CMS Update

Kimberly Brandt, J.D., M.A.
Principal Deputy
Administrator for Operations and Policy,
Centers for Medicare & Medicaid Services

1

Today's presentation

- COVID-19
- CMS Strategic Framework
- Patients Over Paperwork
- Interoperability
- Updating the Physician Self-Referral Law
- Program Integrity
- Fighting the Opioid Epidemic

2

COVID-19 Public Health Emergency

- President's declaration of a public health emergency (PHE) on March 13 empowered HHS to authorize CMS to provide unprecedented flexibility for certain Medicare, Medicaid, and CHIP program requirements
- Blanket waivers allow providers to not have to apply for individual waivers under section 1135 of the Social Security Act
- 1135 waivers apply to federal requirements only, not those established by states, and are retroactive to March 1, 2020
- CMS also issued to regulations to provide further flexibility to health systems
- The PHE was renewed for another 90 days, effective October 23

3

3

COVID-19 Waivers

Total Number of Medicare Blanket Waivers: **Over 130**

https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

Total Number of State 1135, 1115, Disaster SPA, and IT Funding Request Approvals: **Over 150**

https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/coronavirus-disease-2019-covid-19/index.html

4

4

Telehealth

- CMS is expanding access to health care services via telehealth to ensure continuity of care and reduce risk of transmission
- Starting March 6, Medicare can pay for telemedicine services from a broad range of providers
- Three main types of services: telehealth visits, virtual check-ins, e-visits
- 146 new CPT codes added to the Medicare telehealth services list and 89 of those are authorized to be furnished via audio-only devices
- Expanded benefit available to beneficiaries in all areas (not just rural)

5

5

COVID-19 Interim Final Rules

- CMS provided relief to a wide and unprecedented range of regulatory requirements to maximize the health system's preparedness in weeks when normally, rulemaking takes at least a year
- Key elements of the first interim final rule with comment (IFC):
  - Provided many provider types flexibility to use telecommunications technology to visit and monitor Medicare beneficiaries
  - New payments for laboratories to collect specimens from homebound patients and inpatients (not in a hospital) for COVID-19 testing
  - Expansion of Part B ambulance coverage for the transport of patients to all facility destinations, such as community mental health centers and Federally Qualified Health Centers (FQHCs)

6

6

COVID-19 Interim Final Rules (cont'd)

- Key elements of the second interim final rule with comment (IFC):
  - Established Medicare coverage for serology (antibody) tests
  - Established separate payment to hospital outpatient departments and physician practices to collect lab samples. Medicare will also pay pharmacies who are enrolled as labs to perform tests for beneficiaries
  - Further expanded access to telehealth services available for Medicare beneficiaries, including by lifting restrictions on the type of clinical practitioners that can furnish telehealth services
  - Helped hospitals increase their supply of beds to manage a surge of COVID-19 patients while maintaining stable, predictable Medicare payments

7

7

COVID-19 Interim Final Rules (cont'd)

- Key elements of the third interim final rule with comment (IFC):
  - Required long-term care facilities to test facility residents and staff
  - Established new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking the incidence and impact of COVID-19 and to report daily important data to public officials
  - Established requirements for all CLIA laboratories to report COVID-19 test results to the Health and Human Services Secretary
  - Revises the previous policy by establishing 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

8

8

COVID-19 Interim Final Rules (cont'd)

- Key elements of the fourth interim final rule with comment (IFC):
  - Establishes enhanced Medicare payments for new COVID-19 treatments
  - Creates flexibilities in the public notice requirements and post-award public participation requirements for a State Innovation Waiver under Section 1332 of the Patient Protection and Affordable Care Act during the COVID-19 PHE
  - Creates flexibilities for states maintaining Medicaid enrollment during the COVID-19 PHE
  - Takes steps to ensure price transparency for COVID-19 tests

9

9

Using COVID-19 Data

For Operations

- CMS is using administrative claims and encounter data to track the utilization of healthcare services related to COVID-19 in the Medicare and Medicaid programs and monitor the effects of the outbreak on program utilization
- CMS is also collaborating with CDC to collect and release nursing home COVID-19 cases and deaths to improve public health responses and inform the public
- CMS monitors Special Enrollment Period (SEP) enrollment data for Federally-facilitated Marketplace

10

10

Using COVID-19 Data (cont'd)

For Program Integrity

- CMS is in the process of analyzing the COVID-19 waivers and flexibilities to identify program integrity risks and develop monitoring strategies
- CMS is collaborating with stakeholders to inform beneficiaries about scams and potentially fraudulent activities

