

Medicare Coverage of Substance Use Disorder Care:

A Landscape Review of Benefit Coverage,
Service Gaps and a Path to Reform

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Executive Summary

Overview

Medicare is the federal insurance program for individuals ages 65 and over as well as younger individuals with disabilities, covering about 62 million lives in 2020. National data shows that over 1.2 million individuals ages 65 and over had a substance use disorder (SUD) diagnosis in 2019, and yet only 284,000 individuals (23.6%) in this age range received any SUD treatment that year. Although overdose death rates had begun to decline in the general population before the COVID-19 public health emergency, hospitalizations and deaths related to opioid overdoses were continuing to rise among older adults ages 65 and older. COVID-19, which has disproportionately affected both older adults and people with SUDs, has both highlighted and exacerbated the health needs of older adults who face these dual epidemics.

Medicare, while often the standard-setter for other health care financing systems, falls far behind the SUD benefit coverage standards that have become more common in private insurance and Medicaid since the enactment of the Affordable Care Act. Medicare generally covers SUD prevention, early intervention, and treatment in office-based and hospital inpatient settings – the bookends for health care delivery – but does not cover intermediate levels of care that are required to treat individuals with a chronic disease. While Medicare has taken important steps to expand coverage for the treatment of opioid use disorders, it has not systematically revamped its coverage to deliver services required under evidence-based standards of care.

Unlike most private and employer-based insurance and Medicaid plans, Medicare is not subject to the 2008 Mental Health Parity and Addiction Equity Act (Parity Act), which requires health plans that offer SUD and mental health benefits to provide coverage that is on par with the medical and surgical benefits they offer. Without this anti-discrimination requirement, Medicare has not systematically addressed significant gaps in the coverage of SUD benefits, and Medicare beneficiaries have more limited access to SUD care than to other medical care.

The purpose of this report was to examine the SUD services that may be reimbursed under Medicare, identify the gaps in coverage, and offer initial recommendations to address these service gaps through the application of the Parity Act to Medicare.

Key Findings

Despite the growing need for services, Medicare's coverage of SUD care is strikingly limited and out of sync with evidence-based treatment models and the current delivery system of SUD treatment. This report tracks Medicare's coverage of SUD benefits against the widely accepted SUD continuum of care standards that have been developed by the American Society of Addiction Medicine (ASAM). The reasons for the coverage gaps vary, but generally fall into four categories:

- Medicare does not authorize, as a provider-type, or reimburse most facilities that provide SUD care, specifically freestanding SUD treatment facilities that offer community-based care.
- Medicare does not authorize, as a provider-type, or allow billing by the full range of addiction practitioners that make up a significant part of the SUD treatment workforce.
- Medicare does not cover certain levels of care, such as intensive outpatient and residential programs, and other levels of care that are covered do not meet the standards set out in the ASAM criteria, such as partial hospitalization programs.
- Medicare does not have adequate reimbursement or bundled episode of care payments that would enable beneficiaries to access the range of services they need at each ASAM level of care.

A crosswalk of Medicare benefit coverage and the ASAM levels of care reveals the gaps in Medicare coverage.

ASAM Level	Medicare Coverage	Medicare Gaps
Level 0.5 – Early Intervention	<ul style="list-style-type: none"> • Screening, Brief Intervention and Referral to Treatment (SBIRT) • Alcohol Misuse and Counseling – once per year with up to 4 counseling visits • Screening for SUD in Initial Preventative Physical Examination and Annual Wellness Visits 	
Level 1 – Outpatient Services	<ul style="list-style-type: none"> • Office-based counseling and care management • Hospital outpatient-based counseling • Opioid Treatment Programs • Telehealth for SUD counseling and certain 	<ul style="list-style-type: none"> • Freestanding SUD treatment facilities are not covered • Licensed counselors and certified addiction counselors and peer counselors are not covered, unless providing “incident to” services under the supervision of a physician

