare.gov consumers were able to shop and pick a plan with minimal interruption throughout the entire enrollment period.[129] As a result, **consistent with 2018, the consumer satisfaction rate at the Call Center in 2019 remained at an all-time high, averaging 90%.**
- Along with improvements to the enrollment portal itself, CMS also established the **Enhanced Direct Enrollment (EDE), a key development that allows CMS to partner with the private sector to provide more avenues for consumers to apply and shop for marketplace coverage**.[130]

  - For the 2021 plan year, the second year EDE was available through the full open enrollment period, EDE accounted for 31% of active agent and broker assisted plan selections.[131]
  - The new EDE program also increased combined open enrollment traffic through CMS' "Classic" Direct Enrollment and EDE channels through private sector vendors, increasing traffic through these two channels from 29% of active plan selections in 2020 to 37%. The entire increase is attributable to a more than doubling in the use of the EDE channel, which increased from approximately 521,000 to 1,130,000 plan selections.
  - Within two years, EDE more than quadrupled the number of participating private sector entities in the EDE program from 9 in 2019 (2 primary partners and 7 upstream issuers leveraging those platforms) to 43 in 2021 (10 primary partners and 33 upstream issuers leveraging those platforms).
  - Finally, EDE also attracted a higher mix of consumers new to the Marketplace, improving the viability of the channel and its ability to contribute to the overall stability of the Exchanges; during plan year 2021 Open Enrollment, 39% of consumers brought in via the EDE channel were new to the Marketplace as opposed to 33% in the Classic Direct Enrollment channel and 25% of consumers brought in via non-DE channels.

- By improving its operational efficiency, over the past four years, CMS has reduced its federal marketplace spending by $100 million per year – where it was at $2 billion per year, it is now $1.65 billion and falling.
  - **These savings in administrative costs directly benefit consumers financially.** By reducing costs on HealthCare.gov, CMS was able to lower HealthCare.gov user fees on issuers from 3.5% to 3% of premiums for the 2020 benefit year and then recently proposed to lower the fee further from 3% to 2.25% for the 2022 benefit year. This user fee is passed on to patients in the form of higher premiums, and their reduction enables issuers to pass these savings on to patients.[132]

Protecting Taxpayer Dollars

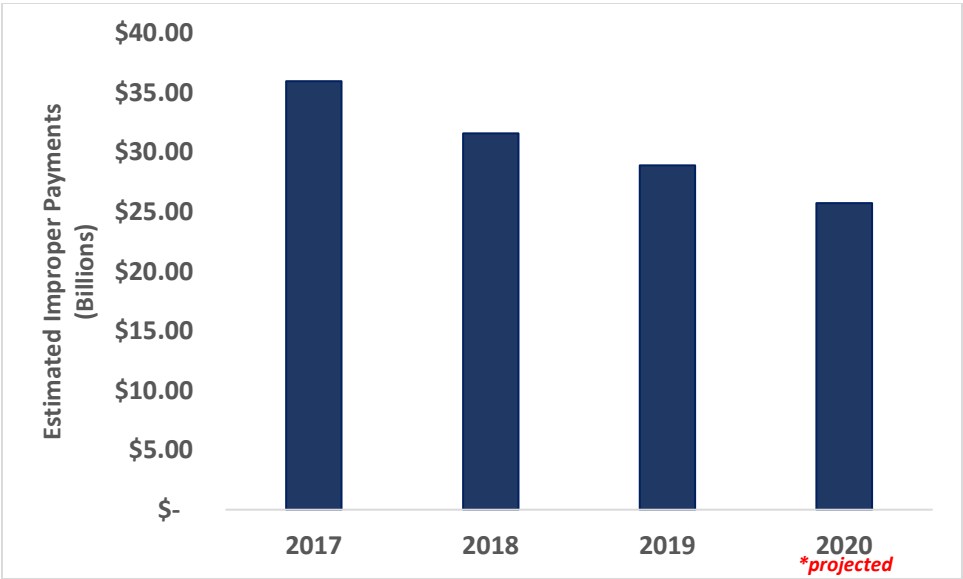
In October 2019, President Trump announced an Executive Order instructing CMS to undertake efforts to enhance fiscal sustainability of the program by detecting and preventing fraud, waste and abuse and more aggressively ensure the integrity of federal healthcare programs, including the development of regulatory policies to strengthen our program integrity efforts.[133] While addressing fraud and abuse has long been part of CMS' program integrity efforts, the Executive Order underscored the urgency and importance of doing the utmost to ensure every dollar spent in Medicare, Medicaid, CHIP and the Marketplaces meets program requirements. Over the past five years, CMS has also taken bold steps to respond to address areas of high-risk identified by the Government Accountability Office and the HHS Office of Inspector General.



Accomplishments

"At a time when Medicare's ballooning costs are threating the long-term sustainability of the program, President Trump is taking action to protect the program," said Administrator Seema Verma, "Every dollar spent inappropriately is one that should have been used to benefit patients. Under President Trump's leadership, CMS is pulling every lever at its disposal to safeguard precious resources and direct them to those who truly need them – both today and in the future."[134] Through aggressive program integrity measures, described in more detail below, CMS lowered the Medicare FFS improper payment rate from 11% in 2016 to 6.27% in FY 2020, the lowest rate since 2010.

Figure 7. CMS Estimated Improper Payments for Medicare FFS, 2017-2020*



Source: CMS data[135]

Reducing Billing Errors Through Targeted Probe and Educate (TPE)

- In October 2017, CMS launched a nationwide program, the TPE program, to better target medical review and emphasize education and assistance to correct claims errors.[136] The TPE program is designed to help providers and suppliers with high claim error rates or unusual billing practices, as well as reduce claim denials and appeals through one-on-one help.
- **Between October 2017 and February 2019, CMS worked with 20,000 providers and suppliers through the TPE program to provide one-on-one education.**[137] As a result, approximately 80% of those providers and suppliers were relieved from subsequent review.
- TPE for home health agencies **resulted in a significant $5.32 billion decrease in estimated improper payments from FY 2016 to FY 2019.**[138]
    - This dramatic reduction in error rate marks the fifth year in a row of such reductions, and the first time in 10 years where the rate has dipped below 8%.[139,140]

Leveraging New Technology to Combat Fraud

- In 2019, CMS updated its Fraud Prevention System to expand the agency's payment integrity capabilities, analyzing 11 million claims daily for new areas of fraud, waste, and abuse. **Through technology provided by the Advanced Provider Screening system, which checks the eligibility of providers, and risk evaluations, the Center for Program Integrity removed 564 problematic providers in 2019.**[x]
    - Paired with revamped contractor arrangements, such as the five Uniform Program Integrity Contractors (which replaced zone contractors) and the Recovery Audit Contractors, the Center for Program Integrity is tackling fraud, waste, and abuse across the programs.
- In October 2019, CMS issued two RFIs soliciting input from stakeholders—notably clinicians and the healthcare IT industry—on ways CMS can transform program integrity as the healthcare industry evolves, emphasizing a reduction in provider burden and using advanced technology such as artificial intelligence and machine learning. In addition to the RFIs, CMS held three listening sessions (San Francisco, Dallas and Philadelphia) and one national webinar. CMS leadership engaged with stakeholders to obtain their input on ideas, strategies and tools.
    - CMS is compiling this feedback to build into future modernized program integrity strategies.[141,142]

Releasing a New Comprehensive Medicaid Integrity Plan (CMIP)

- CMS released the most recent iteration of the recurring five-year Comprehensive Medicaid Integrity Plan (CMIP) for FYs 2019-2023. This strategy has resulted in several new or enhanced initiatives that will create greater transparency and accountability for Medicaid program integrity performance, enable increased data sharing and robust analytic tools, and seek to reduce Medicaid improper payments across states.[143]
- These initiatives include stronger eligibility audit functions and financial management reviews, increased beneficiary eligibility oversight, and enhanced enforcement of state compliance with federal rules.

[x] Such removals were triggered by felony convictions such as healthcare fraud and violent sex offenders.

- CMS conducted reviews of the California, New York, Kentucky, and Louisiana Medicaid beneficiary eligibility systems to assess the accuracy of eligibility determinations for the adult expansion group. CMS began reviews in four additional states in late 2020, which will include both Medicaid and CHIP beneficiary eligibility determinations and will be broadened to cover more eligibility categories. CMS also reviewed the twenty-two (22) Medicaid managed care plans (MCPs) in California to make sure data submitted by the MCPs supported the minimum Medical Loss Ratio requirements and calculations for the expansion population.
- CMS collaborated with 37 states to investigate provider fraud, waste, and abuse.[144]

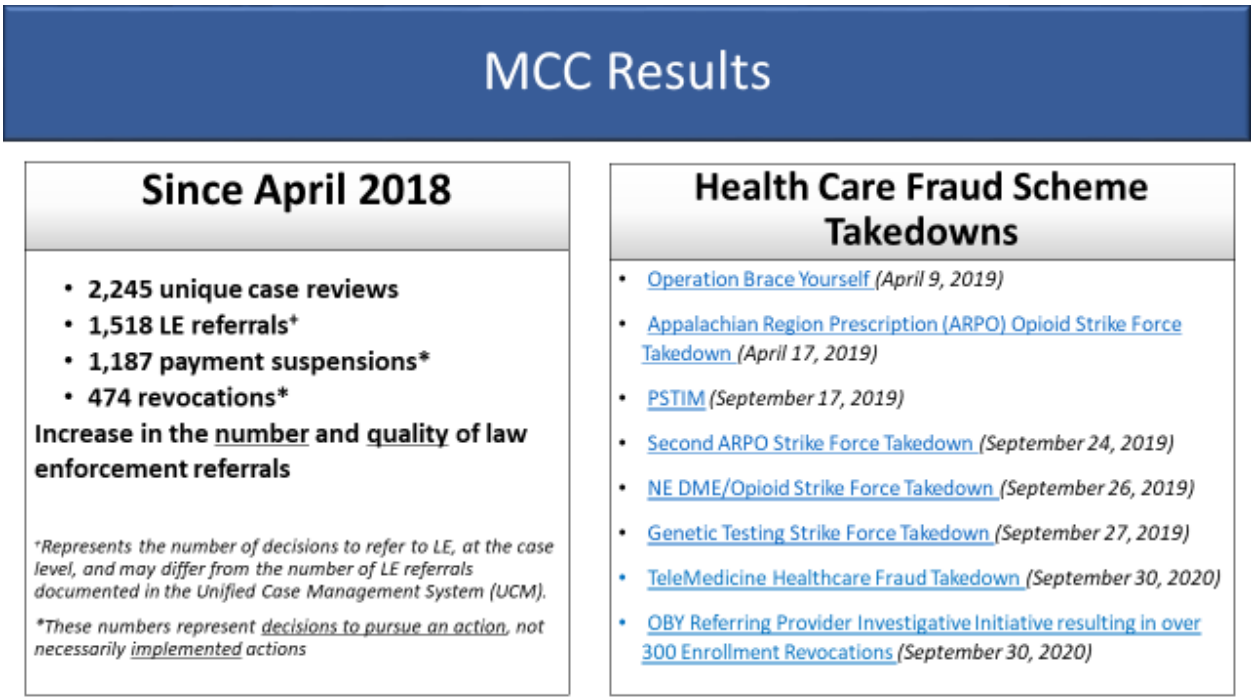
Testing New Ideas to Reduce Waste in Medicare FFS

- Starting in April 2018, CMS began mailing all Medicare beneficiaries new Medicare cards.[145] These cards replaced beneficiaries' old Medicare number—which used beneficiaries' social security number—with a new Medicare Beneficiary Identifier (MBI). A unique, randomly assigned combination of letters and numbers, the MBI protects personal information while also reducing opportunities for fraud and abuse.
- **CMS sent these new cards to more than 61 million beneficiaries in nine months, completing the mailings three months ahead of schedule.[146]**
- By January 2019, healthcare providers submitted 58% of all Medicare FFS claims using a beneficiary's MBI. **CMS estimates that this effort prevented between $5 and $23 billion in fraud.**

Collaborating with Law Enforcement to Prosecute Fraudulent Activity

- Since 2017, HHS and CMS have continued to partner with the Department of Justice in aggressively targeting schemes billing Medicare and Medicaid for medically unnecessary care that often were never even purchased, prescribed, and/or provided to beneficiaries.
- Under these joint Health Care Fraud (HCF) Strike Force teams, the agencies combine data analytics and traditional law enforcement investigative techniques to bring prosecutions against the worst actors in the healthcare field across the country.
    - During FY 2019, HCF Strike Force efforts: (1) filed 359 indictments, investigations, and complaints involving charges filed against 673 defendants who allegedly billed federal healthcare programs more than $5.1 billion; (2) negotiated 323 guilty pleas; (3) litigated 233 jury trials, with guilty verdicts against 35 defendants; and (4) securing imprisonment for 340 defendants sentences, averaging nearly 49 months incarceration.[147]
- In its 2020 National Health Care Fraud and Opioid takedown, **the DOJ filed charges against 345 defendants - including more than 100 doctors, nurses and other licensed medical professionals - in prosecutions spanning the country, representing the largest amount of fraud ever charged by the department in a single National Takedown**.[148]

Figure 8. CMS Law Enforcement Referrals



Partnering with Private Industry to Stop Fraud and Abuse

- To combat fraud and abuse more effectively, CMS has continued to leverage private sector relationships.
- Under the Healthcare Fraud Prevention Partnership (HFPP), CMS convenes over 170 partners, including federal agencies, anti-fraud associations, private payers, and others, to identify and reduce fraud and waste through collaboration, data and information sharing, and cross-payer research studies.[149]
    - The HFPP also includes over 40 state and local partners, including a number of states that are submitting data for cross-payer studies. The HFPP has strategically positioned itself as a leading body to reduce fraud across the healthcare industry by providing a vast cross-payer data source to identify trends and share solutions.[150]
- CMS is also using data on provider relationships to ensure bad actors are not provided entry into the programs. To prevent questionable providers and suppliers from entering the Medicare program, and to promptly identify and act on improper behavior, CMS finalized the Program Integrity Enhancements to the Provider Enrollment Process Final Rule in September 2019.[151]
    - Among the new revocation and denial authorities included in this final rule, CMS finalized a policy allowing 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.

Improving the Risk Adjustment Data Validation Program

- The main way CMS ensures proper payments for the MA program is through auditing these plan contracts using the contract-level Risk Adjustment Data Validation (RADV) program.

- CMS performs random and targeted RADV audits to verify the accuracy of payments made to MA organizations and recover improper payments.[152] Under random RADV, MA plans are randomly selected for auditing. Targeted CMS RADV is applied to MA plans who have raised red flags, such as a large increase in risk scores.
    - Both random and targeted CMS RADV use blended sample of one-third of patients with high-risk scores, one-third of patients with medium risk scores, and one-third of low risk scores to validate the payment CMS provided was valid according to the conditions of the patient population.
    - **By using RADV, CMS estimates it will collect approximately $600 million in overpayments.**

Improving Prior Authorization Use

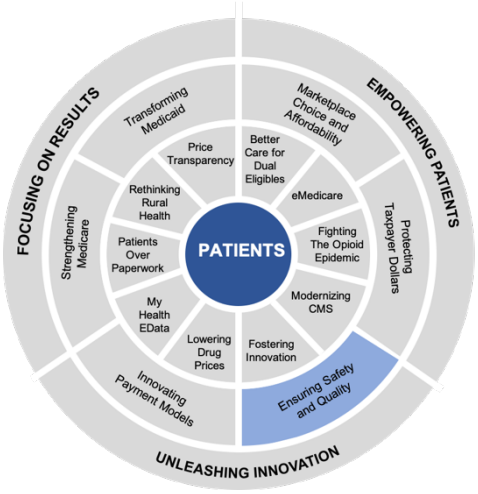
- CMS began using prior authorization as a program integrity tool in 2017. Since then CMS has pursued regulatory authority as well as used demonstration authority to continue to test the use of prior authorization as a program integrity tool.
    - In July 2017 CMS began the nationwide DMEPOS prior authorization program with the inclusion of 2 power mobility device codes. An additional 31 power mobility device codes were added in 2018. In FY 2020 CMS expanded nationwide a requirement for prior authorization expanded nationwide for five Pressure Reducing Support Surface codes.
- The Review Choice Demonstration (RCD) for Home Health Services gives providers in certain areas an initial choice of claim review options– including pre-claim review and post-payment review- to demonstrate compliance with Medicare rules. Pre-claim review is similar to prior authorization in that providers can request a provisional affirmation of coverage of services prior to claim submission and payment, however, providers can begin rendering services during the review process, eliminating delays in care and ensuring beneficiaries have access to covered services. The RCD was implemented in Illinois on June 1, 2019, in Ohio on September 30, 2019, in Texas on March 2, 2020, and in North Carolina and Florida on August 31, 2020.
- On December 14, 2020, CMS began the Paperwork Reduction Act approval process for a new Review Choice Demonstration for Inpatient Rehabilitation Facilities (IRF) services. This demonstration will mirror the RCD for home health services and give IRFs in the demonstration states a choice of claim review options to demonstrate their compliance. The demonstration develops improved methods for the identification, investigation, and prosecution of potential Medicare fraud, and is anticipated to begin in FY2021.

Preserving Quality of Care and Access to Essential Services

- On September 23, 2020, HHS announced that it will expand a prior authorization model for repetitive scheduled non-emergent ambulance transport nationwide, as the model has met all expansion criteria.[153]
    - Ambulance services have long been associated with inappropriate overuse and high improper payments, meaning many payments do not meet program requirements – intentional or otherwise –and contribute to inappropriate spending of Americans' tax dollars.
    - This model has saved the Medicare program about $650 million over four years while preserving quality of care and access to essential services.

Ensuring Safety and Quality

CMS is charged with setting the quality and safety standards for patients across the care continuum so that all patients receive high quality care regardless of where they go to get care, including the long-term care setting. To be stewards of its resources and ensure that it is influencing the healthcare market and the lives of beneficiaries in the most meaningful way, CMS must not only set, but also evaluate the quality and safety of care provided across care settings. Since 2017, CMS has diligently sought to ensure not only that beneficiaries are receiving safe, quality care, but that they can also choose their care based on publicly available quality metrics for each provider. To help guide efforts to ensure safety and quality in America's nursing homes, CMS issued a five-part strategy focused on Strengthening Oversight, Enhancing Enforcement, Increasing Transparency, Improving Quality and Putting Patients over Paperwork.



Accomplishments

Focusing on Meaningful Measures

- Launched in 2017, Meaningful Measures assess performance on only those core issues that are most vital to providing high-quality care and improving patient outcomes, with an emphasis on outcome-based measures, reducing unnecessary burden on providers, and putting patients first.[154]
    - Working collaboratively with the Health Care Payment Learning & Action Network, the National Academies of Medicine, the Core Quality Measures Collaborative, and the National Quality Forum, CMS reprioritized the measures used to assess performance,[155] consolidating and reducing duplicative and disparate measures to reduce burden to providers by decreasing reporting on measures which are not meaningful and streamline the data consumers need to make meaningful choices about their care.
        - **Through Meaningful Measures, CMS rolled back nearly 20% of measures that were either "topped out"[xi], duplicative, or simply overly burdensome to report for little gain, eliminating 79 measures across CMS' quality reporting and value-based payment programs.[156]**
    - In the second half of 2020, CMS began to work on a strategy to make long-term improvements to the initiative, called Meaningful Measures 2.0. Meaningful Measures 2.0 will continue to reduce reporting burden while prioritizing measures that have the greatest impact in terms of outcome and value for patients as well as those that promote equity. Meaningful Measures 2.0 will align measures across various federal quality reporting program as well as with private payers and entities. Finally, Meaningful Measures 2.0 will accelerate the transformation of current quality measures to be fully digital by 2025.
- CMS also applied the meaningful measures initiative to the Merit-based Incentive Payment System (MIPS) measure set and across CMS programs.

[xi] "Topped out" refers to measures where so many clinicians have incorporated these practices into their work that they no longer impact patient care.

- Because of these efforts, **CMS saved clinicians $128 million and 3.3 million hours of administrative documentation and reporting**.[157] Through similar efforts in the acute inpatient hospital quality programs, **CMS saved hospitals approximately 43,200 hours and approximately $1.6 million associated with administrative burden**.
    - By reducing administrative waste, CMS is putting money back into helping our clinicians achieve better outcomes for our patients.

Increasing Quality

- As CMS refines measurement sets in programs, there continue to be improvements in the quality of care and safety of care for patients. For example, hospital readmissions for every condition measured have decreased since 2017. Based on the 2019 PEC Leading Indicator report, there has been a 0.22% improvement in readmissions rates overall, a 32.2% improvement in catheter-associated urinary tract infections, and a 28.7% improvement in central line-associated bloodstream infections.[i]

- We've seen plan quality improve over time through Star Ratings with majority of plans having 4 stars or higher and the average star rating has gone up. (The average star rating for all Medicare Advantage plans with prescription drug coverage has improved to 4.16 out of 5 stars in 2020, increasing from 4.02 in 2017.)

- In CY 2021 OPPS/ASC Final Rule, for the first time in rulemaking, CMS finalized an update to the Overall Hospital Quality Star Ratings methodology to improve simplicity, understandability, and comparability of ratings across hospitals.

Driving Toward Value-Based Care in CMS Quality Programs

- In 2020, CMS continued efforts to evolve MIPS by introducing the MIPS Value Pathways (MVPs) into the Quality Payment Program (QPP).[158] The MVPs help move MIPS away from a siloed system of reporting and towards a framework that aligns the four current MIPS performance categories – Quality, Cost, Improvements Activities, and Promoting Interoperability – for different specialties and conditions, and creates a core set of measures that are clinically related, relevant to a clinician's scope of practice, and meaningful to patients. This alignment and connection of measures and activities will streamline MIPS reporting, reduce complexity and burden, and improve measurement. Additionally, the MVP framework will allow clinicians to gain experience in VBP, therefore readying themselves for what would be expected in an alternative payment model (APM).
    - CMS is collaborating with the stakeholder community and specialty societies to develop these MIPS Value Pathways, with a goal of having MVPs available for 75% of clinician types who participate in MIPS by 2024.

Strengthening Oversight of State Survey Agencies (SSAs)

- In recent years, CMS has found variation across State Survey Agencies in the identification of issues and application of civil monetary penalties for noncompliance. **To ensure that providers are consistently held accountable for the quality of care they provide, CMS overhauled its 10 regional offices and integrated them with a central office**.
    - This structural realignment not only ensures staff utilize similar tools and technologies, but also reinforces consistent monitoring, performance, and enforcement across the country.[159]

  - CMS established a national Critical Enforcement Review Panel to evaluate substantive enforcement action, such as involuntarily terminating providers/supplies from the Medicare program or imposing very high Civil Monetary Penalties (CMPs), to ensure the remedies are appropriate under applicable law and the relevant circumstances. This Panel also helps to ensure quality and consistency in key enforcement actions to limit variation.

- Beginning in FY 2020, CMS modified its State Performance Standards System (SPSS) to create uniform standards for frequency of surveys and documenting and remediating noncompliance.[160]
  - CMS also streamlined guidance to SSAs to provide clear and consistent procedures when evaluating a situation where a nursing home's noncompliance has placed the health and safety of residents in its care at risk for serious injury, harm, impairment or death, called "Immediate Jeopardy."
  - As the most serious finding that a SSA can make, the most detrimental to patient safety, and the most consequential for facilities' payments, CMS is helping protect residents by issuing streamlined guidelines for determining this situation.

Increasing Access to Kidney Transplants

- At any one time, more than 113,000 people in the United States are on the wait list for a lifesaving organ transplant, which far exceeds the number of transplantable organs available. On average, 20 people die every day because not enough organs are available for transplant.[161]
- In November 2020, CMS finalized changes to the Conditions of Participation for Organ Procurement Organizations (OPOs) to improve access to organ transplantation for patients awaiting transplant, including kidney transplant. Several key provisions included:
  - Changing the OPO donation rate measure to the number of organ donors in the OPO's donation service area (DSA) as a percentage of inpatients death among patients 75 years old or younger with a primary cause of death that is consistent with organ donation. A key change from the previous outcome measure is that a donor is now defined as a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted, not just procured for transplant, or an individual from whom a pancreas is procured and is used for research or islet cell transplantation.
  - Changing the OPO transplantation rate measure to the number of transplanted organs from and OPO's DSA as a percentage of inpatient deaths among patients 75 years old or younger with a primary cause of death that is consistent with organ donation.
  - Establishing the donation and transplantation performance rates that an OPO is encouraged to meet as the lowest rates of the top 25 percent of OPOs from the previous 12-month period, a ranking that will be publicly available.
  - Allowing CMS to review OPO performance every 12 months throughout the four-year recertification cycle to ensure fewer viable organs are wasted and more timely transplants occur.
  - Creating performance tiers so that at the end of each re-certification cycle, each OPO will be assigned a tier ranking based on its performance for both the donation rate and transplantation rate measures and its performance on the re-certification survey.

  - Increasing competition by ensuring that OPO DSAs are awarded to the highest performing OPOs.
  - Using objective, transparent, and reliable data for the new outcome measures versus self-reported data to establish the donor potential in the OPO's DSA.