11

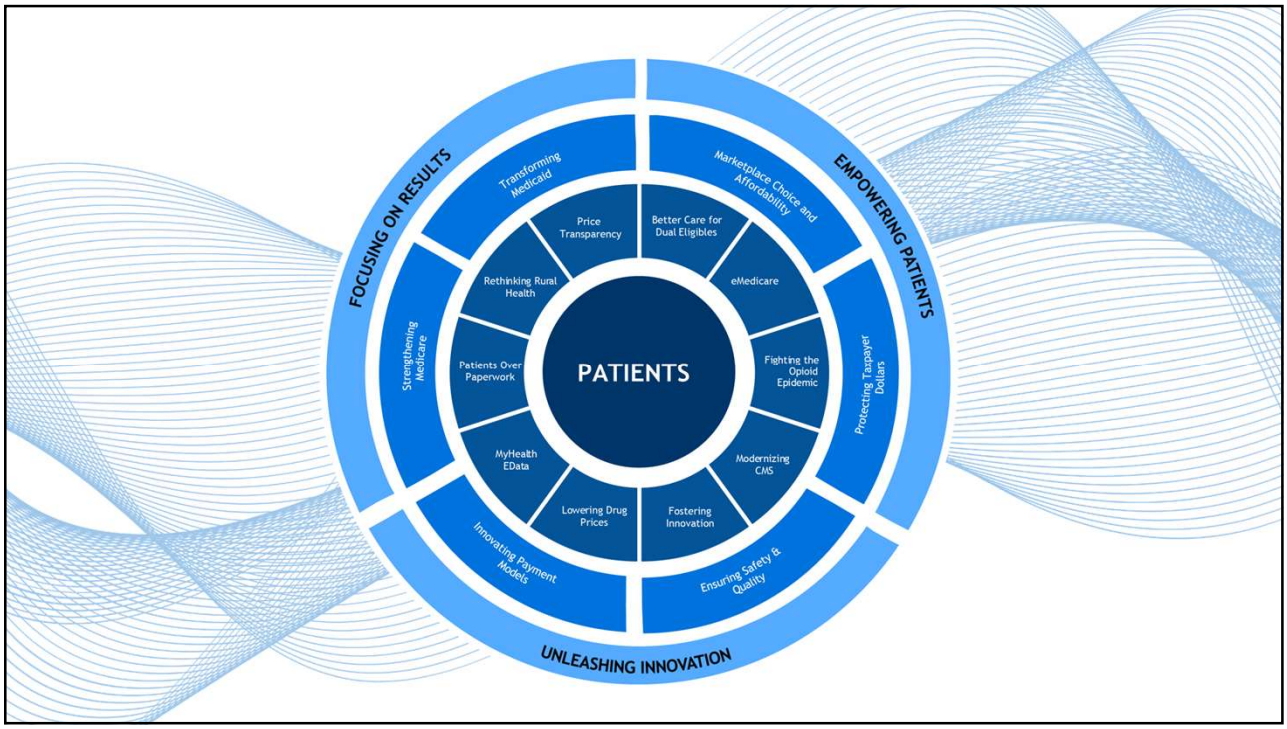
11

After the PHE

- 1135 waivers end no later than the end of the emergency period, or 60 days after the waiver was published, unless the HHS Secretary extends the waiver by notice for additional periods of up to 60 days
- CMS is reviewing waivers and flexibilities created in response to the PHE and engaging with stakeholders about their suitability for a post-PHE environment

12

12



13

Patients over Paperwork

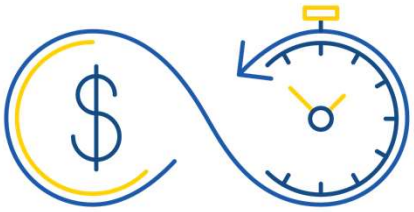
PATIENTS OVER PAPERWORK

- CMS is putting patients first and empowering them to make the best decisions for themselves and their families
- Agency-wide initiative to remove regulatory obstacles and allow providers to focus on improving their patients' health
- In 2017, CMS solicited comments on specific ideas to reduce burdens through several Requests for Information (RFIs)
- As of this month, we have resolved or are actively addressing over 80% of the burden topics identified in the RFIs that are actionable for CMS

14

14

Patients over Paperwork (cont'd)



Between 2018 and 2021, CMS projects Patients over Paperwork will save:

6.6 billion dollars &
42 million hours

15

15

Simplifying Documentation Requirements

To make it easier for providers and to reduce improper payments and appeals, we are working to:

- Eliminate sub-regulatory documentation requirements that are no longer needed
- Simplify remaining sub-regulatory documentation requirements

16

16

Simplifying Documentation Requirements (cont'd)

Two-pronged solution to provide information on Medicare Fee-for-Service documentation requirements in a more clear and concise manner:

Provider Documentation Checklist

- Web-based and accessible at any point in the lifetime of a claim
- Centralize all documentation requirements in one place

Provider Documentation Requirements Lookup Service

- Directly integrated into provider workflow through EHRs
- Providers will be able to discover Medicare FFS prior authorization and documentation requirements at the *time of service* and *within their EHR*

17

17

Interoperability & Patient Access Final Rule

- On March 9, 2020 CMS finalized policy changes, in a final rule, supporting its MyHealthEData initiative to improve patient access and advance electronic data exchange and care coordination throughout the healthcare system
  - Published in the Federal Register on May 1
- Our vision is a future where open APIs allow seamless data sharing in all aspects of healthcare
- Our vision also includes a future where researchers and innovators have access to CMS data to support advancements in healthcare delivery and quality as well as to develop tools to support patient and provider decision-making

18

Interoperability & Patient Access Final Rule (cont'd)

- All health plans doing business in Medicare, Medicaid, and through the federal exchanges will be required to share health claims data and other important information with patients electronically
- CMS-regulated payers are required to make provider directory information publicly available via a standards-based API
- A patient's health information should follow a patient as they move from plan to plan, creating a longitudinal health record for the patient at their current plan

19

Interoperability & Patient Access Final Rule (cont'd)

- A payer may ask third-party application developers to attest to certain privacy provisions that can help keep a patient's data private and secure are in place
- Publicly identify doctors, hospitals, and other providers who engage in information blocking
- Require that all hospitals send electronic notifications to designated health care providers when their patients are admitted, discharged, or transferred from the hospital

20

Interoperability & Patient Access Final Rule (cont'd)

- Publicly report those providers who do not have digital contact information included or updated in the National Plan and Provider Enumeration System (NPPES)
- Improve the dually eligible experience by increasing the frequency of federal-state data exchanges

21

Updating the Physician Self-Referral Law

- Comments received in response to an RFI posted on June 25, 2018 provided examples in which Physician Self-Referral Law (PSL), also known as "Stark" Law, discourages arrangements to coordinate care and improve patient experiences
- On October 17, CMS published a proposed rule to modernize and clarify regulations for the PSL
- The comment period for the proposed rule ended on December 31, 2019
- The proposed rule is one of the most significant updates to these regulations since they were implemented in 1989
- PSL was enacted to prevent referrals by physicians based on their financial self-interest rather than the good of the patient
- Key PSL provisions operating in a primarily fee-for-service environment have not kept up with evolution towards value-based care

22

22

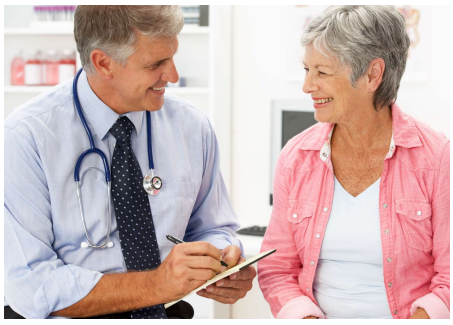
Updating the Physician Self-Referral Law (cont'd)

- The proposed rule includes:
  - Permanent regulatory exceptions to Physician Self-Referral Law for value-based arrangements
  - Guidance and clarifications on the law's key requirements
  - Protection for non-abusive, beneficial arrangements between physicians and other health care providers, including for donations of cybersecurity technology
  - Requests for comment on the role of price transparency at the point of referral
- The proposal advances the CMS "Patients Over Paperwork" initiative by reducing burdens on providers who participate in value-based arrangements while protecting patients from unnecessary services and lower quality care
- The effort also contributes to the HHS Regulatory Sprint to Coordinated Care initiative

23

23

Updating the Physician Self-Referral Law (cont'd)



Expected Patient Impact

- **Improving Patient Care:** the proposed rule opens additional avenues to coordinate the care patient care, allowing providers to work together to ensure patients receive the highest quality of care
- **Maintaining Patient Protections:** the proposed rule includes a carefully woven fabric of safeguards to ensure that the Physician Self-Referral Law continues to protect patients from unnecessary services and being steered to less convenient, lower quality, or more expensive services because of a physician's financial self-interest