	OTP services, which beneficiaries can access from their homes	
Level 2 – Intensive Outpatient/Partial Hospitalization Services	<ul style="list-style-type: none"> Partial hospitalization services in hospital outpatient settings and Community Mental Health Centers 	<ul style="list-style-type: none"> Freestanding SUD treatment facilities are not covered Intensive Outpatient services are not covered Partial Hospitalization services are not available for patients with a SUD primary diagnosis
Level 3 – Residential/ Inpatient Services		<ul style="list-style-type: none"> Freestanding SUD treatment facilities are not covered Residential services are not covered
Level 4 – Medically Managed Intensive Inpatient Services	<ul style="list-style-type: none"> Hospital-based intensive inpatient SUD treatment 	<ul style="list-style-type: none"> 190-day lifetime limit for inpatient psychiatric care
Withdrawal Management	<ul style="list-style-type: none"> Office-based withdrawal management Hospital-based withdrawal management 	<ul style="list-style-type: none"> Freestanding SUD treatment facilities are not covered Licensed counselors and certified addiction counselors and peer counselors are not covered, unless providing “incident to” services under the supervision of a physician

Recommendations

Congress and the Centers for Medicare and Medicaid Services (CMS) must remedy these gaps in SUD coverage in Medicare, by:

- Covering services provided in all settings in which SUD services are appropriately and effectively delivered, including community-based SUD treatment facilities;
- Covering services provided by all practitioners authorized by state law to deliver SUD care;
- Adopting reimbursement standards based on the service delivery models; and

- Applying the Parity Act standards to protect beneficiaries with SUDs from discriminatory financial and other treatment limitations in Medicare.

Application of the Parity Act to Medicare would ensure that beneficiaries with SUDs do not experience discrimination in their health care coverage and would promote greater access to SUD prevention and treatment. The Parity Act, as applied currently to private and Medicaid plans, would require the Medicare program to address the following structural barriers to care:

- Eliminate the coverage exclusions of intensive outpatient and residential treatment for SUDs.
- Authorize care delivery and reimbursement to SUD treatment facilities that provide community-based care for all levels of SUD care.
- Authorize care delivery and reimbursement for licensed counselors and require adequate networks of providers and facilities that furnish SUD treatment to Medicare beneficiaries.
- Eliminate the lifetime treatment limitation on inpatient psychiatric hospitalization days.
- Prevent utilization management practices for services and medications for SUDs that are not comparable to or more stringently applied than those used for services and medications for medical conditions.
- Require the establishment of reimbursement rates and policies for SUD services to be comparable to and no more stringently applied than those used for medical services.

While some of these barriers to SUD treatment could be resolved through incremental legislative and regulatory changes, expanding the Parity Act to Medicare and Medicare Advantage Plans would require CMS to take steps, including statutory expansion, to ensure comprehensive and non-discriminatory coverage of SUD care. The health care needs of millions of Medicare beneficiaries require the program to align with evidence-based practices, current service-delivery models, and standards that apply to virtually all other major health care financing programs.

Overview

Despite the growing need for substance use disorder (SUD) services among Medicare beneficiaries, the Medicare program's coverage of SUD care is strikingly limited and out of sync with evidence-based treatment models and the current delivery system of SUD treatment. This report examines the SUD services that may be reimbursed under Medicare, identifies gaps in coverage, and offers initial recommendations to address these service gaps through the application of the 2008 Mental Health Parity and Addiction Equity Act to Medicare.

Introduction

Medicare is the federal health insurance program for individuals ages 65 years and older and those with disabilities under age 65. In 2020, 62 million individuals were covered by Medicare.¹ A significant number of Medicare beneficiaries have a SUD, including over one million individuals ages 65 and older with alcohol dependence in 2019,² and approximately 300,000 Medicare beneficiaries who are diagnosed annually with an opioid use disorder (OUD).³ Moreover, the data reveal that these numbers are rising. Between 1993 and 2012, Medicare experienced the largest annual increase in billing for hospital inpatient care related to opioid overuse among all payers (Medicaid, private insurance, uninsured and other payers), which was more than double the Medicaid-annual increase.⁴ From 2018 to 2019 alone, the number of individuals over the age of 65 with a SUD diagnosis rose 26%.⁵ Although overdose death rates had begun to decline in the general population before the COVID-19 public health emergency, hospitalizations and deaths related to opioid overdoses were continuing to rise among older adults ages 65 and older.⁶ COVID-19, which has disproportionately affected both older adults

¹ *CMS Fast Facts*, Centers for Medicare & Medicaid Services (July 2020), available for download at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts>.

Roughly 54 million beneficiaries qualify for Medicare based on age, and 8.5 million qualify based on disability.

² Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality, *2019 National Survey on Drug Use and Health*, Detailed Tables, Table 5.2A, <https://www.samhsa.gov/data/sites/default/files/reports/rpt29394/NSDUHDetailedTabs2019/NSDUHDefTabsSect5pe2019.htm> [hereinafter *2019 National Survey on Drug Use and Health*].