Simplifying Clinician Participation in the Quality Payment Program

- The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established a new approach to payment known as QPP that rewards the delivery of high-quality patient care through two avenues: Advanced Alternative Payment Models (Advanced APMs) and MIPS.
  - MIPS combined 3 Medicare "legacy" programs – the Physician Quality Reporting System, Value-based Payment Modifier, and the Medicare EHR Incentive Program for Eligible Professionals – into a single comprehensive program.
- Since the QPP launched in 2017, CMS has taken incremental steps to update both MIPS and Advanced APMs tracks to acknowledge the unique variation in clinician practices, further refine program requirements, respond to stakeholder feedback, reduce reporting burden, encourage meaningful participation, and improve patient outcomes.
- In 2018, CMS launched the new data submission system on the Quality Payment Program (QPP) website (qpp.cms.gov) to reduce burden by offering providers a single entry portal and streamlining data submission; unlike the former systems under the CMS legacy programs, which require clinicians to submit data on multiple websites, eligible clinicians can now use a single data system to submit their data across the multiple submission options.
- The flexibilities CMS created for QPP, especially within MIPS, resulted in **overall participation rates by MIPS eligible clinicians of 95% and 98% for the 2017 and 2018 performance periods,** respectively. These flexibilities included raising the low-volume threshold which excluded clinicians or groups billing less than or equal to $90,000 in Medicare Part B allowed charges or treating less than or equal to 200 Part B beneficiaries as a means of reducing participation burden on small practices, incrementally increasing the performance threshold to afford clinicians additional time to familiarize themselves with the program, providing 5 additional points for clinicians treating complex patients, and allowing solo practitioners and small groups the opportunity to partner and participate within MIPS as a virtual group. Additionally, CMS awarded 5 points to the final scores of all small practices as well as continued providing no-cost technical assistance through the Small, Underserved, and Rural Support initiative.
- CMS continues to be committed to supporting solo practitioners and clinicians in small and rural practices participating in QPP by providing assistance through the no-cost **Small, Underserved, and Rural Support initiative**. In efforts to further reduce burden for clinicians in small and rural practices, CMS provided flexibility by granting hardship exemptions and reducing various requirements. Because of this tailored support, **94% of eligible rural clinicians participated in the QPP program in 2018**.[162]

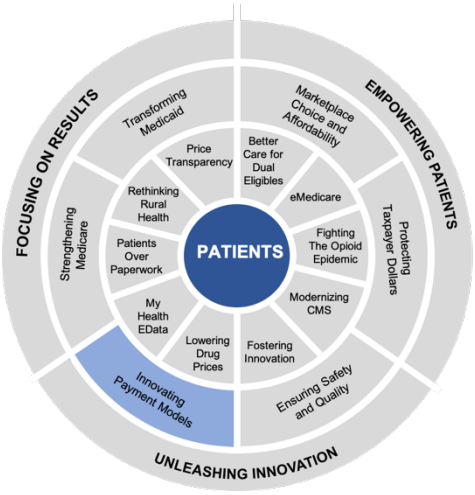
Streamlining Long-Term Care Facility Requirements

- In April 2019, CMS published a five-part approach guiding the agency as it ensures safety and quality in long-term care (LTC) facilities, or nursing homes. As part of this strategy, on July 18, 2019, CMS published a proposed rule that would remove requirements for participation identified as unnecessary, obsolete, or excessively burdensome on LTC facilities.[163]

- This proposed rule would, among other things: (1) reduce the frequency LTC facilities are required to conduct a facility assessment; (2) allow LTC facilities to streamline their compliance and ethics programs; and (3) allow LTC facilities greater flexibility in tailoring their Quality Assurance Program Improvement (QAPI) program to the specific needs of their individual facility by eliminating prescriptive requirements.

CMS estimates the provisions in this rule, if finalized, will achieve $616 million in savings annually for these facilities.[164]

Innovating Payment Models



The CMS Innovation Center (CMMI) was established through the Patient Protection and Affordable Care Act (ACA) in 2010 to test innovative payment and care delivery models for Medicare, Medicaid, and CHIP beneficiaries. CMMI has launched over 40 models since its inception. These models and statutorily mandated demonstrations aim to accelerate the development of new payment and services delivery methods, or to speed the adoption of best practices, many of which focus on preventing disease and addressing upstream factors that impact health. By testing innovative payment and care delivery structures, CMS is able to evaluate the impact of these alternative payment models without introducing unnecessary confusion or risk to the larger healthcare marketplace. Additionally, successful CMMI pilots and demonstrations can serve as models for private sector to adopt across the nation's healthcare system.

Model tests, however, have not consistently delivered positive results. An internal review of model test performance showed that only five model tests have shown statistically significant savings to taxpayers and the Medicare Trust Funds and three have satisfied the statutory requirements for expansion.[165] Though model tests have maintained the quality of care (one of the requirements of statute), only a few of the early model tests demonstrated statistically significant improvements on quality metrics. Based on finding from the internal review, the CMS Innovation Center is adjusting current models to improve performance and rebalance the portfolio.

The internal review found four major reasons for this negative performance, which the CMS Innovation Center is actively working to address: 1) adverse selection created by voluntary models; 2) benchmark inaccuracy; 3) quality measure misalignment; and 4) lack of greater data transparency.

Other improvements in model testing and operations are being introduced to make CMS Innovation Center model testing more effective and efficient, in order to better serve American patients, beneficiaries, and taxpayers, and to accelerate the adoption of value-based care. The CMS Innovation Center will make timely improvements to models to address emerging issues and, when appropriate, end models early should they prove unsuccessful.

For example, CMS announced changes to the existing Bundled Payments for Care Improvement Advanced Model for Model Year 4, which begins on January 1, 2021, after the internal review revealed that the model was on pace to lose close to $2 billion over the model's ten performance periods. After a comment solicitation from participants on how to adjust the model, the CMS Innovation Center made several revisions, most of which were recommended by at least one, if not multiple, model participants.

To improve efficiency, in 2020 the CMS Innovation Center launched a comprehensive review of all model test budgets and Center-wide operations. Through this initiative, CMMI found over $350 million of potential cost savings that could be realized through streamlining contracts, centralizing common functions, and reducing duplication across core data systems. These new efficiencies should enable the CMS Innovation Center to invest more wisely in model testing, and expand its model testing capacity, and further advance value-based care transformation.

Accomplishments

Healthcare researchers and policymakers alike agree that innovation is the key to increasing value in the American healthcare system. CMS, through CMMI, is testing multiple approaches to healthcare delivery innovation so the best ideas can be brought to scale within the Medicare, Medicaid, and CHIP programs, and later emulated in other healthcare plans as well.

Accelerating Development and Testing of New Payment and Service Delivery Models

- Announced in November 2020, the Most Favored Nation (MFN) Model will lower prescription drug costs by paying no more for high-cost Medicare Part B drugs and biologicals than the lowest price that drug manufacturers receive in other similar countries.
    - The MFN Model will also pay providers a flat add-on amount for each dose of an MFN drug, instead of a percentage of each drug's cost, removing the tie between drug cost and the add-on amount. Beneficiaries will pay lower coinsurance for these high-cost Part B drugs and will not pay coinsurance on the add-on payment.
- The Medicare Advantage (MA) Value-Based Insurance Design (VBID) Model is testing a broad array of MA service delivery and/or payment approaches. The aim of the VBID Model is to reduce burden and control costs while enhancing care through reduced cost-sharing and additional supplemental benefits, including for "non-primarily health related" items or services, for enrollees, based on chronic condition, socioeconomic status, or both.[166]
    - The VBID Model was recently modified to allow MA organizations to offer beneficiaries hospice benefits in their Part A benefits package, allowing CMS to test how this hospice benefit component can improve beneficiary care through greater care coordination, reduced fragmentation, and transparency.[167]
        - Under current law, MA plans are prohibited from covering the Part A hospice benefit. By including the Medicare hospice benefit in the MA benefit package, CMS will test the impact on service delivery and quality of MA plans providing all original Parts A and B Medicare items and services, including the hospice benefit.
        - In response to President Trump's Executive Order 13890 on Protecting and Improving Medicare for our Nation's Seniors, the VBID Model was revised to test two new model components: (1) flexibility to share beneficiary rebates savings more directly with beneficiaries and (2) new and innovative technologies or Federal Drug Administration (FDA) approved medical and supplemental benefits for targeted enrollees.
- CMS is also testing innovations in nontraditional areas of care. The Emergency Triage, Treat, and Transport (ET3) Model is a voluntary, five-year payment model that provides greater flexibility to ambulance care teams to address emergency healthcare needs of Medicare FFS beneficiaries following a 911 call.[168]
    - The model aims to reduce expenditures and preserve or enhance quality of care by providing person-centered care, encouraging appropriate utilization of services and increasing efficiency of the emergency medical services system.
- Built on lessons learned from the Comprehensive Primary Care Initiative, Comprehensive Primary Care Plus (CPC+) is a national advanced primary medical home model that aims to strengthen primary care through regionally-based multi-payer payment reform and care delivery transformation.[169]

  - CPC+ practices are split into two practice tracks, with incrementally advanced care delivery requirements and payment options to meet the diverse needs of primary care practices across the country.
  - In its first two years, CPC+ has had a few, very small favorable impacts on some measures of service use, quality of care, and patient experience.[170]

- The Primary Care First model is a set of voluntary five-year payment options that reward value and quality by offering an innovative payment structure to support delivery of advance primary care.[171]
  - These model options reflect a regionally-based, multi-payer approach to care delivery and payment, and foster practitioner *independence* by increasing flexibility for primary care, providing practitioners with the freedom to innovate their care delivery approach based on their unique patient population.

- CMS' Part D Senior Savings Model enables participating Part D enhanced plans to lower Medicare beneficiaries' out-of-pocket costs for insulin to a maximum $35 copay per thirty-day supply throughout the benefit year. As beneficiaries have more consistent, predictable access to the prescription drugs they need, the model projects that health will improve and total cost of care will decline for our nation's seniors. [172]
  - **CMS projects the Part D Senior Savings Model will result in $250 million in savings for the federal government over a five-year period**, primarily due to pharmaceutical manufacturers paying additional coverage gap discounts.[173]

Introducing Specialty Care Models

- To target patients before they progress to full ESRD, in December 2019, CMS announced the Kidney Care Choices (KCC) Model. The KCC Model is aimed at providing incentives for kidney care providers to improve management of care for patients with late-stage chronic kidney disease (CKD) and ESRD to delay the onset of dialysis and encourage kidney transplant.
  - Key features of the KCC Model include holding a single, identified set of providers (clinicians and facilities) accountable for the longitudinal care provided to late-stage CKD patients with the goal of delaying or preventing the need for dialysis. In addition, transplant patients will be included to encourage management of post-transplant care and outcomes.
  - The model includes Medicare benefit enhancements that will provide greater flexibility and access to kidney care education, home-based care, and telehealth outside of rural areas. Participating providers will receive a new quarterly capitated payment for managing CKD patients, along with an adjusted monthly ESRD payment.[174]

- In September 2020, CMS finalized the ESRD Treatment Choices (ETC) Model to improve or maintain the quality of care and reduce Medicare expenditures for patients with chronic kidney disease.[175] The ETC Model delivers on President Trump's Advancing Kidney Health Executive Order and encourages an increased use of home dialysis and kidney transplants to help improve the quality of life of Medicare beneficiaries with ESRD.
  - The ETC Model will test shifting Medicare payments from traditional fee-for-service payments to payments where providers are incentivized for encouraging receipt of home dialysis and kidney transplants. This value-based payment model will encourage

participating care providers to invest in and build their home dialysis programs, allowing patients to receive care in the comfort and safety of their home.

  - Because transplantation is widely viewed as the optimal treatment for most patients with ESRD, the ETC Model also incentivizes transplantation by financially rewarding ESRD facilities and clinicians based on their transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate.
  - The ETC Model will impact approximately 30% of kidney care providers and will be implemented on January 1, 2021 with an estimated savings of $23 million over five and a half years.

- On September 18, 2020, CMS also finalized the Radiation Oncology (RO) Model.[176] The RO Model is expected to improve the quality of care for cancer patients receiving radiotherapy and reduce Medicare expenditures through bundled payments allowing providers to focus on delivering high-quality treatments.
  - Specifically, this model will test whether changing the current fee-for-service payments to site-neutral, prospective, predictable, episode-based or bundled payments will create an incentive for physicians to deliver higher-value radiotherapy care.
  - **After taking effect, the RO Model, is estimated to save Medicare $230 million over 5 years.**
- In August 2020, CMS announced the creation of the Community Health Access and Rural Transformation (CHART) Model, which aims to continue addressing rural health disparities by providing a way for rural communities to transform their healthcare delivery systems by leveraging innovative financial arrangements as well as operational and regulatory flexibilities.[177]
  - The CHART Model will fund two separate "tracks" for innovation—a Community Transformation Track and an Accountable Care Organizations Track—to test whether upfront investments, predictable capitated payments, and operational and regulatory flexibilities will enable rural healthcare providers to improve access to high quality care while reducing healthcare costs.[178]

Expanding Accountable Care Organization (ACO) Programs

- In December 2018, CMS redesigned the Medicare Shared Savings Program through new Pathways to Success policies, which puts ACOs on a quicker path to taking on performance based risk, with accountability for spending increases (down-side risk) generally required after two years for new ACOs, while closely monitoring the quality of care provided.
  - When CMS first announced Pathways to Success, stakeholders said providers may be reluctant to join and accelerate to downside risk. However, as a result of two application cycles, the number of ACOs taking on downside financial risk has nearly doubled and the number of Medicare fee-for-service beneficiaries receiving care from heath care providers in an ACO continued to grow.
  - **Based on the first 6 months of results,** ACOs under Pathways to Success participation options performed better than legacy track ACOs, showing net per-beneficiary savings of $169 per beneficiary compared to $106 per beneficiary for legacy track ACOs, while new entrant ACOs under Pathways to Success achieved net per-beneficiary savings of $150. This is the first time ACOs new to the program had lower spending relative to their benchmarks in their first performance year.

  - **Overall, ACOs have continued to improve the quality of care for more than 11.2 million Medicare beneficiaries while producing net program savings of $1.19 billion, which is the third consecutive year of positive net program savings.[179]**

- The ACO Investment Model, implemented in 2016 and operated under the Shared Savings Program, provided up-front payments to select ACOs to use for investments in infrastructure and staffing.[180]
  - **A September 2019 analysis of the ACO Investment Model's first two performance years found model participants decreased total Medicare spending and had greater reductions in total Medicare spending than similar ACOs not participating in the model**.[181]

- Another promising model set is the Direct Contracting model options, a set of three voluntary payment models aimed at reducing expenditures and preserving or enhancing quality of care for beneficiaries in Medicare FFS.[182] These payment model options create opportunities for a broad range of organizations to participate with CMS in testing, in the form of Direct Contracting Entities (DCEs), the next evolution of risk-sharing arrangements to produce value and high-quality care.
  - The Professional and Global options aim to attract a range of healthcare providers operating under a common governance structure, with attention given to advancing primary care as a means to better managing healthcare overall. CMS expects that the use of voluntary alignment will attract organizations that previously were ineligible because of their low volume of Medicare FFS beneficiaries, such as organizations that currently operate in the MA program. Each payment model option includes features aimed at encouraging organizations focused on care for patients with complex, chronic conditions, and seriously ill populations to participate.
  - In addition to Standard, New Entrant and High Needs Population DCEs, CMS implemented a fourth DCE type for Managed Care Organizations (MCOs). CMS will test whether putting MCOs or their corporate affiliates at risk for Medicare fee-for-service costs for their full-benefit dually eligible Medicaid MCO enrollees, in addition to the risk the MCOs currently have under Medicaid, will lead to innovative strategies for improving care for this high-risk population. DCEs will have a new financial interest in lowering Medicare FFS spending because they will be able to share in Medicare savings or losses.
  - The Geographic Direct Contracting Model, announced in December 2020, will test whether a geographic-based approach to value-based care can improve quality of care and reduce costs for Medicare beneficiaries across an entire geographic region. Within each region, organizations with experience in risk-sharing arrangements and population health will partner with healthcare providers and community organizations to better coordinate care.

Refining Episode-Based Payment Initiatives

- The Bundled Payments for Care Improvement (BPCI) Advanced Model[xii] aims to address the challenges the BPCI initiative experienced and build upon the promise of episode-based payment.
    - This model offers bundled payments for additional clinical episodes beyond those that were included in the BPCI initiative, including – for the first time – outpatient episodes.[183]
    - CMS plans to continue pursuing value-based care while leveraging lessons learned over the BPCI Advanced Model's history, making modifications as needed.
        - For example, in September 2020, CMS updated policy and pricing methodology for clinical episodes in year 4 of the BPCI Advanced Model to improve target price accuracy for both CMS and model participants. Included in the update is the adoption of a realized trend adjustment to final target prices that will protect both model participants and CMS from fluctuations in cost and practice patterns that may occur over time.
            - CMS is making this change in response to the need to make the model payments less susceptible to unpredictable changes in policy, coding, and clinical practice.[184]

Supporting Model Participation

- The CMS Innovation Center is increasing the amount of data shared with model participants, including providing standardized data analyses to less sophisticated model participants and building APIs for more sophisticated model participants who have the capability to analyze data themselves. In 2020 the Center began both scaling the use of APIs for data sharing, including an initial pilot with NextGen Participants and purchasing a commercially available tool to increase transparency across models. When implemented the Value Based Care System will streamline model payment operations and provide a transparent view into performance and payment data for both participants and model teams.

Envisioning the Future of Model Development and Implementation

- In addition to the statutorily-mandated evaluations of its ongoing models, CMS has undertaken a top-to-bottom review of the more than 30 models currently underway to evaluate what was working, what wasn't, and discuss next steps for these models based on their evaluation reports.
- CMS Innovation Center models that meet the criteria for expansion in paragraphs (1) through (3) of section 1115A(c) can be certified for expansion.
    - The Chief Actuary of CMS certified that a nationwide expansion of the Repetitive Scheduled Non-Emergent Ambulance Transport (RSNAT) Medicare Prior Authorization Model would meet the requirements of section 1115A(c)(2); and the Secretary has determined that the model meets the requirements for expansion described in section 1115A (c)(1) and (c)(3).
    - The Bipartisan Budget Act of 2018 required the Medicare Advantage Value-Based Insurance Design (VBID) Model to include all states beginning in 2020. Additionally,

[xii] The initial BPCI initiative tested whether linking payments for all providers that furnish Medicare-covered items and services during and related to an inpatient hospitalization can reduce Medicare expenditures, while maintaining or improving quality of care. CMS took the learnings from the BPCI initiative to develop the BPCI Advanced model.

CMS will allow eligible MA plans to begin a test of allowing MA enrollees to access the Medicare hospice benefit through their MA plan beginning January 1, 2021.[185] By reducing fragmentation and increasing financial accountability, CMS is enabling MA organizations to better coordinate palliative and hospice care for beneficiaries that choose MA.

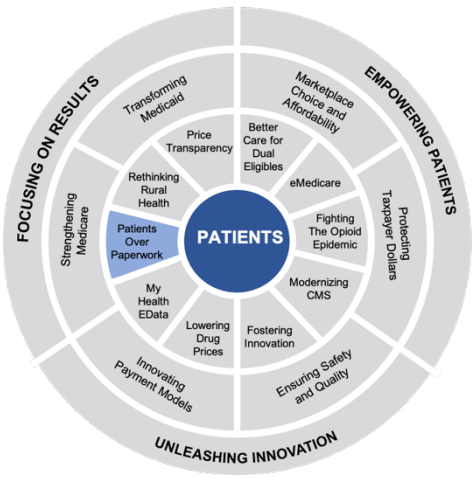
- The CMS Innovation Center has created new models that build on existing models to take advantage of evaluation findings and new ideas about care delivery and payment learned from physicians and other innovators in the healthcare community.
    - Primary Care First Model, which was developed based on insights from the previous CPC+ and CPC Models
    - Maryland Total Cost of Care Model, which built upon the positive results from the previous Maryland All-Payer Model
    - Existing models are also continually being refined: After an evaluation of the Next Generation ACO (NGACO) model test showed $349 million of gross Medicare savings over the first three performance years (2016–2018), but $178 million in net Medicare losses (after deducting shared savings payments and Coordinated Care Reward payments), the CMS Innovation Center made several changes to elements of the Model's methodology in its fourth performance year (2019) designed to shift the focus of the model test from an emphasis that rewards ACOs for improvement to one that rewards ACOs for attained efficiency in their expenditures, while still maintaining or improving the quality of care.
    - CMS has proposed adjustments to the Comprehensive Care for Joint Replacement (CJR) model through rulemaking since benchmarking issues failed to accurately project spending, and the model test is on a pace to lose millions in its final performance years. These adjustments are reflected in the proposed rule, Three-Year Extension and Modification of the Comprehensive Joint Replacement (CJR) Model.
- The CMS Innovation Center also has a statutory obligation to modify or terminate models unless the model is expected to improve quality without increasing spending, reduce spending without reducing quality, or improve quality and reduce spending after testing has begun. Models and demonstrations that have ended:
    - Community-Based Care Transitions Program (a part of the Partnership for Patients) - Performance Period: February 1, 2012 to January 31, 2017
    - Graduate Nurse Education Demonstration - Performance Period: August 1, 2012 to July 31, 2018
    - Health Care Innovation Awards Round Two - Performance Period: September 1, 2014 to September 1, 2017
    - Medicare Prior Authorization: Non-Emergent Hyperbaric Oxygen Therapy - Performance Period: March 1, 2015 to February 28, 2018
    - Pioneer ACO Model - Performance Period: January 1, 2012 to February 22, 2017
    - Strong Start for Mothers and Newborns Strategy Two - Performance Period: February 15, 2013 to February 14, 2017

Launching the Part D Payment Modernization Model

- In January 2020, CMS launched the Part D Payment Modernization Model to test the impact of a revised Part D program design and improved alignment of financial risk incentives on overall Part D prescription drug spending and beneficiary out-of-pocket costs.[186]

Patients Over Paperwork

CMS publishes nearly 11,000 pages of regulations every year. While many of these are important policies, they often have the side effect of increasing burden on providers. In 2017, the American Hospital Association published a report showing that health systems, hospitals, and post-acute care providers must comply with 629 mandatory regulatory requirements and spend nearly $39 billion a year solely on the administrative activities required by these regulations. This report found that, instead of focusing on patient care, clinical staff time was allocated to administrative tasks, where a study found that for every hour providers spend seeing patients, they spend nearly two additional hours on paperwork.[187]



Accomplishments

To cut the red tape of government, and direct clinician focus on patient care, CMS launched the Patients over Paperwork initiative. **CMS burden reduction efforts under this initiative are estimated to save the medical community $6.6 billion and 42 million burden hours in administrative burden through 2021**, with additional savings expected as additional burden reduction measures are finalized.

Formalizing the Office of Burden Reduction and Health Informatics

- In July 2020, to formally embed a culture of burden reduction across all platforms of CMS agency operations, CMS launched the Office of Burden Reduction and Health Informatics to unify the agency's efforts to reduce administrative burden through policy changes, advancements in interoperability, and implementation and enforcement of national standards under HIPAA.

Eliminating Unnecessary Regulations

- To better understand where changes should be made, CMS solicited feedback on how providers and patients were impacted by CMS regulations. CMS directly engaged providers, beneficiaries, family members, caretakers, and healthcare professionals using human centered design (HCD) methodology and other qualitative methods to gauge what was working and what needed to be improved. The Agency met with providers across the nation, conducting 57 site visits, nearly 900 customer interviews, 200 subject matter expert interviews, and holding 102 listening sessions resulting in over 10,800 comments
    - CMS also asked stakeholders, through a series of RFIs in 2017, receiving 2,830 comment letters that related to over 1,100 different issues. CMS heard from providers that not only were regulations failing to increase the quality of care or improve health outcomes, but many of these regulations were also duplicative and at times contradictory, actively contributing to adverse outcomes. CMS addressed or is working to address 83% of the burden issues that were actionable for CMS.
    - Based on this stakeholder feedback, in 2019, CMS finalized the **Omnibus Conditions of Participation Final Rule** to eliminate outdated and burdensome regulations across hospitals, surgery centers, hospices, transplant programs, home health agencies, Religious Nonmedical Health Care Institutions, psychiatric hospitals, community mental health center, rural health centers, and federally qualified health centers.[188] In total, the revised

rules **saved providers an estimated 4.4 million hours of time previously spent on paperwork and $800 million[xiii] annually**.[189]

- Since launching the Quality Payment Program (QPP), CMS has reduced reporting burden substantially, including a reduction of 1,006,658 burden hours and $7.4 million in labor costs (CY 2017), 171,264 burden hours and $13.9 million in labor costs (CY 2018), and 35,968 burden hours and $3.2 million in labor costs (CY 2019).

Revising Reporting at Skilled Nursing Facilities

- On June 6, 2019, CMS issued a second RFI seeking public comments on how to improve quality and operational efficiency for skilled nursing facilities (SNFs). CMS also launched the Patient Driven Payment Model, a new case-mix classification that applies to Medicare payments to SNFs, on October 1, 2019.[190]
  - This new model ties Medicare payments to patients' conditions and care rather than the quantity of services provided in nursing homes. This simplification to patient assessments will significantly **reduce reporting burden by an estimated $2 billion over 10 years.**[xiv]
- Additionally, effective April 30, 2018, CMS updated the SNF Advanced Beneficiary Notice of Non-coverage (ABN), a form explaining why an item or a service may not be covered by Medicare.[191] This updated SNF ABN discontinues the five SNF denial letters and the Notice of Exclusion from Medicare Benefits and instead **empowers patients to make one of three options to take control of their healthcare**.
  - Patients can now choose from the following options when making decisions about their care: (1) agreeing to the care, accepting financial responsibility if Medicare does not pay, and allowing for an appeal to Medicare; (2) agreeing to the care, paying out of pocket, and no longer having the right to appeal to Medicare; or (3) declining the healthcare and no longer having the right to appeal to Medicare.

Reducing Burden through Coding and Documentation Reform

- In 2019, CMS finalized policies to largely adopt evaluation and management (E/M) coding[xv] changes set forth by the American Medical Association Current Procedural Terminology (CPT) Editorial Panel.[192] This high-volume code set needed to be updated for changes in the practice of medicine and to reduce the administrative burden and time associated with the selection of code level and associated documentation.
  - Effective January 1, 2021, these CPT coding changes retain five levels of coding for established patients, reduce the number of levels to four for office/outpatient E/M visits for new patients and revise the definitions of the codes with revised times, medical decision-making guidelines, and include history and exam only as medically appropriate.

[xiii] These burden reduction estimates are from the Omnibus Burden Reduction Final Rule, and represents the broader scope of burden reduction activities undertaken by CMS.

[xiv] Estimates are based on changes made prior to the current public health emergency. It remains to be seen how Post-COVID administrative changes will affect these estimates.

[xv] Based upon a CMS internal evaluation, Evaluation and Management (E/M) services furnished to patients during an office visit make up about 20% of allowed charges under the Physician Fee Schedule and consume much of clinicians' time. This high-volume code set needed to be updated for changes in the practice of medicine and to reduce the administrative burden and time associated with the selection of code level and associated documentation.

        - The CPT code changes also allow clinicians to choose the E/M visit level based on either medical decision making or time.[193]
        - CMS also created an add-on code to account for visit complexity that is unique to primary care and other specialty care.

