

# **The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions**

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**Suzanne M. Kirchhoff,**  
**Coordinator**  
Analyst in Health Care  
Financing

## **The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions**

On October 24, 2018, President Trump signed into law the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act; P.L. 115-271). The conference report on the bill was approved by the House 393-8 on September 28, 2018, and it cleared the Senate 98-1 on October 3, 2018.

The law was enacted in response to growing concerns among the U.S. public and lawmakers about increasing numbers of drug overdose deaths. Opioid overdose deaths, in particular, have increased significantly since 2002. In 2015, an estimated 33,091 Americans died of opioid-related overdoses, almost three times as many as in 2002, around the beginning of the opioid epidemic in the United States. In 2016, that number had increased to 42,249. In October 2017, President Trump declared the opioid epidemic a public health emergency.

The SUPPORT Act is a sweeping measure designed to address widespread overprescribing and abuse of opioids in the United States. The act includes provisions to bolster law enforcement, public health, and health care financing and coverage, including under Medicare and Medicaid. It imposes tighter oversight of opioid production and distribution; requires additional reporting and safeguards to address fraud; alters programs related to the provision of support to children in the child welfare system because of their parent's or caregiver's opioid use; and limits coverage of prescription opioids. It also expands coverage of and access to opioid addiction treatment services. In addition, the act authorizes programs to expand consumer education on opioid use and train additional providers to treat individuals with opioid use disorders (OUDs). The Congressional Budget Office (CBO) forecast that the SUPPORT Act would increase the on-budget deficit by \$1,001 million over 5 years (FY2019-2023) but reduce the on-budget deficit by \$52 million over 10 years (FY2019-FY2028).

The SUPPORT Act is one of several recent laws aimed at addressing the opioid epidemic. The 114<sup>th</sup> Congress enacted the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198). CARA addressed substance use issues broadly, targeting the opioid crisis predominantly through public health and law enforcement strategies. The 21<sup>st</sup> Century Cures Act (Cures Act; P.L. 114-255), also enacted in 2016, authorized new funding for medical research, amended the Food and Drug Administration (FDA) drug approval process, and authorized additional funding to combat opioid addiction, among other provisions.

The SUPPORT Act consists of eight titles. The Congressional Research Service is publishing a series of reports on this law, organized by title. This report provides a section-by-section description of Medicare provisions in Titles II and VI, as well as one Medicare budget offset in Title IV.

Among significant Medicare changes, the law creates a Medicare bundled payment for an incident of medication-assisted treatment (MAT), which combines medications with counseling and behavioral therapies to provide a holistic approach to treating OUD and makes federally registered opioid treatment programs (OTPs) approved Medicare providers. It also requires private insurers that offer Medicare Part D prescription drug plans to implement "lock-in" programs, starting in CY2022, that limit the number of pharmacies and prescribers used by enrollees identified as at risk of opioid abuse. This report is intended to reflect the SUPPORT Act at enactment (i.e., October 24, 2018); it does not track the act's implementation or funding. This report will not be updated.

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## Introduction

On October 24, 2018, President Trump signed into law the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act; P.L. 115-271). The conference report on the bill was approved by the House 393-8 on September 28, 2018, and it cleared the Senate 98-1 on October 3, 2018.<sup>1</sup>

The law was enacted in response to growing concerns among the U.S. public and lawmakers about increasing numbers of drug overdose deaths. Opioid overdose deaths, in particular, have increased significantly since 2002. In 2015, an estimated 33,091 Americans died of opioid-related overdoses, almost three times as many as in 2002, around the beginning of the opioid epidemic in the United States.<sup>2</sup> In 2016, that number had increased to 42,249.<sup>3</sup> In October 2017, President Trump declared the opioid epidemic a national public health emergency.<sup>4</sup>

The SUPPORT Act is a sweeping measure designed to address widespread overprescribing and abuse of opioids in the United States. The act includes provisions to bolster law enforcement, public health, and health care financing and coverage, including under Medicare and Medicaid. The legislation imposes tighter oversight of opioid production and distribution; requires additional reporting and safeguards to address fraud; and limits coverage of prescription opioids. It also expands coverage of and access to opioid addiction treatment services. In addition, the act authorizes programs that seek to expand consumer and provider education on opioid use and train additional providers to treat individuals with opioid use disorders (OUDs).

## Budgetary Impact

The SUPPORT Act includes numerous legislative changes that affect direct spending and revenues. This report describes specific programmatic changes in the Medicare program in the SUPPORT Act. As such, this report does not discuss the budgetary impact of individual provisions, with the exception of Section 4002, which is related to Medicare (see “Title IV: Offsets”).

Overall, the Congressional Budget Office (CBO) estimated the SUPPORT Act would increase the on-budget deficit by \$1,001 million over 5 years (FY2019-2023) but reduce the on-budget deficit by \$52 million over 10 years (FY2019-FY2028).<sup>5</sup> Generally, pay-as-you-go (PAYGO) scorecards

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<sup>1</sup> A different version of H.R. 6 passed the House on June 22, 2018, by a vote of 396-14, and an amended version of the bill passed the Senate on September 17, 2018, by a vote of 99-1. On September 28, 2018, the House passed a final agreement on H.R. 6 by a vote of 393-8; on October 3, the Senate passed the final version of H.R. 6 by a vote of 98-1. See House Committee on Energy and Commerce, “Opioid Legislation,” October 24, 2018, at <https://energycommerce.house.gov/opioids-legislation/>.

<sup>2</sup> Department of Health and Human Services (HHS), National Institutes of Health, National Institute on Drug Abuse, *Overdose Death Rates*, updated September 2017, at <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.

<sup>3</sup> Centers for Disease Control and Prevention, “Data Brief 294. Drug Overdose Deaths in the United States, 1999-2016,” Data for Figure 4, December 2017, at [https://www.cdc.gov/nchs/data/databriefs/db294\\_table.pdf#1](https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#1).

<sup>4</sup> White House, “President Donald J. Trump Is Taking Action on Drug Addiction and the Opioid Crisis,” October 26, 2017, at <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/>.

<sup>5</sup> Congressional Budget Office (CBO), *Estimated Direct Spending and Revenue Effects of H.R. 6, Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act*, September 27, 2018, at <https://www.cbo.gov/system/files?file=2018-09/hr6ConferenceSept27.pdf>.

record the effects of legislative changes on direct spending and revenues; however, Section 8231 of the SUPPORT ACT excludes such budgetary effects from PAYGO scorecards, thus precluding any possible sequestration as a result of the legislation's enactment.<sup>6</sup>

## **Related Prior Laws**

The SUPPORT Act builds on several prior laws that aimed to address the opioid epidemic. During the 114<sup>th</sup> Congress, the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198) was enacted. CARA addressed substance use issues broadly, targeting the opioid crisis predominantly through public health and law enforcement strategies.<sup>7</sup> CARA included new authority for Part D sponsors to implement drug management programs for beneficiaries deemed at risk of misusing or abusing frequently abused drugs, including by limiting the number of prescribers and pharmacies used by such enrollees.<sup>8</sup>

The 21<sup>st</sup> Century Cures Act (Cures Act; P.L. 114-255), also enacted in 2016, largely addressed cures and treatment research by authorizing new funding for medical research, amending the Food and Drug Administration (FDA) drug approval process, and authorizing additional funding to combat opioid addiction, among other things.<sup>9</sup> Specifically, Title B of the Cures Act, the Helping Families in Mental Health Crisis Reform Act, made numerous changes to authorities and programs of the Substance Abuse and Mental Health Services Administration, the primary agency within the Department of Health and Human Services (HHS) tasked with increasing access to community-based services to prevent and treat mental disorders and substance use disorders (SUDs).

## **SUPPORT ACT Provisions**

The SUPPORT Act consists of eight titles

- Title I: Medicaid Provisions to Address the Opioid Crisis
- Title II: Medicare Provisions to Address the Opioid Crisis
- Title III: FDA and Controlled Substance Provisions
- Title IV: Offsets
- Title V: Other Medicaid Provisions
- Title VI: Other Medicare Provisions
- Title VII: Public Health Provisions
- Title VIII: Miscellaneous

The Congressional Research Service is publishing a series of reports on this law, organized by title. This report covers Medicare provisions in Title II and Title VI and one Medicare budget

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<sup>6</sup> For more information on the PAYGO scorecards, see CRS Report R41157, *The Statutory Pay-As-You-Go Act of 2010: Summary and Legislative History*, and CRS Report RL31943, *Budget Enforcement Procedures: The Senate Pay-As-You-Go (PAYGO) Rule*.

<sup>7</sup> CRS Report R44493, *The Comprehensive Addiction and Recovery Act of 2016 (S. 524): Comparison of Senate- and House-Passed Versions*.

<sup>8</sup> The Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198), §704(g)(3); Social Security Act (SSA) 1860D-4(c).

<sup>9</sup> CRS Report R44720, *The 21st Century Cures Act (Division A of P.L. 114-255)*, and CRS Report R44718, *The Helping Families in Mental Health Crisis Reform Act of 2016 (Division B of P.L. 114-255)*.



offset in Title IV. (See **Table A-1** for a list of abbreviations used in this report and **Table A-2** for a table that includes implementation and reporting deadlines for specific provisions.)

## Medicare Coverage of Opioids and OUD Treatment

Medicare is a federal program that provides health coverage for qualified individuals aged 65 and older and certain individuals under the age of 65 who have permanent disabilities.<sup>10</sup> The program served an estimated 60 million elderly and disabled individuals in 2018.

Medicare benefits are provided through Part A, which covers hospital (inpatient) services and skilled nursing care; Part B, which covers physician services, other outpatient services, and physician-administered prescription drugs; Part C Medicare Advantage (MA), a managed care option that covers Part A and B benefits (except hospice care); and Part D, a voluntary program that provides coverage of outpatient prescription drugs through private health plans. Medicare may provide coverage for opioids prescribed by approved providers in a variety of settings including outpatient care, a hospital, a skilled nursing facility, or a hospice.

Medicare currently does not have a distinct benefit category for SUD treatment, although the program pays for certain services, such as psychiatric care and prescription drugs, deemed reasonable and necessary for treatment of alcoholism and opioid abuse when provided in settings certified by HHS.<sup>11</sup> OUD is a type of SUD,<sup>12</sup> defined by diagnostic criteria in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*. Diagnostic criteria for OUD describe a problematic pattern of opioid use leading to clinically significant impairment or distress.

Opioid overutilization is a significant issue in Medicare. A July 2018 report by the HHS Office of Inspector General (HHS OIG) found that in 2017, about one in three Part D enrollees, or 14.1 million of the 45.2 million enrollees that year, received at least one prescription opioid.<sup>13</sup> Of that group, 458,935 Part D beneficiaries received what the HHS OIG identified as high amounts of opioids (a 120 morphine milligram equivalent [MME] average dose for at least three months). That figure excludes beneficiaries with cancer or who are in hospice care. An MME measures the cumulative use of opioids over a 24-hour period.

HHS has taken a number of steps to reduce opioid prescribing and bolster treatment for enrollees who are overusing opioids. Since 2013, the HHS Centers for Medicare & Medicaid Services (CMS) has operated a voluntary opioid overutilization monitoring system (OMS) in Medicare Part D, under which CMS and Part D plan sponsors track enrollees' opioid use and may provide case management, or individual review and monitoring, for those deemed to be at risk of opioid abuse.<sup>14</sup> As noted, CARA includes provisions allowing Part D plans to limit the number of

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<sup>10</sup> CRS Report R40425, *Medicare Primer*.

<sup>11</sup> CRS In Focus IF10875, *Medicare Coverage of Opioid Addiction Treatment Services*.

<sup>12</sup> There are 11 opioid use disorder (OUD) symptoms, with severity determined by the number of symptoms individuals experience within a 12-month period: mild (2-3 symptoms), moderate (4-5 symptoms), or severe (6 or more symptoms). American Society of Addiction Medicine, "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," June 1, 2015.

<sup>13</sup> HHS Office of Inspector General (HHS OIG), "Opioid Use in Medicare Part D Remains Concerning," HHS OIG Data Brief OEI-02-18-00220, June 2018, at <https://oig.hhs.gov/oei/reports/oei-02-18-00220.pdf>. About 3% of Part D enrollees receiving opioid prescriptions received high dosages of opioids.

<sup>14</sup> CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.



prescribers and pharmacies used by at-risk enrollees, to better control drug use. CARA may implement these “lock-in” programs for enrollees identified as at risk through the OMS, starting in 2019.

HHS, Congress, and outside experts have suggested additional actions to address Medicare opioid overutilization in a more comprehensive way.<sup>15</sup> One area of focus is preventing opioid abuse by improving Medicare provider and enrollee education, limiting access to opioids, and researching and providing evidence-based opioid alternatives where possible.<sup>16</sup>

Another area of suggested action is improving Medicare coverage of medication-assisted treatment (MAT), which combines medications with counseling and behavioral therapies to provide a holistic approach to addressing OUD. MAT is considered one of the most effective treatments for the condition.<sup>17</sup> Medicare covers discrete MAT treatments, such as counseling, outpatient prescription drugs, and prescription drugs administered by a physician or other practitioner in a certified setting.<sup>18</sup> However, Medicare does not cover MAT services in federally registered opioid treatment programs (OTPs, or methadone clinics). Even when Medicare covers MAT drugs and counseling, enrollees can face interruptions if they move between care settings and cost sharing can vary.<sup>19</sup>

## Medicare Provisions of the SUPPORT Act

The SUPPORT Act includes provisions to expand Medicare coverage for MAT and strengthen Medicare Part D lock-in programs. It also contains provisions to institute new controls to prevent Medicare prescription opioid fraud and abuse by enrollees, practitioners, or dispensers. The law also includes requirements for beneficiary education regarding opioids, assuring access to evidence-based alternatives, and addressing fraud. Among major changes to Medicare, the SUPPORT Act

- Creates a new Medicare bundled payment for MAT, effective in 2022. The payment covers MAT services provided in federally registered OTPs, including dispensing of methadone.<sup>20</sup>

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<sup>15</sup> For example, see House Committee on Ways and Means, “Committee Calls on Administration to Protect Medicare Patients from Opioid Epidemic,” March 1, 2018, at <https://waysandmeans.house.gov/committee-calls-administration-protect-medicare-patients-opioid-epidemic/>.