24

24

Innovative Payment Models

- The CMS Innovation Center's purpose is to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for beneficiaries of Medicare, Medicaid, and CHIP.
- Since 2010, CMMI has tested 54 alternative payment models that focus on critical areas of care, specific health conditions, and geographic areas with unique barriers to care.
- Five models have produced statistically significant savings and three models have been expanded nationwide
- Important lessons learned from an evaluation of Center's models:
  - Value-based models with both upside and downside risk are more likely to produce statistically significant savings
  - Bonus payments must be tied to fair and accurate financial benchmarks
  - CMMI must support participants with more actionable data and analytics

25

25

Medicare Coverage of Innovative Technology (MCIT)

- On August 31, 2020, CMS issued a proposed rule (CMS-3372-P) that would speed up the process to grant Medicare beneficiaries access to the latest, most cutting-edge medical devices
- The MCIT proposal would create a new Medicare coverage process for innovative products that the FDA deems "breakthrough"
- Medicare would provide national coverage simultaneously with FDA approval, for a period of four years
- The MCIT proposal would cover devices the FDA approved for use in 2019 or 2020

26

26

Program Integrity Focus Areas

PROTECTING TAXPAYER DOLLARS

- Prior Authorization
- Medicare Advantage and Part D efforts
- Enhanced Medicaid oversight
- Major Case Coordination

27

Program Integrity Focus Areas

CMS's program integrity activities, including both the prevention and recovery of improper payments, saved Medicare an estimated

$12 billion

in FY 2018.

28

28

Prior Authorization

CMS is leading Prior Authorization (PA) and Pre-Claim Review initiatives to prevent improper payments and decrease appeals in the Medicare fee-for-service program:

- **PA of Certain DMEPOS Items**
  - Master list of items for potential PA that CMS chooses based on potential FWA
  - As of May 2020, CMS requires PA on 40 Power Mobility Devices (PMD), 5 Pressure Reducing Support Surfaces (PRSS)
- **PA of Repetitive Scheduled Non-Emergent Ambulance Transports (Model)**
  - Tests whether PA helps reduce expenditures and improper payments, while maintaining or improving access to and quality of care
  - Since implementation, spending has decreased on average approximately $9 million per month, resulting in savings of approximately $710 million while maintaining and improving access to and quality of care
  - CMS announced nationwide expansion on September 22, 2020

29

29

Prior Authorization (cont'd)

CMS is leading Prior Authorization (PA) and Pre-Claim Review initiatives to prevent improper payments and decrease appeals in the Medicare fee-for-service program:

- **Home Health Review Choice Demonstration**
  - Provides flexibility, provider choice, and risk-based changes to providers who bill accurately
  - Includes HHAs in IL, OH, TX, NC, and FL
  - Initial analysis of the demonstration indicates that HHAs have a good understanding of the medical necessity and documentation requirements for the home health benefit
  - CMS continues to implement the demonstration and analyze results
- **PA of Certain Hospital Outpatient Department Services**
  - Nationwide PA process and requirements for certain hospital OPD services
  - As of July 2020, CMS requires PA for 5 groups of services: Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, and Vein Ablation

30

30

Program Integrity: Proposed Changes

CMS continues to work to modernize the Medicare Advantage and Part D programs.

- **Strengthening collaboration and oversight of Part C and D programs through the implementation of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act)**
- **Addressing overutilization of opioid prescribing through outreach and education**
  - CMS sent 600 + letters in January 2020 to prescribers of concurrent opioid and benzodiazepine medications comparing them to their peers, defined as those within the same specialty and State.
  - This effort is included under SUPPORT Act, Sec. 6065 and is part of our data driven efforts to combat the nation's opioid crisis
- **Risk Adjustment Data Validation audits and recovery of improper payments**
  - Start payment year 2014 and 2015 contract level audit this fiscal year
  - Reduce the burden on audited plans while expanding the reach of the audits to more plans
  - CMS extended the comment period for the RADV provision, to August 28, 2019, to give the public an opportunity to submit meaningful comments to the RADV provision proposal