- CMS has also revised its teaching physician rules in order to reduce administrative burden associated with documenting and billing services performed jointly with an intern, resident, or fellow in an approved graduate medical education program.
    - In 2018, CMS empowered students to document services in a patients' medical record with the teaching physician's verification. This change eliminated the requirement a teaching physician re-document any notes taken by a student in order to receive payment for services rendered.[194]

Streamlining Long-Term Care Facility Requirements

- In April 2019, CMS published a five-part approach guiding the agency as it ensures safety and quality in long-term care (LTC) facilities, or nursing homes. As part of this strategy, on July 18, 2019, CMS published a proposed rule that would remove requirements for participation identified as unnecessary, obsolete, or excessively burdensome on LTC facilities.[195]
    - This proposed rule would, among other things: (1) reduce the frequency LTC facilities are required to conduct a facility assessment; (2) allow LTC facilities to streamline their compliance and ethics programs; and (3) allow LTC facilities greater flexibility in tailoring their Quality Assurance Program Improvement (QAPI) program to the specific needs of their individual facility by eliminating prescriptive requirements.
    - **CMS estimates the provisions in this rule, if finalized, will achieve $616 million in savings annually for these facilities.[196]**

Updating the Physician Self-Referral Law

- On October 9, 2019, CMS issued a proposed rule[197] to modernize and clarify the regulations that interpret the Medicare physician self-referral law (often called the "Stark Law"), which has not been significantly updated since it was enacted in 1989. As value-based arrangements become more common in healthcare, CMS is reforming and modernizing these regulations to support the necessary evolution of the American healthcare delivery and payment system.
- The rule was finalized on November 20, 2020. With this final rule, CMS is ensuring the regulation interpreting the Stark Law allows for changes that will help modernize the healthcare system. The rule finalizes many of the proposed policies from the notice of proposed rulemaking, including:
    - Finalizing **new, permanent exceptions for value-based arrangements** to that will permit physicians and other healthcare providers to design and enter into value-based arrangements without fear that legitimate activities to coordinate and improve the quality of care for patients and lower costs would violate the physician self-referral law. This supports CMS' broader push to advance coordinated care and innovative payment models across Medicare, Medicaid, and private plans.
    - Finalizing **additional guidance on key requirements of the exceptions to the physician self-referral law** to make it easier for physicians and other healthcare providers to make sure they comply with the law.

  - **Finalizing protection for non-abusive, beneficial arrangements** that apply regardless of whether the parties operate in a fee-for-service or value-based payment system – such as donations of cybersecurity technology that safeguard the integrity of the healthcare ecosystem.
  - **Reducing administrative burdens that drive up costs** by taking money previously spent on administrative compliance and redirecting it to patient care.

- The final rule supports the CMS "Patients over Paperwork" initiative by reducing unnecessary regulatory burden on physicians and other healthcare providers while reinforcing the Stark Law's goal of protecting patients from unnecessary services and being steered to less convenient, lower quality, or more expensive services because of a physician's financial self-interest.[198]
- Since these rules also extend to the Medicaid program, CMS ensured that improvements reduce burden in every program. In the CY 2021 OPPS/ASC rule, CMS removed certain Stark related provisions in the expansion exception process that are applicable to hospitals that qualify as "high Medicaid facilities" because such provisions are not mandated by Section 1877 of the Act.[i]
- Specifically, CMS removed: (1) the cap on the number of additional operating rooms, procedure rooms, and beds that can be approved in an exception; and (2) the restriction that the expansion must occur only in facilities on the hospital's main campus.[i]
  - In addition, a high Medicaid facility could apply for an exception more than once every two years from the time of a decision by CMS, provided that the hospital submits only one expansion exception request at a time.
  - This provides additional flexibility to physician owned hospitals that qualify as high Medicaid facilities, which, by definition, serve more Medicaid inpatients than other hospitals in the counties in which they are located.

Updating Prior Authorization Requirements

- CMS continues to believe prior authorization is an effective mechanism to simultaneously meet two goals; to ensure Medicare beneficiaries receive medically necessary care, and to protect the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments. Prior authorization requires coordinated communication between doctor, patient, and payer and a workflow necessary to make things happen. CMS has therefore endeavored to build prior authorization initiatives that do not put additional burden on providers.
  - Previously, CMS piloted demonstrations for prior authorization for supplies like durable medical equipment and in care settings such as home health.[i] Early CMS prior authorization initiatives surfaced flaws that added burden for beneficiaries, clinicians, providers, and payers.
  - CMS learned that beneficiaries frequently cannot locate information needed for prior authorization, and there is lack of communication about their healthcare benefits and requirements that contribute to delays in care and possibly harm.
- To address burden concerns with prior authorization, CMS took numerous steps to uncover the pain points in the process. **Between August 2019 and March 2020, CMS conducted 35 listening session where it heard from 331 customers and 17 prior authorization subject matter experts. Additionally, CMS conducted five site visits gathering in total 2,439 data points to improve the prior authorization process.**

  - CMS partners also worked together to create pending legislation, principles, and consensus statement aimed at improving the prior authorization process. The healthcare industry is partnering with CMS because it believes when CMS implements these ideas, along with CMS' focus on improving prior authorization efficiency, transparency, and standardization, the remainder of the healthcare industry will follow.

- Based on this burden reduction collaboration with stakeholders, CMS now requires the same information that is currently necessary to support Medicare payment, just earlier in the process. This modification helps providers and suppliers address claim issues early and avoid denials and appeals. Prior authorization and pre-claim review have the added benefit of offering providers and suppliers some assurance of payment for items and services receiving a provisional affirmation decision.[199]

- CMS is continuing to refine prior authorization to ensure that covered services are medically necessary. For example, CMS is building on the learning from the prior authorization demonstrations in the outpatient setting by proposing in the CY 2021 OPPS/ASC proposed rule to require prior authorization for Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators.[200]
- In December 2020, CMS issued a proposed rule (pending finalization) that would improve the electronic exchange of healthcare data among payers, providers, and patients, and streamline processes related to prior authorization to reduce burden on provider and patients in Medicaid, CHIP, and Qualified Health Plans (QHP) on the Federally-facilitated Exchanges.

Revising Guidance on Two-Midnight Rule

- CMS recognized that overuse of inpatient status for patients hospitalized overnight leads to increased charges to CMS.[201] To mitigate this issue, CMS developed the "two-midnight rule."

- The Two-Midnight Rule declares that inpatient admission and payment are appropriate when the treating physician expects the patient to require a stay that crosses two midnights and admits the patient based on that expectation. This rule was created to alleviate inappropriate charges but created misalignments with some valid hospitalizations based on physician judgment.

- To streamline applicability of the Two-Midnight Rule, CMS finalized a two-year exemption from certain medical review activities related to the two-midnight rule for procedures newly removed from the Inpatient Only (IPO) list.

  - On August 4, 2020,[202] CMS proposed to continue the two-year exemption from certain medical review activities relating to patient status for procedures removed from the IPO list beginning in CY 2020 and subsequent years.

Making it Easier for Consumers and Providers to Pay Medicare When Needed

- CMS is also building capability with automation and new tools, bringing convenience to beneficiaries and providers while also reducing operational burden.

  - One example is the **automation of payment mechanisms** for the Medicare premium Easy Pay payment option on the MyMedicare.gov website and the Medicare Secondary Payor Recovery (MSPRP) portal on CMS.gov.

  - There are two million direct-billed beneficiaries in Medicare and having an electronic payment option means they can securely pay plan premiums without needing to mail

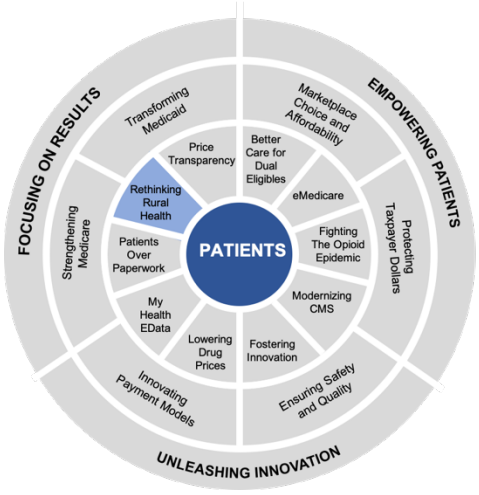
checks or worry that late payments will jeopardize the continuity of their plan coverage.[xvi]

- **More than 1 million electronic payments have been made through this new web-based option since launch**.[203] By processing these payments electronically, CMS is simplifying administrative procedures.

- CMS automated the payment of money owed to Medicare by providers and others. Medicare often needs to recoup money that Medicare paid for services that were the responsibility of other insurers, such as liability insurance, no-fault insurance, and workers' compensation. To streamline this process, CMS now accepts payment through Pay.gov.
  - Electronic debt payments through Pay.gov creates a direct means to settle these outstanding debts, while reducing administrative burden on the customer and on CMS.[204]

[xvi] For more discussion of these accomplishments, see "eMedicare".

Rethinking Rural Health



Approximately 60 million Americans live in rural areas across the United States, including millions of Medicare and Medicaid beneficiaries.[205] Compared to their urban counterparts, rural Americans have more chronic conditions, are more likely to be living in poverty, are uninsured or underinsured, and are medically underserved.[206] Rural Americans often encounter barriers to healthcare that limit their ability to obtain the care they need, including a fragmented healthcare delivery system, stretched and diminishing rural health workforce, unaffordability of insurance, and lack of access to specialty services and providers. As a result of operating challenges, 130 rural hospitals have closed since 2010.[207] This is especially impactful for the surrounding communities, since studies show that when rural hospitals close inpatient mortality increases by 8.7%.[208] The financial uncertainty of hospital closings contributes to increasing the rural provider workforce shortage, with an estimated deficit of 20,000 primary care providers in rural communities by 2025.[209]

The CMS Rural Health Strategy identifies five objectives intended to provide a proactive approach on healthcare issues to ensure that the nearly one in five individuals who live in rural America have access to high quality, affordable healthcare:

- Apply a rural lens to CMS programs and policies;
- Improve access to care through provider engagement and support;
- Advance telehealth and telemedicine;
- Empower patients in rural communities to make decisions about their healthcare; and
- Leverage partnerships to achieve the goals of the CMS Rural Health Strategy. Footnote 95

Accomplishments

While CMS has long recognized the unique healthcare challenges facing rural Americans, the Agency renewed its focus on rural health over the past three years. Starting with the establishment of the Rural Health Council, and continuing throughout the past four years, CMS has made rural health considerations a cornerstone of both its current policy development and innovation efforts.[210]

Publishing the First-Ever CMS Rural Health Strategy

- In 2018, CMS published the CMS Rural Health Strategy, to inform its work as it relates to rural health, thereby helping CMS achieve its vision for equitable rural health and healthcare.[211]
- The Rural Health Strategy's first objective, "Apply a rural lens to CMS programs and policies", builds upon previous efforts to implement conscious and consistent consideration of rural health impacts of policies under review.
    - **By optimizing its policy review and development for health equity, CMS can now more easily identify areas where it can better meet the needs of vulnerable populations, and avoid unintended negative consequences of policy and program implementation for rural and other vulnerable populations and communities.**

Extending the Rural Community Hospital Demonstration

- First implemented in 2004, the Rural Community Hospital Demonstration is an ongoing demonstration to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries.[212]
    - The demonstration focuses on hospitals that may lack economies of scale but are too large to be critical access hospitals, and therefore cannot receive cost-based reimbursement for services provided to Medicare beneficiaries.
    - Since its creation, 33 hospitals have participated in this demonstration.
- CMS released its Report to Congress summarizing key findings from the twelve-year demonstration period in 2018, which indicated **the demonstration's financial structure provides a revenue cushion that allows participants to operate with fewer resource-related constraints and greater cash flow.**[213]

Announcing the Community Health Access and Rural Transformation Model

- In August 2020, CMS announced the creation of the Community Health Access and Rural Transformation (CHART) Model, which aims to continue addressing rural health disparities by providing a way for rural communities to transform their healthcare delivery systems by leveraging innovative financial arrangements as well as operational and regulatory flexibilities.[214]
    - The CHART Model will fund two separate "tracks" for innovation—a Community Transformation Track and an Accountable Care Organizations Track—to test whether upfront investments, predictable capitated payments, and operational and regulatory flexibilities will enable rural healthcare providers to improve access to high quality care while reducing healthcare costs.[215]
    - The model aims to increase financial stability for rural providers through the use of new ways of reimbursing providers that provide up-front investments and predictable, capitated payments that pay for quality and patient outcomes; remove regulatory burden by providing waivers that increase operational and regulatory flexibility for rural providers; and enhance beneficiaries' access to healthcare services by ensuring rural providers remain financially sustainable for years to come and can offer additional services such as those that address social determinants of health including food and housing
    - Through the model, **CMS is directly providing a pool of $75 million in upfront, seed funding, with 15 rural communities applying for up to $5 million to develop local transformation plans.**
        - With this upfront seed funding, CMS is also providing regulatory and operational flexibility for updated service delivery models as well as changing how participating hospitals in these communities are paid, from a system based on volume to stable, monthly payments.
    - In addition to supporting these 15 rural communities, CMS is also looking for 20 rural Accountable Care Organizations to participate in the model, paying shared savings upfront so that ACOs have infrastructure funding to be successful on the move towards achieving better outcomes. Taken together, these are substantial and tangible actions to support healthcare in our rural communities.

- The CHART Model included a number of flexibilities, most notably the Skilled Nursing Facility (SNF) 3 Day Rule Waiver, which waives the rule requiring a three-day stay in a Participant Hospital with swing-bed (Section 1861(i) of the Act) for approval of Medicare post-hospital extended care services prior to admission to a SNF. Additional flexibilities include the Telehealth Expansion, Care Management Home Visits, Waiver of certain Medicare Hospital and/or CAH Conditions are Participation (CoPs) and CAH 96 Hour Certification Rule.

Implementing the Pennsylvania Rural Health Model

- In 2017, CMS announced the creation of the Pennsylvania Rural Health Model, an initiative aimed at increasing rural Pennsylvanians' access to high-quality care while also reducing the growth of hospital expenditures across payers, including Medicare, and increasing the financial viability of the state's rural hospitals.[216]
  - In the pre-implementation phase of the model in 2017 and 2018, the participating rural hospitals developed Rural Hospital Transformation Plans describing how they intend to improve quality, increase access to preventive care, and generate savings to the Medicare program, which they submitted to Pennsylvania and CMS for approval.[217]
  - Beginning January 2019, the participating rural hospitals are paid based on prospectively-set, all-payer global budgets, as they implement their Rural Hospital Transformation Plans.
  - These plans are important in **assisting Pennsylvania meet its commitment to achieving $35 million in cumulative Medicare hospital savings over the course of the model**.[218]

Improving Access, Quality, and Outcomes to Rural Maternal Healthcare

- CMS has also sought to improve access to maternal healthcare for those living in rural communities. Key to this effort is a partnership with the providers and stakeholders in the communities; learning and working collaboratively to better understand where the failures are and where there are opportunities for improvement.
- In June 2019, CMS and partners hosted an interactive conference, "Conversation on Maternal Healthcare in Rural Communities: Charting a Path to Improved Access, Quality, and Outcomes", attended by nearly 1,000 partners, stakeholders, and healthcare professionals. Afterward, CMS publicly released a brief, "Improving Access to Maternal Health Care in Rural Communities" to advance understanding of issues facing mothers in rural areas, before, during, and after pregnancy.[219]
- In 2020, Administrator Verma announced an RFI on Rural Maternal Healthcare seeking public comments on opportunities to improve healthcare access, quality, and outcomes for women and infants before, during, and after pregnancy in rural communities.[220]

Changing the Hospital Wage Index

- In 2019, CMS finalized changes to the hospital wage index in inpatient and outpatient settings to address Medicare payment disparities for all payment rules that account for differences in local labor cost.[221] These changes improved the accuracy of wage index calculation by including a methodology to increase the wage index for certain low wage index hospitals and change how the statutory rural floor wage index values are calculated.[222]

- These changes ensure that people living in rural areas have access to high quality, affordable healthcare so that "low-wage and rural hospitals will be able to increase employee compensation and have sustainability".[223]

Addressing the Supervision Threshold for Hospital Outpatient Therapeutic Services

- In November 2019, CMS finalized a change to the generally applicable minimum required level of supervision for hospital outpatient therapeutic services furnished by all hospitals and Critical Access Hospitals (CAHs) from direct supervision to general supervision.[224]
  - General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's physical presence is not required during the performance of the procedure.[225]
  - This change should provide more flexibility to rural hospitals, particularly CAHs, in providing care for their patients.

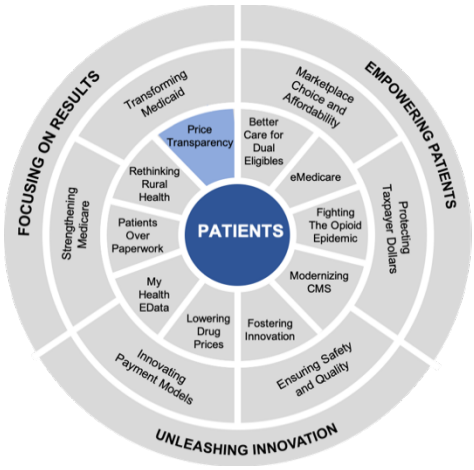
Unleashing the Potential of Technology

- CMS now pays for virtual check-ins that allows a patient to meet with their clinician by phone or other telecommunication system and send videos or images to their clinician. These help the clinician decide whether the patient needs to make a trip to be seen in-person.[226]
- As a result of the COVID-19 PHE,[xvii] CMS has expanded telehealth coverage during the PHE to people living in all areas of the country so that beneficiaries living in both rural and urban settings can get care from their home rather than unnecessarily traveling to their doctor's office.
- In the CY 2021 Physician Fee Schedule Final Rule, CMS finalized that more than 60 services to the Medicare telehealth list that will continue to be covered beyond the end of the PHE, and we will continue to gather more data and evaluate whether more services should be added in the future. These additions allow beneficiaries in rural areas who are in a medical facility (like a nursing home) to continue to have access to telehealth services such as certain types of emergency department visits, therapy services, and critical care services.
- In addition, CMS has expanded the types of services patients can receive via telehealth, the types of healthcare providers that can provider telehealth services including rural health clinics and federally qualified health centers, and Medicare payment for telehealth services during the PHE.[227]
- **CMS recognized technology-based and remote evaluation services for rural health clinics and federally qualified health centers** by finalizing payment for these services when there is no associated billable visit. This way, RHC or FQHC practitioners are paid when they have medical discussions or perform remote evaluations of conditions not related to an RHC or FQHC service provided within a certain timeframe.[228]

[xvii] For more information regarding CMS' response to the COVID-19 PHE, see "Case Study: COVID Response".

PRICE TRANSPARENCY

As in any other industry, healthcare consumers must have meaningful information to enable the market forces necessary to create competition and bring down costs. Yet, patients often do not know how much a healthcare service costs until they receive their bill. CMS is aware of the lack of price transparency in healthcare and has taken major steps to increase patient access to information and increase competition.



CMS has advanced an agenda that empowers patients with comparable information on costs of prescription drugs, procedures in hospitals, and health plans as a complement to the quality information available on CMS websites. This Administration has taken unprecedented steps forward to provide patients with cost information, beginning to put them back in control of their healthcare.

Accomplishments

Information on medical care costs are frequently withheld from patients until after the service is rendered, or the prescription filled. Due to this lack of transparency, many patients are often surprised by higher costs than anticipated, which leads some to forgo care in fear of being saddled with a bill they cannot afford. Patients are demanding more accessible, real-time, personalized information to understand their options, pick high value providers to avoid surprise bills, and make decisions about their care.

Streamlining and Redesigning Compare Tools

- In late summer of 2020, CMS launched Care Compare, a streamlined redesign of eight existing CMS healthcare compare tools available on Medicare.gov.[229] Care Compare provides a single user-friendly interface that patients can use to make informed decisions about their healthcare based on cost, quality of care, volume of services and other data.
- Patients can start their search at Care Compare to find and compare providers that meet their healthcare needs that includes information about quality measures presented similarly and clearly across all provider types and care settings.

Increasing Price Transparency for Hospital Services

- Independent survey data demonstrates that consumers want greater price transparency. When surveyed, 91% of the 1,342 respondents to a survey conducted by YouGov said they believe hospitals and healthcare facilities should be required to publicly disclose the costs of their services.[230]
- The poll also found that 66% of Americans would shop for care if prices were publicly disclosed, a finding that conflicts claims often made by hospitals and groups in opposition to healthcare price transparency.
- Through recent Administration initiatives, **CMS is requiring price transparency for hospital services for all healthcare consumers, not just those enrolled in CMS programs**, to level the playing field and put information and control back in the hands of the consumer.
- In November 2019, CMS finalized a rule requiring hospitals to provide information on "standard charges," making it easier to shop and compare across hospitals, as well as mitigating billing surprises.

  - Starting January 01, 2021, **patients will have cost information on 300 "shoppable services,"** including x-rays, outpatient visits, imaging and laboratory tests or bundled services like a cesarean delivery.[231]
  - Hospitals' standard charges include the gross charges, payer-specific negotiated charges, the amount the hospital is willing to accept in cash from a patient, and the minimum and maximum de-identified negotiated charges.
  - This pricing information must also include additional standard information such as common billing or accounting codes used by the hospital (such as Healthcare Common Procedure Coding System (HCPCS) codes) and a description of the item or service, so consumers can compare standard charges across hospitals.
  - **In addition to posting the shoppable services in a consumer-friendly format, this rule also requires that by January 1, 2021 the hospital posts a freely available file of standard charges** in a machine-readable format for all services rendered in the hospital.
  - CMS expects that this machine-readable file will be a transformative tool for developers who can drive innovation by developing additional transparency tools for consumers, and also for researchers, who will have access to important data that can aid in understanding economic trends in healthcare.

- To ensure compliance with these new requirements, CMS has several safeguards in place including a process for consumers to alert CMS when hospitals are not posting prices, including increased monitoring for hospital noncompliance, and actions to address any situation of hospital noncompliance once identified.
  - CMS developed robust resources, including a FAQ, checklists, and step-by-step instructions are available to hospitals to help ensure compliance.[xviii]
  - The rule also empowers CMS to act when noncompliance is detected, including imposing a civil monetary penalty on the hospital and publicize the penalty on a CMS website.

Increasing Price Transparency for Health Plans

- To extend the benefit of pricing information further into the healthcare marketplace, CMS posted a final rule on October 29, 2020 that applies price transparency requirements to health plans and issuers.
- The rule, which applies to most non-grandfathered group health plans and health insurance issuers**,** requires that they offer an internet based self-service tool to their customers that will show a personalized out-of-pocket cost estimate, which includes the underlying negotiated rates, for all healthcare items and services, including prescription drugs.
- Additionally, most non-grandfathered group health plans and health insurance issuers will be required to offer three separate machine-readable flat files that will detail the negotiated rates for all in-network medical items and services; allowed amounts and billed charges for all out of network items and services; and the negotiated rate and historical net price for all pharmaceuticals.
  - Specifically, plans and issuers subject to the rule are required to offer an internet based self-service tool for 500 of the most shoppable items and services starting on January 1, 2023.The remainder of all items and services will be required to be added to the self-service tool for plan years that begin after January 1, 2024.[232]

[xviii] https://www.cms.gov/hospital-price-transparency

  - The three machine readable files will be required to be made public starting on January 1, 2022 and each will need to be refreshed on a monthly basis. Like price transparency requirements for hospitals, this information would be required to be provided in a machine-readable file in a standardized way so developers, researchers and other stakeholders can easily utilize the information.[233]
  - Like price transparency requirements for hospitals, this information would be required to be provided in a machine-readable file in a standardized way so developers, researchers and other stakeholders can easily utilize the information.[234]

- Additionally the rule **encourages health insurance issuers to offer new or different plan designs that incentivize consumers to shop for services from lower-cost, higher-value providers** by allowing issuers to take credit for "shared savings" payments in their medical loss ratio (MLR) calculations.[235]

Increasing Price Transparency for Prescription Drugs[xix]

- While many efforts have attempted to stem the rising costs of prescription drugs, there remains a tremendous gap between prices Americans pay versus what the rest of the world pays for the same prescription drug.[236]
  - Among Medicare beneficiaries, 21% of out-of-pocket spending in 2016 went to prescription drugs.[237]
  - In a survey of 1,001 patients conducted in November 2019, 94% of patients who reported not taking their prescribed medication said they would have taken a lower cost alternative if it had been suggested to them. Additionally, the survey also revealed that many patients are willing to make changes with how they interact with their doctor to have cost conversations.[238]
- Under the Medicare Advantage and Part D Drug Pricing Final Rule finalized in May 2019, starting in January 2021, Part D plans will be **required to provide access to price estimator tools integrated into clinicians' electronic prescribing or EHR systems**.[239]
- To further promote transparency, the rule also requires the Explanation of Benefits document that Part D enrollees receive each month to include **information on drug price increases and lower-cost therapeutic alternatives.**
- In addition, the rule implements in Part D legislation a **prohibition against pharmacist "gag clauses,"** which prevent pharmacists from telling patients when they could pay less for a drug by paying cash, instead of billing their insurance and paying the required copay or deductible.[240]

Increasing Quality Transparency for Consumers

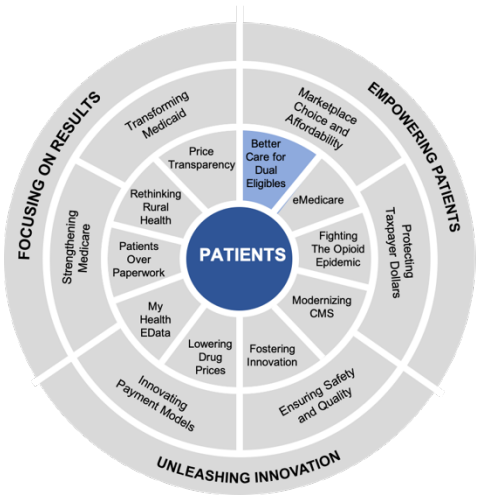
- CMS is empowering consumers, their families, and their caregivers by giving them the resources they need to make informed decisions, and key to that effort is the redesigned Care Compare site, as further discussed in the *eMedicare* section of this report.
- CMS enhanced transparency within nursing homes as a part of the Administrator's Five-Part Approach to Ensuring Nursing Home Safety and Quality by adding a consumer alert icon next to each facility that was cited for incidents of abuse, neglect, or exploitation to help residents and their families make the best decisions about their care.

[xix] For more discussion of these accomplishments, see "Lowering Drug Prices".