<sup>16</sup> Testimony of Brett P. Giroir, Assistant Secretary for Health and Senior Adviser to the Secretary for Mental Health and Opioid Policy, and Kimberly Brandt, Principal Deputy Administrator for Operations, Centers for Medicare & Medicaid Services (CMS), in U.S. Congress, Senate Committee on Finance, *Tracking Opioid and Substance Use Disorders in Medicare Medicaid, and Human Services Programs*, 115<sup>th</sup> Cong., 2<sup>nd</sup> sess., April 19, 2018, at <https://www.hhs.gov/about/agencies/asl/testimony/2018-04/tracking-opioid-and-substance-use-disorders-medicare-medicaid-hhs-programs.html>. Hereinafter Giroir and Brandt, *Tracking Opioid and Substance Use Disorders*.

<sup>17</sup> CRS In Focus IF10875, *Medicare Coverage of Opioid Addiction Treatment Services*, and SAMHSA, “Medication and Counseling Treatment,” at <https://www.samhsa.gov/medication-assisted-treatment/treatment>.

<sup>18</sup> Giroir and Brandt, *Tracking Opioid and Substance Use Disorders*.

<sup>19</sup> CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*.

<sup>20</sup> Medicare typically pays for health care on a service-by-service basis. Under a bundled payment, CMS combines payments for physician, hospital, or other health care services into a single amount based on the expected costs of items and services furnished to a beneficiary during an episode of care. CMS operates bundled payment programs through the Center for Medicare and Medicaid Innovation (CMMI), which address different care needs and episodes of payment. CMS, “BPCI Advanced,” at <https://innovation.cms.gov/initiatives/bpci-advanced>. See also “Section 6001. Testing of Incentive Payments for Behavioral Health Providers for Adoption and Use of Certified Electronic Health Record Technology”

- Requires Part D plans to administer lock-in programs for enrollees identified as at risk of opioid abuse, beginning in 2022.
- Requires electronic prescribing of controlled substances in Medicare Part D to reduce errors and fraud, effective in 2021.
- Allows Part D plans to suspend payments to pharmacies in cases where there are credible allegations of fraud, beginning in 2020.

**Table 1**, below, lists Medicare provisions of the SUPPORT Act by topic. Some SUPPORT Act provisions fit into more than one category.

A section-by-section analysis of the SUPPORT Act follows **Table 1**. The section-by-section descriptions generally are organized sequentially by title and section number. In several instances where more than one provision amends the same section of law, however, the provisions are grouped together for easier reference.

**Table 1. Medicare Provisions, by Category**

Category	Section Number
Anti-fraud Activities Related to Prescribing and Dispensing Opioids	<p>Section 2003. Every Prescription Conveyed Securely</p> <p>Section 2004. Requiring Prescription Drug Plan Sponsors Under Medicare to Establish Drug Management Programs for At-Risk Beneficiaries</p> <p>Section 2008. Suspension of Payments by Medicare Prescription Drug Plans and MA-PD Plans Pending Ending Investigations of Credible Allegations of Fraud by Pharmacies</p> <p>Section 6063. Program Integrity Transparency Measures Under Medicare Parts C and D</p> <p>Section 6111. Fighting the Opioid Epidemic with Sunshine</p>
Opioid Prescribing Monitoring and Best Practices	<p>Section 2003. Every Prescription Conveyed Securely</p> <p>Section 2004. Requiring Prescription Drug Plan Sponsors Under Medicare to Establish Drug Management Programs for At-Risk Beneficiaries</p> <p>Section 2006. Encouraging Appropriate Prescribing Under Medicare for Victims of Opioid Overdose</p> <p>Section 6032. Action Plan on Recommendations for Changes Under Medicare and Medicaid to Prevent Opioids Addictions and Enhance Access to Medication-Assisted Treatment</p> <p>Section 6052. Grants to Provide Technical Assistance to Outlier Prescribers of Opioids</p> <p>Section 6062. Electronic Prior Authorization for Covered Part D Drugs</p> <p>Section 6065. Commit to Opioid Medical Prescriber Accountability and Safety for Seniors</p> <p>Section 6082. Review and Adjustment of Payments Under the Medicare Outpatient Prospective Payment System to Avoid Financial Incentives to Use Opioids Instead of Non-opioid Alternative Treatments</p> <p>Section 6092. Developing Guidance on Pain Management and Opioid Use Disorder Prevention for Hospitals Receiving Payment Under Part A of the Medicare Program</p> <p>Section 6095. Requiring the Posting and Periodic Update of Opioid Prescribing Guidance for Medicare Beneficiaries</p>
Improving Medicare Coverage of Treatment for Opioid Use Disorder	<p>Section 2001. Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders</p>

Category	Section Number
	<p>Section 2004. Requiring Prescription Drug Plan Sponsors Under Medicare to Establish Drug Management Programs for At-Risk Beneficiaries</p> <p>Section 2005. Medicare Coverage of Certain Services Furnished by Opioid Treatment Programs</p> <p>Section 6001. Testing of Incentive Payments for Behavioral Health Providers for Adoption and Use of Certified Electronic Health Record Technology</p> <p>Section 6032. Action Plan on Recommendations for Changes Under Medicare and Medicaid to Prevent Opioids Addictions and Enhance Access to Medication-Assisted Treatment</p> <p>Section 6042. Opioid Use Disorder Treatment Demonstration Program</p> <p>Section 6064. Expanding Eligibility for Medication Therapy Management Programs Under Part D</p> <p>Section 6083. Expanding Access Under the Medicare Program to Addiction Treatment in Federally Qualified Health Centers and Rural Health Clinics</p> <p>Section 6084. Studying the Availability of Supplemental Benefits Designed to Treat or Prevent Substance Use Disorders Under Medicare Advantage Plans</p>
Improving Information Sharing/Education on Opioid Use	<p>Section 2002. Comprehensive Screenings for Seniors</p> <p>Section 6021. Medicare Opioid Safety Education</p> <p>Section 6102. Requiring Medicare Advantage Plans and Part D Prescription Drug Plans to Include Information on Risks Associated with Opioids and Coverage of Non-pharmacological Therapies and Non-opioid Medications or Devices Used to Treat Pain</p> <p>Section 6103. Requiring Medicare Advantage Plans and Prescription Drug Plans to Provide Information on the Safe Disposal of Prescription Drugs</p>
Mandated Studies and Reports	<p>Section 6012. Study on Abuse-Deterrent Opioid Formulations Access Barriers Under Medicare</p> <p>Section 6072. Medicare Payment Advisory Commission Report on Opioid Payment, Adverse Incentives, and Data Under the Medicare Program</p> <p>Section 6085. Clinical Psychologist Services Models Under the Center for Medicare and Medicaid Innovation; Government Accountability Office Study and Report</p> <p>Section 6086: Dr. Todd Graham Pain Management Study.</p> <p>Section 6092. Developing Guidance on Pain Management and Opioid Use Disorder Prevention for Hospitals Receiving Payment Under Part A of the Medicare Program</p> <p>Section 6093. Requiring the Review of Quality Measures Relating to Opioids and Opioid Use Disorder Treatments Furnished Under the Medicare Program and Other Federal Health Care Programs</p> <p>Section 6094. Technical Expert Panel on Reducing Surgical Setting Opioid Use; Data Collection on Perioperative Opioid Use</p> <p>Section 6104. Revising Measures Used Under the Hospital Consumer Assessment of Healthcare Providers and Systems Survey Relating to Pain Management</p>
Medicare Funding Offset	<p>Section 4002. Requiring Reporting by Group Health Plans of Prescription Drug Coverage Information for Purposes of Identifying Primary Payer Situations Under the Medicare Program</p>

**Source:** Congressional Research Service (CRS) analysis of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act; P.L. 115-271).

## **Title II: Medicare Provisions to Address the Opioid Crisis**

### **Section 2001. Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders**

#### ***Background***

In general, telehealth services can be provided to Medicare beneficiaries under Parts A and B, although a separate payment for telehealth services may apply in certain situations.<sup>21</sup> Under Part A, telehealth services may be used to treat hospital inpatients, but there is no statutory authority for a separate payment under the Medicare hospital Inpatient Prospective Payment System (IPPS). Although no payment is involved, CMS guidance for Part A explicitly identifies telehealth as an alternative to face-to-face encounters when a physician writes an order for home health services.

Under Part B, payments for telehealth services must follow Social Security Act (SSA) Section 1834(m), which places restrictions on the location, provider, telehealth technology, and certain other parameters. The facility where the beneficiary is located is referred to as the *originating site*, and the site where the practitioner is located is referred to as the *distant site*. Medicare makes a payment to the physician or practitioner at the distant site for rendering the telehealth service, and a separate facility fee to the originating site. SSA Section 1834(m) requires that the originating site meet one of three conditions (two of which are geographic, one programmatic): telehealth service originating sites must be located in a rural health professional shortage area or a county not included in a Metropolitan Statistical Area (MSA), or from an entity that participates in a federal telemedicine demonstration project. Qualifying originating sites include an office of a physician or practitioner, a critical access hospital (CAH), a rural health clinic, a federally qualified health center, a hospital, a hospital- or CAH-based renal dialysis center, a skilled nursing facility, or a community mental health center. Under Part C, MA plans must provide telehealth services to the extent that they are a covered service under Medicare Part B.

The Bipartisan Budget Act of 2018 (BBA 18; P.L. 115-123) expands telehealth under Medicare in four ways: (1) by increasing the opportunities for certain accountable care organization (ACO) and Medicare shared savings plans models to receive telehealth payments, beginning January 1, 2020 (BBA 18 §50324); (2) by eliminating the originating site restrictions for telehealth services for acute stroke evaluation, beginning January 1, 2019 (BBA 18 §50325); (3) by allowing MA plans to provide additional telehealth benefits (minus capital and infrastructure costs), which are treated as if they are benefits required under original Medicare (Parts A and B) for payment purposes starting in plan year 2020 (BBA 18 §50323); and (4) by permitting Medicare patients with end-stage renal disease on home dialysis to receive monthly clinical assessments at home or at freestanding dialysis facilities via telehealth, beginning January 1, 2019 (BBA 18 §50302).

#### ***Provision***

Section 2001 amends SSA Section 1834(m) to eliminate the geographic originating site requirements listed above for telehealth services furnished for treating SUD and co-occurring mental health disorders. In order to receive a facility fee for SUD telehealth services, the originating site must be one of the qualifying originating sites listed above (excluding freestanding dialysis facilities). The provision also adds the home of an individual as a

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<sup>21</sup> CMS, “Telehealth Services,” at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf>.

permissible originating site for SUD telehealth services; however, facility fees would not apply to originating sites from homes. Although the provision states that the amendments in this section are to take effect beginning July 1, 2019, the HHS Secretary (Secretary) is given the authority to implement the modifications immediately by interim final rule.

No later than five years after enactment, the Secretary is to report to Congress on the impact of this modification on health care utilization and health outcomes related to substance use disorders, including emergency department visits. To support this effort, \$3 million is to be transferred from the Medicare Part B Trust Fund to remain available until expended.

## **Section 2002. Comprehensive Screenings for Seniors**

### ***Background***

Medicare beneficiaries are entitled to annual “well” visits. The first such visit, furnished in the first year of enrollment, is the Initial Preventive Physical Examination (IPPE), often called the “welcome to Medicare” visit (SSA §1861(w)). Annually thereafter, beneficiaries are entitled to an annual wellness visit (AWV) and personalized prevention plan services (SSA §1861(hhh)). Regulations at 42 C.F.R. Part 410, Subpart B, specify, for each visit, the provision of a health assessment; a suite of physical measurements (e.g., blood pressure); and education, counseling, and referral for additional preventive services that are covered separately. Consultative services that must be furnished include, among others, end-of-life planning (upon agreement with the patient) and screenings for depression and alcohol misuse.

### ***Provision***

Section 2002 amends the IPPE authority in SSA Section 1861(w) to include a review of the beneficiary’s current opioid prescriptions, defined as (1) a review of potential risk factors for OUD; (2) an evaluation of pain severity and the treatment plan; (3) the provision of information on non-opioid treatment options; and (4) referral to a specialist, as appropriate. In addition, it adds to the required elements of the IPPE “screening for potential substance use disorders.” It also amends the AWV authority in SSA Section 1861(hhh) to include the same review of the beneficiary’s current opioid prescriptions as for the IPPE, as well as “screening for potential substance use disorders and referral for treatment as appropriate.” These additional requirements apply to visits furnished on or after January 1, 2020. The provision shall not be construed to prohibit separate payments for additional services for substance abuse that are furnished on the same day as an IPPE or AWV.