³ Anna Lembke, Jonathan H. Chen, *Use of Opioid Agonist Therapy for Medicare Patients in 2013*, 73 *JAMA Psychiatry* 990 (Sept. 2016), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2535238>.

⁴ Pamela L. Owens et al., *Hospital Inpatient Utilization Related to Opioid Overuse Among Adults, 1993–2012*, Agency for Healthcare Research & Quality (July 2014), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.jsp>.

⁵ *2019 National Survey on Drug Use and Health*, *supra* note 2 (an increase from 974,000 individuals in 2018 to 1,228,000 in 2019).

⁶ Leigh Wedenoja, *The Facts Underlying America's First Decline in Overdose Mortality in 20 Years*, Rockefeller Institute of Government (June 4, 2020), <https://rockinst.org/blog/the-facts-underlying-americas-first-decline-in-overdose-mortality-in-20-years/>.

and people with SUDs, has both highlighted and exacerbated the health needs of older adults who face these dual epidemics.⁷

Despite the significant and growing need for SUD treatment services for older adults, Medicare does not have a distinct benefit category for SUDs and does not cover the full continuum of services that are covered by private insurance and Medicaid.⁸ In response to the opioid epidemic, Medicare has begun to cover some SUD services explicitly, including screening for potential SUDs during annual wellness visits, office-based management and counseling treatment for SUDs, and facility-based care at opioid treatment programs (OTPs). Medicare beneficiaries are also able to access “reasonable and necessary” SUD services when provided by a Medicare-certified facility and/or practitioner under an approved plan of care. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 424.5(a).⁹ While federal policymakers are beginning to address the costly and deadly limitations to SUD treatment coverage in Medicare, more must be done to ensure that Medicare beneficiaries have access to comprehensive care for SUDs.

The purpose of this report is to examine the SUD services that may be reimbursed under Medicare, identify the gaps in coverage, and offer initial recommendations to address these service gaps. For many older adults, enrollment in Medicare *means less generous insurance coverage* for SUD treatment than their Medicaid, employer health plan, or other private insurance plan. Medicare reform is needed to ensure beneficiaries do not face undue barriers or burdensome out-of-pocket costs when seeking to enroll in or continue SUD treatment.

To assess the breadth of coverage and reimbursement for SUD services under Medicare, this landscape review tracks Medicare services against the widely accepted SUD continuum of care standards, developed by the American Society of Addiction Medicine (ASAM). The ASAM Criteria classifies treatment for SUD as a continuum of five levels of care,¹⁰ consistent with other chronic care disease models:

- Level 0.5: Early Intervention
- Level 1: Outpatient Services
- Level 2: Intensive Outpatient/Partial Hospitalization Services

⁷ Wossenseged B. Jemberie et al., *Substance Use Disorders and COVID-19: Multi-Faceted Problems Which Require Multi-Pronged Solutions*, 11 *Front Psychiatry* 714 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7396653/>.

⁸ Medicare Learning Network, *Medicare Coverage of Substance Abuse Services*, *MLN Matters #SE1604*, Centers for Medicare & Medicaid Services 2 (rev. May 10, 2019), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1604.pdf> [hereinafter *MLN Matters #SE1604*].

⁹ *Treatment for Alcoholism and Substance Use Disorder*, Medicare Interactive, <https://www.medicareinteractive.org/get-answers/medicare-covered-services/mental-health-services/treatment-for-alcoholism-and-substance-abuse> (last visited Oct. 28, 2020); U.S. Government Accountability Office, GAO-20-408, *CMS Should Provide Beneficiaries More Information about Substance Use Disorder Coverage* 5-6, 37 (May, 2020), <https://www.gao.gov/assets/710/707117.pdf> [hereinafter GAO-20-408].

¹⁰ David Mee-Lee et al., eds., *The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions* 105-06 (3rd ed. 2013) [hereinafter *The ASAM Criteria*].