- Additionally, in May 2019, CMS took steps to increase transparency for nursing home residents and their families, in particular by releasing a monthly list of underperforming nursing homes that are participants or candidates of the Special Focus Facility program. Along with their names, CMS releases important information as to the methodology of the program, so that nursing home residents and family members better understand why a particular facility made the list. Furthermore, CMS is surveying these facilities twice as often as others.
    - Added a consumer alert icon next to nursing homes on the Nursing Home Compare website in October 2019, indicating which nursing homes have been cited for abuse, neglect, or exploitation resulting in harm or potential harm.[241]
    - Launched Care Compare in September 2020, which is a streamlined redesign of eight CMS healthcare compare tools available on Medicare.gov that provides a single platform where patients and caregivers can quickly search for key quality, cost, and service data to make informed decisions about their healthcare. [242]

Better Care for Dual Eligibles

Approximately twelve million Americans are dually eligible for Medicaid and Medicare. In Medicare, this represents 20% of the patient population, but nearly a third of the costs. State expenditures for Medicaid face an even bigger imbalance – with Medicare-Medicaid dually eligible individuals historically comprising 15% of the program and 33% of spending. CMS and the states spend over $300 billion is spent each year on services for this population, yet health outcomes and experiences are still sub-optimal.[243]



Dually eligible individuals experience high rates of chronic illness, with many having long-term care needs and social risk factors that can lead to poor health outcomes.[244] However, there is great potential for improving coordination and efficiency; studies show that **25% of hospitalizations for dually eligible individuals were potentially avoidable.** [245]

CMS continues to foster innovation in integrate care through new and existing CMS models and demonstrations within the Medicare FFS and MA programs. Integrated care maximizes Medicare-Medicaid care coordination and mitigates cost-shifting incentives by creating total-cost-of-care accountability across the two programs. Most importantly, it provides a seamless, holistic experience for beneficiaries to help achieve positive health outcomes. For example, the Direct Contracting Model places Managed Care Organization (MCOs) at risk for both Medicare and Medicaid spending. This risk arrangement aligns the plans' financial incentives with whole person care and will likely reduce over spending across both programs.

Accomplishments

Promoting Integrated Care

- CMS continues to foster innovation in integrated care through new and existing CMS models and demonstrations within Medicare FFS and MA programs. In 2011, only 162,000 dually eligible individuals were enrolled in any type of program that integrates their Medicare and Medicaid coverage.[246] **In 2020, CMS met its OKR of having over 1 million dually eligible individuals in integrated care programs**.[247]

- In April 2019, CMS finalized provisions in the 2020 Medicare Advantage and Part D Final Rule, including policies that would create standards to better integrate MA dual eligible special needs plans (D-SNPs), as well as a new Medicare-Medicaid integrated appeals process for beneficiaries in fully integrated plans.[248] **Since the publication of the rule, CMS has worked with over 40 state Medicaid agencies** on contracting with MA D-SNPs.

- CMS has created new options for providers in every state to better serve high-need beneficiaries, including dually eligible individuals, through new forms of capitated population-based payments (PBPs), enhanced payment options, and flexibilities to increase the number of tools providers have to meet beneficiaries' medical and non-medical (e.g., social determinants of health) needs. These options include the Direct Contracting model, through which organizations can take accountability to serve groups of high-need dually eligible beneficiaries. In April 2019, CMS also released a State Medicaid Director letter inviting all states to partner with CMS to test innovative approaches to better serve individuals dually eligible for Medicare and Medicaid.

- In December 2020, CMS introduced a new type of Direct Contracting Entity (DCE) to better serve the needs of dually eligible individuals. This new DCE type will allow Medicaid Managed Care Organizations (MCOs) to better coordinate care for their dually eligible Medicaid managed

care enrollees as MCO-based DCEs. CMS will test whether putting MCOs or their corporate affiliates at risk for Medicare fee-for-service costs for their full-benefit dually eligible Medicaid MCO enrollees, in addition to the risk the MCOs currently have under Medicaid, will lead to innovative strategies for improving care for this high-risk population. DCEs will have a new financial interest in lowering Medicare FFS spending because they will be able to share in Medicare savings or losses.

- In May 2020, CMS finalized provisions in the 2021 Medicare Advantage and Part D Final Rule to phase out "dual eligible special needs plans (D-SNPs) look-alikes" that undermine state efforts to integrate care.
- In May 2019, CMS updated regulations for the Programs of All-Inclusive Care for the Elderly (PACE), a fully integrated model of managed care service delivery for the frail elderly, most of whom are dually eligible. The rule applies best practices in caring for frail and elderly individuals, including implementing flexibilities in the composition of the interdisciplinary team who coordinate care for participants to allow the team to better meet beneficiaries' needs.
    - CMS also finalized several other flexibilities, **including allowing non-physician primary care practitioners to provide some services in the place of primary care physicians**. As a result, PACE organizations have flexibility to improve efficiency, while ensuring they continue to meet the needs and preferences of beneficiaries they serve.[249]

Improving the Dual Eligible Experience by Modernizing the Medicare Savings Programs

- Millions of Americans rely on the Medicare Savings Programs (MSPs) to help cover Medicare premiums or cost sharing. The assistance provided under the MSPs is significant. Beneficiaries in the MSPs can save upwards of $1,600 a year through the coverage of Medicare Part B premiums alone– money that beneficiaries can use for food, housing, or other necessities.[250] While the benefits are worthwhile, payment and coordination of benefits in the MSPs are complex and can produce substantial inefficiencies for all parties.
- In the Qualified Medicare Beneficiary (QMB) program,[xx] CMS is creating avenues for information sharing regarding QMB status.
    - CMS has enabled providers and suppliers to better identify QMBs before they submit claims. CMS is also notifying providers and suppliers not to bill the QMB beneficiaries for claim balances.
    - **CMS is making sure QMB participants are well informed** by providing individualized information about their cost sharing liability and protections through the quarterly issued Medicare Summary Notice.[251]
- In March 2020, **the Interoperability and Patient Access Final Rule** updated requirements for states to exchange certain enrollee data for individuals dually eligible for Medicare and Medicaid, including state buy-in files and "MMA files"[xxi] from monthly to daily exchanges. These changes will help CMS, states, and the plans that serve these dually eligible individuals improve program coordination using the most up-to-date information and ensure these individuals have access to the full complement of appropriate services under each program.

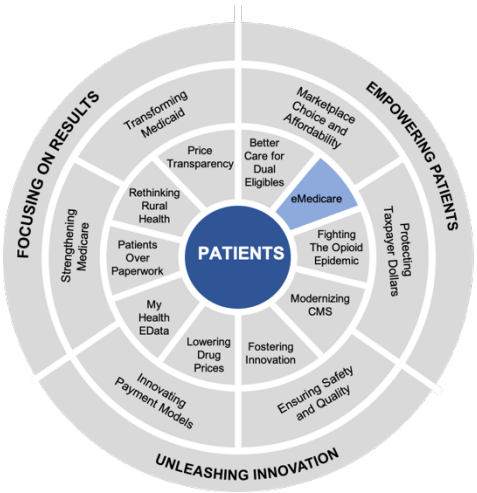
[xx] QMB is a Medicaid benefit that assists low income Medicare beneficiaries with Medicare Part A and Part B premiums and cost sharing, including deductibles, coinsurance, and copayments. By law, Medicare providers may not bill QMB for Medicare Parts A and B cost sharing amounts.

[xxi] These files are called "MMA files" after the acronym for the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

  - By exchanging data more frequently, CMS can **also monitor that services are billed appropriately the first time, eliminating waste and burden**. States will be required to begin this daily exchange starting April 1, 2022.[252]

- CMS published a full overhaul of the state-facing governing documents for the MSP process for the first time in over 20 years.[253]
- CMS worked collaboratively with the Social Security Administration on extensive business process modeling to find efficiencies in shared processes and data exchanges.[254]
- Early data shows these changes are making an impact. **CMS has seen a 10% reduction in a certain type of transaction rejections** between CMS and the states.[255]
- In September 2020, CMS released the latest analytic files for research purposes using Medicare-Medicaid linked claims and enrollment data.[256] CMS continues to create and publish new tools to support research and analysis. CMS is equipping researchers with as much data as possible to assist in finding innovative ways to improve care for dually eligible individuals now and into the future.

eMedicare



Information technology is an ever-increasing aspect of the daily lives of beneficiaries and providers. According to a 2016 survey conducted by the Pew Research Center, 67% of adults ages 65 and older say they access the internet. Additionally, roughly half of older adults who own cellphones reported having some type of smartphone.[257] To meet the growing expectations and needs of tech-savvy Medicare beneficiaries and their loved ones, CMS launched the eMedicare initiative in 2018 with the goal of further empowering beneficiaries with easy-to-use digital support tools, cost information, and enhanced customer support on their computers, tablets, and mobile devices. eMedicare is an innovative, multi-year initiative that provides a seamless online healthcare experience enabling patients to interact with Medicare online, on the phone, or through other channels, ultimately modernizing the way beneficiaries get information about Medicare and creating new ways to help them make the best decisions for themselves and their families.

Accomplishments

Preliminary analysis has shown a growing appetite for web-based technology among Medicare beneficiaries and their caregivers. By focusing on making its own website and call center user experience as modernized and streamlined as possible, CMS is better able to meet patients where they are with their technological capabilities and ensure patients have the resources necessary to make informed decisions about their care.

Modernizing Medicare.gov and Redesigning the Medicare Plan Finder

- Since 2017, CMS has been maturing the Medicare.gov website and has completely redesigned the top used tool, the Medicare Plan Finder making significant improvements to the old system. Plan Finder allows beneficiaries to compare options and choose how they get their Medicare coverage between a Medicare Advantage Plan or Original Medicare and Prescription Drug Plans and potentially a Medigap plan. The Medicare.gov site now offers several customized experiences for beneficiaries and additional capabilities for those logging in with an account. For example those new to Medicare are offered a tailored interface since their needs and choices are different than current Medicare beneficiaries.
    - Over 15 million people have signed up to receive email notifications from CMS, up from less than 1 million in 2016.
    - Total online enrollments during this Open Enrollment (OE) (984K) were 23% higher than in 2016 (799K) as a result of improvements to the Medicare Plan Finder. Call Center enrollments were down this OE compared to 2016 as a result of website improvements that reduced the number of call center inquiries.
    - Plan Finder was streamlined and rebuilt in 2019. The new tool offers users a simplified and streamlined way to compare options. As a result, Plan Finder sessions for all of OE were 10.5M, up 6% from OE last year. Page views were 141M, up 2% from Open Enrollment last year.
    - This year we had significantly more users creating My Medicare accounts than in 2016. There were 756.8K new accounts this year vs. only 53.5K in 2016 (a 1316% increase). In addition, we had many more users logging in to My Medicare this year. 7.5M logins this year vs. 1.3M in 2016 (a 480% increase).

- For the first time in a *decade*, CMS launched a modernized and redesigned Medicare Plan Finder in the fall of 2019.[258] The redesigned Medicare Plan Finder offers a simplified, streamlined, mobile friendly user interface, and enhanced web chat, to empower patients with the information they need to get the best value from their Medicare coverage. Plan Finder allows beneficiaries to compare options and choose how they get their Medicare coverage between a Medicare Advantage Plan or Original Medicare and Prescription Drug Plans and potentially a Medigap plan.
    - CMS rebuilt the system using lessons learned from the original Plan Finder, many rounds of consumer testing and continues to incorporate user feedback as it builds new improvements into the system.
    - Plan Finder can now **provide additional personalization, for example pre-populating the prescription drug lists** based on a beneficiaries' actual drug usage.
    - **Plan Finder experienced exceptional system performance with 100% system uptime throughout all of Medicare Open Enrollment and a 10% increase in customer satisfaction**.[259]
        - Sessions per user dropped by 36%, suggesting more users were able to conduct their business in a single visit with the new tool.

Streamlining and Redesigning Search Tools

- In late summer of 2020, CMS launched Care Compare, a streamlined redesign of eight existing CMS healthcare compare tools available on Medicare.gov.[260] Care Compare provides a single user-friendly interface that patients can use to make informed decisions about their healthcare based on cost, quality of care, volume of services and other data.
- **With just one click, patients can find information that is easy to understand about doctors, hospitals, nursing homes, and other healthcare services** instead of searching through eight different tools.
    - Previously, a patient planning to have bypass surgery would need to visit Hospital Compare, Nursing Home Compare, and Home Health Compare individually to research providers for the different phases of their surgery and rehabilitation.
- Patients can start their search at Care Compare to find and compare providers that meet their healthcare needs that includes information about quality measures presented similarly and clearly across all provider types and care settings.
    - Patients will also find helpful hints and guides throughout Care Compare. For example, if searching for a nursing home, patients can utilize a checklist with common questions and considerations when selecting a nursing home.
- In December 2020, CMS launched an enhanced Supplier Directory that is more robust and helps beneficiaries learn about durable medical supplies and equipment, including where these products are available in their area. This tool is a visual refresh to align with other Medicare tools and is available on Medicare.gov.
    - This redesign is an important step towards improving the beneficiary customer experience across multiple Medicare tools. Offering Medicare tools with a similar "look and feel" will make it easier for beneficiaries to search for durable medical supplies and equipment to guide important healthcare decisions.

- New features incorporate intelligent search where a user can input a broad search term, with the tool offering a choice of plain language product categories or suppliers in response to user input. This allow users to further customize their search for product and supplier information.

Offering Online Premium Payment

- Prior to February 2019, approximately 2.2 million beneficiaries are required to mail their premiums directly to Medicare each month because they are not yet receiving Social Security benefits. In 2018 and 2019, CMS developed and implemented a way for beneficiaries to pay their bill online through their secure online Medicare.gov account, 24 hours a day, seven days a week.[261]
  - Having an electronic payment option means they can securely pay plan premiums without needing to mail checks or worry that late payments will jeopardize their plan coverage.[xxii]
  - **Adoption of the online premium payment feature has far exceeded expectations, totaling 1.5 million electronic payments made and over $690 million in payments processed since its launch in February 2019.[262]**
  - Additionally, the number of premium billing-related inquiries to 1-800-MEDICARE has plateaued and customer satisfaction on those premium-related inquires has climbed to over 96%.

Publishing the Enhanced Provider Data Catalog

- Launched in September 2020, the Provider Data Catalog (PDC) was built to give those interested in detailed CMS provider data a customized area to access, download, and use CMS Compare data sets like those currently available for researchers on data.Medicare.gov.
  - Data users can access information on providers such as doctors and clinicians as well as facilities and care settings such as dialysis facilities, hospitals, hospice care and home health services.
- **The PDC makes quality datasets available through an API,** allowing application developers and innovators in the field to easily access CMS publicly reported data and make it useful for patients.

Launching the Procedure Price Lookup Tool

- CMS launched the Procedure Price Lookup (PPL) tool on November 27, 2018 to give consumers the ability to compare national average prices for procedures that are performed in both hospital outpatient departments and ambulatory surgical centers.[263]
- The PPL tool displays national averages for the amount Medicare pays the hospital or ambulatory surgical center where the procedure takes place, as well as the national average copayment amount a beneficiary without Medicare supplemental insurance would pay for the procedure.
  - In late summer 2020, **CMS added physician fees to the PPL tool to give Medicare beneficiaries a more comprehensive and accurate prediction of out-of-pocket costs for several procedures**.
  - The PPL tool now makes data available through an API and integrates Current Procedural Terminology (CPT) code data from the American Medical Association

[xxii] For more discussion of these accomplishments, see "Modernizing CMS".

(AMA) which allows patients and providers to focus on the costs of the specific procedure of interest.

Improving Information through Text Messaging and Launched "What's Covered" App

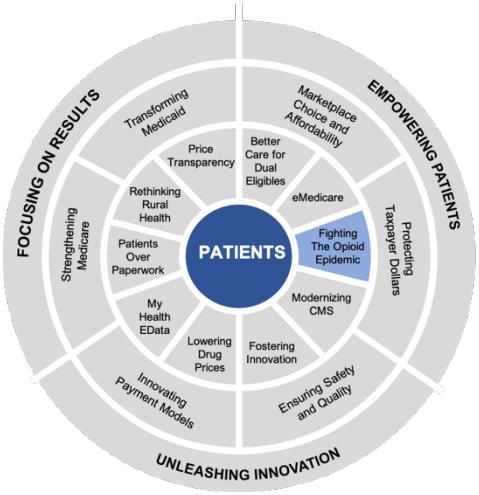
- Questions about Medicare coverage are some of the most frequent inquiries that CMS receives; there are approximately **15 million page views annually for coverage-related content on Medicare.gov**, and **over 3 million coverage-related calls to 1-800-Medicare annually.**
    - To make information more accessible for those who prefer to call 1-800-Medicare, CMS is now offering convenient text messaging from the call center for referrals and other information sent directly to a beneficiaries' phone. This includes information on what Medicare covers as well as other common topics.
- As an alternative to calling 1-800-Medicare or searching the CMS website, on February 6, 2019, CMS launched the free "What's Covered" app, which delivers accurate cost and coverage information on mobile devices so Medicare beneficiaries and their caregivers can quickly see whether Medicare covers an item or service.[264]
    - This free service is available with or without internet connection so that Medicare beneficiaries can learn what is covered, how and when to get covered benefits, and basic cost information at any time.
- As shown in Figure 6, the usage of eMedicare tools continues to rise.

Figure 6. CMS eMedicare Tool Utilization Rates

eMedicare Tools	Usage (July 2018-July 2020 unless otherwise noted)
Procedure Price Lookup	107K unique users
What's Covered App	656K downloads
Medicare Plan Finder	39M unique sessions (reflects both new & old MPF)
MyMedicare Accounts	13M (total accounts as of July 2020)
Online Premium Payment	1.5M payments online, totally over $690M in payments collected

Fighting the Opioid Epidemic

From 1999 to 2018, over 767,000 Americans lost their lives to drug addiction and overdose, with seven out of every ten drug overdoses attributed to opioid use.[265] In 2016, more than 11.5 million Americans ages 12 and older reported misuse of prescription opioids in the past year.[266] The Centers for Disease Control and Prevention estimates that the total economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[267]



In response to this crisis, on October 26, 2017, President Trump declared a Nationwide Public Health Emergency, mobilizing his entire administration to address drug addiction and opioid abuse. Less than a year later, the President signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act).[268] **CMS leads 49 out of the 153 provisions in the SUPPORT Act.** As a leader in the work to combat substance use disorders (SUD), CMS developed an Opioids Roadmap that focuses on actions to combat the opioids crisis through prevention, treatment, and data.[269]

Accomplishments

As a result of a coordinated effort across the Trump Administration, CMS is making headway in combatting this healthcare crisis. CMS' efforts toward reducing OUD/SUD have begun to move the needle across multiple domains[xxiii]:

- Between 2017 and 2018, among 38 states with prescription opioid overdose death data, 17 states saw a decline in death rates; none experienced a significant increase.[270]
- Opioid overdose deaths associated with abuse of commonly prescribed opioids also decreased by 13.5% from 2017 to 2018.[271]
- In 2018, the United States achieved a **4.1% decline in all drug-related deaths from 2017** (70,237- 67,367 deaths)[272] – the first decline in this measure in ***over a decade***.[273]

Expanding Access to Medication-Assisted Treatment

- Effective January 2020, Medicare began covering services to treat OUD at Opioid Treatment Programs (OTPs) through bundled payments.[xxiv] Under the new OTP benefit, Medicare covers a range of benefits including methadone for medication-assisted treatment (MAT), dispensing and administration of other MAT medications (if applicable), substance abuse counseling, individual and group therapy, toxicology testing, intake activities and periodic assessments.[274]
    - CMS has enrolled **over 1,000 OTPs** to date.[275]

Expanding Access to Non-Opioid Pain Management Alternatives

[xxiii] While these improvements may be affected by the COVID-19 PHE, taken together, these findings indicate a positive impact of interventions in this area, with space for continued improvement.

[xxiv] To receive Medicare payment, OTPs must meet certain conditions, such as entering into a standard Medicare provider agreement, paying an application fee, and being SAMHSA-certified. OTPs could begin enrolling in Medicare in November 2019.

- On January 21, 2020, Medicare reconsidered its longstanding national non-coverage of acupuncture treatment by issuing a National Coverage Determination (NCD)[276] **extending coverage for up to 12 acupuncture sessions in 90 days, with an additional eight sessions annually, for those patients with chronic low back pain who demonstrate improvement.**[277]
    - To build awareness of treatment options, CMS added information coverage of OUD treatment to the *Medicare and You* handbook, which is distributed to Medicare beneficiaries annually and available online.
    - On August 19, 2019, CMS published a Medicare Learning Network Matters Special Edition article that outlined the integrative and non-pharmacological treatments covered under Medicare as treatments for pain.[278]

Improving Drug Utilization Review Controls under Part D

- In April 2018, CMS established a drug management framework under which Part D plans will engage in case management for beneficiaries at risk for prescription drug abuse or misuse to limit beneficiaries' access to frequently abused drugs.
- At the same time, CMS codified its Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) and integrated this policy into the drug management programs. CMS evaluates Part D prescription drug event and encounter data received through OMS and sends plan sponsors quarterly reports on enrollees who meet clinical criteria for being at risk of opioid overutilization. Plans are required to conduct case management for at-risk enrollees to determine appropriateness and safety of prescribed medications, and if necessary, limit an enrollee's access to controlled substances to selected prescriber(s) and/or network pharmacies.
    - While drug management programs are relatively new, CMS' earlier adoption of the DUR policy corresponded with a 76% decrease in the number of Part D beneficiaries identified as potential very high risk opioid overutilizers from 2011 through 2017.[279]
    - **Drug management programs will expand upon an existing approach that has shown success in reducing opioid overutilization in the Part D program by improving quality of care through coordination while maintaining access to necessary pain medications**, and will be an important next step in addressing the opioid epidemic and safeguarding the health and safety of Medicare beneficiaries. **Starting in Plan Year 2019, CMS expects sponsors to implement formulary-level opioid safety edits.**
    - The purpose of the opioid safety edits is to prompt prescribers and pharmacists to conduct additional safety review to determine if the enrollee's opioid use is appropriate and medically necessary. Plan sponsors should implement the edits in a manner that minimizes any additional burden on prescribers, pharmacists, and beneficiaries.[280]

Funding State Innovation in and Expanding Access to SUD Treatment

- On June 25, 2019, CMS, in consultation with the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Agency for Healthcare Research and Quality, announced a

demonstration project to increase the treatment capacity of Medicaid providers to deliver SUD treatment and recovery services.[xxv]

- **By September 2019, CMS had awarded 14 states and the District of Columbia a total of $48.4 million dollars in planning grants.**[xxvi] At the conclusion of the 18-month planning process, up to five states will receive approval to conduct a 36-month demonstration.
- In November 2017, CMS announced it would consider Medicaid demonstration waivers for OUD and SUD treatment provided to non-elderly patients in "institutions for mental disease" (IMDs).[281] This option provided states the flexibility to design demonstrations aimed at improving access to the full continuum of clinically appropriate treatment for these disorders, while also introducing metrics for demonstrating improvement in outcomes for Medicaid beneficiaries.
    - **As of November 2020, 30 states and the District of Columbia have received approval for these 1115 waivers; a further five have pending applications or amendments seeking similar demonstration authority**.[282]
    - CMS increased by seven fold the number of approved state Medicaid demonstrations for Opioid Use Disorder (OUD)/Substance Use Disorder (SUD) treatment, going from four approved demonstrations in 2017 to 31 approved demonstrations as of December, 2020. These demonstrations significantly increase access to high quality, evidence-based treatment options for Medicaid beneficiaries with SUD to improve health outcomes.

Making Data on SUD Rates and Treatment Publicly Available

- In October 2019, CMS released the first annual T-MSIS SUD Data Book. The SUD Data Book reports the number of Medicaid beneficiaries with a SUD and the services they received during CY 2017, the most recent complete year of T-MSIS enrollment and claims data available when the analysis was conducted.[283]
    - This data book, which is also available in an interactive format, is useful to states and other entities interested in SUD data in quantifying the pressing need for SUD treatment and prevention services, with a focus on opioid use. The data book also represents the first public release of nationwide analysis using T-MSIS.

Improving Coverage for Opioid Reversal Agents

- In its 2020 Medicare Advantage and Part D Rate Announcement and Final Call Letter, CMS strongly encouraged Part D sponsors to provide lower cost sharing for opioid reversal agents, such as naloxone.[284]
- In 2020, all plans included at least one opioid reversal agent in their generic tier. Reducing the high out-of-pocket costs for opioid reversal agents will reduce barriers to access to these life-saving treatments.

[xxv] Section 1003 of the SUPPORT Act (Pub.L. 115-271) authorizes CMS to conduct a 54-month demonstration project to increase substance use provider capacity, beginning with an 18-month planning phase.

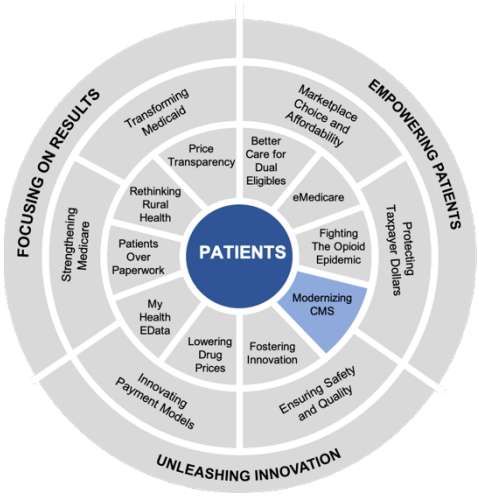
[xxvi] The following State Medicaid Agencies were awarded 18-month planning grants: Alabama, Connecticut, Delaware, District of Columbia, Illinois, Indiana, Kentucky, Maine, Michigan, Nevada, New Mexico, Rhode Island, Virginia, Washington, and West Virginia.

Increasing Access to and Coordination of Treatment for Vulnerable Populations

- In addition to the above, CMS has launched the Integrated Care for Kids (InCK) and Maternal Opioid Misuse (MOM) models.[xxvii] CMS will continue to evaluate their achievement toward the goals of fostering coordinated and integrated care for at-risk patients, expanding access to care, and creating sustainable, state-based strategies for addressing the opioid epidemic in a manner most respectful to and reflective of the state's specific needs.
    - Launched January 1, 2020, the InCK model is a child-centered local service delivery and state payment model aimed at reducing expenditures and improving the quality of care for children covered by Medicaid and CHIP through prevention, early identification, and treatment of priority health concerns, including OUD.[285]
    - Similarly, the MOM model seeks to address fragmentation of care for pregnant and postpartum Medicaid beneficiaries with OUD and their infants through state-driven transformation of the delivery system surrounding this population.[286]

[xxvii] The InCK and MOM models' pre-implementation periods began in January 2020. The InCK model's performance period will run through 2026, and the MOM model's through 2024.

Modernizing CMS



CMS is responsible for providing health coverage to more than 142 million people through Medicare, Medicaid, CHIP, and the Health Insurance Marketplace.[287] CMS also serves as a health plan provider, healthcare funder, health safety regulator, data researcher, healthcare innovator and steward and protector of taxpayer money.