## **Section 2003. Every Prescription Conveyed Securely**

## **Section 6062. Electronic Prior Authorization for Covered Part D Drugs<sup>22</sup>**

### ***Background***

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173) established a voluntary, outpatient prescription drug benefit under Medicare Part D, effective January 1, 2006. Under Part D, private insurers and other sponsors enter into annual contracts

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<sup>22</sup> Section-by-section descriptions in this report generally are organized sequentially by title and section number. In instances where more than one provision amends the same section of law, the provisions are grouped together for easier reference.

with CMS to provide a defined package of outpatient drug benefits. Part D prescription drug coverage is provided through drug-only plans (PDPs) or Part C managed care plans that include a Part D benefit (MA-PDs). (This report generally will refer to Part D plans, unless the legislative language specifies only one type of plan.)

As part of contract requirements, Part D plans must support an electronic prescription (e-prescribing) program, defined by CMS as the use of electronic media to transmit prescription-related information between a prescriber, dispenser, pharmacy benefit manager, and/or health plan, either directly or through an intermediary, including an e-prescribing network.<sup>23</sup> Part D plans' e-prescribing systems are to allow the exchange of specific information, including Part D enrollee eligibility; plan benefits; the drug being prescribed or dispensed; other drugs listed in a medication history; and the availability of lower-cost, therapeutically appropriate alternatives (if any) for the drug prescribed. Technical transmission requirements for e-prescribing networks are based on standards set by the National Council for Prescription Drug Programs (NCPDP) and other outside organizations. E-prescribing is optional for physicians and pharmacies. However, physicians and pharmacies that transmit e-prescriptions and related communications with Part D plans must use CMS standards.

### ***Provisions***

Section 2003 amends SSA Section 1860D-4(e) to require that a prescription for a covered Part D Schedule II, III, IV, or V controlled substance be transmitted by a health care practitioner electronically in accordance with an approved electronic prescription drug program.<sup>24</sup> The change will apply to drugs prescribed on or after January 1, 2021.

The Secretary is to define circumstances in which the e-prescribing requirement may be waived, including

- cases where the prescriber and dispenser are the same entity;
- prescriptions that cannot be transmitted electronically due to the constraints of the most recently implemented version of NCPDP standards known as NCPDP SCRIPT;
- a prescription issued by a practitioner who has received a maximum one-year waiver (or renewal of a waiver) of the e-prescribing requirement due to demonstrated economic hardship, technological limitations not reasonably within the control of the practitioner, or other exceptional circumstances;
- a situation where a practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition;
- a prescription under a research protocol;
- a prescription the FDA requires to contain certain elements that cannot be accomplished with electronic prescribing, such as a drug with risk evaluation and mitigation strategies; and

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<sup>23</sup> CMS, "E-Prescribing," at <https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html>. See also SSA §1860D-4(e) and 42 C.F.R. §423.505(b)(6).

<sup>24</sup> Drugs and other substances considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. A list of the schedules is published annually in Title 21 C.F.R. §§1308.11-1308.15. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused.



- a prescription for an individual who receives hospice care that is not covered under the title or is a resident of a nursing facility who is dually eligible for Medicare and Medicaid.

Part D sponsors and pharmacists are not required to verify that prescribers have a waiver from e-prescribing rules. The requirements are not to be construed as affecting a Part D plan's ability to cover, or a pharmacist's ability to continue to dispense, Part D drugs from otherwise valid written, oral, or fax prescriptions consistent with applicable laws and regulations.

No later than one year after enactment, the U.S. attorney general is to update requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances.<sup>25</sup>

Section 6062 amends SSA Section 1860D-4(e) to require that Part D e-prescribing systems allow for processing of formulary prior authorization requirements. *Prior authorization* refers to a requirement that a network pharmacy receive approval from a Part D plan before filling a prescription for a covered drug. Beginning no later than January 1, 2021, the Medicare Part D e-prescribing system is to provide for secure electronic transmittal of (1) a prior authorization request from a prescribing health care professional to the plan sponsor for a covered drug for a Part D enrollee and (2) a response from the plan to the prescribing professional. To be treated as an electronic transmission, a transmission must comply with technical standards adopted by the Secretary in consultation with the NCDPC; other standard-setting organizations deemed appropriate by the Secretary; and stakeholders including plan sponsors, health care professionals, and health information technology software vendors. For purposes of the provision, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form is not treated as an electronic transmission.

## **Section 2004. Requiring Prescription Drug Plan Sponsors Under Medicare to Establish Drug Management Programs for At-Risk Beneficiaries**

## **Section 2006. Encouraging Appropriate Prescribing Under Medicare for Victims of Opioid Overdose**

## **Section 2007. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program for At-Risk Beneficiaries<sup>26</sup>**

### ***Background***

Since 2013, CMS has operated a two-part system to combat inappropriate use of opioids in Part D. First, CMS has encouraged Part D sponsors to identify potential opioid overutilizers, conduct

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<sup>25</sup> Drug Enforcement Administration rules for electronic prescribing of schedules II, III, IV, and V controlled substance prescriptions at 21 C.F.R. 1311.120 include requirements for two-factor authentication. Such authentication is to include two of the following three items: (1) something only the practitioner knows, such as a password or response to a challenge question; (2) something the practitioner is, biometric data such as a fingerprint or iris scan; and (3) something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access. Regulations are at [https://www.deadiversion.usdoj.gov/21cfr/cfr/1311/subpart\\_c100.htm#116](https://www.deadiversion.usdoj.gov/21cfr/cfr/1311/subpart_c100.htm#116).

<sup>26</sup> Section-by-section descriptions in this report generally are organized sequentially by title and section number. In instances where more than one provision amends the same section of law, the provisions are grouped together for easier



retrospective reviews of prescribing data, and perform case management with beneficiaries' prescribers to coordinate care.<sup>27</sup> Plan sponsors implementing this review system may reject opioid claims that exceed medical necessity. Second, CMS has operated the system-wide OMS, which separately reviews Part D prescription data to identify enrollees who may be at significant risk of overutilizing opioids based on (1) opioid dosage and (2) the number of prescribers or pharmacies used by an enrollee.<sup>28</sup> Part D plans that operate drug management programs must review the opioid use of enrollees who are identified by CMS through the OMS.

CARA allows Part D plans to limit (*lock in*) the number of prescribers and pharmacies used by enrollees at risk of opioid overutilization, starting in 2019. In April 2018, CMS issued rules to implement CARA that integrated the lock-in provisions with the OMS and Part D plan review system.<sup>29</sup> Under the rules, plans that operate a drug management program can limit a beneficiary's access to coverage to frequently abused drugs through a beneficiary-specific pharmacy control and/or a lock-in requirement. The rules require Part D plans to perform case management for enrollees identified through OMS criteria as *potentially* at risk for opioid abuse. After reviewing OMS information and consulting with prescribers, Part D plans are to determine whether to give a potentially at-risk enrollee the more stringent designation of an at-risk enrollee. Plans may enroll at-risk enrollees in lock-in programs.

Part D sponsors must follow specific procedures when implementing CARA lock-in programs. Plans must provide enrollees identified as potentially at risk with an initial notice of their status. The initial notice informs the enrollee that he or she has 30 days to submit relevant information and to provide any pharmacy and prescriber preferences. Enrollees determined to be at risk after plan review receive a second notice (within 60 day of the initial notice) telling them of their designation, their pharmacy and prescriber choices, and their right to a redetermination.<sup>30</sup> Enrollees are exempted from lock-in programs if they are in long-term or hospice care or if they are being actively treated for cancer pain, and the Secretary is allowed to set additional exemptions. Individual lock-in limitations expire (1) when a beneficiary demonstrates she or he is no longer at risk; (2) at the end of a one-year period, unless the limitation is extended for an additional year; or (3) at the end of a two-year period, if the limitation was extended. If a lock-in limitation is continued beyond an initial 12-month period, the enrollee receives an additional second notice.<sup>31</sup>

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reference.

<sup>27</sup> CMS, "Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 2, 2012, p. 131, at <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf>. The monitoring excludes beneficiaries with cancer or who are in hospice care.

<sup>28</sup> For a description of the overutilization monitoring system, see CMS "Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," p. 234; at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>.

<sup>29</sup> CMS, "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," 83 *Federal Register* 16440, April 16, 2018. For purposes of the program, CMS designated opioids and benzodiazepines as frequently abused drugs.

<sup>30</sup> Enrollees determined not to be at risk receive an alternate second notice informing them of such and telling them they are not subject to the lock-in provisions.

<sup>31</sup> CMS, CARA/Opioids, Powerpoint Presentation, May 3, 2018, at [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Medicare-Part-D-Spring-Conference-2018-CARA\\_Opioid-Presentation.pdf](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Medicare-Part-D-Spring-Conference-2018-CARA_Opioid-Presentation.pdf).

## **Provisions**

Section 2004 amends SSA Section 1860D-4(c) to require Part D plans to implement lock-in provisions for at-risk beneficiaries for plan years beginning on or after January 1, 2022.

Section 2006 amends SSA Section 1860D-4(c)(5)(C) to require that, for plan years beginning no later than January 1, 2021, a Part D-eligible individual who is identified as having a history of opioid-related overdoses (as defined by the Secretary), and who is not exempted from lock-in requirements, shall be included as a potentially at-risk beneficiary under a drug management program. The Secretary shall identify Part D-eligible individuals with a history of opioid-related overdoses and notify the Part D sponsor of the plan in which the individual is enrolled of the identification.

Section 2007 amends SSA Section 1860D-4(c)(5) to expedite the appeal process of Part D enrollees determined to be at risk of opioid abuse. If an enrollee appeals his or her at-risk designation and a plan sponsor denies the appeal in whole or in part, the case is to be automatically forwarded to an independent, outside entity contracted with the Secretary. The change applies no later than January 1, 2021.

## **Section 2005. Medicare Coverage of Certain Services Furnished by Opioid Treatment Programs**

### ***Background***

OUD often is treated through medication-assisted treatment (MAT), which combines medication with other services, such as behavioral and cognitive therapies.<sup>32</sup> The FDA has approved three drugs for use in MAT: methadone, buprenorphine, and naltrexone.<sup>33</sup> Due to the potential for abuse, methadone and buprenorphine are scheduled drugs under the Controlled Substances Act.<sup>34</sup> Naltrexone is not a controlled substance, because it carries no known risk of abuse; as a result, most health care providers who are licensed to prescribe drugs may prescribe naltrexone.

Methadone is a Schedule II controlled substance, with high abuse potential. Buprenorphine is a Schedule III controlled substance, with some abuse potential but less than methadone. Practitioners must have specific training and approval to treat OUD with buprenorphine.<sup>35</sup> Under federal law, methadone for OUD treatment is available only through opioid treatment programs (OTPs).<sup>36</sup> The OTPs, often called methadone clinics, provide services to treat individuals diagnosed with OUD, including dispensing buprenorphine and naltrexone and administering methadone on a daily basis, with staff observing patients, who usually take the drug orally as a

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<sup>32</sup> Substance Abuse and Mental Health Services Administration (SAMHSA), “Medication Assisted Treatment (MAT),” at <https://www.samhsa.gov/medication-assisted-treatment>.

<sup>33</sup> Methadone is prescribed in other forms to treat acute and chronic pain.

<sup>34</sup> CRS Report R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis*, and CRS Report R45279, *Buprenorphine and the Opioid Crisis: A Primer for Congress*.

<sup>35</sup> The Drug Addiction and Treatment Act of 2000 (DATA 2000; P.L. 106-310) enables a physician to obtain a waiver to treat opioid addiction with buprenorphine outside an opioid treatment program (OTP). The CARA-authorized nurse practitioners and physician assistants who meet certain criteria obtain DATA 2000 waivers.

<sup>36</sup> For a definition of OTPs, see 42 C.F.R. 8.2, Definitions.

liquid.<sup>37</sup> Under federal law, OTP treatment for OUD must include behavioral therapy as well as methadone maintenance treatment or other MAT drug treatments.<sup>38</sup>

Medicare covers items and services included in broad Medicare benefit categories, such as hospital care, physician services, prescription drugs, and many other areas, but Medicare law generally does not explicitly list all reasonable and necessary items and services that might be required to treat a beneficiary.<sup>39</sup> Medicare does not explicitly offer an OUD benefit, although many of the services considered reasonable and necessary for OUD treatment are covered under broad Medicare benefit categories, such as prescription drugs, qualified psychologist services, physician services, and hospitalization. Medicare statutes do not recognize OTP clinics for reimbursement. Because methadone for MAT may be provided only in OTPs, it is not covered by Medicare.

In addition, Medicare law often does not group necessary treatments to treat specific conditions, diseases, or diagnoses as a payment package or bundle, including OTP services.<sup>40</sup>

### ***Provision***

Section 2005 amends SSA Section 1861(s)(2) to add Medicare coverage for items and services provided by OTPs for OUD treatment. Under the provision, Medicare-covered OTP services are to include the dispensing and administration of various forms of FDA-approved MAT drugs; SUD counseling as authorized under state law; individual and group therapy; toxicology testing; and other items and services as determined appropriate by the Secretary, except for meals and transportation.

Beginning on or after January 1, 2020, Medicare will pay OTPs 100% (less any beneficiary co-payments) of a bundled payment for OUD treatment provided to Medicare beneficiaries during an episode of care (as defined by the Secretary). The Secretary may implement one or more OTP payment bundles based on the medication dispensed, the scope of furnished services, beneficiary characteristics, and other factors the Secretary determines appropriate. In developing payment bundles, the Secretary may consider OTP payment rates for comparable services paid by Medicaid or TRICARE.<sup>41</sup> OTP payment bundles are to be updated annually.

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<sup>37</sup> When methadone is used to treat OUD, it is only dispensed and is not available by prescription.

<sup>38</sup> OTPs, 42 C.F.R. 8.2, Definitions.

<sup>39</sup> Medicare covers services that are “reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member,” SSA §1862(a)(1).