31

31

Program Integrity: Medicaid Strategy

- **Released the Comprehensive Medicaid Integrity Plan (CMIP) for FYs 2019-2023, which describes CMS' 5-year plan to protect taxpayer dollars by combatting fraud, waste, and abuse in Medicaid and the Children's Health Insurance Program (CHIP)**
- **The CMIP includes several oversight activities, such as:**
  - Continued audits of state beneficiary eligibility determinations
  - Continued audits of Medicaid managed care Medical Loss Ratio (MLR)
  - Review and assist states with the development of Payment Error Rate Measurement (PERM) Corrective Actions Plans (CAPs) to address the state-specific drivers of improper payments
  - Provide guidance, support, and oversight for states' Medicaid Eligibility Quality Control (MEQC) pilots and CAPs
  - Optimize PI use of T-MSIS data, conduct data analytics pilots with states, and improve state access to data sources that are useful for PI
  - Collaborate with states to ensure compliance with the Medicaid managed care final rule and implementation of PI safeguards
- **Also released the first MLR audit report for California that identified several areas for improvement, such as documentation requirements to support MLR calculations**

32

32

Major Case Coordination (MCC)

Results since April 2018:

- 1,500+ Unique Case Reviews
- 900+ Law Enforcement Referrals
- 350+ Revocations
- 700+ Payment Suspensions Identified

Increase in **number** and **quality** of law enforcement referrals

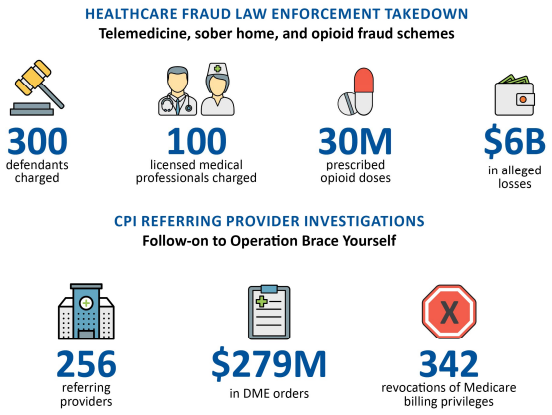
Health Care Fraud Scheme Takedowns:

- Operation Brace Yourself *(April 9 and September 27, 2019 and September 30, 2020)*
- Appalachian Region Prescription (ARPO) Opioid Strike Force Takedown *(April 17, 2019)*
- PSTIM *(September 17, 2019)*
- Second ARPO Strike Force Takedown *(September 24, 2019)*
- NE DME/Opioid Strike Force Takedown *(September 26, 2019)*
- *Home Health RAP Fraud (September 27, 2019)*
- Genetic Testing Strike Force Takedown *(September 27, 2019)*

33

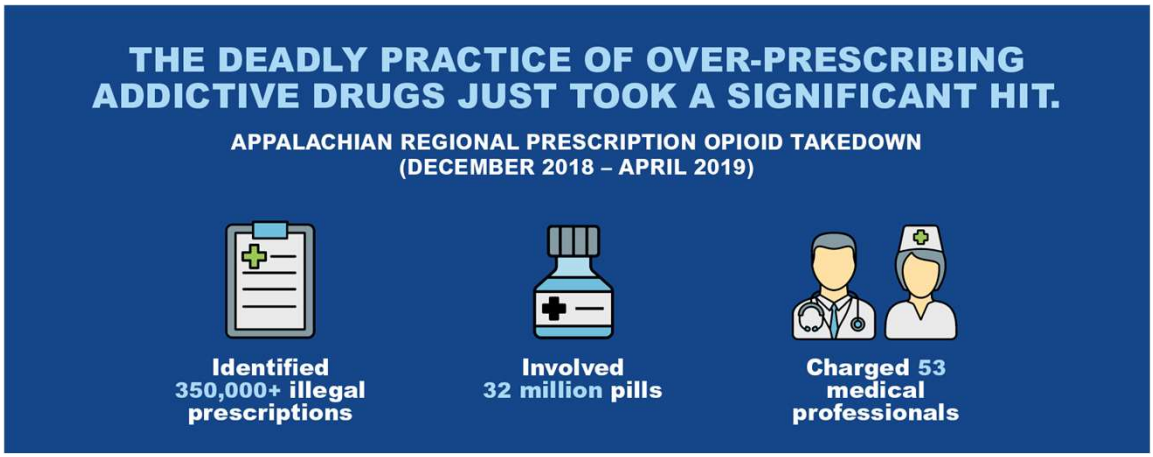
Operation Brace Yourself

On September 30, 2020, the DOJ, OIG, and CPI initiated these actions against in the fight against healthcare fraud:



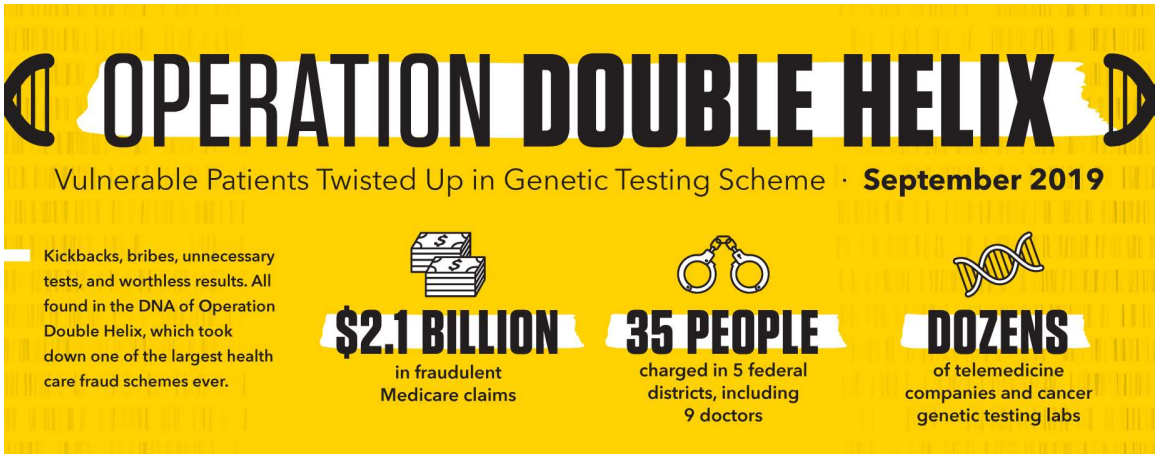
34

ARPO



35

Operation Double Helix



36

Key Areas of CMS Focus

FIGHTING THE OPIOID CRISIS

CMS's **Opioid Roadmap** is a three-pronged approach to combating the opioid epidemic focusing on:

- **Prevention** of new cases of opioid use disorder (OUD);
- **Treatment** of patients who have already become dependent on or addicted to opioids; and
- Utilization of **data** from across the country to target prevention and treatment activities

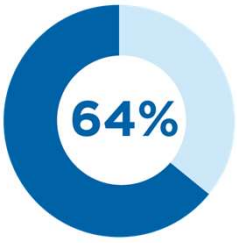
PREVENTION

TREATMENT

DATA

37

SUPPORT Act Implementation



CMS is the lead on 49 provisions of the SUPPORT Act.
As of November 1, 2020 we have completed 25, including:

Sec. 1010: Medicaid non-opioid pain guidance

- Reviewed prescribing guideline strategies used by states in FFS and with MCO contracts
- Described best practices employed successfully in several states
- Preliminary data suggests that implementing opioid prescribing guidelines, such as those recommended by CDC, can decrease the quantity of opioids prescribed and dispensed
- Highlighted a range of options states have to cover non-pharmacologic chronic pain management services

38

SUPPORT Act Implementation (cont'd)

Sec. 1015: SUD Data book using T-MSIS data

- First release of nationwide data using the new national data on Medicaid and the Children's Health Insurance Program (CHIP) represented in Transformed Medicaid Statistical Information System (T-MSIS)
- Provides the number and prevalence of SUD in the Medicaid beneficiary population and the SUD services provided to them for treatment

39

SUPPORT Act Implementation (cont'd)

Sec. 2005: New Medicare Part B Benefit for Opioid Treatment Programs

- Methadone covered by Medicare for the first time
- Medicare now pays enrolled OTPs bundled payments based on weekly episodes of care for services including FDA-approved medications for treatment of OUD and SUD counseling
- Medicare beneficiaries will not have a copayment for OTP services in 2020
- As of November 1, 1,096 approved OTPs and 53 more applications in-process

40

SUPPORT Act Implementation (cont'd)

Sec. 5052: State Medicaid Director letter on guidance for state option to cover care provided in Institutions for Mental Diseases (IMDs)

- Generally, there is a prohibition on Medicaid payment for any services provided to any individual under age 65 who resides in an IMD, including care provided outside the IMD facility or hospital
- For Medicaid beneficiaries age 21 through 64 who have at least one substance use disorder (SUD) diagnosis and reside in an eligible IMD
- Designed to supplement and be coordinated with outpatient, community-based care as part of a comprehensive continuum of services
- May be used concurrently with 1115 demonstration authority to improve continuum of care for SUD patients

41

Thank you!

kimberly.brandt1@cms.hhs.gov

410.786.3151

42