CMS recognized that while the scope of the agency's responsibilities have dramatically increased over the last decade, in many ways the agency was still operating under a legacy mindset.[xxviii] To achieve the bold objectives CMS set for the past three years, CMS had to rethink how to optimize its people, processes, structure and capabilities to meet the challenges of the next decade and beyond. The "Modernizing CMS" strategic initiative was developed to maximize operational effectiveness by identifying opportunities to leverage CMS expertise more efficiently and tie CMS work together seamlessly across the many components of the agency.

The Modernizing CMS strategic initiative was launched in the fall of 2018 based on the identification of CMS' top operational challenges and opportunities from multiple sources including a half day event with over 70 senior leaders, a survey open to all employees that garnered almost 1,600 responses, and over 50 detailed interviews of managers and staff. Modernizing CMS is built upon four pillars: People, Process, Structure, and Capability. The Modernizing CMS strategic initiative is built upon four pillars: People, Process, Structure, and Capability.

FRAMEWORK

CMS had to evaluate its structures and processes to ensure the Agency was in the best position to make long-term changes that would benefit patients and delivery high-quality, high-value care. CMS selected 16 strategic initiatives as a framework around which bold projects are built.

Each of these initiatives shares the same focus - the patient. CMS built this patient-centered framework as a structural guide, and matched it with a process that CMS selected to obtain and then surpass the objectives CMS seeks to achieve. CMS looked to models in the private sectors focused on achieving success. For example, CMS looked to *Measure What Matters*, written by John Doerr, which outlines the process by which high-performing companies use his method of setting Objectives to drive Key Results, also referred to by their acronym OKRs.[288]

Objectives are goals and intents, while Key Results are time-bound and measurable milestones under these goals and intents. OKRs are built on the foundation of "FACTS" - Focus, Alignment, Commitment, Tracking, and Stretching. The benefits of a process that is built around FACTS is why CMS has so heavily leaned on using OKRs in strategic planning and performance management.

CMS tracks OKRs for each of the 16 strategic initiatives, components, and operational divisions in monthly performance meetings using a dashboard approach to review the progress toward its key results. Consistent monitoring and review provide CMS the knowledge to adjust objectives that need attention and stretch objectives that have "topped out". Leveraging data to inform progress and next steps helps keep a pulse on the measureable impact of CMS' change journey, holds it accountable for delivering against priorities, and better enables leadership to make enterprise-level decisions. By developing the 16

[xxviii] CMS' workforce has grown from approximately 4,200 employees in 2010 to over 6,200 employees in 2020. During that time, CMS has expanded to oversee legislative changes such as the Affordable Care Act, expansion of centers and programs like the Quality Payment Program and innovation center, and expansion of authority such as prior authorization, to mention a few.

strategic initiatives and using the OKR process, CMS has not only built a way to improve its current programs, it has also created a roadmap to the future of CMS.

CMS adopted the Objectives and Key Results (OKRs) as a tool to define ambitious and measureable goals that indicate progress against its key strategic priorities. OKRs allowed CMS to communicate and align on priorities and create accountability for progress against goals. Leveraging data to inform progress and next steps helps keep a pulse on the measureable impact of CMS' change journey, holds it accountable for delivering against priorities, and better enables leadership to make enterprise-level decisions.

Driven by the desire to make CMS one of the most effective agencies in government, CMS is upgrading, and in some areas developing, new organizational capabilities to improve upon CMS' advanced analytics, program and performance improvement management, strategic planning, and strategic procurement and vendor management.[289] As a result of this improved organizational performance management, CMS will be able to track and evaluate progress toward objectives over time, more readily identify areas for improvement, and set targets to achieve ambitious goals.

CMS developed the first holistic, enterprise-level performance dashboard to enable leadership to use data to measure enterprise performance, to better prioritize critical resources, and for making decisions on enterprise strategic priorities through monthly review of an Executive Dashboard, a visual representation of key CMS OKRs, and leveraged its dashboarding capabilities to quickly stand up a COVID-19 dashboard during the PHE.

- CMS has focused resources and attention to areas of need, and as a result has **driven 76% of the projects and deliverables on the 2019 strategic plan to completion**.[290]
    - With a goal of December 31, 2020 as its key result, CMS completed all major facets of the One CMS plan by August 2020.
- CMS selected ambitious customer service OKRs, leading CMS to achieve an **all-time high of 90% satisfaction with the marketplace call center** during 2019 open enrollment and to maintain scores of 94-95% in customer satisfaction with Medicare call centers.[291,292]
    - In FY 2019, CMS served as HHS's primary lead for the President's Management Agenda Cap Goal #4 on Customer Service, a reflection of CMS' superior abilities in this area.
- Additionally, CMS expanded the process improvement journey by looking to engage directly with employees for improvement ideas. In 2019, CMS announced the "i-Challenge" to solicit suggestions from CMS employees for improving CMS internal processes.
    - **CMS received and reviewed more than 300 ideas for improvement**, categorizing winning ideas into immediately implementable and long-term solutions, and acting on those ideas accordingly.

      Selected winning improvements were in various stages of implementation as of July 2020, with three fully implemented.

Accomplishments

STRUCTURE: Becoming One CMS

- In May 2019, CMS announced it was becoming "One CMS."[293] One CMS leverages the expertise of all CMS staff, especially regional offices, into an organizational structure that improves integration of regional office staff into policy development and implementation, putting similar activities together to make the work easier and more efficient. The goal is to provide better communication, coordination, and alignment across CMS programs.

  - **CMS created a unified home for all quality improvement and survey and enforcement activities**, regardless of CMS location, in the Center for Clinical Standards and Quality.
  - **CMS consolidated all Medicaid & CHIP work occurring across CMS' locations in the Center for Medicaid & CHIP services**, enabling the creation of centers of excellence focused on key programmatic and operational areas.
  - **The regional press officers were aligned to the Office of Communications'** Media Relations Group, enabling the agency to more easily coordinate this function across all locations to ensure consistent messaging.

- Additional CMS structural changes were the creation of new offices:
  - CMS connected regional leadership directly to the Office of the Administrator by **creating the Office of Program Operations and Local Engagement (OPOLE)**. OPOLE conducts local outreach and education to strengthen customer understanding of national policy and Agency initiatives, improve customer experience by streamlining touchpoints for external partners and increases cohesion & integration within each regional location, across program areas, program centers and external partners.
  - **The Office of Burden Reduction and Health Informatics (OBRHI)** was created to help reduce unnecessary burden, increase efficiencies, continue administrative simplification, increase the use of health informatics, and improve the beneficiary experience.[294]
  - **The new Office of Strategy, Performance, and Results** is responsible for enterprise wide strategic planning and performance management, and was established to advance the Modernizing CMS principles of being a data driven, customer centric organization with a culture of continuous improvement and resiliency.
  - **The new Office of Stakeholder Engagement** within the Office of the Administrator to ensure better and consistent communication with external partners.
  - **The Technology, Coding and Pricing Group** in the Center for Medicare was created to engage with stakeholders on new technologies and their impact on beneficiaries. This new group supports the agency's commitment to increase its focus and accessibility to stakeholders who are driving innovation.[xxix]

- These notable realignments enabled the agency to respond more nimbly to the COVID-19 pandemic.[xxx] All of CMS' locations were integrated into the response enabling faster waiver approvals, coordinated and targeted survey and enforcement work, and robust inquiry response and local outreach and education activities.

PEOPLE: Improving Talent Management

- Improving talent management and employee recruitment was the highest priority identified by leadership for strengthening CMS. First, CMS structurally aligned its Office of Human Capital (OHC) to better address priority areas and to increase transparency and efficiency in supporting CMS' human capital needs. Leadership in OHC championed a "whatever it takes" mindset to improve hiring, including dissecting the process step by step, identifying the root causes by engaging with customers, and making very specific changes to the process.

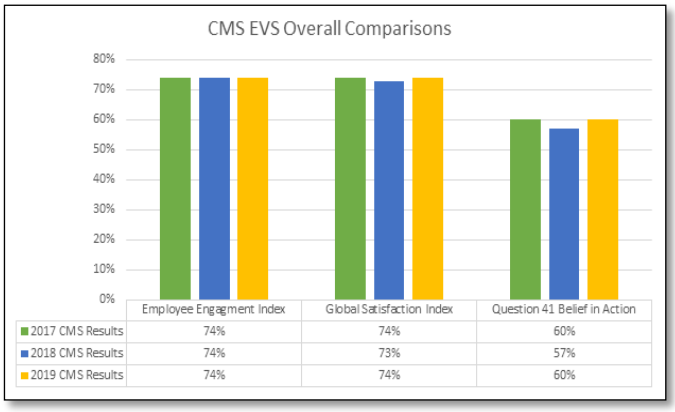
[xxix] For more discussion of these accomplishments, see "Fostering Innovation".
[xxx] For more discussion of CMS' response to the COVID-19 PHE, see "Case Study: COVID Response".

- **OHC developed a pilot program that reduces the hiring timeline to 90-days for competitive hires**. To date, OHC has reduced the average time to hire by 30%, and reinforced the commitment to fact-based decision making to drive to outcomes with enterprise-wide impact.[295] OHC developed a pilot program that reduces the hiring timeline to 90-days for competitive hires.[296]
    - **CMS has surpassed its goal of meeting a 90-day or under time to hire average**: data from September 2019 to January 2020 show the average time to hire for competitive hiring reduced to 92.6 days, and as of June 30, 2020 the average is now 87 days from recruit to hire. This is down from the 2019 baseline of 125 days.[297]
    - **Additionally, 82% of the 439 hiring managers surveyed reported being satisfied or highly satisfied** with quality of hire.[298]
- To develop CMS employees into the next generation of CMS leaders, CMS also developed a highly successful intra-agency rotation opportunity under which selected participants are matched with a 3-month lateral rotational assignment outside of their home component.
    - Through nine cohorts, **CMS has placed a total of 232 participants with 19 components** offering host assignments.
    - Participants have reported being highly satisfied with the assignments, with an **average participant evaluation rating of 4.7 out of 5**.[299]

PEOPLE: Focusing on Employee Engagement, Talent Recruitment, and Development

- In 2018, CMS instituted "You Speak, We Listen, Things Happen", a leadership commitment to employees to take employee feedback and act on it, which set the tone for the work of the entire CMS leadership team.
- Through its efforts to increase employee engagement, **CMS achieved a 74.5% participation rate for the 2019 Federal Employee Viewpoint Survey (FEVS),** besting the HHS rate of 71.9%, and the government wide rate of 42.6%.[300] The almost 75% response rate was a large increase from the 2018 response of 61.1% for CMS.[301]

Figure 6. CMS FEVS Indices Results



- In addition to the tremendous increase in the CMS response rate, analysis of the data also confirmed improvement across all three indices for which HHS and CMS has prioritized its focus: the Employee Engagement Index (EEI); the Global Satisfaction Index (GSI); and Belief in Action.[xxxi]

[xxxi] EEI is comprised of 15 FEVS questions divided into three sub-indexes, measuring the workforce conditions that support employee engagement. GSI is a combination of 4 FEVS questions, measuring employees' satisfaction with their jobs, their pay, and their organization, plus their willingness to recommend their organization as a good place to work. Belief in Action gauges the degree to which employees believe the FEVS results are used to make their agency a better place to work.

- CMS has demonstrated its commitment to improvement by maintaining and sustaining high scores in all key areas of focus.[302]
- **While overall the scores were solid, earning a 74% on the EEI**, some working units in CMS showed room for improvement. CMS applied developmental services to these areas and as a result, of the 12 lowest scoring units in CMS, 10 improved their EEI scores and 6 of those rose out of the bottom 20% in 2019.[303]

PROCESS: Increasing Organizational Performance Management and Goalsetting

- CMS responded to 356 final reports from the HHS Office of Inspector General (OIG) and the US Government Accountability Office (GAO) and closed a record 722 recommendations from mid-2017 to end of 2020. These results were attributable to establishing a process for tracking the recommendations more vigorously and establishing quarterly meetings with both OIG and GAO to discuss the findings and recommendations in order to ensure better follow up.
    - Prior to 2017, the average number of annual closures was approximately 166 per year.
    - In 2017, CMS leadership began a concerted effort to collaborate with OIG/GAO. Senior officials at both CMS and OIG/GAO met quarterly to communicate on open audits and other progress CMS was making towards the implementation of OIG/GAO recommendations, or other high risk program areas. The results of CMS' efforts showed through an initial surge in closures from 2017 to 2019, at an average closure rate of 208 closures per year. The increased closures also resulted from CMS staff performing a targeted analysis of old recommendations, ensuring all those closures were reflected in CMS' system of record and accurately reconciled with OIG/GAO auditors.
    - As to be expected, the urgency of CMS' response to the COVID-19 pandemic was prioritized over implementation of OIG/GAO recommendations in 2020. Yet, the total closures from 2017 through 2020 totaled 722 closed recommendations.

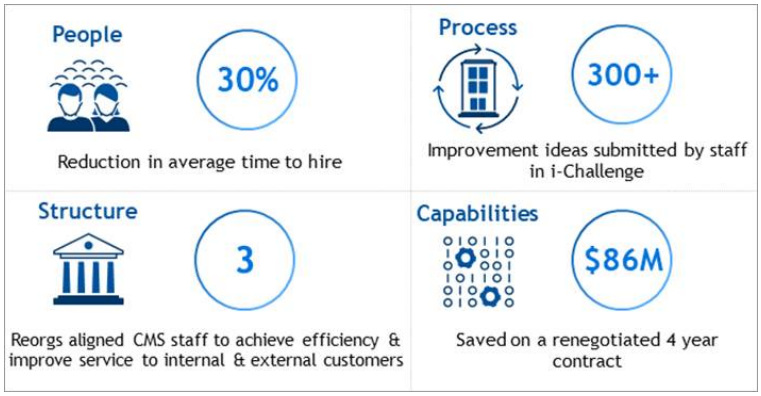
CAPABILITY: Introducing Tools to Improve CMS Efficiency and Maximize Effectiveness

- The final pillar in the modernizing CMS strategy is geared toward maximizing CMS capability. For CMS this means arming staff with up-to-date tools and skill sets, including data and analytics, which will help save money, decrease operational errors, reduce regulatory burden, increase program effectiveness and strengthen customer focus.
- CMS has strengthened capability across several domains by incorporating human centered design, procurement spend optimization, and automation of processes.
    - By keeping the needs of the end user—the patient, provider, or data consumer—at the center of its IT development process, CMS has begun the transition from siloed, black-box development to user-focused, iterative development.
    - CMS has **systematically employed the techniques of human centered design** and agile development- first in IT development and now in all major projects, to determine how to best serve the needs of the customer.
    - CMS has also recently introduced a new clearance system intended to make regulatory clearance more effective and efficient. CMS has transformed this process from an email-based system to a centralized communication system that reducing administrative functions, improves collaboration, and provides better visibility.
    - CMS established an approach to embed metrics tracking and continuous improvement into every project, which now undergo rigorous ROI assessments, and are reviewed for key learnings and major unlocks to inform future efforts.

- This approach manifested itself in the seamless way CMS was able to move to agency-wide telework during the COVID-19 PHE in large part due to a focus on making sure all employees had the technology they needed to be successful, such as the rapid deployment of Zoom, and the successful shift to onboarding of employees virtually.
- CMS **developed a new negotiation model** to leverage the subject matter expertise in policy areas with the contract expertise in the acquisitions area. This model was first tested on a major IT investment which **saved $86 million through a renegotiation of the last four years of the contract**.
    - FY 2019 and 2020 projects have net $22.5 million in FY 2020 savings.
    - CMS also reports total savings for FY 2019 contract actions, which span periods of performance to FY 2024 at $12.6 million and total savings for FY 2020 projects during this same time period (FY 2019-FY 2024) at $79.5 million, for a **grand total savings from FY 2019-FY 2024 of $92 million.**[304]
    - With these enhanced capabilities CMS is holding vendors to higher expectations. If a vendor comes forward claiming a skillset, it is expected that they excel in that area. CMS is looking to close the gap between the language of some of these innovations and ensuring they reap the benefits thereof.[305]

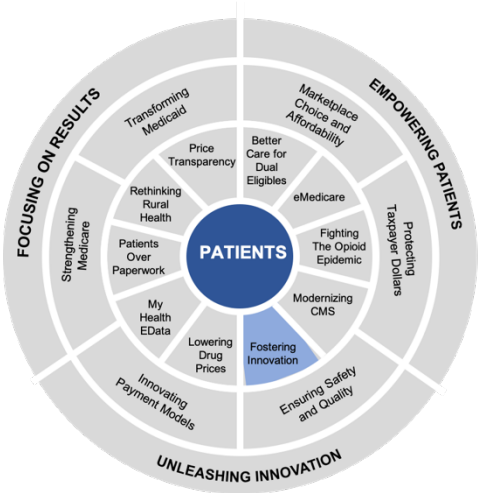
IMPACT:

CMS Operational Impact



- ❖ Achieved a 74.5% participation rate for the 2019 FEVS, besting the HHS rate of 71.9%, and the government wide rate of 42.6%.
- ❖ Showed improvements across all three indices of the FEVS for which HHS and CMS has prioritized its focus: the Employee Engagement Index (EEI), which measures workforce conditions that support employee engagement; the Global Satisfaction Index (GSI), which measures employee satisfaction with their job, pay and organization; and Belief in Action, which measures the degree to which employees believe the FEVS results are used to improve the workplace.
- ❖ 82% of the 439 hiring managers surveyed as "Satisfied" or "Highly satisfied" with quality of their hires.
- ❖ Collected over 300 ideas for internal CMS process improvements through the I-Challenge initiative. Selected winning improvements were in various stages of implementation as of July 2020, with three fully implemented.
- ❖ Experienced exceptional system performance for Plan Finder, with 100% system uptime throughout all of Medicare Open Enrollment and a 10% improved customer satisfaction.
- ❖ Increased number of Medicare beneficiaries with Plan Finder accounts by 667% in 2019.
- ❖ Achieved an all-time high of 90% satisfaction with the Marketplace call center during 2019 open enrollment.
- ❖ Maintained scores of 94-95% in customer satisfaction with Medicare call centers.

Fostering Innovation



Moving medical innovation from the scientific bench to the patient bedside is often a complex process, but it is critical that we use innovation to make the system work better to leverage technology to improve quality, efficiency, and health outcomes. Even after a technology is approved by FDA, it still requires CMS to agree the technology is medically necessary. CMS makes the decision to "cover" a new item or service under the authorities conferred to the Secretary in 1862(a)(1)(A) of the Social Security Act, which declares an item or service eligible for coverage if it meets the test of being reasonable and necessary for the treatment of the beneficiary. Studies have shown the gap between the FDA approval and CMS coverage determination for novel therapeutics to be a median time of 17 (interquartile range, 13–36) months.[306] Additionally, payment and coding decisions may also be necessary before a technology is reimbursed in the Medicare program. CMS recognized this time lag as not just a barrier to innovation, but also a detriment to patients eager to access these life-saving breakthroughs in care.

Accomplishments

A series of CMS policy initiatives have delivered on the promise to expedite access to lifesaving technologies. By ensuring that providers have appropriate financial support to introduce and implement new devices and treatments, reforming the Local Coverage Determination process, establishing coverage for lifesaving, innovative technologies for diagnosing and treating cancer, and removing administrative barriers that slowed adoption of new technology CMS has brought new technology to patients in need faster than ever.

Expanding Coverage and Payment for Innovative Technologies

- In January 2021, published the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" final rule. This rule:
    - Automatically **grant coverage for new FDA-breakthrough devices by creating a new coverage pathway that covers devices the same day as FDA approves the device for marketing**;[307] and
    - **For the first time, define the reasonable and necessary statutory standard for Medicare** as an item or service that must be safe and effective, not experimental or investigational, and appropriate for the Medicare patients.[308] This definition allows CMS to review commercial health insurer coverage policies and analyze them for coverage parameters applicable to the Medicare population.
- CMS significantly reduced a backlog of requests for National Coverage Determinations (NCDs), some of which have been on a list awaiting approval since 2014. In 2019 there were 11 NCD applications waiting for CMS review. By the end of 2020, CMS will have addressed nine of those 11. CMS also increased its transparency for stakeholders by posting a dashboard about the status of NCD requests under review, on the wait list, open with a national coverage analysis underway, or finalized in the last 12 months.
- CMS also took action to make it easier for new medical devices designated by the FDA as Breakthrough Devices to qualify for transitional additional payments in inpatient and outpatient hospital settings. FDA's Breakthrough Devices Program helps expedite the development and review of transformative new devices that are intended to treat serious or life-threatening diseases

or conditions for which there are unmet medical needs. CMS' actions support access for beneficiaries to these new devices.

- From 2004 to 2017, 66 New Technology Add-on Payment (NTAP) applications were submitted. In comparison, for the four fiscal year cycles of the Administration (FY 2018-2021), 70 applications were submitted. In FY 2022, CMS received a record number of applications, nearly a 60% increase over the prior year and over a 400 percent increase relative to four years ago.
- The FY 2020 IPPS/LTCH PPS Final Rule established an alternative pathway for medical devices approved for marketing by the FDA as part of the Breakthrough Devices program to achieve NTAP status. CMS will consider Breakthrough Devices to have met the criteria for newness and substantial clinical improvement for at least two years.[309]
  - This final rule **increased the amount of the add-on payment to up to 65%** of the cost of the new technology (previously 50%).[310]
- The CY 2020 OPPS/ASC Final Rule established a similar alternative pathway for newly approved medical devices with the FDA Breakthrough Device designation to qualify for the device pass through payment in the outpatient setting.
  - Such devices will not have to be evaluated to meet the criteria for substantial clinical improvement. CMS will deem that Breakthrough Device status as determined by the FDA demonstrates the device meets that standard.[311]

- In the FY 2021 IPPS/LTCH PPS Final Rule, **CMS expanded the add-on payment alternative pathway for antimicrobial products** approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway), which encourages the development of safe and effective drug products that address unmet needs of patients with serious bacterial and fungal infections.[312] Under this rule, an antimicrobial drug approved under FDA's LPAD pathway would be considered new and not substantially similar to an existing technology and would not need to demonstrate that it meets the substantial clinical improvement criterion (the technology would need to meet the cost criterion). [313]
- In the CY 2020 ESRD Final Rule, CMS established a **new transitional add-on payment adjustment** to support the use of certain new and innovative renal dialysis equipment or supplies furnished by ESRD facilities, called the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). Technology that meet certain criteria, including demonstrating substantial clinical improvement, will receive TPNIES for 2 calendar years, after which the equipment or supply will qualify as an outlier service and no change to the ESRD PPS base rate will be made.[314]
- In 2015, CMS centralized the clinical protocol review process for Investigational Device Exemption Trials, the process by which patients can have access to certain new investigational devices while the device is undergoing a safety and efficacy determination by the FDA.
  - As a result, since 2017, **CMS has reviewed and covered more than 300 studies**, which included numerous novel technologies.

Reforming the Local Coverage Determination (LCD) Process

- In October 2018, CMS finalized an overhaul of Medicare's LCD process to facilitate swifter adoption of innovative technologies and treatments to meet Medicare beneficiaries' needs. Under the revised process, clinicians, patients and other stakeholders have a transparent process for requesting a new or revised LCD with timelines for decision making, clear instruction for initiating the process, and creating criteria for evidence-based decision making.

  - **Patients and members of the public will have a stronger voice** in the process with mandated open public meetings and comment periods.[315]

- Since there are a greater number of LCDs compared to NCDs, these reforms will ensure appropriate evidence-based decisions of medical and technological advances possible.
- These improvements respond to stakeholders' suggestions for more transparency, including multiple opportunities for engagement with CMS and our MACs.[316]

Increasing Access to Innovative Technology for Managing Diabetes

- To improve diabetes management, in January 2017 Medicare started covering the cost of certain types of continuous glucose monitoring devices (CGM) for beneficiaries with diabetes. These devices are important for diabetes management because they allow beneficiaries with diabetes and their physicians to better understand their blood glucose levels and identify issues to help prevent further health complications.
- In 2018, through a Local Coverage Determination (LCD), the Durable Medical Equipment Medicare Administrative Contractors corrected the initial coverage policy by allowing for coverage of CGM devices when used with a data receiver as well as a smart phone app.
- **This expansion makes it easier than ever before for beneficiaries and caregivers to share blood glucose data with their clinicians, allowing for informed treatment adjustments and improved patient self-management**.[317]
  - Additionally, while typically, Medicare beneficiaries need to attend an in-person clinic visit and meet certain clinical criteria that require lab tests to get a CGM, during the COVID-19, CMS is waiving these requirements.
  - CMS' waiver greatly increases access to these devices and removes the additional paperwork and red tape usually in place for providers to prescribe CGMs.

Expanding Medicare Coverage for Cancer

- Many of the most rapid and impactful medical advances are taking place in oncology and CMS has taken action to ensure that Medicare beneficiaries can access the latest advances in cancer care.
- In August 2019, CMS finalized a new NCD extending Medicare coverage of Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers. CAR T-cell therapy was the first FDA-approved gene therapy and uses the patient's own immune system to fight the cancer.
  - The NCD requires nationwide coverage of CAR T-cell therapy for patients with cancers expressing at least one chimeric antigen receptor. For FDA-approved CAR T-cell therapies, Medicare will cover both labeled indications and off-label indications if the off-label use is supported by CMS-approved evidence, such as inclusion in a drug compendium.[318]
  - This decision focused on patient by supporting FDA requirement of patient reported outcomes.
- **CMS also ensured that cutting edge diagnostics were coverable consistently across FFS Medicare.** Next Generation Sequencing (NGS) tests provide the most comprehensive genetic analysis of a patient's cancer because they enable simultaneous detection of multiple types of genetic alterations. Medicare first began covering laboratory diagnostic tests using NGS in March 2018 for Medicare patients with advanced cancer that met specific criteria. In January 2020, CMS expanded coverage of NGS to also include certain hereditary cancers.

  - To keep pace with evolving clinical practice, in the NCD, CMS provided Medicare's Administrative Contractors (MAC) with discretion over whether to cover certain other indications.

- In September 2019, the Durable Medical Equipment (DME) MACs used the new LCD process to provide coverage for the first time for tumor treatment fields therapy (TTFT) for the treatment of newly diagnosed Glioblastoma Multiforme (GBM) when all of the criteria specified in the LCD are met. Continued coverage beyond the first three months is allowed where an evaluation by a practitioner shows the patient is benefiting from the treatment.[319]
  - Since DME MACs are required by CMS to follow identical policies across the Medicare program, this decision covered every Medicare beneficiary across the United States, similar to an NCD.