<sup>40</sup> Medicare typically pays for health care on a service-by-service basis. Under a bundled payment, CMS combines payments for physician, hospital, or other health care services into a single amount based on the expected costs of items and services furnished to a beneficiary during an episode of care. Medicare covers most care for certain diseases through bundled payments, such as end-stage renal disease.

<sup>41</sup> TRICARE is part of the Department of Defense health care delivery system, which purchases services from civilian providers through a health insurance-like program. See CRS In Focus IF10530, *Defense Primer: Military Health System*.

## **Section 2008. Suspension of Payments by Medicare Prescription Drug Plans and MA-PD Plans Pending Ending Investigations of Credible Allegations of Fraud by Pharmacies**

### ***Background***

The Secretary may suspend payments to Medicare providers and suppliers pending an investigation of credible fraud allegations, unless there is good reason not to suspend payments.<sup>42</sup> The Secretary is required to consult with the HHS OIG or, as appropriate, the Department of Justice to determine whether the fraud allegations are credible.<sup>43</sup>

### ***Provision***

Section 2008 amends SSA Section 1860D-12(b) by adding a new paragraph authorizing Medicare Part D plan sponsors to suspend payments to pharmacies in the plans' networks, pending investigation of a credible fraud allegation. Plan sponsors are required to notify the Secretary of any payment suspension and may do so using a secure website portal, such as the program integrity portal established under Section 6063. When a Part D plan sponsor suspends payments pending a credible fraud allegation investigation, the plans may conduct post-payment review of the suspect pharmacy's Part D claims. Section 2008 also clarifies that a fraud hotline call, without further evidence, is not considered a credible fraud allegation for payment suspension purposes. The section applies to Part D plan years beginning January 1, 2020.

## **Title IV: Offsets**

## **Section 4002. Requiring Reporting by Group Health Plans of Prescription Drug Coverage Information for Purposes of Identifying Primary Payer Situations Under the Medicare Program**

### ***Background***

Medicare generally is the *primary payer* for medical services, meaning it pays health claims first. If a beneficiary has other health insurance, that insurance is billed after Medicare has made payments to fill all, or some, of any gaps in Medicare coverage. In certain situations, however, the Medicare Secondary Payer Act (MSP) prohibits Medicare from making payments for an item or service when payment has been made, or can reasonably be expected to be made, by another insurer, such as an employer-sponsored group health plan.<sup>44</sup> Congress initiated the MSP in 1980 to ensure that certain insurers met their contractual obligations to beneficiaries and to reduce Medicare expenditures.<sup>45</sup>

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<sup>42</sup> SSA §1862(g)(3)(o).

<sup>43</sup> 42 C.F.R. 405.371, "Suspension, Offset, and Recoupment of Medicare Payments to Providers and Suppliers of Services."

<sup>44</sup> CMS, *Medicare Secondary Payer Manual*, Chapter 2 "MSP Provisions," Rev. April 28, 2016, at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019017.html>. Hereinafter CMS, *Medicare Secondary Payer Manual*.

<sup>45</sup> CMS, *Medicare Secondary Payer Manual*. The Omnibus Budget Reconciliation Act of 1980 (P.L. 96-499) set MSP rules for non-group health plans. Congress has amended MSP standards numerous times since 1980.

Congress requires group health plans to submit information to the Secretary regarding active, covered individuals in their plans. Active, covered individuals are people who may be Medicare eligible and who are currently employed or who are spouses or dependents of workers who are covered by a group health plan and may be Medicare eligible. The Medicare program, after receiving the data on these individuals, provides insurers with information about primary and secondary coverage for individuals that are identified as Medicare beneficiaries.

### ***Provision***

Section 4002 amends SSA Section 1862(b)(7)(A) to add a requirement that group health plan sponsors identify situations in which the plans are to be the primary payer with respect to benefits relating to Medicare Part D prescription drug coverage. The change aims to help ensure that Medicare is billed properly. The provision is effective starting January 1, 2020.<sup>46</sup>

## **Title VI: Other Medicare Provisions**

### **Section 6001. Testing of Incentive Payments for Behavioral Health Providers for Adoption and Use of Certified Electronic Health Record Technology**

#### ***Background***

The Health Information Technology for Economic and Clinical Health Act (P.L. 111-5) established Medicare and Medicaid electronic health record (EHR) incentive programs to encourage widespread adoption of EHR technology. (The programs are now called the Medicaid and Medicare Promoting Interoperability Programs.) The programs, launched in 2011, established incentive payments to acute-care hospitals and nonhospital-based physicians that demonstrate “meaningful use” of certified EHR technology (i.e., by using electronic health systems to perform specified functions associated with the delivery of health care). As required in statute, the incentive payments are to be phased out over time (for Medicare, the payments have been phased out). Many behavioral health providers are not eligible to participate in these programs.

The Center for Medicare and Medicaid Innovation (CMMI), established by SSA Section 1115A, was given the task of testing innovative health care payment and delivery models with the potential to preserve or improve quality of care and reduce Medicare, Medicaid, and State Children’s Health Insurance Program (CHIP) expenditures. In selecting models, the Secretary is required to give preference to those that improve the coordination, quality, and efficiency of health care services. The Patient Protection and Affordable Care Act (P.L. 111-148, as amended) appropriated \$10 billion to support CMMI activities from FY2011 through FY2019 and \$10 billion for each subsequent 10-year period. CMMI innovation models include Episode-based Payment Initiatives; Accountable Care Organization Initiatives (e.g., Next Generation ACO Model); Primary Care Transformation Initiatives (e.g., Comprehensive Primary Care Plus); and Initiatives to Speed the Adoption of Best Practices (e.g., Partnership for Patients), among others.

#### ***Provision***

Section 6001 amends SSA Section 1115A(b)(2)(B) to expand the list of models that CMMI may test to include a model that provides incentive payments to behavioral health providers, as

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<sup>46</sup> CBO, Estimated Direct Spending and Revenue Effects of H.R. 6, Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, September 27, 2018, at <https://www.cbo.gov/system/files?file=2018-09/hr6ConferenceSept27.pdf>.

specified, in exchange for the providers' adopting and using certified EHR technology to improve care coordination and quality.

## **Section 6012. Study on Abuse-Deterrent Opioid Formulations Access Barriers Under Medicare**

### ***Background***

The MMA bars the Secretary from setting a Part D central formulary, or list of covered drugs.<sup>47</sup> However, individual Part D plans must comply with requirements designed to ensure provision of adequate formularies. Part D plans must cover at least two drugs in each category or class used to treat the same medical condition (unless only one drug is available in the category or class, or two drugs are available but one drug is clinically superior). Part D plans also must cover substantially all available drugs in six categories: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. Part D plans are allowed to institute formulary utilization restrictions, including imposing higher cost sharing for more expensive drugs; requiring enrollees to receive prior approval before filling certain prescriptions; or instituting step therapy, meaning enrollees must first try a plan's preferred alternative to a prescribed drug. CMS reviews Part D formularies annually to ensure they include the required range of drugs and are not designed in such a way as to discriminate against individuals with certain health conditions.<sup>48</sup>

### ***Provision***

Section 6012 requires that, no later than one year after enactment, the Secretary send a study to Congress determining whether Part D enrollees with chronic pain have adequate access to abuse-deterrent opioids. The provision defines an *abuse-deterrent opioid* as an opioid with physical or chemical barriers, agonist or antagonist combinations, aversion properties, delivery system mechanisms, or other features designed to prevent abuse of such opioid.<sup>49</sup>

The study is to consider any barriers to use of abuse-deterrent opioids, such as cost-sharing tiers, step therapy requirements, drug price, and prior authorization requirements. In addition, the study is to assess the effectiveness of abuse-deterrent opioid formulations in preventing opioid abuse or misuse; the impact of the use of abuse-deterrent opioid formulations on the use or abuse of other prescription or illicit opioids (including changes in deaths from such opioids); and other possible public health consequences of abuse-deterrent opioids, such as an increase in rates of human immunodeficiency virus.

## **Section 6021. Medicare Opioid Safety Education**

### ***Background***

The Secretary is required to prepare and distribute a public notice each year explaining Medicare benefits. This benefit-related overview must explain the scope of medical services that are—and

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<sup>47</sup> The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) noninterference provision can be found at SSA §1860D-11(i).

<sup>48</sup> CMS, *Medicare Prescription Drug Manual*, Chapter 6, "Part D Drugs and Formulary Requirements," Rev. January 15, 2016, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>.

<sup>49</sup> An *agonist* activates certain receptors in the brain. An *antagonist* blocks opioids by attaching to opioid receptors without activating them.



are not—covered by Medicare. It also must contain information regarding specified Medicare beneficiary rights, responsibilities, and educational resources (SSA §1804). The Secretary is required to consult with health insurers and groups representing seniors during preparation of the notice. The completed notice must be delivered to all individuals entitled to benefits under Medicare Parts A or B.

To meet the notice requirement, the CMS produces a handbook entitled *Medicare & You* (CMS Product No. 10050). CMS mails the handbook to Medicare beneficiaries in late September, prior to the Part C and Part D open enrollment period. *Medicare & You* also is available publicly on the CMS website, where beneficiaries may opt out of receiving a physical copy of the handbook and instead choose electronic delivery of future releases. In addition to setting forth statutory requirements, the handbook includes Medicare information, such as answers to frequently asked questions and lists of available health and drug plans.

### ***Provision***

Section 6021 amends SSA Section 1804 to require the Secretary to compile and provide educational resources in the annual notice, beginning in 2019, covering the topics of opioid use, pain management, and alternative pain management treatments. Section 6021 also requires the annual notice to include a suggestion that Medicare beneficiaries consult with a physician on opioid use and pain management.

## **Section 6032. Action Plan on Recommendations for Changes Under Medicare and Medicaid to Prevent Opioids Addictions and Enhance Access to Medication-Assisted Treatment**

### ***Background***

The Secretary declared the opioid crisis a public health emergency in October 2017, due to increasing rates of opioid-related deaths and OUD.<sup>50</sup> The Secretary extended the initial public health emergency in January, April, July, and October 2018.<sup>51</sup>

According to experts, a number of factors may have contributed to the opioid crisis, including changes in medical practice, overprescribing of opioid drugs, poor social and economic conditions, improvements in manufacturing that make concentrated forms of opioid drugs readily available, and inadequate oversight.<sup>52</sup> Some reports have attributed prescription opioid overutilization to aggressive treatment of chronic and acute pain.<sup>53</sup> Section 101 of CARA required the Secretary to establish a Pain Management Best Practices Inter-Agency Task Force (Pain Task

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<sup>50</sup> HHS, “Determination That a Public Health Emergency Exists” October 26, 2017, at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx>.

<sup>51</sup> The opioid crisis public health emergency was extended on January 19, 2018; April 20, 2018; July 18, 2018; and October 19, 2018. U.S. Government Accountability Office, *Opioid Crisis: Status of Public Health Emergency Authorities*, September 26, 2018.

<sup>52</sup> Nabarun Dasgupta, “Opioid Crisis: No Easy Fix to Its Social and Economic Determinants,” *American Journal of Public Health*, vol. 108, no. 2 (February 2018), pp. 182-186; and *The President’s Commission on Combating Drug Addiction and the Opioid Crisis, Final Report*, November 1, 2017, at [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-1-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf).

<sup>53</sup> *The President’s Commission on Combating Drug Addiction and the Opioid Crisis, Final Report*, November 1, 2017, at [https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-1-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf). See also CRS CRS In Focus IF11041, *The Opioid Epidemic and the U.S. Labor Market*.



Force).<sup>54</sup> In cooperation with the Department of Veterans Affairs and the Secretary of Defense, the Pain Task Force was to identify, review, and determine whether there were gaps or inconsistencies in pain management best practices developed or adopted by federal agencies. The Pain Task Force also was to make recommendations to address best practice gaps, obtain public comment, and develop a strategy for disseminating pain management best practices.

In addition to the Pain Task Force, the Secretary identified a five-part strategy to combat the health emergency presented by the opioid abuse crisis<sup>55</sup>

- Improve access to treatment and recovery services.
- Promote use of overdose-reversing drugs.
- Strengthen understanding of the epidemic through better public health surveillance.
- Support cutting edge research on pain and addiction.
- Advance better practices for pain management.

### ***Provision***

Section 6032 directs the Secretary to collaborate with the Pain Task Force to develop an action plan and recommendations on changes to Medicare and Medicaid to prevent opioid addiction and enhance access to MAT.<sup>56</sup> MAT is defined to include OTPs, behavioral therapy, and medications to treat SUD. In developing the action plan, the Secretary must review Medicare and Medicaid payment and coverage policies that may pose obstacles to effectively responding to the opioid crisis and make recommendations as the Secretary determines appropriate on specified areas related to OUD treatment.

Beginning within three months of enactment, Section 6032 requires the Secretary to convene a public stakeholder meeting and request public feedback on ways CMS can address the opioid crisis through development and application of the action plan. The Secretary is to include federal agency, industry, researcher, provider, and patient representatives in the stakeholder meeting.

Section 6032 requires the Secretary, before June 1, 2020, to submit to Congress and make public a report that summarizes the results of the Secretary's action plan review and any recommendations; identifies the Secretary's planned next steps for the action plan; and evaluates price trends for drugs used to reverse opioid overdoses, such as naloxone, including recommendations to lower consumer costs.

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<sup>54</sup> The Pain Management Best Practices Inter-Agency Task Force was established under CARA §101. See CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*.