- Level 3: Residential/Inpatient Services
- Level 4: Medically Managed Intensive Inpatient Services

The ASAM Criteria also establish medical necessity standards for each level of care. Practitioners assess a patient's condition based on multidimensional factors and determine the correct level of care based on the required intensity of care.¹¹ Many states require payers in the private and public insurance markets to use the ASAM Criteria as the standard for making medical necessity determinations and reimbursement decisions,¹² as they align with generally accepted standards of care.¹³ Furthermore, ASAM recognizes that its criteria must be tailored to specific populations, such as older adults, because of their unique needs and circumstances.¹⁴ For example, older adults may have mobility and sensory limitations, more chronic conditions that require them to take more medications, and less adequate support systems, all of which can affect their treatment.¹⁵ Accordingly, ASAM offers specific recommendations for the assessment and treatment of SUD in older adults to meet these needs.¹⁶

The ASAM levels of care – Medicare coverage crosswalk demonstrates that:

- Medicare Part A covers inpatient hospital treatment and certain extended care services, which generally map onto ASAM's Level 4, the most intensive level of care for SUD treatment.
- Medicare Part B covers medical and other health services that are typically delivered on an outpatient basis, which generally covers ASAM's two least intensive levels: early intervention (ASAM Level 0.5) and outpatient services (ASAM Level 1).
- Medicare Part D covers prescription drugs which include medications for the treatment of SUDs, specifically alcohol use disorders and opioid use disorders.

The levels of care that are not covered under Medicare are most of ASAM's intermediate levels of care – ASAM Levels 2 and 3. Services at these levels are typically furnished in the

¹¹ The six dimensions used to assess the severity of a patient's condition and level of functioning are: acute intoxication and /or withdrawal potential; biomedical conditions and complications; emotional, behavioral or cognitive conditions or complications; readiness to change; relapse, continued use or continued problem potential; and recovery/living environment. *Id.* at 43.

¹² Legal Action Center and Partnership to End Addiction, *Spotlight on Medical Necessity Criteria for Substance Use Disorders: An Analysis of Requirements for Health Plans to Use Specific Criteria and Assessment Tools to Determine Medical Necessity* 6 and Ex. A (Nov. 1, 2020), <https://www.lac.org/resource/spotlight-on-medical-necessity-criteria-for-substance-use-disorders>.

¹³ *Wit v. United Behavioral Health*, No. 14-cv-02346-JCS, 2019 WL 1033730, at *14 (N.D. Cal. Mar. 5, 2019).

¹⁴ *The ASAM Criteria*, *supra* note 10, at 307.

¹⁵ *Id.* at 307-09.

¹⁶ *Id.* at 307-17.

community by freestanding SUD treatment facilities, which are not authorized as provider types under Medicare.¹⁷

Additionally, Medicare rules limit coverage and reimbursement for SUD care such that treatment is not as extensive as it is for other medical conditions.¹⁸ While most commercial insurance and Medicaid plans are subject to the 2008 Mental Health Parity and Addiction Equity Act (Parity Act),¹⁹ Medicare is the single largest payer that is exempt from this federal anti-discrimination law, which requires coverage of SUD and mental health benefits to be comparable to and no more restrictive than medical and surgical benefits.²⁰ Medicare's limitations on covered settings and provider types, reimbursement rates and policies, and benefit coverage, among others, would likely be invalid if the Parity Act applied.

As the number of Medicare beneficiaries, including those with SUD, continues to grow, Congress and the Centers for Medicare and Medicaid Services (CMS) must remedy these gaps in coverage, with specific attention to:

- Covering the settings in which SUD services are appropriately and effectively delivered;
- Covering all practitioners authorized by state law to deliver SUD services;
- Adopting reimbursement standards based on the service delivery models; and
- Applying the Parity Act standards to protect beneficiaries with SUDs from discriminatory financial and other limitations in their health plans.

Medicare Substance Use Disorder Coverage Overview

Medicare is generally comprised of three parts, each of which covers specific services. Medicare Part A covers inpatient hospital services; Part B covers most outpatient care and physician services; and Part D covers prescription drugs. Beneficiaries can elect to enroll in a Part C plan, which combines the benefits in Medicare Parts A and B and sometimes additional benefits, such as those available under Part D. Some SUD benefits are explicitly covered under

¹⁷ *Id.* at 308.

¹⁸ *Medicare Coverage of Mental Health and Substance Abuse Services*, Center for Medicare Advocacy, <https://medicareadvocacy.org/medicare-info/medicare-coverage-of-mental-health-services/> (last visited Oct. 28, 2020).

¹⁹ Mental Health Parity and Addiction Equity Act, Pub. L. 110-343 (Oct. 3, 2008).