Increasing Transparency and Predictability of CMS Coding Decisions

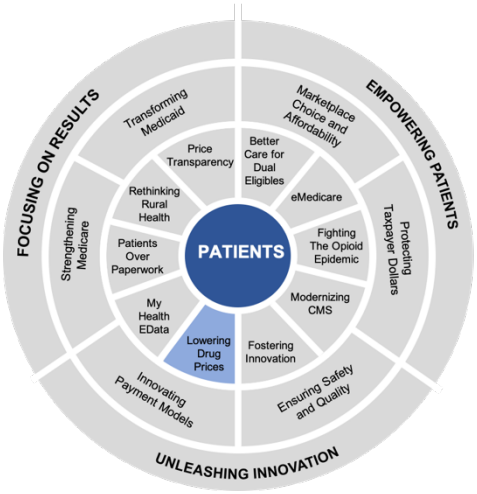
- When CMS sought feedback from innovators regarding the barriers to bringing new services to patients, the agency heard several concerns regarding coding for procedures, including the length of time to receive a code from CMS, the issuance of temporary versus permanent codes and the lack of transparency in CMS decisions concerning code applications.[320]
- CMS, in response to these concerns, revised the coding process to provide quarterly opportunities for submissions and decisions for drugs and semi-annual opportunities for devices.
  - CMS eliminated the requirement that a new item have a three percent market share in order to qualify for a code.[321]
  - **These changes remove barriers that innovators experience when moving through the technology adoption curve**, and potentially reduce the need for out-of-cycle temporary codes.
- CMS addressed concerns that MACs were automatically non-covering technologies with category III CPT codes.
  - CMS expects MACs to follow the new LCD process for each local coverage decision they make. CMS issued clarification that MACs cannot make local coverage decisions that automatically non-cover an item or service simply because it has a category III code. Accordingly, MACs would need to follow the new process to make a coverage determination about a particular category III code.

Reducing the Complexity of Interacting with CMS on New Technologies

- Created a six-month pilot of CMS FFS Navigators to assist stakeholders through coverage, coding, payment processes.
- This new internal coordination will help CMS better assist innovators as they seek to secure Medicare coverage and payment for their newly FDA-approved products.[322]

Lowering Drug Prices

The Trump Administration has prioritized lowering drug prices for Medicare and Medicaid beneficiaries since the beginning of his term. Combined, the Medicare and Medicaid Programs represent 40% of the prescription drug market in the United States, and are the largest purchasers of prescription drugs in the world.[323] This large market share represents a growing total spend, with Medicare spending on prescription drugs rising from $109 billion in 2012 to $185 billion in 2017.[324] Over the past three years, CMS has implemented a number of policies intended to increase access to medication and lower prices, such as empowering MA and Part D plans to negotiate lower costs for prescription drugs and reducing insulin costs. [325]

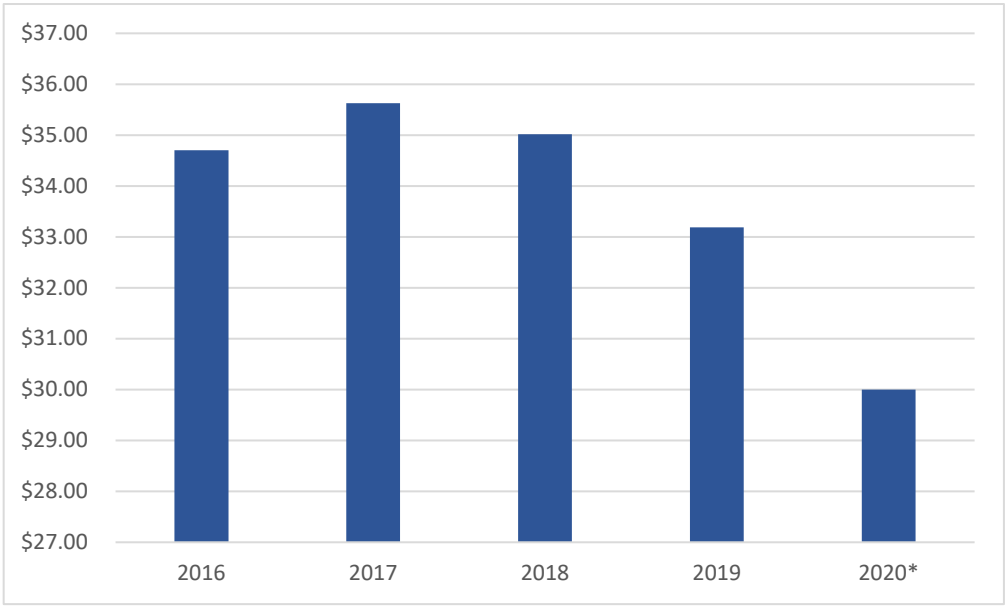


Accomplishments

Reducing Premiums in the Part D Program

- **As a result of this Administration's efforts, basic premiums for Part D plans in CY 2020 decreased by 13.5% since 2017, saving beneficiaries around $1.9 billion in premium costs over that time.**[326]

Figure 17. Average Basic Part D Premiums, 2016-2020



- Additionally, Part D has seen enrollment for 2020 increase by 12.2% since 2017.[327]

Increasing Transparency for Consumers in the Part D Program

- On May 16, 2019, CMS published the Medicare Advantage and Part D Drug Pricing Final Rule that modernizes and improves the MA and Part D programs.[328] These policy changes ensure patients have greater transparency into the cost of prescription drugs in Part D.

  - As part of the rule, beginning January 1, 2021, CMS will require that each Part D plan adopt one or more Real Time Benefit Tools (RTBTs) that are capable of integrating with at least one prescriber's ePrescribing system or EHR.
    - RTBTs have the capability of informing prescribers when lower-cost alternative therapies are available under the beneficiary's prescription drug benefit, which can improve medication adherence and lower prescription drug costs and out of pocket expenses for beneficiaries.
  - The final rule also requires the Explanation of Benefits document Part D enrollees receive each month to include information on drug price increases and lower-cost therapeutic alternatives.[329]
    - The rule requires plans to post historic net price for all covered drugs in the plan by pharmacy location, which aims to provide information on the actual price less any rebates the health plan receives.[330]
  - In addition, in a proposed rule issued in February 2020, CMS proposed to require all plans to offer a Beneficiary RTBT beginning January 1, 2022 that will provide much of the same information to Medicare beneficiaries, empowering consumers to shop for lower-cost alternative therapies under their prescription drug benefit plan.[331]

- The May 2019 final rule also implemented legislation signed by President Trump that bars "gag clauses" in pharmacy contracts. This provision restricts Part D sponsors from prohibiting or penalizing a pharmacy from disclosing a lower cash price to an enrollee, helping to lower out-of-pocket costs of prescription drugs for Medicare beneficiaries by ensuring that providers can inform their patients about lower cost alternatives.[332]

Introducing MA Step Therapy for Part B Drugs

- The May 2019 final rule also codified a policy enabling beneficiaries to select a MA plan that negotiates prices for physician-administered medicines when beneficiaries are beginning a new medication.[333]
- Many physician-administered medicines are biologics, which are some of the most expensive therapies in use today. Lower-cost biosimilars are coming to market to compete with biologics, and this policy helps foster innovation and drive competition in the market for physician-administered drugs.[334]
  - Under this step therapy approach, MA plans are able to ensure patients new to a treatment to receive the most preferred drug therapy first and progress to other, more costly therapies only if necessary.

Empowering State Innovation Through Value-Based Purchasing Agreements

- As part of its effort to incentivize states to pursue innovative approaches to address rising drug prices, CMS has approved eight state plan amendment proposals to negotiate supplemental rebate agreements.[335] These supplemental rebate agreements are value-based purchasing arrangements with drug manufacturers that allow states to link payment for prescription drugs to the value delivered to patients.
  - Increasing states' flexibility empowers them to develop policies that are effective and responsive to local conditions and price "hot spots" that lower costs, increase the predictability of expenses, and improve access for patients.

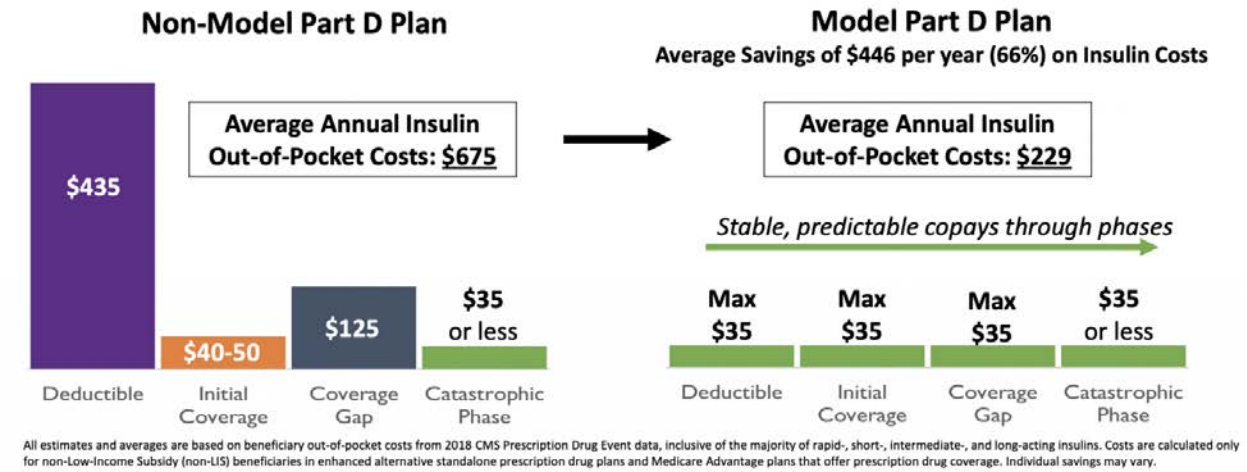
Increasing Beneficiary Access to Medications by Promoting Value-Based Purchasing

- In December 2020, CMS finalized further policy changes that would begin removing barriers to value-based agreements between drug manufacturers and payers.[336] Value-based payment for pharmaceuticals has the potential to increase patient access to new medicines by holding pharmaceutical manufacturers accountable for outcomes their drug achieves, as well as creating alternatives to traditional cost controls that impede patient access.[337]
    - Regulatory changes seek to remove these barriers by allowing manufacturers to report multiple best prices for a drug under the Medicaid drug rebate program when part of value-based arrangement among other new flexibilities.
    - Value-based payment for pharmaceuticals has the potential to increase patient access to new medicines by holding pharmaceutical manufacturers accountable for outcomes their drug achieves, as well as creating alternatives to traditional cost controls that impede patient access.[338]

Reducing Insulin Costs through the Part D Senior Savings Model

- One-third of Medicare beneficiaries suffer from diabetes, and over 3.3 million Medicare beneficiaries use one or more of the common forms of insulin.[339] Access to insulin is critical for these beneficiaries, and barriers to access such as the costs of insulin exacerbate risk for developing deadly, expensive complications.[340] CMS' Part D Senior Savings Model encourages practices of diabetes management to address high prescription drug costs and provide Medicare patients with new choices of Part D plans that offer insulin at an affordable and predictable cost -- no more than $35 for a thirty-day supply.[341]
    - Because of the cap of $35 per 30-day supply, beneficiaries who take insulin and enroll in a plan **participating in the Part D Senior Savings Model should save an average of $446[342] in annual out-of-pocket costs for insulin, or over 66%, relative to their average cost-sharing for insulin without the model**. In addition to the total savings, beneficiaries will also have a consistent and predictable costs that they can more easily budget monthly.
    - Finally, **CMS projects the Part D Senior Savings Model will result in $250 million in savings for the federal government over a five-year period**, primarily due to pharmaceutical manufacturers paying additional coverage gap discounts.[343]

Figure 18. Comparison of Estimated Insulin Costs, Non-Model Part D Plan vs. Model Part D Plan



CMS-generated graphic, 2020.[344]

Launching the Part D Payment Modernization Model

- In January 2020, CMS launched the Part D Payment Modernization Model to test the impact of a revised Part D program design and improved alignment of financial risk incentives on overall Part D prescription drug spending and beneficiary out-of-pocket costs.[345]
    - The voluntary, five-year model aims to promote a decrease in total Part D program spending in two ways:
        - Creating new incentives for plans, patients, and providers to choose drugs with lower list prices to better manage catastrophic phase federal reinsurance subsidy spending by introducing two-sided risk to align payment incentives for plan sponsors with their enrollees and CMS; and
        - Providing several programmatic flexibilities to ensure Medicare beneficiaries are able to maintain affordable access to the prescription drugs they need.

Announcing the Most Favored Nation Model

- In November 2020, executing on President Trump's mandate to lower drug costs and Executive Order on Lowering Drug Prices by Putting America First, CMS announced the Most Favored Nation (MFN) Model and issued a corresponding Interim Final Rule with Comment Period. The seven-year, mandatory MFN Model will lower prescription drug costs by paying no more for high-cost Medicare Part B drugs and biologicals than the lowest price that drug manufacturers receive in other similar countries. [346]
    - The MFN Model will also pay providers a flat add-on amount for each dose of an MFN drug, instead of a percentage of each drug's cost, removing the tie between drug cost and the add-on amount.
    - Beneficiaries will pay lower coinsurance for these high-cost Part B drugs and will not pay coinsurance on the add-on payment.
    - The MFN Model will require participation of Medicare providers and suppliers that receive separate Medicare Part B fee-for-service payment for the model's included drugs, with certain exceptions.

Enhancing Drug Dashboards

- Through its Drug Spending Dashboard, CMS publishes data on Medicare and Medicaid spending for prescription drugs in an interactive web-based tool so researchers and consumers can easily sort the data to identify trends.[347]

- Over the past four years, the Administration has continued to expand the data included in this dashboard to include reporting on any discarded amount of a single use vial or other single-use packaged drug[348], payments for prescription drugs in their first year on the market[349], and information on the manufacturers responsible for price increases[350].

Incentivizing Innovation Through Part B Coding for Biosimilars

- In November 2017, CMS announced that, effective January 1, 2018, all approved biosimilars[xxxii] would receive their own HCPCS codes.[351] Under this revised coding system[xxxiii], CMS now pays for biosimilars under the Medicare Part B Physician Fee Schedule based on the Average Sales Price for the biosimilar plus 6% of its specific reference product.

- Encouraging innovation in the marketplace, this policy change results in additional manufacturers participating in the licensing of biosimilar products, thus creating a stable and robust market.[352]

    - Carrying out this policy change as early as possible, rather than waiting, is expected to bring more certainty to the new and developing market.

Encouraging Availability of Lower Cost Drugs

- Many plans offering prescription drug coverage place drugs into different "tiers" on their formularies. Today, all drugs on a plan's specialty tier – the tier that has the highest-cost drugs – have the same level of cost sharing. CMS proposed to allow a second, "preferred" specialty tier in Part D with a lower cost sharing amount. This change is designed to give Part D plans more tools to negotiate drug prices with manufacturers and lower out-of-pocket costs for enrollees. Plans will be able to demand a better deal from manufacturers of the highest-cost drugs in exchange for placing their products on the "preferred" specialty tier.

- CMS recently sought feedback on developing measures of generic and biosimilar utilization in Medicare Part D as part of a plan's star rating. This would reward plans based on the rate at which they encourage market adoption of these competitor products and lower costs for patients.

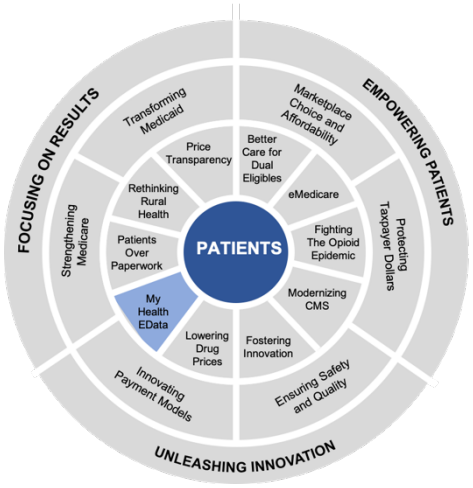
- Also, under the Part D program, plans currently do not have to disclose to CMS the measures they use to evaluate pharmacy performance in their network agreements. CMS has heard concerns from pharmacies that the measures plans use to assess their performance are unattainable or otherwise unfair. The measures used by plans potentially impact pharmacy reimbursements. We've proposed to require Part D plans to disclose such information so we can track how plans are measuring and applying pharmacy performance measures. CMS will also be able to report this information publicly to increase transparency on the process and to inform the industry in its new efforts to develop a standard set of pharmacy performance measures. CMS also sought comment on Part D pharmacy performance measures more broadly, including

[xxxii] A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biosimilar

[xxxiii] Under the previous coding system, biosimilars for a common reference product were grouped under the same Healthcare Common Procedure Coding System (HCPCS) code, meaning all biosimilars relying on a common reference product were grouped into the same payment calculation for determining payment

stakeholders' recommendations for potential Part D Star Ratings metrics that could incentivize the uptake of a standard set of measures once the industry establishes one.

MyHealthEData



For too long, patients have faced a healthcare system that is complex, opaque, and difficult to navigate. Though patients have had the legal right to see and get a copy of their health records since 1996, through the enactment of the Health Insurance Portability and Accountability Act (HIPAA), patients have struggled to gain full control over their own healthcare information. After 10 years and $36 billion dollars of government investment, a recent survey conducted by the Center for Connected Medicine found that less than 4 in 10 health systems can share data with other health systems.[353] Whether that means having to call multiple doctor's offices to transfer records between providers, handing over copies of scans or test results in a CD-ROM, or having to give the same patient history over and over again, CMS recognizes the hardship that a lack of interoperability places on providers and patients alike.

MyHealthEData, a government-wide initiative developed under the leadership of the White House Office of American Innovation, seeks to change that by helping to break down the barriers that prevent patients from having electronic access and use of their own health records from the device or application of their choice.

In April 2018, CMS released preliminary Medicare Advantage encounter data publicly to researchers for the first time. Also, in November 2019 Medicaid and Children's Health Insurance Program (CHIP) data including use and spending under Managed Care was released to the public for the first time. This data is part of the Transform Medicaid Statistical Information System (T-MSIS).

Accomplishments

The MyHealthEData strategic initiative unleashes data, in a private, secure, and usable format, to give patients access and use of their healthcare information and allow that data to follow them throughout their healthcare journey. As a result, patients now have access to and the ability to control their own essential records, test results, and basic information about the providers who treat them. Over the last two years, **CMS has worked with federal and private industry partners to rapidly advance interoperability standards uptake** and drive a connected and interoperable healthcare system for the more than 130 million beneficiaries and enrollees CMS serves through the Medicare, Medicaid, CHIP programs and Marketplaces. An additional 85 million patients will get access to even more data under the policies finalized in the Interoperability and Patient Access Final Rule.

Developing a Data Driven Patient Care Strategy

- CMS developed a Data Driven Patient Care Strategy to empower patients and make data more available. An application programming interface (API) is a software intermediary that essentially allows two applications to talk to each other. By adopting the use of APIs to exchange healthcare data in a secure and private manner, CMS is improving access to healthcare data for all patients. **This was the first step to putting the patient at the center of our healthcare system with the information they need to make informed healthcare decisions.**

Launching Blue Button 2.0

- On March 6, 2018, CMS launched Blue Button 2.0, which significantly improves the Medicare beneficiary experience by providing beneficiaries with their own claims data through a developer-friendly, standards-based API. With Blue Button 2.0, beneficiaries can connect their claims data to mobile applications (apps) designed to help them manage their health, find health plans, make

appointments, or even share their health information with their providers to improve clinical decision-making.

- To date, **more than 70 apps have launched** for beneficiaries to use and nearly 4,000 developers are creating more apps that leverage the Blue Button 2.0 standards-based API.[354] These apps allow beneficiaries and their caregivers to download and access information from claims in a fully portable manner so that medical data now can be accessed wherever the beneficiary goes – whether that be the doctor's office, pharmacy, or kitchen table.
- CMS facilitated the creation of a developer community to spur further innovation under Blue Button 2.0 by developing:
    - A developer sandbox or preview program where developers can test apps using synthetic claims data;
    - A Google Group for developers to connect with one another; and
    - A blog to quickly share news and updates on Blue Button 2.0.[355]
- CMS has held two Blue Button 2.0 Developer Conferences to bring together tech industry leaders and application developers to help build and develop new tools that help patients understand their health data. These conferences allowed developers to learn, build software, and share insights on how Medicare claims can be leveraged to improve health outcomes.

Publishing Unified Interoperability Rules

- To increase the ability of patients and providers to access to healthcare data, CMS, in concert with the Office of the National Coordinator for Health IT, released the Interoperability and Patient Access Final Rule in March 2020.[356]
- This landmark rule put patients at the center of care and helps make them more informed decision makers, while reducing burden and cost, and ultimately supporting improved patient outcomes. The final rule is focused on driving interoperability and patient access to health information by liberating claims data for 85 million patients using CMS authority to regulate MA, Medicaid, CHIP, and Qualified Health Plan issuers in the Marketplace.
- Under the rule, **CMS promotes an HHS-wide move to Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) APIs** to support interoperability across the healthcare system. This rule requires CMS-regulated payers to:
    - Implement and maintain a secure, standards-based API that allows patients to easily access their claims and encounter information, including cost, as well as a defined subset of their clinical information through third-party applications of their choice;
    - Make provider directory information publicly available via a standards-based API; and
    - Require **CMS-regulated payers to exchange data at the payer level beginning January 1, 2022**.[357]
        - Similar to Blue Button 2.0, payers are required to exchange the USCDI version 1 data set information.
        - Patients will be able to take their information with them as they move from payer to payer over time to help create a cumulative health record with their current payer.
- The rule modifies Conditions of Participation to **require hospitals to send electronic patient event notifications of a patient's admission, discharge, and/or transfer** to another facility or to another community provider or practitioner starting May 2021.

- In 2018, CMS overhauled the Promoting Interoperability Programs, and the new program requirements became effective in 2019. Under the new requirements, 3,869, or 77.8 percent, of the eligible 4,973 hospitals and critical access hospitals (CAHs) participated in the Promoting Interoperability Program. Within the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program, approximately 70 percent of the 964,604 MIPS eligible clinicians that submitted data successfully reported for the Promoting Interoperability performance category.
    - These accomplishments demonstrate an enhanced use of certified electronic health records by hospitals and clinicians, thus facilitating an ever-increasing number of patients have access to their own data for decision-making, and clinicians who can better coordinate patient care through streamlined, accelerated information exchange.

Improving Prior Authorization

- In December 2020, CMS issued a rule that proposes significant changes to improve the patient experience and alleviate some of the administrative burden prior authorization causes healthcare providers. The proposed rule would reduce the amount of time providers wait to receive prior authorization decisions from payers.

Facilitating Patient Engagement through Data at the Point of Care

- In February 2019, CMS launched the Beneficiary Claims Data API (BCDA), which uses the FHIR bulk specification to share claims data with Accountable Care Organizations (ACOs) participating in the CMS Shared Savings Program. This API was one of the first uses of bulk data access, which supports the transfer of population level data rather than individual patient data.
- On July 30, 2019, CMS launched the "Data at the Point of Care API" (DPC API) pilot to make a patient's Medicare Parts A, B and/or D claims data available to the clinician directly in their workflow to support treatment decision-making.[358]
- Further enhancements of the strategy include building a bulk data access API, the A&B2D API, to provide Prescription Drug Plan (PDP) sponsors access to plan enrollees' claims data.
- Nearly 600 provider organizations and over 200 vendors have signed up to test synthetic data in the DPC sandbox

Launching the Data Element Library

- On June 21, 2018, CMS launched the Data Element Library (DEL) to serve as a comprehensive, electronic, distributable, and centralized resource of CMS patient assessment instrument content for the public.
- The DEL supports the goals of MyHealthEData and is a public resource for use by providers, vendors, researchers, and the public that facilitates health information exchange.
- The DEL does not contain patient-level data, but rather is a one-stop-shop for CMS assessment questions, response options, and associated HIT attributes. The DEL currently contains data elements from the patient assessment instruments for six patient care settings.[359] The six care settings currently included in the DEL are: (1) inpatient rehabilitation facilities; (2) home health agencies; (3) long-term care hospitals; (4) skilled nursing facilities; (5) hospice care; and (6) home and community-based services.

Hosting Artificial Intelligence (AI) Health Outcomes Challenge

- CMS partnered with the American Academy of Family Physicians and the Laura and John Arnold Foundation to launch a prize-based challenge for innovators from all technology sectors to demonstrate how AI tools, such as deep learning and neural networks, can be used to predict unplanned hospital and skilled nursing facility admissions and adverse events.

- On October 31, 2019, CMS announced the top 25 innovators out of a pool of over 300 applicants selected to participate in Stage 1 of the AI Health Outcomes Challenge.[360]
- On October 29, 2020, CMS announced seven participants will advance to Stage 2, where these finalists will further develop algorithms that demonstrate how AI tools can be used to predict unplanned hospital and skilled nursing facility admissions and adverse events, and also will develop predictive algorithms for a standard target to be selected by CMS.[361]
- At the conclusion of the Challenge, a grand prize winner will receive $1 million, rewarding innovation and spurring free-market competition to help realize the potential of AI in healthcare decision-making.