<sup>55</sup> HHS, "Secretary Price Announces HHS Strategy for Fighting Opioid Crisis," April 19, 2017, at <https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html>; and HHS, "HHS Establishing Pain Management Task Force/Seeks Member Nominations," August 25, 2017, at <https://www.hhs.gov/about/news/2017/08/25/hhs-establishing-pain-management-task-force-seeks-member-nominations.html>.

<sup>56</sup> CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*.

## **Section 6042. Opioid Use Disorder Treatment Demonstration Program**

### ***Background***

During the current opioid crisis, policymakers have identified potential OUD treatment barriers that may have contributed to the increasing prevalence of opioid addictions. Such barriers include a limited number of approved addiction treatment providers, particularly in rural areas; limited insurance coverage; and health insurance prior authorization and step therapy (or fail-first) requirements.<sup>57</sup> Medicare and Medicaid payment for OUD treatment, as well as the legal status and restrictions on some MAT drugs, also may have limited OUD treatment access.<sup>58</sup>

Some addiction specialists argue that MAT drugs are the most important OUD treatment component. These specialists contend that if MAT drugs were more accessible through primary care providers, more individuals could readily receive treatment and fewer patients would relapse.<sup>59</sup> Other policymakers note that MAT might not be right for all individuals with OUD and that treatment approaches might need to be tailored to an individual.<sup>60</sup> Some individuals might benefit most from counseling and related support services, and some might benefit from one drug regimen over another.

### ***Provision***

Section 6042 amends SSA Title XVIII by adding new Section 1866F, which requires the Secretary to conduct a four-year demonstration project on ways to increase Medicare beneficiary access to OUD treatment services, improve beneficiary physical and mental health outcomes, and reduce Medicare expenditures, beginning no later than January 1, 2020.

Section 6042 requires the Secretary to design the demonstration so it can be evaluated to determine the extent to which it achieved specified purposes. Within three months of enactment, the Secretary is to consult with addiction specialists, primary care clinicians, and beneficiary groups on the demonstration design. Entities interested in participating in the demonstration must meet specified requirements, although the Secretary may give preference to entities in areas with OUD prevalence that exceeds the national average. Demonstration participants must establish OUD care teams that include specified practitioners, including at least one physician who furnishes primary care or addiction treatment services. Care teams may include other state-licensed practitioners who can provide psychological counseling, social support, and other services.

To receive payment under the demonstration, participants must furnish OUD treatment services to beneficiaries through OUD care teams; meet minimum criteria established by the Secretary; and submit data on each beneficiary, as specified by the Secretary. The data must be appropriate to monitor and evaluate the demonstration, determine if minimum criteria are met, and determine specified incentive payments.

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<sup>57</sup> CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*. Step therapy approaches require a patient to try counseling or other psychosocial approaches before being offered more intensive forms of treatment or MAT.

<sup>58</sup> CRS Report R44987, *The Opioid Epidemic and Federal Efforts to Address It: Frequently Asked Questions*.

<sup>59</sup> Jeffrey H. Samet, Michael Botticelli, and Monica Bharel, “Methadone in Primary Care—One Small Step for Congress, One Giant Leap for Addiction Treatment,” *New England Journal of Medicine*, July 11, 2018.

<sup>60</sup> Kate Sheridan, “How Effective Is Medication-Assisted Treatment for Addiction? Here’s the Science,” *STAT*, May 15, 2017.

To be eligible to participate in the demonstration, physicians and other practitioners must be enrolled in Medicare; be authorized to prescribe or dispense narcotic drugs; and have a current Drug Addiction and Treatment Act of 2000 (DATA 2000; P.L. 106-310) waiver, which allows them to prescribe Schedule III, IV, and V controlled substances.<sup>61</sup> For beneficiaries to voluntarily enroll in the demonstration (or terminate at will), they must be entitled to or enrolled in Medicare Parts A and B but not Medicare Part C, have a current OUD diagnosis, and meet other criteria the Secretary deems appropriate. Individuals eligible for both Medicare and Medicaid (*dual eligibles*) also are eligible for the demonstration. Up to 20,000 individuals may enroll in the demonstration. All applicable beneficiaries must agree to receive OUD treatment services from participating providers.

Section 6042 prohibits providers from limiting applicable beneficiaries' access to Medicare services, and beneficiaries are not required to relinquish access to Medicare services as a condition of receiving demonstration services. The Secretary is required to establish a monthly per-applicable-beneficiary care management fee. The monthly fee will be paid to participating providers in addition to Medicare payments for other services to beneficiaries. Participating providers may use the monthly care management fee to deliver additional services to applicable beneficiaries, including services not covered by Medicare.

Section 6042 requires the Secretary to establish a performance-based incentive payment to encourage other payers to provide similar provider payments and authorizes the Secretary to enter into agreements with other payers to align OUD treatment payments. In addition, it requires the Secretary to conduct an intermediate and final evaluation to determine the extent to which demonstration purposes were accomplished. The Secretary must submit to Congress (1) an intermediate evaluation within three years of the demonstration implementation date and (2) a final evaluation within six years of the demonstration implementation date.

Section 6042 makes available \$5 million from the Medicare Part B Trust Fund to implement, administer, and carry out the demonstration program. In addition, it makes available \$10 million from the Medicare Part B Trust Fund to pay OUD care management fees and incentive payments to participants for each of FY2021 through FY2024. Implementation and care management funding are to be available until expended.

## **Section 6052. Grants to Provide Technical Assistance to Outlier Prescribers of Opioids**

## **Section 6065. Commit to Opioid Medical Prescriber Accountability and Safety for Seniors**

### ***Background***

Medicare Part D plan sponsors process prescription claims submitted by network pharmacies at the point of sale and send summary extracts of those claims, known as Prescription Drug Event (PDE) records, to CMS.<sup>62</sup> The PDE records contain multiple data fields, which CMS uses for plan payment, research, quality monitoring, and the identification of potential fraud.

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<sup>61</sup> SAMHSA, "Buprenorphine Waiver Management," at <https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver>.

<sup>62</sup> HHS OIG, "CMS Ensured Nearly All Part D Drug Records Contained Valid Prescriber Identifiers in 2016," OEI-03-

In response to concerns about invalid provider identification on Part D claims, Congress, in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10), required Part D claims to include National Provider Identifiers (NPIs) determined to be valid by the Secretary, beginning in 2016.<sup>63</sup> An NPI is a unique identification number for covered health care providers.<sup>64</sup> The HHS OIG monitored implementation of the MACRA requirements.<sup>65</sup>

### ***Provisions***

Section 6065 amends SSA Section 1860D-4(c)(4) to require the Secretary, in consultation with stakeholders, to establish technical thresholds for identifying Part D opioid prescribers who are outliers compared to other prescribers in a specific practice specialty and geographic area. The analysis is to be based on opioid claims issued under valid NPIs but is to exclude claims for Part D enrollees who are receiving hospice care or are under treatment for cancer, as well as claims from prescribers who are the subject of an investigation by CMS or the HHS OIG.

No later than January 1, 2021, the Secretary is to begin providing annual notification to prescribers identified as opioid outliers. The notification is to describe how the prescriber compares to other prescribers in the same specialty and area, and it is to include information on appropriate opioid prescribing guidelines, which may be based on input from the Centers for Disease Control and Prevention and physician organizations. Starting five years after enactment, the Secretary may change the frequency of required notifications. The Secretary also may expand notifications to cover drugs prescribed concurrently with opioids.

Prescribers persistently identified as opioid outliers may be required to enroll in a program of enhanced oversight and monitoring. Such enrollment would be required only after other remedies had been attempted, including education on best practices for opioid prescribing. The Secretary is to communicate information on persistent outliers to Part D plan sponsors and to make publicly available aggregate information about such prescribers.

Section 6052 authorizes CMS to award grants, contracts, or cooperative agreements (1) to educate and provide outreach to outlier prescribers about best practices for prescribing opioids, (2) to educate and provide outreach to outlier prescribers about non-opioid pain management therapies, and (3) to reduce the amount of opioids prescribed by outlier prescribers. Entities eligible to apply for the grants include organizations with demonstrated experience providing technical assistance to health care professionals on a state or regional basis that have at least one consumer representative and one health care provider representative on their governing bodies. Eligible entities also include contracted quality improvement organizations.<sup>66</sup> To fund this provision, \$75 million is to be made available from the Part B Trust Fund.

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17-00040, October 2017, at <https://oig.hhs.gov/oei/reports/oei-03-17-00040.asp>.

<sup>63</sup> Medicare Access and CHIP Reauthorization Act of 2015 (P.L. 114-10), §507.

<sup>64</sup> National Provider Identifiers originally were created under the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191).

<sup>65</sup> HHS OIG, “CMS Ensured Nearly All Part D Drug Records Contained Valid Prescriber Identifiers in 2016,” OEI-03-17-00040, October 2017, at <https://oig.hhs.gov/oei/reports/oei-03-17-00040.asp>.

<sup>66</sup> Quality improvement entities with contracts under Part B of Title XI of SSA (42 U.S.C.1320c et seq.).

## **Section 6063. Program Integrity Transparency Measures Under Medicare Parts C and D**

### ***Background***

Medicare Part C MA plans and Part D drug-only plans (PDPs) are required to establish compliance programs to prevent, detect, and correct fraud, waste, and abuse. The Secretary is required to establish contracts with Medicare Drug Integrity Contractors (MEDICs) to support Parts C and D program integrity activities. CMS, the Secretary, and the MEDICs audit MA plans and PDPs to ensure their compliance programs meet Medicare requirements and investigate MA and PDP reports of provider and supplier fraud, waste, and abuse. MA plans and PDPs may, but are not required to, report fraud, waste, or abuse activities to the Secretary or MEDICs provider or supplier. The Secretary may share provider and supplier fraud, waste, or abuse information among other MA and PDPs but is not required to disseminate that information.

The Secretary is authorized to impose civil monetary penalties on individuals, organizations, agencies, or other entities that engage in improper conduct. In some situations, the Secretary may be required to exclude those individuals, organizations, or other entities from federal health program participation. In other situations, pending an investigation of credible fraud allegations, the Secretary may suspend Medicare provider or supplier payments.

### ***Provision***

Section 6063 amends SSA Section 1859 by adding a new subsection. It amends SSA Section 1857(e) by adding a new paragraph, and it amends SSA Section 1860D-4 by adding a new subsection.

Within two years of the enactment date, Section 6063 requires the Secretary to establish a secure internet website portal. The website is to be used to communicate and facilitate data sharing with MA plans and Part D PDPs and MEDICs. The website also is to enable MA plans and PDPs to refer substantiated or suspicious provider or supplier fraud, waste, and abuse activities to MEDICs to initiate or assist in investigations.

The Secretary is required to use the website to disseminate information to MA plans and PDPs on providers and suppliers that were recently referred for fraud, waste, and abuse; were excluded or had a payment suspension; had their Medicare participation revoked; or had administrative actions imposed for similar activities. Using guidance, such as in the *Medicare Program Integrity Manual* (4.8), the Secretary specifies what constitutes substantiated or suspicious fraud, waste, and abuse activities.

Within two years of enactment, Section 6063 requires the Secretary to disseminate quarterly reports to MA plans and PDPs on fraud, waste, and abuse schemes and suspicious activity trends reported through the website. The Secretary's reports are to maintain the anonymity of information submitted by plans and to include administrative actions, opioid overprescribing information, and other data the Secretary, in consultation with stakeholders, determines important. Section 6063 does not prohibit referrals to the HHS OIG or other law enforcement entities.

Beginning with plan year 2021, Section 6063 requires MA organizations and PDP sponsors to submit to the Secretary information on credible evidence of suspected fraud and other actions related to inappropriate opioid prescribing. Before January 1, 2021, in consultation with stakeholders, the Secretary is required to establish a process for MA plans and PDPs to submit required information on inappropriate opioid prescribing. To implement the suspected fraud

information reporting process, the Secretary is required to issue regulations that define the term *inappropriate prescribing of opioids*, identify a method to determine if providers prescribed a high volume of opioid drugs, and identify the information plans are required to submit.

## **Section 6064. Expanding Eligibility for Medication Therapy Management Programs Under Part D**

### ***Background***

Medicare Part D plans (with some exceptions) must offer Medication Therapy Management (MTM) programs that provide coordinated pharmacy care for patients with multiple medical conditions who may be seeing multiple practitioners and using more than one covered drug.<sup>67</sup> An MTM program includes medication reviews, patient consultation and education, and other services. CMS must review and approve each Part D plan's MTM program annually, and the program is one of several required elements considered when CMS evaluates a sponsor's bid to participate in the Part D program for an upcoming contract year.

Part D sponsors have some latitude in designing MTM programs but must enroll certain targeted beneficiaries. Targeted beneficiaries are defined by CMS as those who (1) have multiple chronic diseases, with three being the maximum that can be required; (2) are taking at least two to eight Part D drugs; and (3) are likely to have annual covered drug costs that exceed \$4,044 in 2019.<sup>68</sup>

### ***Provision***

Section 6064 amends SSA 1860D-4(c)(2)(A)(ii) to add Part D enrollees identified as at risk for prescription drug abuse to the list of targeted MTM program enrollees. The provision takes effect on January 1, 2021.<sup>69</sup>

## **Section 6072. Medicare Payment Advisory Commission Report on Opioid Payment, Adverse Incentives, and Data Under the Medicare Program**

### ***Background***

No applicable provision of current law.

### ***Provision***

Section 6072 requires the Medicare Payment Advisory Commission (MedPAC), no later than March 15, 2019, to submit a report to Congress that

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<sup>67</sup> CMS, "Medication Therapy Management Program," at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html>.