²⁰ *The Mental Health Parity and Addiction Equity Act (MHPAEA)*, Centers for Medicare & Medicaid Services, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/mhpaea_factsheet (last visited Oct. 28, 2020).

each of these parts. Additionally, because SUD is an illness, certain diagnostic and treatment services for SUDs may be covered when they are “reasonable and necessary,” even when they are not explicitly incorporated in statute or regulation, so long as they are furnished by Medicare-certified providers. See 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. §§ 424.5(a)(1) – (2).

Medicare Part A: Hospital Insurance

Individuals who are 65 years and older, as well as those under 65 who are eligible based on disability, are entitled to receive Medicare Part A benefits. 42 U.S.C. § 1395c. Part A covers inpatient hospital services at a hospital or Critical Access Hospital (CAH), as well as psychiatric hospitals on a more limited basis. §§ 1395d(a)(1), 1395d(b)(3). Part A also covers post-hospital extended care services and home health services. §§ 1395d(a)(2) – (3). **Medicare beneficiaries with SUD conditions who meet the medical necessity criteria for inpatient hospital care would be eligible for Medicare coverage of their treatment.**

Inpatient Hospital Services

Individuals are considered “inpatients” if they are formally admitted to a hospital or CAH with the expectation that they will require hospital care for at least two nights.²¹ Medicare covered inpatient hospital services include bed and board; nursing services and other related services; use of hospital or CAH facilities, medical social services; drugs, biologicals, supplies, appliances, and equipment; certain other diagnostic or therapeutic services; medical or surgical services provided by certain interns or residents-in-training; and transportation services, including transport by ambulance. 42 C.F.R. § 409.10(a). Medicare covers medical social services if furnished by the hospital or CAH to improve the treatment of the patient’s condition. § 409.12(a). These services include, but are not limited to, “[a]ssessment of the social and emotional factors related to the patient’s illness, ... obtain[ing] case work services to assist in resolving problems in these areas; and assessment of the relationship of the patient’s medical and nursing requirements to their home situation, financial resources, and the community resources available to them...” in connection with discharge planning.²²

Drugs or biologicals are covered when they are ordinarily furnished by the hospital for the care and treatment of inpatients and represent a cost to the institution in rendering services to the beneficiary. § 409.13(a). The drugs must also be included or approved for inclusion in the latest edition of one of three national drug compendium; and their use must be safe, effective, and otherwise reasonable and necessary.²³ Any medication provided as part of inpatient treatment would be bundled into the inpatient payment and not paid separately under Medicare Part D.²⁴

²¹ Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 1 – Inpatient Hospital Services Covered Under Medicare Part A* § 10 (Rev. 234, Mar. 10, 2017), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf>.

²² *Id.* § 20.2.

²³ *Id.* § 30.

²⁴ *MLN Matters #SE1604, supra* note 8, at 1-2.

Part A also pays for a limited supply of drugs for use outside the hospital or CAH if it is medically necessary to facilitate the patient's departure from the hospital and required until the patient can obtain a continuing supply. § 409.13(b).

Inpatient Psychiatric Hospital Services

Inpatient psychiatric hospital services are reimbursable under Medicare Part A when patients with psychiatric conditions participate in active treatment that can reasonably be expected to improve their conditions. 42 U.S.C. § 1395f(a)(2)(A); 42 C.F.R. § 412.27(a).²⁵ Coverage in this setting is only available for patients with a psychiatric principal diagnosis that is listed in the International Classification of Diseases, Tenth Revision, Clinical Modification, which includes the full range of SUDs. 42 C.F.R. § 412.27(a).²⁶ Facilities must furnish psychological services, social work services, psychiatric nursing, and therapeutic services through the use of qualified personnel. § 412.27(b). All services must be provided under an individual comprehensive written treatment plan, which must include the substantiated psychiatric diagnosis and the short- and long-term goals to meet the active treatment requirement. § 412.27(c)(3)(i).

Medicare imposes a lifetime limit of 190 days for inpatient psychiatric hospital services. In contrast, all other Part A benefit quantitative limitations are for a course of treatment for a spell of illness, rather than the more restrictive lifetime limit. See 42 U.S.C. § 1395d(b)(3). **This quantitative limit on SUD and psychiatric care violates Parity Act standards.**

While Medicare does not explicitly include medically-managed intensive inpatient services (ASAM Level 4) as an authorized benefit, these SUD services may be furnished and reimbursed when provided to Medicare beneficiaries in certified settings – hospitals, CAHs, and psychiatric hospitals – and under the care of certified providers. Additional professional services may be covered in inpatient settings under Part A, though they are billed separately under Part B if those services and providers are authorized under Part B and considered separate from the inpatient stay.²⁷ **Thus, ASAM Level 4 can be a covered benefit through Medicare.**