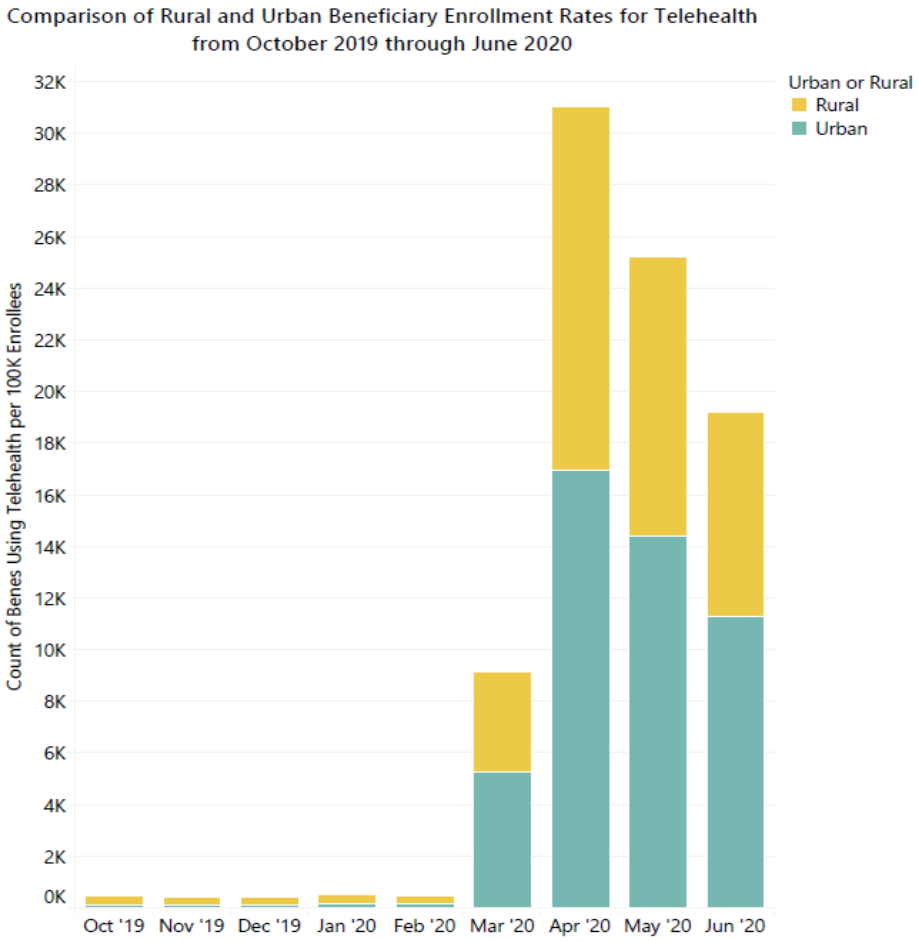
Appendix A. List of Acronyms

ACA	Patient Protection and Affordable Care Act
ACO	Accountable Care Organization
AI	Artificial Intelligence
API	Application Programming Interface
APM	Alternative Payment Model
CARA	Comprehensive Addiction and Recovery Act of 2016
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
CMMI	Center for Medicare and Medicaid Innovation
COVID-19	Novel Coronavirus
CPT	Current Procedural Terminology
DEL	Data Element Library
DME	Durable Medical Equipment
EHR	Electronic Health Record
E/M	Evaluation and Management
FDA	U.S. Food and Drug Administration
FFS	Fee-for-service
FHIR	Fast Healthcare Interoperability Resources
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act

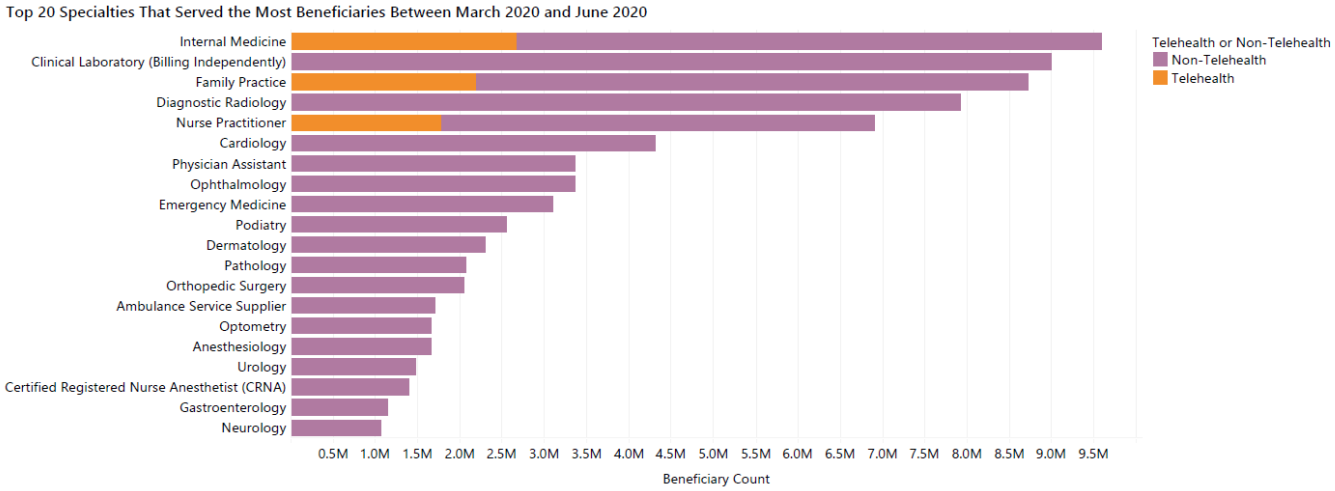
HIT	Health Information Technology
HL7	Health level 7
IFC	Interim Final Rule with Comment Period
LCD	Local Coverage Decision
MA	Medicare Advantage
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
MLR	Medical Loss Ratio
NCD	National Coverage Decision
NTAP	New Technology Add-on Payment
OASH	Office of the Assistant Secretary for Health
OUD	Opioid Use Disorder
PHE	Public Health Emergency
QIO	Quality Improvement Organization
RFI	Request for Information
SUD	Substance Use Disorder
SUPPORT Act	Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
T-MSIS	Transformed Medicaid Statistical Information System
USCDI	U.S. Core Data for Interoperability

Appendix B. Supporting Tables and Figures

B.1 COVID Telehealth Data Analysis

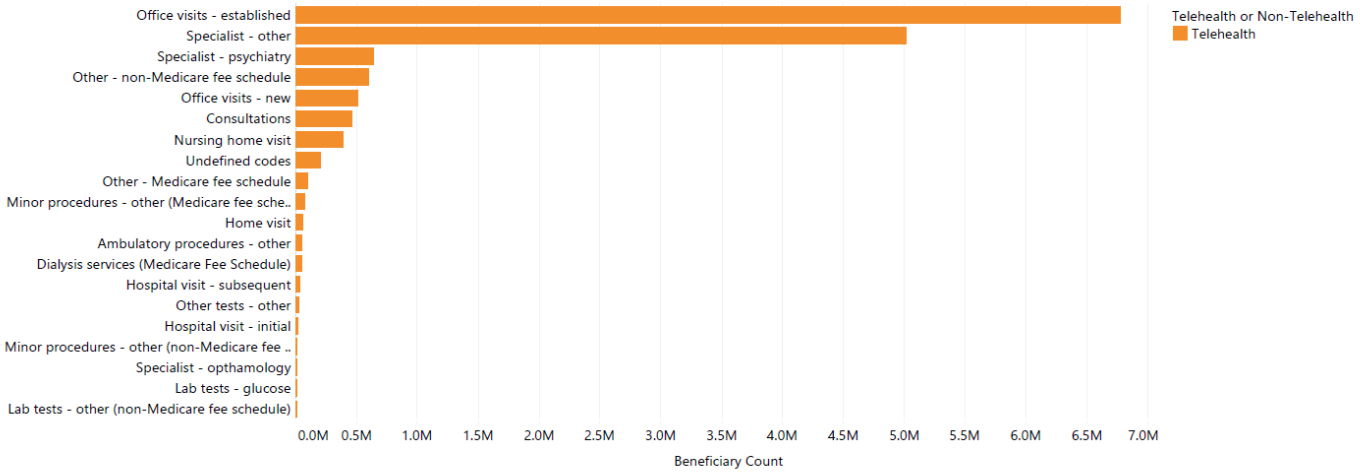


Sum of N Benes Rate for each Month + Year Month. Color shows details about Urban or Rural. The data is filtered on Month + Year (MY), which excludes 9 members.



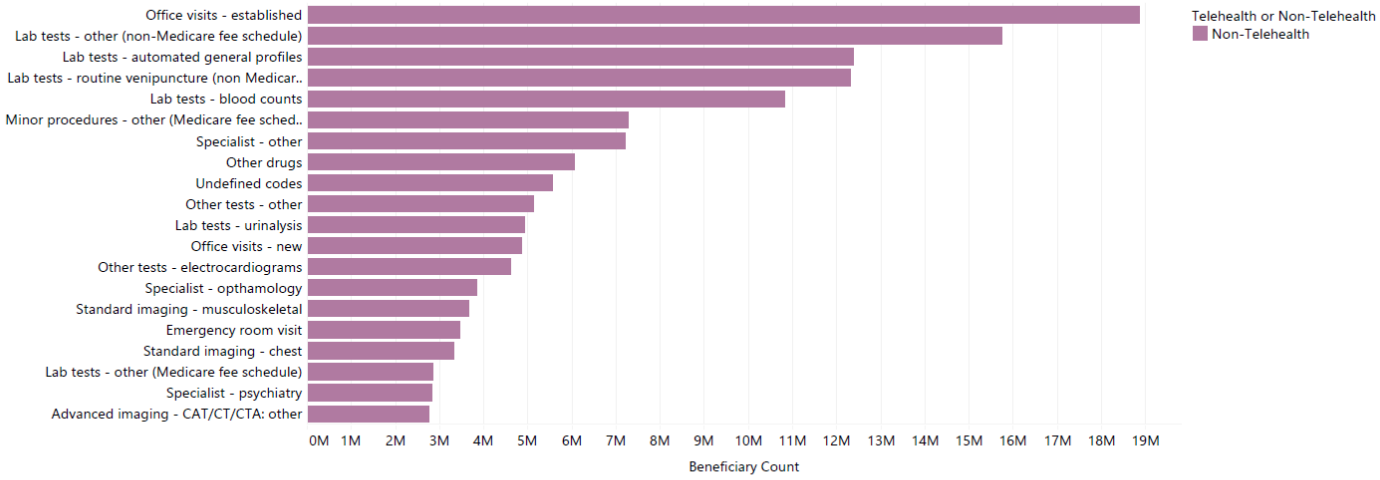
Sum of N Benes for each Clm Prvdr Spclty Cd Desc. Color shows details about Telehealth or Non-Telehealth. The data is filtered on Rank, which keeps 20 members. The view is filtered on sum of N Benes and Clm Prvdr Spclty Cd Desc. The sum of N Benes filter ranges from 1.0M to 13.7M. The Clm Prvdr Spclty Cd Desc filter keeps 25 of 102 members.

Top 20 BETOS Designations with the Most Beneficiaries Served Via Telehealth Between March 2020 and June 2020



Sum of N Benes for each Rank broken down by Hcpcs Betos Cd Desc. Color shows details about Telehealth or Non-Telehealth. The view is filtered on sum of N Benes, Telehealth or Non-Telehealth, Rank and Hcpcs Betos Cd Desc. The sum of N Benes filter ranges from 0.0M to 25.6M. The Telehealth or Non-Telehealth filter keeps Telehealth. The Rank filter keeps 20 members. The Hcpcs Betos Cd Desc filter keeps 74 of 104 members.

Top 20 BETOS Designations with the Most Beneficiaries Served for Non-Telehealth Between March 2020 and June 2020



Sum of N Benes for each Hcpcs Betos Cd Desc. Color shows details about Telehealth or Non-Telehealth. The data is filtered on Rank, which keeps 20 members. The view is filtered on sum of N Benes, Telehealth or Non-Telehealth and Hcpcs Betos Cd Desc. The sum of N Benes filter ranges from 2,000,000 to 25,625,887. The Telehealth or Non-Telehealth filter keeps Non-Telehealth. The Hcpcs Betos Cd Desc filter keeps 28 of 104 members.

B.2 COVID-19 Stakeholder Engagement Series

Meeting Purpose: CMS established a series of COVID-19 Stakeholder calls to communicate and clarify CMS policies with those on the front lines and obtain feedback.

- **Office Hour Calls**, joined by several thousand stakeholders weekly, provide an opportunity for hospitals, health systems, and providers to ask questions to CMS' subject matter experts regarding CMS' temporary actions that empower local hospitals and healthcare systems to:
    - Increase Hospital Capacity – CMS Hospitals Without Walls;
    - Rapidly Expand the Healthcare Workforce;
    - Put Patients Over Paperwork; and
    - Further Promote Telehealth in Medicare
- **Care Site Specific Calls:** CMS hosts four calls on a bi-weekly basis focusing on a specific stakeholder group every other week, including nurses, home health and hospice, nursing home, and dialysis organizations and other types of clinicians to provide targeted updates on the agency's latest COVID-19 guidance. One to two leaders in the field also share best practices with their peers and answer questions from participants. Up to 2000 stakeholders join these bi-weekly calls.
- **Lessons from the Front Lines Calls** are a joint effort between Administrator Verma, FDA Commissioner Stephen Hahn, MD, and the White House Coronavirus Task Force. Physicians and other clinicians are invited to share their experience, ideas, strategies, and insights with one another related to their COVID-19 response. There is an opportunity to ask questions of presenters. Approximately 4,000 – 8,000 stakeholders join this bi-weekly call.

B.3 "New to ASC List" Procedure Utilization, 2017-2020 Qtr 1

Analysis: Unique beneficiary counts for select new HCPCS codes approved in the ASC setting Settings: Outpatient, ASC, Inpatient* Years: 2017-2019, 2020 Q1	Procedures 2017	Percent of total	Procedures 2018	Percent of Total	Procedures 2019	Percent of Total	Procedures 2020 QTR1	Percent of Total
93451 - Right heart cath	**37,782**		**39,428**		**41,149**		**9,527**	
Outpatient	18,632	49.3%	18,843	47.8%	19,206	46.7%	4,374	45.9%
ASC	-	0.0%	-	0.0%	149	0.4%	49	0.5%
Inpatient	19,150	50.7%	20,585	52.2%	21,794	53.0%	5,104	53.6%
93452 - Left hrt cath w/ventrclgrphy	**4,585**		**3,806**		**3,621**		**745**	
Outpatient	1,656	36.1%	1,409	37.0%	1,334	36.8%	259	34.8%
ASC		0.0%	-	0.0%	1	0.0%	2	0.3%
Inpatient	2,929	63.9%	2,397	63.0%	2,286	63.1%	484	65.0%
93453 - R&l hrt cath w/ventriclgrphy	**3,129**		**2,849**		**2,563**		**596**	
Outpatient	1,546	49.4%	1,378	48.4%	1,332	52.0%	284	47.7%
ASC	-	0.0%	-	0.0%	3	0.1%	-	0.0%
Inpatient	1,583	50.6%	1,471	51.6%	1,228	47.9%	312	52.3%
93454 - Coronary artery angio s&i	**119,423**		**122,534**		**127,505**		**27,554**	
Outpatient	63,057	52.8%	65,658	53.6%	68,631	53.8%	14,856	53.9%
ASC	-	0.0%	-	0.0%	87	0.1%	69	0.3%
Inpatient	56,366	47.2%	56,876	46.4%	58,787	46.1%	12,629	45.8%
93455 - Coronary art/grft angio s&i	**29,569**		**28,537**		**28,396**		**5,837**	
Outpatient	15,326	51.8%	15,203	53.3%	15,055	53.0%	3,031	51.9%
ASC	-	0.0%	-	0.0%	18	0.1%	13	0.2%
Inpatient	14,243	48.2%	13,334	46.7%	13,323	46.9%	2,793	47.8%
93456 - R hrt coronary artery angio	**17,614**		**18,749**		**20,031**		**4,402**	
Outpatient	11,017	62.5%	11,715	62.5%	12,483	62.3%	2,671	60.7%
ASC	-	0.0%	-	0.0%	19	0.1%	10	0.2%
Inpatient	6,597	37.5%	7,034	37.5%	7,529	37.6%	1,721	39.1%
93458 - L hrt artery/ventricle angio	**514,044**		**501,393**		**501,438**		**108,525**	
Outpatient	282,681	55.0%	277,877	55.4%	279,516	55.7%	58,694	54.1%
ASC	-	0.0%	-	0.0%	2,200	0.4%	1,097	1.0%
Inpatient	231,363	45.0%	223,516	44.6%	219,722	43.8%	48,734	44.9%
93459 - L hrt art/grft angio	**99,580**		**92,937**		**88,658**		**18,758**	
Outpatient	54,042	54.3%	50,497	54.3%	48,080	54.2%	10,061	53.6%
ASC	-	0.0%	-	0.0%	370	0.4%	157	0.8%
Inpatient	45,538	45.7%	42,440	45.7%	40,208	45.4%	8,540	45.5%
93460 - R&l hrt art/ventricle angio	**87,891**		**87,924**		**88,365**		**19,381**	
Outpatient	54,939	62.5%	55,139	62.7%	55,592	62.9%	12,089	62.4%
ASC	-	0.0%	-	0.0%	487	0.6%	180	0.9%
Inpatient	32,952	37.5%	32,785	37.3%	32,286	36.5%	7,112	36.7%
93461 - R&l hrt art/ventricle angio	**15,157**		**14,603**		**13,937**		**2,938**	
Outpatient	9,113	60.1%	8,774	60.1%	8,415	60.4%	1,729	58.8%
ASC	-	0.0%	-	0.0%	76	0.5%	20	0.7%
Inpatient	6,041	39.9%	5,828	39.9%	5,446	39.1%	1,189	40.5%

	Procedures 2017	Percent of total	Procedures 2018	Percent of Total	Procedures 2019	Percent of Total	Procedures 2020 QTR1	Percent of Total
93567 - Inject suprvlv aortography	**34,395**		**30,522**		**27,937**		**5,633**	
Outpatient	20,436	59.4%	18,156	59.5%	16,771	60.0%	3,334	59.2%
ASC	-	0.0%	-	0.0%	5	0.0%	-	0.0%
Inpatient	13,959	40.6%	12,366	40.5%	11,161	40.0%	2,299	40.8%
93571 - Heart flow reserve measure	**69,748**		**73,468**		**77,076**		**16,859**	
Outpatient	46,374	66.5%	49,479	67.3%	51,669	67.0%	11,231	66.6%
ASC	-	0.0%	-	0.0%	-	0.0%	3	0.0%
Inpatient	23,374	33.5%	23,989	32.7%	25,407	33.0%	5,625	33.4%
93572 - Heart flow reserve measure	**11,292**		**12,211**		**13,014**		**2,821**	
Outpatient	7,677	68.0%	8,450	69.2%	8,861	68.1%	1,917	68.0%
ASC	-	0.0%	-	0.0%	-	0.0%	1	0.0%
Inpatient	3,614	32.0%	3,761	30.8%	4,153	31.9%	903	32.0%
27447 - Total knee arthroplasty	**291,957**		**321,180**		**331,434**		**81,213**	
Outpatient	481	0.2%	72,938	22.7%	105,605	31.9%	34,293	42.2%
ASC	-	0.0%	-	0.0%	29	0.0%	1,448	1.8%
Inpatient	291,461	99.8%	248,222	77.3%	225,800	68.1%	45,472	56.0%
92920 - Prq cardiac angioplast 1 art	**25,435**		**24,665**		**24,236**		**5,260**	
Outpatient	11,337	44.6%	11,010	44.6%	10,705	44.2%	2,278	43.3%
ASC	-	0.0%	-	0.0%	-	0.0%	36	0.7%
Inpatient	14,098	55.4%	13,655	55.4%	13,531	55.8%	2,946	56.0%
92921 - Prq cardiac angio addl art	**8,206**		**8,021**		**7,938**		**1,809**	
Outpatient	5,031	61.3%	4,947	61.7%	4,798	60.4%	1,067	59.0%
ASC	-	0.0%	-	0.0%	-	0.0%	2	0.1%
Inpatient	3,175	38.7%	3,074	38.3%	3,140	39.6%	740	40.9%
92928 - Prq card stent w/angio 1 vsl	**121,014**		**115,544**		**114,239**		**24,746**	
Outpatient	11,104	9.2%	8,573	7.4%	7,757	6.8%	1,520	6.1%
ASC	-	0.0%	-	0.0%	-	0.0%	65	0.3%
Inpatient	109,910	90.8%	106,971	92.6%	106,482	93.2%	23,161	93.6%
92929 - Prq card stent w/angio addl	**7,488**		**7,415**		**7,610**		**1,688**	
Outpatient	784	10.5%	693	9.3%	684	9.0%	108	6.4%
ASC	-	0.0%	-	0.0%	-	0.0%	3	0.2%
Inpatient	6,704	89.5%	6,722	90.7%	6,926	91.0%	1,577	93.4%
C9600 - Perc drug-el cor stent sing	**104,960**		**105,543**		**106,203**		**22,654**	
Outpatient	104,960	100.0%	105,537	100.0%	106,196	100.0%	22,271	98.3%
ASC	-	0.0%	-	0.0%	-	0.0%	383	1.7%
Inpatient	-	0.0%	6	0.0%	7	0.0%	-	0.0%

*Inpatient settings were identified using the "Place of Service" code on physician claims, rather than using inpatient claims, as HCPCS codes are not available on inpatient hospital claims.

Endnotes

[1] https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx
[2] https://www.cms.gov/newsroom/press-releases/cms-prepares-nations-healthcare-facilities-coronavirus-threat
[3] https://www.cms.gov/newsroom/press-releases/trump-administration-drives-telehealth-services-medicaid-and-medicare.
[4] https://www.cms.gov/newsroom/press-releases/cms-announces-temporary-policy-premium-reductions
[5] https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-19
[6] https://www.federalregister.gov/documents/2020/05/08/2020-09608/medicare-and-medicaid-programs-basic-health-program-and-exchanges-additional-policy-and-regulatory
[7] https://www.cms.gov/newsroom/press-releases/trump-administration-strengthens-covid-19-surveillance-new-reporting-and-testing-requirements
[8] Id.
[9] https://www.hhs.gov/about/news/2020/07/28/hhs-issues-new-report-highlighting-dramatic-trends-in-medicare-beneficiary-telehealth-utilization-amid-covid-19.html
[10] https://www.cms.gov/newsroom/press-releases/trump-administration-releases-covid-19-telehealth-toolkit-accelerate-state-use-telehealth-medicaid.
[11] https://www.healthaffairs.org/do/10.1377/hblog20200715.454789/full/
[12] Figure 4 data are sourced from the T-MSIS Analytic Files v4 in AREMAC, using final action claims. They are based on June T-MSIS submissions with services through the end of May. Recent dates of service have very little time for claims runout and we expect large changes in the results after each monthly update. For this figure, California, North Dakota, Iowa, Indiana, and Tennessee are unusable.
[13] Figure 2 data are sourced from the T-MSIS Analytic Files v4 in AREMAC, using final action claims. They are based on June T-MSIS submissions with services through the end of May. Recent dates of service have very little time for claims runout and we expect large changes in the results after each monthly update. For these figures, California, North Dakota, Iowa, Indiana, and Tennessee are unusable.
[14] https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf
[15] https://www.cms.gov/newsroom/press-releases/cms-announces-comprehensive-strategy-enhance-hospital-capacity-amid-covid-19-surge
[16] https://www.cms.gov/newsroom/press-releases/cms-approves-approximately-34-billion-providers-acceleratedadvance-payment-program-medicare
[17] https://www.cms.gov/newsroom/press-releases/cms-approves-approximately-34-billion-providers-acceleratedadvance-payment-program-medicare
[18] https://www.cms.gov/newsroom/press-releases/cms-takes-steps-ensure-medicare-beneficiaries-have-wide-access-covid-19-antibody-treatment
[19] https://www.cms.gov/research-statistics-data-systems/preliminary-medicare-covid-19-data-snapshot.
[20] https://www.cms.gov/newsroom/press-releases/cms-announces-temporary-policy-premium-reductions
[21] https://qsep.cms.gov/COVID-Training-Instructions.aspx
[22] https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/
[185] https://www.cms.gov/About-CMS/Story-Page/Clinician-Letter-Reducing-Burden-Documentation-and-Coding-Reform-.pdf
[186] https://www.cms.gov/About-CMS/Story-Page/Clinician-Letter-Reducing-Burden-Documentation-and-Coding-Reform-.pdf
[25] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/CCM-Toolkit-Updated-Combined-508.pdf
[26] https://www.cms.gov/newsroom/fact-sheets/finalized-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar
[27] https://www.cms.gov/newsroom/press-releases/trump-administration-finalizes-permanent-expansion-medicare-telehealth-services-and-improved-payment
[28] https://www.cms.gov/newsroom/fact-sheets/finalized-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar
[29] https://www.ahrq.gov/practiceimprovement/delivery-initiative/holtropstudysnapshot/index.html
[30] CMS internal data.

[31] https://www.cms.gov/newsroom/press-releases/trump-administration-finalizes-policies-give-medicare-beneficiaries-more-choices-around-surgery
[32] https://www.cms.gov/newsroom/press-releases/trump-administration-finalizes-policies-give-medicare-beneficiaries-more-choices-around-surgery
[33]https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2020-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0
[34]https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0
[35]https://www.cms.gov/newsroom/fact-sheets/cy2020-end-stage-renal-diseasedurable-medical-equipment-final-rule-cms-1713-f
[36]https://www.cms.gov/newsroom/fact-sheets/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-renal-dialysis-services#:~:text=On%20November%2002%2C%202020%2C%20the,or%20after%20January%201%2C%202021.
[37] Culleton, Bruce F. et al. (2007). "Effect of Frequent Nocturnal Hemodialysis vs Conventional Hemodialysis on Left Ventricular Mass and Quality of Life". Journal of the American Medical Association. 298 (11): 1291–9.
[38]https://www.cms.gov/newsroom/fact-sheets/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-renal-dialysis-services#:~:text=On%20November%2002%2C%202020%2C%20the,or%20after%20January%201%2C%202021.
[39]https://www.cms.gov/newsroom/fact-sheets/cy2020-end-stage-renal-diseasedurable-medical-equipment-final-rule-cms-1713-f
[40]https://www.cms.gov/newsroom/fact-sheets/cy2020-end-stage-renal-diseasedurable-medical-equipment-final-rule-cms-1713-f
[41] https://www.cms.gov/files/document/dmepos-cbp-r2021-contract-supplier-fact-sheet.pdf
[42] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/CCM-Toolkit-Updated-Combined-508.pdf
[43] https://www.cms.gov/newsroom/fact-sheets/finalized-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar
[44]https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year
[45]https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year
[46]https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year
[47]https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-medicare-physician-fee-schedule-calendar-year-2018
[48]https://www.cms.gov/newsroom/fact-sheets/finalized-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar
[49]https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2020-hospice-payment-rate-update-final-rule.
[50]https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2021-hospice-payment-rate-update-final-rule-cms-1733-f
[51] Id.
[52]https://www.cms.gov/newsroom/fact-sheets/medicare-issues-fiscal-year-2019-payment-policy-changes-skilled-nursing-facilities
[53]https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2021-payment-and-policy-changes-medicare-skilled-nursing-facilities-cms-1737-f
[54]https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2020-payment-and-policy-changes-medicare-skilled-nursing-facilities-cms-1718-f
[55]https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2021-final-medicare-payment-and-policy-changes-inpatient-psychiatric-facilities-cms-1731
[56] https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2020-payment-and-policy-changes-medicare-inpatient-rehabilitation-facilities-cms-1710-f
[57] https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-inpatient-rehabilitation-facility-irf-prospective-payment-system-pps-cms-1729-f
[58] https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-inpatient-rehabilitation-facility-irf-prospective-payment-system-pps-cms-1729-f
[59] https://www.cms.gov/newsroom/press-releases/trump-administration-drives-down-drug-costs-seniors
[60] https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/

[61] https://www.cms.gov/newsroom/press-releases/trump-administration-drives-down-medicare-advantage-and-part-d-premiums-seniors
[62] https://www.cms.gov/newsroom/press-releases/cms-lowers-cost-prescription-drugs-medicare-beneficiaries
[63] https://www.cms.gov/newsroom/press-releases/cms-lowers-cost-prescription-drugs-medicare-beneficiaries
[64] https://www.cms.gov/newsroom/fact-sheets/contract-year-2021-medicare-advantage-and-part-d-final-rule-cms-4190-f1-fact-sheet
[65] https://www.cms.gov/newsroom/press-releases/trump-administration-announces-historically-low-medicare-advantage-premiums-and-new-payment-model
[66] https://www.cms.gov/newsroom/press-releases/cms-lowers-cost-prescription-drugs-medicare-beneficiaries
[67] https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-prescription-drug-prices-and-increase-transparency
[68] https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-prescription-drug-prices-and-increase-transparency
[69] Id.
[70] https://www.cms.gov/newsroom/fact-sheets/contract-year-2020-medicare-advantage-and-part-d-flexibility-final-rule-cms-4185-f
[71] https://www.cms.gov/newsroom/fact-sheets/2019-medicare-advantage-and-part-d-prescription-drug-program-landscape
[72] "The Promise and Pitfalls of Medicare Advantage Encounter Data, " Health Affairs Blog, February 25, 2019. DOI: 10.1377/hblog20190221.696651
[73] https://avalere.com/press-releases/medicare-advantage-achieves-better-health-outcomes-and-lower-utilization-of-high-cost-services-compared-to-fee-for-service-medicare
[74] https://www.cms.gov/newsroom/fact-sheets/2021-medicare-advantage-and-part-d-rate-announcement-fact-sheet
[75] https://www.cms.gov/newsroom/press-releases/trump-administration-drives-down-medicare-advantage-and-part-d-premiums-seniors
[76] https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-federation-american-hospitals-2019-public-policy-conference;
[77] https://www.cms.gov/newsroom/press-releases/cms-announces-initiatives-strengthen-medicaid-program-integrity
[78] https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html
[79] https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf
[80] CMS internal data
[81] CMS internal data
[82] CMS internal data
[83] CMS internal data
[84] CMS internal data
[85] Id.
[86] https://www.medicaid.gov/medicaid/managed-care/guidance/medicaid-and-chip-managed-care-final-rules/index.html.