<sup>68</sup> Part D sponsors may target beneficiaries with any chronic diseases or with specific chronic diseases. If plans target beneficiaries with specific diseases, they must include at least five of the diseases CMS has defined as nine core chronic conditions. The core diseases are Alzheimer's disease, chronic heart failure, diabetes, dyslipidemia, end-stage renal disease, hypertension, respiratory disease (such as asthma or chronic lung disorders), bone disease-arthritis, and mental health (such as depression, schizophrenia, or bipolar disorder). Dollar thresholds for covered drug costs are updated annually.

<sup>69</sup> For information on designation as an at-risk enrollee for prescription drug abuse, see "Section 2004. Requiring Prescription Drug Plan Sponsors Under Medicare to Establish Drug Management Programs for At-Risk Beneficiaries."



- describes how the Medicare program pays for pain management treatments (both opioid and non-opioid pain management alternatives) in both inpatient and outpatient hospital settings,
- identifies incentives for prescribing opioids and non-opioid treatments under the hospital inpatient prospective payment system (IPPS) and the hospital outpatient prospective payment system (OPPS) and recommends appropriate congressional actions for addressing any adverse incentives, and
- describes how opioid use is tracked and monitored through Medicare claims data and other mechanisms and identifies any areas in which further data and methods are needed to improve data and understanding regarding the use of opioids.

## **Section 6082. Review and Adjustment of Payments Under the Medicare Outpatient Prospective Payment System to Avoid Financial Incentives to Use Opioids Instead of Non-opioid Alternative Treatments**

### ***Background***

No applicable provision of current law.

### ***Provision***

Section 6082 amends SSA Section 1833(t) to require the Secretary to review Medicare payments made through the hospital OPPS and payments to ambulatory surgery centers (ASCs) to ensure there are no financial incentives to use opioids instead of evidence-based non-opioid alternatives. If the Secretary identifies financial incentives to use opioids instead of evidence-based non-opioid alternatives, Section 6082 requires the Secretary to revise OPPS and ASC payments through rulemaking. The Secretary also may review payments through a demonstration.

Section 6082 requires the Secretary to review payments for services covered under the OPPS and ASC systems as soon as practicable and subsequently as appropriate, to ensure there are no financial incentives to use opioids instead of evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation). The review could include a request for information and would consider how modifications to payment for these services (such as the creation of additional groups of covered outpatient department services to classify procedures that use opioids for pain management separately from procedures that use non-opioid alternatives for the same purpose) might reduce payment incentives to use opioids instead of non-opioid alternatives.

Should the Secretary identify revisions to payments for services that satisfy this condition, the Secretary would make such revisions for services furnished on or after January 1, 2020. The provision would allow the Secretary to conduct a demonstration prior to making the revisions.

In conducting the review, the Secretary is to focus on covered outpatient department services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary that generally involve treatment for pain management.



## **Section 6083. Expanding Access Under the Medicare Program to Addiction Treatment in Federally Qualified Health Centers and Rural Health Clinics**

### ***Background***

The federal Health Center Program, administered by the Health Resources and Services Administration, awards grants to support outpatient primary care facilities serving low-income individuals.<sup>70</sup> Health Center Program sites, as well as other types of health centers, may receive Medicare designation as Federally Qualified Health Centers (FQHCs) if they meet certain requirements, including enrollment as Medicare and/or Medicaid providers.<sup>71</sup> Health centers designated as FQHCs are paid on a cost-based prospective payment system that generally provides higher payment rates than other providers receive from Medicare and Medicaid for comparable services provided in physician offices.<sup>72</sup> In October 2018, there were approximately 8,500 FQHCs.<sup>73</sup>

Medicare may designate outpatient primary care facilities located in rural and medically underserved areas that meet certain conditions as Rural Health Clinics (RHCs).<sup>74</sup> RHCs were established to address an inadequate supply of physicians serving Medicare patients in rural areas and to increase the use of nonphysician practitioners.<sup>75</sup> These facilities are paid an annually updated, all-inclusive rate for services to Medicare and Medicaid beneficiaries. Similar to the FQHC prospective payment system, the all-inclusive rate payment generally is greater than what other providers would receive for providing the same services to Medicare and Medicaid beneficiaries. In January 2018, there were approximately 4,100 RHCs.<sup>76</sup>

A DATA 2000 waiver is required to prescribe Schedule III, IV, and V controlled substances. To obtain a DATA waiver, physicians, nurse practitioners, and physician assistants must apply and complete eight hours of required training. Physicians and other practitioners who complete the training and are approved by U.S. Drug Enforcement Administration (DEA) receive a special identification number, in addition to the regular DEA registration number, that must be included on all buprenorphine prescriptions.<sup>77</sup>

### ***Provision***

Section 6083 amends SSA Sections 1834(o) and 1833. Beginning January 1, 2019, subject to available funds, Section 6083 authorizes the Secretary to pay training costs of qualified FQHC and RHC physicians and practitioners who want to obtain DATA 2000 waivers to furnish OUD treatment services. To receive payment, FQHCs and RHCs must submit a formal application to the Secretary. The Secretary is to determine the timing and manner of data waiver payments and

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<sup>70</sup> Public Health Service Act §330, Health Centers.

<sup>71</sup> CMS, *Federally Qualified Health Center (FQHC)*, Medicare Learning Network Booklet, January 2018, and SSA §1905(l)(2)(B).

<sup>72</sup> For more information on the federal Health Center Program and FQHC cost-based payments, see CRS Report R43937, *Federal Health Centers: An Overview*.

<sup>73</sup> Health Resources and Services Administration, Data Portal, at <https://data.hrsa.gov/hdw/tools/dataportal.aspx>.

<sup>74</sup> Rural Health Services Act of 1977 (P.L. 95-210).

<sup>75</sup> CMS, *Rural Health Clinics*, Medicare Learning Network Booklet, January 2018, at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/RuralHlthClinfctsh.pdf>. Hereinafter CMS, *Rural Health Clinics*.

<sup>76</sup> CMS, *Rural Health Clinics*.

<sup>77</sup> CRS In Focus IF10219, *Opioid Treatment Programs and Related Federal Regulations*.

may base payments on an estimate of average costs of obtaining the DATA 2000 waiver. The Secretary may make one DATA 2000 waiver payment for each qualified FQHC or RHC physician or practitioner.

To qualify for DATA 2000 waiver payments, physicians or practitioners must be employed by or working under contract with the FQHC or RHC that applies for payment, and the practitioner or physician must have first received a DATA 2000 waiver on or after January 1, 2019.

An appropriation of \$6 million is available until expended from the U.S. Treasury to compensate FQHCs for the cost of obtaining DATA 2000 waivers. In addition, a \$2 million appropriation from the Treasury is available until expended to compensate RHCs.

## **Section 6084. Studying the Availability of Supplemental Benefits Designed to Treat or Prevent Substance Use Disorders Under Medicare Advantage Plans**

### ***Background***

Medicare Part C (MA) is an alternative way for Medicare beneficiaries to receive covered benefits. MA plans also may offer supplemental benefits not covered under original Medicare (such as hearing, dental, or vision benefits), reduced cost sharing, or reduced Part B or Part D premiums.<sup>78</sup> Certain MA plans are available to any Medicare beneficiary living in the plan's service area who is eligible for Part A and enrolled in Part B. However, a Special Needs Plan (SNP) is a type of MA plan that may restrict enrollment to beneficiaries with certain characteristics, such as eligibility for both Medicare and Medicaid (i.e., *dual-eligible SNPs*, or *D-SNPs*).

Under MA, the Secretary pays private health plans a per-person monthly amount to provide Medicare-covered benefits to beneficiaries who enroll in their plans. A plan's payment is determined by comparing its annual bid to a program benchmark. A bid is a plan's estimated cost of providing Medicare-covered services (excluding hospice but including the cost of medical services, administration, and profit) during a plan year. A benchmark is the maximum amount the federal government will pay for those services in a plan's service area. If a plan's bid is less than the benchmark, the plan's payment equals its bid, plus a rebate. The rebate must be returned to enrollees in the form of additional benefits, reduced cost sharing, or reduced Part B or Part D premiums, as mentioned above. The actual dollar amount of the rebate depends on a plan's quality, as measured by a Medicare 5-star quality rating; rebates range from 50% to 70% of the difference between a bid and a benchmark. If a plan's bid is equal to or above the benchmark, its payment equals the benchmark amount; each enrollee in that plan will pay an additional premium that is equal to the amount by which the bid exceeds the benchmark, and no rebate is available to those plan enrollees. Finally, payments to plans are risk-adjusted to take into account the demographic and health history of those who enroll in the plan.<sup>79</sup>

### ***Provision***

Section 6084 requires the Secretary to submit a report to Congress, no later than two years after enactment, that addresses the availability of supplemental benefits designed to treat and prevent SUDs under MA plans and any differences in the availability of such supplemental benefits

<sup>78</sup> CMS, "Health Plans – General Information," at <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/index.html>.

<sup>79</sup> CRS Report R40425, *Medicare Primer*.

between D-SNPs and plans that are not D-SNPs. Development of the report requires consultation with specified stakeholders, including Medicare beneficiaries, beneficiary advocates, organizations that offer MA plans, pharmacy benefit managers, and health care providers and suppliers.<sup>80</sup> The report must include the following:

- the extent to which MA plans offer coverage of MATs for opioid use, SUD counseling, peer recovery support services, or other forms of SUD treatments, as well as non-opioid alternative treatments for pain;
- challenges associated with offering those supplemental benefits;
- the impact, if any, on the availability of such benefits, if rebates for plans that offer such coverage increase; and
- potential ways to improve coverage of these supplemental benefits.

## **Section 6085. Clinical Psychologist Services Models Under the Center for Medicare and Medicaid Innovation; Government Accountability Office Study and Report**

### ***Background***

Medicare Part B covers outpatient mental health services and visits (counseling therapy) with several types of health professionals, including psychiatrists or other doctors, clinical psychologists, and other health professionals (e.g., clinical social workers, clinical nurse specialists, nurse practitioners, and physician assistants). Part B-covered outpatient mental health services include treatment for inappropriate alcohol and drug use.

### ***Provision***

Section 6085 amends SSA Section 1115A(b)(2)(B) to require the Secretary to educate and inform (“familiarize”) Medicare beneficiaries about Part B coverage of clinical psychologist services. It also requires the Secretary to explore ways to avoid unnecessary hospitalizations or emergency department visits for mental and behavioral health services (such as for treating depression) through use of a 24-hour, 7-day-a-week help line that may inform beneficiaries about the availability of treatment options, including clinical psychologist services.

No later than 18 months after enactment, the comptroller general is to submit a report to Congress on mental and behavioral health services under Medicare, including an examination of information about (1) services furnished by psychiatrists, clinical psychologists, and other professionals and (2) ways that Medicare beneficiaries familiarize themselves with the availability of Medicare payment for clinical psychologist services. The report is to include ways in which the provision of such information could be improved.

## **Section 6086: Dr. Todd Graham Pain Management Study**

### ***Background***

No applicable provision in current law.

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<sup>80</sup> Pharmacy benefit managers design formularies; negotiate prescription prices; administer pharmacy claims; and perform other functions for health plans, hospitals, and other health care payers.

## **Provision**

Section 6086 directs the Secretary to conduct a study, no later than one year after enactment, addressing best practices, payment, and coverage of pain management services under Medicare Parts A and B. It also requires the Secretary to submit to the House Ways and Means and Energy and Commerce Committees and to the Senate Finance Committee a report on options for revising Parts A and B payments to providers and suppliers, as well as Medicare coverage related to multidisciplinary, evidence-based, non-opioid treatments for acute and chronic pain management. The report must be publicly available.

Specifically, the report must include the following:

- An analysis of payment and coverage for
  - evidence-based treatments and technologies for chronic and acute pain management, for monitoring substance use withdrawal and overdose prevention, and for addressing SUD;
  - pain management items and services provided through multidisciplinary treatment models, such as primary care medical homes; and
  - items and services for beneficiaries with psychiatric or substance use disorders, who are at risk of suicide, or who have comorbidities and require consultation or management by specialists in pain management, mental health, or addiction treatment.
- An evaluation of
  - barriers inhibiting access to the treatments and technologies discussed above;
  - the costs and benefits of potentially expanding Medicare coverage; and
  - relevant pain management guidance for purposes of rendering Medicare coverage determinations.
- An assessment of HHS guidance published on or after January 1, 2016, related to opioid prescribing. The Secretary must consider incorporating relevant elements of the *Veterans Affairs (VA)/Department of Defense (DOD) Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, including parts of the VA and DOD pain rating scale.
- Legislative and administrative options for
  - improving coverage of and payment for non-opioid pain management therapies and for FDA-approved medical devices and non-opioid pharmacological and non-pharmacological therapies for treatment of pain as alternatives to or to augment opioid therapy;
  - improving and disseminating treatment strategies for beneficiaries with psychiatric or substance use disorders, who are at risk of suicide, or who have comorbidities and require consultation or management by specialists in pain management, mental health, or addiction treatment, and to address health disparities related to opioid use and opioid abuse treatment;
  - educating providers about the risks of co-administration of opioids and other drugs;

- ensuring appropriate management of transitions between inpatient and outpatient care or between opioid and non-opioid therapy;
  - expanding outreach for and education of providers on alternative and non-opioid therapies for acute and chronic pain management; and
  - creating a beneficiary education tool on opioid alternatives for chronic pain management.
- An analysis of the effect of these legislative and administrative options on Medicare expenditures and on prevention and reduction of opioid addiction.

In developing the report, the Secretary must consult with relevant department agencies and other stakeholders. Stakeholders should include health care practitioners, providers, and professionals; Medicare providers and suppliers; substance abuse and mental health services professional organizations; pain management professional and advocacy organizations; medical professional and specialty societies; licensed providers of alternative pain management services; experts in the development of innovative medical technologies for pain management; beneficiary advocacy groups; and other organizations as the Secretary determines appropriate.

## **Section 6092. Developing Guidance on Pain Management and Opioid Use Disorder Prevention for Hospitals Receiving Payment Under Part A of the Medicare Program**

### ***Background***

No applicable provision in current law.

### ***Provision***

Section 6092 requires the Secretary, no later than January 1, 2019, to develop and publish guidance for hospitals receiving payment under Medicare Part A regarding pain management and OUD prevention strategies for Medicare beneficiaries. The guidance is to be published on the CMS website, and it is to be developed in consultation with relevant stakeholders (e.g., medical professional organizations) and to include particular components (e.g., best practices for practitioner education, for tracking opioid prescribing trends, and for informing individuals of the risks associated with opioid use). As part of the guidance, the Secretary is to develop a notification template for individuals prescribed opioids that addresses the risks and side effects of opioid use; how to store an opioid safely; and evidence-based non-opioid alternatives for pain management, among other things.

## **Section 6093. Requiring the Review of Quality Measures Relating to Opioids and Opioid Use Disorder Treatments Furnished Under the Medicare Program and Other Federal Health Care Programs**

### ***Background***

Medicare's transition to value-based purchasing relies on quality measures that span diseases and conditions, care settings, provider types, and measure types. Generating measures for use in Medicare quality programs involves measure development, National Quality Forum (NQF) measure endorsement, and measure selection for use in specific quality programs. Congress

enacted two statutory provisions—SSA Sections 1890 and 1890A—to support these activities with respect to the Medicare program.

Under SSA Section 1890, the Secretary is required to have a contract with a consensus-based entity (currently NQF) to carry out specified duties related to performance improvement and measurement. These duties include, among others, priority setting, measure endorsement, measure maintenance, the convening of multi-stakeholder groups, and annual reporting to Congress and the Secretary.

Under SSA Section 1890A, the Secretary is required to establish a pre-rulemaking process to select Medicare quality measures. Each December, the Secretary publishes a list of all measures under consideration for Medicare quality programs, and the NQF's Measure Applications Partnership (MAP) convenes multi-stakeholder groups to review the measures. In February, after completing the reviews, the MAP provides to the Secretary a published report with recommendations for measure selection. (The first such report was published in February 2012.) The Secretary must consider this input when deciding which quality measures to include in the Medicare program. The Secretary also periodically reviews all measures under use in Medicare with respect to maintaining or retiring the measures.

### ***Provision***

Section 6093 amends SSA Section 1890A to require the Secretary, no later than 180 days after enactment, to establish a technical expert panel to review quality measures related to opioids and OUD (this may be carried out by NQF as part of its contract under SSA Section 1890). No later than one year after the date the panel is established, and periodically thereafter, Section 6093 requires the panel to review existing opioid-related quality measures and those under development; identify gaps and measure development priorities in this area; and recommend quality measures for use under specified Medicare quality programs (e.g., the Hospital Value-Based Purchasing Program, the Merit-Based Incentive Payment System, the Medicare Shared Savings Program), among other things. Section 6093 also requires the Secretary to consider using opioid and OUD measures, including as recommended by the panel, in Medicare quality programs, as specified; to prioritize measure development where the technical panel identifies measure gaps; and to prioritize endorsement of measures relating to opioids and OUD by NQF (through its contract under SSA Section 1890) through December 31, 2023. After that date, the Secretary may prioritize the endorsement of such measures by NQF.

## **Section 6094. Technical Expert Panel on Reducing Surgical Setting Opioid Use; Data Collection on Perioperative Opioid Use**

### ***Background***

No applicable provision in current law.

### ***Provision***

Section 6094 requires the Secretary, no later than six months after enactment, to convene a technical expert panel to provide recommendations on reducing opioid use in inpatient and outpatient settings and best practices for pain management. No later than one year after enactment, Section 6094 requires the Secretary to submit to Congress and make public a report containing this panel's recommendations and an action plan for implementing pain management protocols that limit opioid use in the perioperative setting and at discharge.



This section also requires the Secretary, no later than one year after enactment, to submit a report to Congress on perioperative opioid use. The report is to include Medicare diagnosis-related group codes identified by the Secretary as having the highest volume of surgeries and, for each code, information on available and reported data on opioid use following such surgeries, as specified, and recommendations for improving data collection, including reducing barriers to collecting, reporting, and analyzing data on perioperative opioid use.

## **Section 6095. Requiring the Posting and Periodic Update of Opioid Prescribing Guidance for Medicare Beneficiaries**

### ***Background***

CMS and the Social Security Administration share Medicare beneficiary education and outreach duties. CMS makes available additional educational materials and responses to frequently asked questions on a CMS-maintained website.<sup>81</sup> The website includes information on enrollment, costs, coverage, appeals, and related resources. Numerous Medicare publications on various topics, including the annual handbook *Medicare & You*, also are available on the public website.

### ***Provision***

Section 6095 requires the Secretary, within 180 days of enactment, to post all HHS guidance published on or after January 1, 2016, relating to opioid prescribing and applicable opioid prescriptions for Medicare beneficiaries. The guidance is to be posted to the CMS public website, and the Secretary is to periodically update and revise the postings as the Secretary deems appropriate. Such updates are to be made in consultation with medical professional organizations, providers and suppliers of services, consumers or consumer advocates, and other entities the Secretary determines appropriate.

## **Section 6102. Requiring Medicare Advantage Plans and Part D Prescription Drug Plans to Include Information on Risks Associated with Opioids and Coverage of Non-pharmacological Therapies and Non-opioid Medications or Devices Used to Treat Pain**

### ***Background***

Medicare Part D plans under SSA Section 1860D-4(a) must provide certain information to beneficiaries at the time of enrollment and at least annually thereafter. Among the information that must be provided in a clear, accurate, and standardized form are descriptions of the plan formulary, access to specific Part D-covered drugs, beneficiary cost-sharing requirements, and information about the plan's MTM and drug management programs for individuals at risk of prescription drug abuse.

### ***Provision***

Section 6102 amends SSA Section 1860D-4(a)(1) to require that, beginning in plan year 2021, Part D plans must provide enrollees with information regarding the treatment of pain, including the risks of prolonged opioid use and coverage of non-pharmacological therapies, devices, and

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<sup>81</sup> HHS, "Medicare & You," at <https://www.medicare.gov/medicare-and-you/>.



non-opioid medications. Rather than disclosing the information to all enrollees, a plan sponsor may provide the information through mail or electronic communications to a subset of plan enrollees, such as enrollees who have been prescribed an opioid in the previous two-year period.

### **Section 6103. Requiring Medicare Advantage Plans and Prescription Drug Plans to Provide Information on the Safe Disposal of Prescription Drugs**

#### ***Background***

No applicable provision in current law.

#### ***Provision***

Section 6103 amends SSA Section 1852, which delineates benefits for MA managed care plans, to add a provision requiring information on safe disposal of controlled substances. Under the provision, MA or MA-PD plans must ensure that in-home health risk assessments carried out by MA plans on or after January 1, 2021, include information on the safe disposal of prescription drugs that are controlled substances.<sup>82</sup> The information is to include background on drug takeback programs that meet requirements determined appropriate by the Secretary and information on in-home disposal.

The section also amends SSA Section 1860D-4(c)(2)(B) to state that for plan years beginning on or after January 1, 2021, Part D plan MTM programs shall provide information to enrollees on the safe disposal of prescription drugs that are controlled substances, including information on approved drug takeback programs and in-home disposal and cost-effective means by which an enrollee may safely dispose of such drugs.

### **Section 6104. Revising Measures Used Under the Hospital Consumer Assessment of Healthcare Providers and Systems Survey Relating to Pain Management**

#### ***Background***

In an effort to improve value in the Medicare program, Congress established several hospital-based programs that measure and sometimes reward performance. These programs include, among others, the Hospital Inpatient Quality Reporting (IQR) Program, established at SSA Section 1886(b)(3)(B)(vii) and (viii), and the Hospital Value-Based Purchasing (VBP) Program, established at SSA Section 1886(o). Both programs require participating hospitals to submit specified quality data and have differing payment adjustments based on the data reported.

The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, developed by the Agency for Healthcare Research and Quality, measures patient satisfaction with, and experience of, care in hospitals; it is included in the measure sets for both the Hospital IQR Program and the Hospital VBP Program. Beginning with hospital discharges on January 1, 2018, hospitals are required to use the HCAHPS survey with new questions on communication about pain that replace previous questions relating to pain management. The questions relating to pain on the HCAHPS survey have been the subject of debate with respect to their potential impact on opioid prescribing patterns, and there have been concerns that providers could inappropriately or

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<sup>82</sup> An in-home health risk assessment is carried out by an MA plan or contracted vendor to identify health risks or the presence of a disease or disability.

unnecessarily prescribe opioids in an effort to receive higher ratings from patients on the HCAHPS survey.

Hospital Compare is a public website that reports and presents comparative information about Medicare-certified hospitals, and many VA medical centers, on a number of quality-of-care metrics. Hospital Compare is populated with data from measures submitted under the Hospital IQR Program pursuant to a statutory requirement of the program requiring the Secretary to make information submitted under it available to the public.

### ***Provision***

Section 6104 amends SSA Section 1886(b)(3)(B)(viii) to require that any HCAHPS survey conducted on or after January 1, 2020, as part of the Medicare Hospital IQR program may not include questions regarding communication about pain between hospital staff and patients unless the questions take into account whether the patient experiencing pain was informed about the risks associated with opioid use and about non-opioid alternatives for treating pain. In addition, the section prohibits the Secretary from including on Hospital Compare any measures based on questions in the 2018 or 2019 HCAHPS survey about communication between hospital staff and patients about a patient's pain.

Section 6104 also amends SSA Section 1886(o)(2)(B) to prohibit the Secretary from including in the Hospital VBP Program any measures based on questions in the 2018 or 2019 HCAHPS survey about communication by hospital staff with a patient about the patient's pain.

## **Section 6111. Fighting the Opioid Epidemic with Sunshine**

### ***Background***

In recent years, questions have been raised about certain financial relationships between health care professionals, such as physicians, and the pharmaceutical and other medical industries. As part of these relationships, companies may give gifts or make payments to health care professionals as part of their marketing efforts or for other purposes. In an effort to promote transparency and prevent inappropriate relationships, SSA Section 1128G generally requires applicable drug, device, biological, or medical supply manufacturers that make a payment or other transfer of value to a "covered recipient" to annually report information on such transactions to the Secretary. *Covered recipient* is defined as either a physician or a teaching hospital but does not include physicians who are employees of applicable manufacturers. Categories of reportable payments and transfers of value include amounts for research, gifts, entertainment, consulting fees, grants, meals, or travel. Certain items are exempt from disclosure, including certain very small payments or transfers of value, samples intended for patient use, short-term loans of a covered device, and patient educational materials. Additionally, the Secretary generally is required to have procedures in place to ensure public availability of submitted information, including through a searchable website. This reporting program established by the Secretary is referred to as the Open Payments program.

National Provider Identifiers (NPIs) are unique identifiers for health care providers and others that are used in transactions with Medicare, among other things. SSA Section 1128G requires applicable manufacturers to report to the Secretary NPIs of covered recipients in their submission information about payments and transfers of value, but the Open Payments website cannot contain these NPIs. Some health care commentators have claimed that although covered recipients may be identified by physician or manufacturer name on the Open Payments website, the lack of NPIs limits broader aggregation and analysis of the available data.

***Provision***

Section 6111 amends SSA Section 1128G(e)(6) to expand the definition of *covered recipient* to encompass physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives (excluding employees of applicable manufacturers). Accordingly, Section 6111 requires applicable manufacturers to submit information on payments or other transfers of value to these types of health care professionals. The amendments made by this section apply to information required to be submitted on or after January 1, 2022.

In addition, Section 6111 ends the exclusion of NPIs of covered recipients on the Open Payments website. Under this provision, the exclusion of NPIs from the Open Payments website will apply only to information submitted prior to January 1, 2022.