[87] https://www.cms.gov/newsroom/press-releases/cms-approves-washington-state-plan-amendment-proposal-allow-supplemental-rebates-involving. The four states with approved state plan amendments are Washington, Oklahoma, Michigan, and California.
[88] https://www.cms.gov/newsroom/fact-sheets/value-based-care-state-medicaid-directors-letter.
[89] https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf

[90] CMS internal data
[91] https://www.medicaid.gov/medicaid/data-systems/macbis/transformed-medicaid-statistical-information-system-t-msis/index.html. The T-MSIS data set contains: enhanced information about beneficiary eligibility; beneficiary and provider enrollment; service utilization; claims and managed care data; and expenditure data for Medicaid and CHIP.
[92] https://www.cms.gov/newsroom/press-releases/cms-unveils-scorecard-deliver-new-level-transparency-within-medicaid-and-chip-program
[93] https://www.cms.gov/newsroom/press-releases/cms-issues-first-annual-update-medicaid-and-chip-program-scorecard
[94] https://www.cms.gov/newsroom/press-releases/cms-announces-initiatives-strengthen-medicaid-program-integrity

[95] https://www.medicaid.gov/state-resource-center/downloads/program-integrity-strategy-factsheet.pdf
[96] https://www.medicaid.gov/medicaid/eligibility/medicaid-eligibility-quality-control-program/index.html. Note that, in response to the COVID-19 public health emergency, CMS exercised its enforcement discretion to adopt a temporary policy of relaxed enforcement regarding activities related to this program.
[97] https://www.medicaid.gov/state-resource-center/downloads/program-integrity-strategy-factsheet.pdf
[98] https://www.cms.gov/newsroom/fact-sheets/fact-sheet-2019-medicaid-fiscal-accountability-regulation-mfar
[99] https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-12970.pdf
[100] https://www.healthaffairs.org/do/10.1377/hblog20200617.728496/full/
[101] https://www.healthaffairs.org/do/10.1377/hblog20200617.728496/full/
[102] https://www.cms.gov/newsroom/fact-sheets/data-2019-individual-health-insurance-market-conditions
[103] https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2017-10-20-Issuer-County-Map.pdf
[104] https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Trends-Subsidized-Unsubsidized-Enrollment-BY17-18.pdf
[105] https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2020QHPPremiumsChoiceReport.pdf
[106] https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2021QHPPremiumsChoiceReport.pdf
[107] https://www.cms.gov/newsroom/press-releases/cms-issues-proposed-payment-notice-2020-coverage-year
[108] https://www.cms.gov/files/document/4120-health-insurance-exchanges-2020-open-enrollment-report-final.pdf
[109] https://www.cms.gov/newsroom/press-releases/cms-issues-final-2019-payment-notice-rule-increase-access-affordable-health-plans-americans
[110] https://www.cms.gov/files/document/final-2021-hhs-notice-benefit-and-payment-parameters-fact-sheet.pdf
[111] https://www.cms.gov/files/document/final-2021-hhs-notice-benefit-and-payment-parameters-fact-sheet.pdf
[112] https://www.kff.org/private-insurance/issue-brief/2021-premium-changes-on-aca-exchanges-and-the-impact-of-covid-19-on-rates/
[113] https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/10-16-2020-County-Coverage-Map.pdf
[114] https://www.cms.gov/newsroom/press-releases/premiums-healthcaregov-plans-are-lower-third-consecutive-year
[115] https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2021QHPPremiumsChoiceReport.pdf
[116] https://www.cbo.gov/system/files/2019-01/54915-New_Rules_for_AHPs_STPs.pdf
[117] https://www.federalregister.gov/documents/2019/06/20/2019-12571/health-reimbursement-arrangements-and-other-account-based-group-health-plans
[118] https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-working-improve-health-insurance-coverage-american-workers-help-small-businesses/
[119] https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-working-improve-health-insurance-coverage-american-workers-help-small-businesses/
[120] CMS Internal Data
[121] https://www.federalregister.gov/documents/2017/01/24/2017-01799/minimizing-the-economic-burden-of-the-patient-protection-and-affordable-care-act-pending-repeal
[122] https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation Waivers/Section_1332_State_Innovation_Waivers
[123] https://www.cms.gov/blog/taking-action-and-providing-states-options-minimize-economic-burden-created-aca
[124] https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Data-Brief-June2020.pdf
[125] https://www.cms.gov/newsroom/press-releases/remarks-administrator-seema-verma-americas-health-insurance-plans-ahip-2019-national-conference
[126] https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Data-Brief-June2020.pdf
[127] https://www.cms.gov/newsroom/press-releases/trump-administration-approves-georgias-state-relief-and-empowerment-waiver
[128] https://www.cms.gov/About-CMS/Story-Page/Marketplace-choice-and-affordability-fact-sheet.pdf
[129] https://www.cms.gov/newsroom/press-releases/cms-releases-final-snapshot-2019-federal-exchange-open-enrollment-period
[130] https://www.cms.gov/newsroom/fact-sheets/federal-health-insurance-exchange-2020-open-enrollment
[131] https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-national-association-healthcare-underwriters-nahu

[132] https://www.cms.gov/newsroom/press-releases/cms-issues-final-rule-2020-annual-notice-benefit-and-payment-parameters#:~:text=The%20Centers%20for%20Medicare%20%26%20Medicaid,as%20the%202020%20Payment%20Notice.&text=The%20final%202020%20Payment%20Notice,strengthen%20America's%20health%20insurance%20markets.
[133] https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/
[134] https://www.cms.gov/newsroom/press-releases/fiscal-year-fy-2019-medicare-fee-service-improper-payment-rate-lowest-2010-while-data-points
[135] https://www.cms.gov/newsroom/press-releases/fiscal-year-fy-2019-medicare-fee-service-improper-payment-rate-lowest-2010-while-data-points
[136] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1919OTN.pdf
[137] https://www.cms.gov/blog/future-medicare-program-integrity
[138] https://www.cms.gov/newsroom/fact-sheets/2019-estimated-improper-payment-rates-centers-medicare-medicaid-services-cms-programs
[139] Id.
[140] CMS internal data.
[141] https://www.cms.gov/About-CMS/Components/CPI/Downloads/Center-for-Program-Integrity-Future-of-PI-RFI.pdf
[142] https://www.cms.gov/About-CMS/Components/CPI/Downloads/Center-for-Program-Integrity-Advanced-Technology-RFI.pdf
[143] https://www.cms.gov/files/document/comprehensive-medicaid-integrity-plan-fys-2019-2023.pdf
[144] https://www.medicaid.gov/state-overviews/scorecard/investigations-between-states-and-unified-program-integrity-contractors/index.html
[145] https://www.cms.gov/newsroom/press-releases/cms-finalizes-new-medicare-card-distribution-ahead-deadline-accelerating-fight-against-medicare
[146] https://www.cms.gov/newsroom/press-releases/cms-finalizes-new-medicare-card-distribution-ahead-deadline-accelerating-fight-against-medicare
[147] https://www.justice.gov/criminal-fraud/facts-statistics
[148] https://www.justice.gov/criminal-fraud/hcf-2020-takedown/press-release
[149] https://www.cms.gov/hfpp/about
[150] https://www.cms.gov/hfpp/about/current-partners (as of November 10, 2020)
[151] https://www.cms.gov/newsroom/press-releases/cms-announces-new-enforcement-authorities-reduce-criminal-behavior-medicare-medicaid-and-chip
[152] https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/PaymentValidation
[153] https://www.cms.gov/newsroom/press-releases/cms-expand-successful-ambulance-program-integrity-payment-model-nationwide
[154] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.
[155] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.
[156] https://www.cms.gov/newsroom/press-releases/cms-unveils-major-organizational-change-reduce-provider-and-clinician-burden-and-improve-patient
[157] https://www.cms.gov/newsroom/press-releases/cms-unveils-major-organizational-change-reduce-provider-and-clinician-burden-and-improve-patient
[158] https://www.federalregister.gov/documents/2020/08/17/2020-17127/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part
[159] https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-2020-cms-quality-conference.
[160] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/AdminInfo-20-02-ALL.pdf.
[161] https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-proposed-rule-revisions-outcome-measures-opos
[184] https://www.cms.gov/blog/quality-payment-program-qpp-year-1-performance-results
[163] https://www.federalregister.gov/documents/2019/07/18/2019-14946/medicare-and-medicaid-programs-requirements-for-long-term-care-facilities-regulatory-provisions-to

[164] https://www.cms.gov/newsroom/fact-sheets/medicare-medicaid-programs-requirements-long-term-care-facilities-regulatory-provisions-promote
[165] https://www.modernhealthcare.com/opinion-editorial/correcting-course-value-based-care-models
[166] https://innovation.cms.gov/innovation-models/vbid
[167] https://innovation.cms.gov/innovation-models/vbid
[168] https://innovation.cms.gov/innovation-models/et3.
[169] https://innovation.cms.gov/innovation-models/comprehensive-primary-care-plus.
[170] https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2.
[171] https://innovation.cms.gov/innovation-models/primary-care-first-model-options,
[172] https://www.healthaffairs.org/do/10.1377/hblog20200311.582575/full/.
[173] https://www.healthaffairs.org/do/10.1377/hblog20200311.582575/full/
[174] https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model
[175] https://www.cms.gov/newsroom/press-releases/cms-announces-innovative-payment-model-improve-care-lower-costs-cancer-patients
[176] https://www.cms.gov/newsroom/press-releases/cms-announces-innovative-payment-model-improve-care-lower-costs-cancer-patients
[177] https://www.cms.gov/newsroom/press-releases/trump-administration-announces-initiative-transform-rural-health
[178] https://www.cms.gov/newsroom/fact-sheets/community-health-access-and-rural-transformation-chart-model-fact-sheet.
[179] https://www.healthaffairs.org/do/10.1377/hblog20200914.598838/full/
[180] https://innovation.cms.gov/innovation-models/aco-investment-model.
[181] https://innovation.cms.gov/files/reports/aim-second-annrpt-fg.pdf.
[182] https://innovation.cms.gov/innovation-models/direct-contracting-model-options.
[183] https://innovation.cms.gov/innovation-models/bpci-advanced.
[184] https://innovation.cms.gov/innovation-models/oncology-care.
[185] https://www.cms.gov/newsroom/press-releases/cms-announces-strong-participation-value-based-medicare-advantage-model-cy-2020-and-new
[186] https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model
[187]https://www.acpjournals.org/doi/10.7326/M16-0961?articleid=2546704&
[188] https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and
[189]https://www.cms.gov/newsroom/fact-sheets/omnibus-burden-reduction-conditions-participation-final-rule-cms-3346-f
[187]https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/PDPM
[188] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10567.pdf
[192] https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other
[193]https://www.cms.gov/newsroom/fact-sheets/finalized-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar
[194] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4283CP.pdf
[195] https://www.federalregister.gov/documents/2019/07/18/2019-14946/medicare-and-medicaid-programs-requirements-for-long-term-care-facilities-regulatory-provisions-to
[196] https://www.cms.gov/newsroom/fact-sheets/medicare-medicaid-programs-requirements-long-term-care-facilities-regulatory-provisions-promote
[197] https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations
[198]https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-proposed-rule
[199] https://www.cms.gov/research-statistics-data-systems/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives#:~:text=Prior%20Authorization%20and%20Pre-Claim%20Review%20Initiatives.%20The%20Centers,initiatives%2C%20CMS%20helps%20ensure%20compliance%20with%20Medicare%20rules

[200]https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center
[18]https://www.cms.gov/newsroom/press-releases/cms-issues-fy-2014-inpatient-payment-rule
[19] https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center
[203]CMS internal data.
[204]https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/MSPRP/Medicare-Secondary-Payer-Recovery-Portal
[205] https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.
[206] http://67.59.137.244/documents/Jun12_EntireReport.pdf
[207] https://www.cms.gov/newsroom/fact-sheets/community-health-access-and-rural-transformation-chart-model-fact-sheet
[208] https://www.nber.org/papers/w26182.pdf
[209] https://www.gao.gov/products/GAO-17-411
[210]https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.
[211]https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.
[212]https://www.cms.gov/index.php/newsroom/fact-sheets/rural-community-hospital-demonstration.
[213]https://innovation.cms.gov/files/reports/rch-rtc.pdf.
[214]https://www.cms.gov/newsroom/press-releases/trump-administration-announces-initiative-transform-rural-health.
[215]https://www.cms.gov/newsroom/fact-sheets/community-health-access-and-rural-transformation-chart-model-fact-sheet.
[216]https://www.cms.gov/newsroom/press-releases/pennsylvania-rural-health-model-aims-help-rural-hospitals-improve-quality-address-community-health.
[217]https://www.cms.gov/newsroom/fact-sheets/pennsylvania-rural-health-model
[218] Id.
[219]https://www.cms.gov/About-CMS/Story-Page/Rethinking-rural-health-fact-sheet.pdf
[220]https://www.cms.gov/blog/rethinking-rural-health-maternal-and-infant-health-rfi
[221] https://www.federalregister.gov/documents/2019/08/16/2019-16762/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the
[222] https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2020-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0
[223] https://www.healthcaredive.com/news/cms-tweaks-hospital-wage-index-change-in-final-rule/560170/
[224] https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center
[225] https://www.cms.gov/newsroom/fact-sheets/cy-2020-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0
[226]https://www.cms.gov/About-CMS/Story-Page/Rethinking-rural-health-fact-sheet.pdf
[227] https://www.cms.gov/newsroom/press-releases/cms-administrator-seema-verma-hosts-virtual-roundtable-boston-telehealth
[228]https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year
[229] https://www.medicare.gov/care-compare/.
[230] https://www.lugpa.org/americans-wanthealthcare-price-transparency
[231] https://www.cms.gov/newsroom/fact-sheets/cy-2020-hospital-outpatient-prospective-payment-system-opps-policy-changes-hospital-price
[232] https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-final-rule-fact-sheet-cms-9915-f.
[233] https://www.cms.gov/newsroom/press-releases/trump-administration-announces-historic-price-transparency-requirements-increase-competition-and
[234] https://www.cms.gov/newsroom/press-releases/trump-administration-announces-historic-price-transparency-requirements-increase-competition-and
[235] https://www.cms.gov/newsroom/press-releases/trump-administration-announces-historic-price-transparency-requirements-increase-competition-and
[236]
https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

[237] https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/
[238] https://surescripts.com/docs/default-source/pressrelease-library/2020_price-transparency_data-brief-patient-survey.pdf
[239] https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-prescription-drug-prices-and-increase-transparency
[240] https://www.cms.gov/newsroom/press-releases/cms-takes-action-lower-prescription-drug-prices-and-increase-transparency
[241] https://www.cms.gov/newsroom/press-releases/trump-administration-empowers-nursing-home-patients-residents-families-and-caregivers-enhancing
[242] https://www.cms.gov/newsroom/press-releases/cms-care-compare-empowers-patients-when-making-important-health-care-decisions
[243] https://www.healthaffairs.org/do/10.1377/hblog20190423.701475/full/
[244] https://www.kff.org/wp-content/uploads/2013/01/dual-eligibles-medicaid-s-role-for-low-income-medicare-beneficiaries-fact-sheet.pdf
[245] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Insight-Briefs/Downloads/PAHInsightBrief.pdf
[246] https://www.cms.gov/files/document/mmco-report-congress
[247] CMS internal data.
[248] https://www.cms.gov/files/document/mmco-report-congress.pdf
[249] https://www.cms.gov/newsroom/fact-sheets/programs-all-inclusive-care-elderly-pace-final-rule-cms-4168-f
[250] https://www.healthaffairs.org/do/10.1377/hblog20190423.701475/full/
[251] https://www.cms.gov/files/document/mmco-report-congress.pdf
[252] https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet
[253] https://www.cms.gov/medicare-medicaid-coordination/medicare-medicaid-coordination-office/state-payment-medicare-premiums.
[254] CMS internal data
[255] CMS internal data
[256] https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Analytics.
[257] https://www.pewresearch.org/internet/2017/05/17/technology-use-among-seniors/.
[258] https://www.medicare.gov/plan-compare/#/?lang=en.
[259] CMS internal data.
[260] https://www.medicare.gov/care-compare/.
[261] https://www.medicare.gov/blog/make-medicare-premium-payment-online-2019
[262] CMS internal data.
[263] https://www.medicare.gov/procedure-price-lookup/.
[264] https://www.cms.gov/newsroom/press-releases/new-app-displays-what-original-medicare-covers.
[265]https://www.cdc.gov/drugoverdose/index.html.
[266]https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf.
[267] Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Med Care*. 2016;54(10):901-906. doi:10.1097/MLR.0000000000000625.
[268]https://www.congress.gov/bill/115th-congress/house-bill/6.
[269] https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.
[270]https://www.cdc.gov/mmwr/volumes/69/wr/mm6911a4.htm
[271] https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html.
[272]https://www.cdc.gov/nchs/data/databriefs/db356-h.pdf.
[273] https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates#:~:text=Drug%20overdose%20deaths%20rose%20from,in%202018%20to%2067%2C367%20deaths.
[274]https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program#:~:text=Under%20the%20new%20OTP%20benefit,Substance%20use%20counseling.
[275] CMS internal data.
[276]https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=295
[277]https://www.cms.gov/newsroom/press-releases/cms-finalizes-decision-cover-acupuncture-chronic-low-back-pain-medicare-beneficiaries

[278]https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19008.pdf.
[279]https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf
[280]https://www.cms.gov/files/document/cy-2020-opioid-safety-edits-reminders-and-recommendations.pdf .
[281]https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17003.pdf.
[282]https://www.macpac.gov/subtopic/section-1115-waivers-for-substance-use-disorder-treatment/
[283] https://www.medicaid.gov/medicaid/data-systems/macbis/medicaid-chip-research-files/transformed-medicaid-statistical-information-system-t-msis-analytic-files-taf/index.html
[284] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2020Announcement
[285]https://innovation.cms.gov/innovation-models/integrated-care-for-kids-model
[286] https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model
[287] CMS internal data.
[288] Doerr, J. *Measure What Matters.* Penguin Random House, 2017.
[289] Doerr, J. and Page, L. (2018). Measure what Matters: How Google, Bono, and the Gates Foundation rock the world with OKRs. New York, NY: Portfolio/Penguin Publishers.
[290] CMS internal data.
[291] CMS internal data.
[292] CMS internal data.
[293]https://www.cms.gov/About-CMS/Story-Page/Modernizing-CMS-fact-sheet.pdf
[294] https://www.cms.gov/newsroom/press-releases/cms-unveils-major-organizational-change-reduce-provider-and-clinician-burden-and-improve-patient
[295] CMS internal data.[296] CMS internal data.[297] CMS internal data.
[298] CMS internal data.
[299] CMS internal data.
[300] 2019 Office of Personnel Management Federal Employee Viewpoint Survey, 1st Level Subagency Report.
[301] 2018 Office of Personnel Management Federal Employee Viewpoint Survey, 1st Level Subagency Report.
[302] 2018 Office of Personnel Management Federal Employee Viewpoint Survey, 1st Level Subagency Report.
[303] CMS internal data.
[304] CMS internal data.
[305]https://www.fedhealthit.com/2020/05/organizational-change-and-innovation-at-cms-and-the-role-of-industry/
[306] Roginiel, A. Dhruva, S, and Ross, J. Evidence supporting FDA approval and CMS national coverage determinations for novel medical products, 2005 through 2016: A cross-sectional study. *Medicine* (Baltimore) 2018 Oct; 97(40) Published online 2018 Oct 5.
[307]https://www.cms.gov/newsroom/fact-sheets/proposed-medicare-coverage-innovative-technology-cms-3372-p
[308]
[309] (84 FR 42047)
[310] (84 FR 42047)
[311] (84 FR 61295 – 61297)
[312] https://www.cms.gov/newsroom/press-releases/cms-advancing-seniors-access-cutting-edge-therapies-and-technology-medicare-hospital-rule.
[313] https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute
[314] https://www.cms.gov/newsroom/fact-sheets/cy2020-end-stage-renal-diseasedurable-medical-equipment-final-rule-cms-1713-f
[315] https://www.cms.gov/newsroom/fact-sheets/summary-significant-changes-medicare-program-integrity-manual-chapter-13-local-coverage
[316] https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-medical-device-manufacturers-association-annual-meeting
[317] https://cgsmedicare.com/jb/pubs/news/2018/06/cope8072.html
[318] Centers for Medicare & Medicaid Services. Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N)
[319] Medicare Durable Medical Equipment (DME) Administrative Contractors. Local Coverage Determination (LCD):
Tumor Treatment Field Therapy (TTFT) (L34823)

[320] Temporary HCPCS codes do not have a particular period associated with them, but are issued when there's a need for a new code outside of the annual code application process.
[321] https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-medical-device-manufacturers-association-annual-meeting
[322] https://www.cms.gov/newsroom/press-releases/cms-acts-spur-innovation-americas-seniors .
[323] https://www.cms.gov/About-CMS/Story-Page/Lowering-drug-prices-fact-sheet.pdf
[324] https://www.cms.gov/About-CMS/Story-Page/Lowering-drug-prices-fact-sheet.pdf
[325] https://www.hhs.gov/about/news/2020/07/24/trump-administration-announces-historic-action-lower-drug-prices-americans.html
[326] https://www.cms.gov/newsroom/press-releases/trump-administration-drives-down-medicare-advantage-and-part-d-premiums-seniors#:~:text=The%20projected%20average%20monthly%20basic,of%20lower%20Medicare%20premium%20subsidies.
[327] https://www.cms.gov/newsroom/press-releases/trump-administration-drives-down-drug-costs-seniors
[328] https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf
[329] https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf
[330] https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-final-rule-fact-sheet-cms-9915-f .
[331] https://www.cms.gov/newsroom/press-releases/proposed-changes-medicare-advantage-and-part-d-will-provide-better-coverage-more-access-and-improved-0
[332] https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf
[333] https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf
[334] https://www.govinfo.gov/content/pkg/FR-2019-05-23/pdf/2019-10521.pdf
[335] https://www.cms.gov/newsroom/press-releases/cms-approves-washington-state-plan-amendment-proposal-allow-supplemental-rebates-involving. The four states with approved state plan amendments are Washington, Oklahoma, Michigan, and California.
[336] https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-12970.pdf
[337] https://www.healthaffairs.org/do/10.1377/hblog20200617.728496/full/
[338] https://www.healthaffairs.org/do/10.1377/hblog20200617.728496/full/
[339] https://innovation.cms.gov/innovation-models/part-d-savings-model
[340] https://innovation.cms.gov/innovation-models/part-d-savings-model
[341] https://www.healthaffairs.org/do/10.1377/hblog20200311.582575/full/. This includes rapid-acting, short-acting, intermediate-acting, and long-acting insulins, as well as concentrated and pre-mixed formulations.
[342] These are only annual savings from more predictable out-of-pocket cost for their insulin prescriptions and do not factor in both short- and longer-term costs savings from avoidable medical expenses.
[343] https://www.healthaffairs.org/do/10.1377/hblog20200311.582575/full/
[344] CMS internal data
[345] https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model
[346] https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule
[347] https://www.cms.gov/newsroom/fact-sheets/medicaid-drug-spending-dashboard
[348] https://www.cms.gov/newsroom/press-releases/cms-releases-enhanced-drug-dashboards-updated-data-2018
[349] https://www.cms.gov/newsroom/press-releases/cms-releases-enhanced-drug-dashboards-updated-data-2018
[350] https://www.cms.gov/newsroom/press-releases/cms-updates-drug-dashboards-prescription-drug-pricing-and-spending-data
[351] https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-medicare-physician-fee-schedule-calendar-year-2018
[352] Roth, A. E. (2007). The art of designing markets. Harvard Business Review, 85(10), 118.
[353] https://www.fiercehealthcare.com/tech/fewer-than-4-10-health-systems-can-successfully-share-data-other-hospitals
[354] CMS internal data.
[355] https://Bluebutton.cms.gov
[356] https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf.
[357] https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf.
[358] https://dpc.cms.gov/.

[359] https://del.cms.gov/DELWeb/pubHome. https://www.cms.gov/newsroom/press-releases/cms-announces-artificial-intelligence-health-outcomes-challenge-participants-advancing-stage-1.

[361] https://www.cms.gov/newsroom/press-releases/cms-advances-seven-finalists-artificial-intelligence-health-outcomes-challenge