## Appendix. A

**Table A-1. Abbreviations Used in SUPPORT Act Provisions**

Abbreviation	Title
ACO	Accountable Care Organization
ASC	Ambulatory Surgery Center
AWV	Annual Wellness Visit
CARA	Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198, as amended)
CHIP	State Children's Health Insurance Program
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CURES	21 <sup>st</sup> Century Cures Act (P.L. 114-255)
DATA 2000	Drug Addiction and Treatment Act of 2000 (P.L. 106-310)
DEA	U.S. Drug Enforcement Administration
D-SNP	Dual-Eligible Special Needs Plan
EHR	Electronic Health Record
FDA	Food and Drug Administration
FQHC	Federally Qualified Health Center
HHS	Department of Health and Human Services
IQR	Hospital Inpatient Quality Reporting Program
IPPS	Hospital Inpatient Prospective Payment System
MA	Medicare Advantage
MA-PD	Medicare Advantage plan that includes a Part D drug benefit
MACRA	Medicare Access and CHIP Reauthorization Act of 2015 (P.L. 114-10)
MAT	Medication-Assisted Treatment
MEDIC	Medicare Drug Integrity Contractor
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173)
MME	Morphine Milligram Equivalent
MTM	Medication Therapy Management
NCPDP	National Council for Prescription Drug Programs
NPI	National Provider Identifiers
NQF	National Quality Forum
OIG	Office of the Inspector General
OMS	Overutilization Monitoring System
OTP	Opioid Treatment Program
OD	Opioid Use Disorder
PDP	Stand-Alone Medicare Part D plan
RHC	Rural Health Clinic
SNP	Medicare Special Needs Plan
SSA	Social Security Act
SUD	Substance Use Disorder
VBP	Hospital Value-Based Purchasing Program

**Source:** Congressional Research Service (CRS).

**Note:** SUPPORT Act = Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271).

**Table A-2. Enactment Dates and Deadlines for SUPPORT Act Medicare Provisions**

Provision Number	Title	Brief Description	Implementation/Reporting Deadline
Section 2001	Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders	Eliminates originating site geographic requirements for telehealth services for treating substance use disorders and co-occurring mental health disorders, among other modifications, effective July 1, 2019.	July 1, 2019
		No later than five years after enactment, requires the HHS Secretary to report to Congress on the impact of these modifications on health care utilization and health outcomes related to substance use disorders, including emergency department visits.	No later than five years after enactment, (i.e., October 24, 2023)
Section 2002	Comprehensive screenings for seniors	Requires that Medicare annual wellness visits include a review of a beneficiary's opioid prescriptions, on or after January 1, 2020.	January 1, 2020
Section 2003	Every prescription conveyed securely	Requires prescriptions for Part D controlled substances to be transmitted by a health care practitioner electronically in accordance with an approved electronic prescription drug program, on or after January 1, 2021.	January 1, 2021
		Requires the U.S. attorney general to update requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances no later than one year after enactment.	No later than one year after enactment (i.e., October 24, 2019)
Section 2004	Requiring prescription drug plan sponsors under Medicare to establish drug management programs for at-risk beneficiaries	Requires Part D plans to implement lock-in provisions for at-risk beneficiaries for plan years beginning on or after January 1, 2022.	January 1, 2022
Section 2005	Medicare coverage of certain services furnished by opioid treatment programs	Creates a Medicare bundled payment for items and services provided by outpatient treatment programs for opioid use disorder, including methadone, on or after January 1, 2020.	January 1, 2020
Section 2006	Encouraging appropriate prescribing under Medicare for victims of opioid overdose	Requires that a Part D-eligible individual identified as having a history of opioid-related overdoses be included as a potentially at-risk beneficiary under a drug management program for plan years no later than January 1, 2021.	No later than January 1, 2021
Section 2007	Automatic escalation to external review under a Medicare Part D drug management program for at-risk beneficiaries	Provides expedited appeals process for Part D enrollees determined to be at risk of opioid abuse, no later than January 1, 2021.	No later than January 1, 2021

Provision Number	Title	Brief Description	Implementation/Reporting Deadline
Section 2008	Suspension of payments by Medicare prescription drug plans and MA-PD plans pending investigations of credible allegations of fraud by pharmacies	Authorizes Medicare Part D plan sponsors to suspend payments to pharmacies in the plans' networks, pending investigation of a credible fraud allegation. Applies to Part D plan years beginning January 1, 2020.	January 1, 2020
Section 4002	Requiring reporting by group health plans of prescription drug coverage information for purposes of identifying primary payer situations under the Medicare program	Adds a Medicare Secondary Payer requirement that group health plans identify situations in which a plan should be the primary payer with respect to benefits relating to Medicare Part D coverage, starting in 2020.	January 1, 2020
Section 6012	Study on abuse-deterrent opioid formulations access barriers under Medicare	Requires the Secretary to send a study to Congress determining whether Part D enrollees with chronic pain have adequate access to abuse-deterrent opioids, no later than one year after enactment.	No later than one year after enactment (i.e., October 24, 2019)
Section 6021	Medicare opioid safety education	Requires the Secretary to compile and provide educational resources in the Medicare annual notice of benefits covering the topics of opioid use, pain management, and alternative pain management treatments, starting in 2019.	January 1, 2019
Section 6032	Action plan on recommendations for changes under Medicare and Medicaid to prevent opioids addictions and enhance access to medication-assisted treatment	Directs the Secretary to collaborate with the Pain Management Best Practices Inter-Agency Task Force in developing an action plan on changes to Medicare and Medicaid to prevent opioid addiction and enhance access to medication-assisted treatment.	
		No later than three months after enactment, the Secretary is to convene a public stakeholder meeting and request public feedback on ways the Centers for Medicare Services can address the opioid crisis through development and application of the action plan.	January 24, 2019
		The Secretary is required, no later than June 1, 2020, to submit a report to Congress that summarizes the action plan review; identifies planned next steps; and evaluates price trends for drugs used to reverse opioid overdoses, including recommendations to lower costs.	No later than June 1, 2020



Provision Number	Title	Brief Description	Implementation/Reporting Deadline
Section 6042	Opioid use disorder treatment demonstration program	Requires the Secretary, no later than January 1, 2021, to conduct a four-year demonstration project on increasing access to opioid use disorder treatment, improving beneficiary outcomes, and reducing Medicare expenditures.	No later than January 1, 2021
		Requires the Secretary, within three months of enactment, to consult with addiction specialists, primary care clinicians, and beneficiary groups on demonstration design.	Within three months of enactment (i.e., January 24, 2019)
		Requires the Secretary to submit an intermediate evaluation to Congress no later than three years after program implementation and a final report no later than six years after implementation.	Three years and six years after program implementation, respectively (i.e., October 24, 2021, and October 24, 2024)
Section 6062	Electronic prior authorization for covered part D drugs	Requires Part D e-prescribing systems to allow for processing of formulary prior authorization requirements, beginning no later than January 1, 2021.	No later than January 1, 2021
Section 6063	Program integrity transparency measures under Medicare parts C and D	Requires the Secretary, within two years of enactment, to establish a secure internet website for data sharing and reporting of Medicare Part D waste, fraud, and abuse	Within two years of enactment (i.e., October 24, 2020)
		Requires the Secretary, within two years of enactment, to disseminate quarterly reports to Part D plans on fraud, waste, and abuse and suspicious activity trends reported through the website.	
		Beginning with plan year 2021, Part D sponsors must submit information to the Secretary on credible evidence of suspected fraud and other actions related to inappropriate opioid prescribing.	January 1, 2021
Section 6064	Expanding eligibility for medication therapy management programs under Part D	Adds Part D enrollees identified as at risk for prescription drug abuse to the list of targeted medication therapy management enrollees. The provision takes effect January 1, 2021.	January 1, 2021
Section 6065	Commit to opioid medical prescriber accountability and safety for seniors	Requires the Secretary to establish technical thresholds for identifying Part D opioid prescribers who are outliers compared to other prescribers in a specific practice specialty and geographic area. No later than January 1, 2021, the Secretary is to begin providing annual notification to prescribers identified as outliers.	No later than January 1, 2021

Provision Number	Title	Brief Description	Implementation/Reporting Deadline
Section 6072	Medicare Payment Advisory Commission (MedPAC) report on opioid payment, adverse incentives, and data under the Medicare program	Requires MedPAC to submit a report to Congress no later than March 15, 2019, that describes how Medicare pays for pain management treatment, identifies incentives for prescribing opioids and non-opioid treatments, describes how Medicare tracks and monitors beneficiary claims data, and identifies areas in which improvements are needed.	No later than March 15, 2019
Section 6083	Expanding access under the Medicare program to addiction treatment in federally qualified health centers and rural health clinics	Beginning on or after January 1, 2019, subject to available funds, the Secretary is authorized to pay training costs for rural physicians and practitioners who want to obtain DATA 2000 waivers to furnish OUD treatment services.	January 1, 2019
Section 6084	Studying the availability of supplemental benefits designed to treat or prevent substance use disorders under Medicare Advantage (MA) plans	Requires the Secretary to submit a report to Congress, no later than two years after enactment, on the availability of supplemental benefits designed to treat and prevent substance use disorders under MA plans.	No later than two years after enactment (i.e., October 24, 2020)
Section 6085	Clinical psychologist services models under the Center for Medicare and Medicaid Innovation; Government Accountability Office study and report	Requires the Secretary to educate and inform Medicare beneficiaries about Part B coverage of clinical psychologist services and to explore ways to avoid unnecessary hospitalizations or emergency department visits for mental and behavioral health services through use of a 24-hour, 7-day-a-week help line. Requires the comptroller general, no later than 18 months after enactment, to submit a report to Congress on mental and behavioral health services under Medicare, including an examination of (1) services furnished by psychiatrists, clinical psychologists, and other professionals and (2) ways that Medicare beneficiaries familiarize themselves with the availability of Medicare payment for clinical psychologist services.	No later 18 months after enactment (i.e., April 24, 2020)
Section 6086	Dr. Todd Graham Pain Management Study	Directs the Secretary to conduct a study, no later than one year after enactment, addressing best practices, payment, and coverage of pain management services under Medicare Parts A and B. Requires the Secretary to submit a report to the congressional committees on options for revising Parts A and B payment to providers and suppliers, as well as Medicare coverage related to multidisciplinary, evidence-based, non-opioid treatments for acute and chronic pain management.	No later than one year after enactment (i.e., October 24, 2019)

Provision Number	Title	Brief Description	Implementation/Reporting Deadline
Section 6092	Developing guidance on pain management and opioid use disorder prevention for hospitals receiving payment under Part A of the Medicare program	Requires the Secretary, no later than January 1, 2019, to develop and publish guidance for hospitals receiving payment under Medicare Part A regarding pain management and opioid use disorder prevention strategies for Medicare beneficiaries.	No later than January 1, 2019
Section 6093	Requiring the review of quality measures relating to opioids and opioid use disorder treatments furnished under the Medicare program and other federal health care programs	Requires the Secretary, no later than six months after enactment, to establish a technical expert panel to review quality measures related to opioids and opioid use disorder.  No later than one year after the date the panel is established, and periodically thereafter, the panel is required to review existing opioid-related quality measures and those under development; identify gaps and measure development priorities in this area, and recommend quality measures for use under specified Medicare quality programs.	No later than six months after enactment (i.e., April 24, 2019)  No later than one year after panel is established.
Section 6094	Technical Expert Panel on Reducing Surgical Setting Opioid Use; Data Collection on Perioperative Opioid Use	Requires the Secretary, no later than six months after enactment, to convene an expert panel to provide recommendations on reducing opioid use in inpatient and outpatient settings and best practices for pain management.  Directs the Secretary, no later than one year after enactment, to report to Congress on the panel's recommendations and an action plan for implementing pain management protocols that limit opioid use in the perioperative setting and at discharge.  Requires the Secretary, no later than one year after enactment, to submit a report to Congress on perioperative opioid use.	No later than six months after enactment (i.e., April 24, 2019)  No later than one year after enactment (i.e., October 24, 2019)
Section 6102	Requiring MA plans and Part D prescription drug plans to include information on risks associated with opioids and coverage of non-pharmacological therapies and non-opioid medications or devices used to treat pain	Requires that for plan year 2021 and each subsequent plan year, Part D plans must provide enrollees with information regarding the treatment of pain, including the risks of prolonged opioid use and coverage of non-pharmacological therapies, devices, and non-opioid medications.	January 1, 2021

Provision Number	Title	Brief Description	Implementation/Reporting Deadline
Section 6103	Requiring MA plans and prescription drug plans to provide information on the safe disposal of prescription drugs	Requires MA plans to provide enrollees with information on the safe disposal of controlled substances. MA or MA-PD. Plans must ensure that in-home health risk assessments provided on or after January 1, 2021, include information on the safe disposal of prescription drugs that are controlled substances. In addition, Part D MTM programs must provide information to enrollees on the safe disposal of prescription drugs that are controlled substances.	January 1, 2021
Section 6104	Revising measures used under the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey relating to pain management	Requires that any HCAHPS survey conducted on or after January 1, 2020, as part of the Medicare Hospital IQR program, may not include questions regarding communication about pain between hospital staff and patients unless the questions take into account whether the patient experiencing pain was informed about the risks associated with opioid use as well as non-opioid alternatives for treating pain.  Prohibits the Secretary from including on Hospital Compare any measures based on questions in the 2018 or 2019 HCAHPS survey about communication between hospital staff and patients about a patient's pain.  Prohibits the Secretary from including measures based on questions in the 2018 or 2019 HCAHPS survey about communication by hospital staff with a patient about the patient's pain in the Hospital VBP Program.	January 1, 2020
Section 6111	Fighting the opioid epidemic with sunshine	Expands an existing requirement that applicable drug, device, biological, or medical supply manufacturers that make a payment or other transfer of value to a Medicare "covered recipient" annually report information on such transactions to the Secretary. Expands the definition of <i>covered recipient</i> to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives (excluding employees of applicable manufacturers). The change applies to information submitted on or after January 1, 2022.	January 1, 2022

Provision Number	Title	Brief Description	Implementation/Reporting Deadline
		Ends the exclusion for National Provider Identifiers of covered recipients for information the Open Payments website for information submitted on or after January 1, 2022.	January 1, 2022

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**Source:** Table prepared by CRS based on statutory language contained in Titles II, IV, and VI of the SUPPORT Act.

**Note:** Secretary = Secretary of Health and Human Services; GAO = Government Accountability Office; OUD = Opioid Use Disorder.

## Author Information

Suzanne M. Kirchhoff, Coordinator  
Analyst in Health Care Financing

Amanda K. Sarata  
Specialist in Health Policy

Cliff Binder  
Analyst in Health Care Financing

Jennifer A. Staman  
Legislative Attorney

Jim Hahn  
Specialist in Health Care Financing

Marco A. Villagrana  
Analyst in Health Care Financing

Sarah A. Lister  
Specialist in Public Health and Epidemiology

Phoenix Voorhies  
Analyst in Health Care Financing

Paulette C. Morgan  
Specialist in Health Care Financing

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