Medicare Part B: Supplementary Medical Insurance

Medicare Part B is an optional supplementary medical insurance (SMI) program for individuals who are 65 years and older, as well as people under 65 with disabilities, that helps pay for many medical and other health services that are not covered by Part A. 42 U.S.C. §§ 1395j, 1395k(a); 42 C.F.R. 410.3(a)(3). Beneficiaries are responsible for premiums, an annual deductible, and coinsurance. 42 U.S.C. §§ 1395r(a), 1395l(a) – (b); 42 C.F.R. § 410.3(b). Similar to Part A,

²⁵ Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 2 – Inpatient Psychiatric Hospital Services* § 30.2.2 (Rev. 253, Dec. 14, 2018), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c02.pdf>.

²⁶ Chapter 5 of the International Classification of Diseases, Tenth Revision, Clinical Modification includes substance-related disorders. ICD-10-CM Section F10-F19, <https://icd.codes/icd10cm/chapter5/F10-F19> (last visited Oct, 28, 2020).

²⁷ *MLN Matters #SE1604*, *supra* note 8, at 1-2.

Medicare Part B services must be provided in a certified setting by an enrolled physician or approved practitioner, who must certify that the services are medically necessary. 42 C.F.R. § 410.12(a)(2), (3). Part B also covers drugs and biologicals that are not usually self-administered. § 410.26(a)(8).

Covered Settings

The scope of benefits under Part B includes physician services and certain outpatient services furnished by a hospital or CAH, rural health clinic (RHC), Federally Qualified Health Center (FQHC), the Indian Health Service (IHS), Indian tribe or tribal organization facility, end-stage renal disease (ESRD) outpatient facility, ambulatory surgical center (ASC), home health agency (HHA), comprehensive outpatient rehabilitation facility (CORF), or community mental health center (CMHC). 42 C.F.R. § 410.3(a).

Importantly, “Medicare does not recognize SUD treatment facilities as an independent provider type, nor is there an integrated payment for the bundle of services those providers may provide (either directly, or incident to a physician’s services),” with the exception of opioid treatment programs.²⁸ This coverage gap is critical because, although non-covered facilities may employ covered practitioners and furnish covered services, the facility is not eligible to receive a facility fee or bundled payment for the services they provide. If individual practitioners in these settings were to bill for the services they provide, consistent with the ASAM levels of care, they would be limited to reimbursement for a fraction of the cost of the services furnished to a beneficiary. **The failure to cover SUD facilities on par with other medical facilities means that many Medicare beneficiaries cannot access SUD care and cannot continue their treatment when they become Medicare eligible.**

Covered Practitioners

Medicare Part B pays for authorized services by enrolled physicians (42 C.F.R. § 410.20), clinical psychologists (§ 410.71), clinical social workers (§ 410.73), physician assistants (§ 410.74), nurse practitioners (§ 410.75), clinical nurse specialists (§ 410.76), occupational therapists (§ 410.59), physical therapists (§ 410.60), speech-language pathologists (§ 410.62), certified registered nurse anesthetists (§ 410.69), certified nurse-midwives (§ 410.77), and registered dietitian or nutrition professionals (§ 410.134). Regardless of the category of provider, the services must be of a type that would be covered if they were furnished either by a physician or as “incident to” a physician’s professional service and must meet the requirements of the regulations for each type of provider. 42 C.F.R. § 410.10.

Services and supplies are “incident to” a physician’s services if they are of a type that is commonly furnished in the office or clinic of a physician or other practitioner; an integral, though incidental, part of the service of a physician or other practitioner in the course of diagnosis or

²⁸ *Id.* at 2.

treatment of an injury or illness; and commonly furnished without charge or included in the bill of a physician or other practitioner. § 410.26(b).²⁹ Such services may be provided by auxiliary personnel, which include any qualified individual who is acting under the **direct supervision** of an **on-premises** physician or other practitioner and meets any applicable requirements to provide “incident to” services. § 410.26(a)(1).³⁰

Thus, in an office-based setting, for example, a physician or psychiatrist could develop a treatment plan for a patient with a SUD that includes counseling services that are delivered, under the direct supervision of the on-premises physician, by a qualified SUD or mental health practitioner. Those practitioners could include clinical social workers, psychologists, licensed professional counselors, and even certified SUD or peer counselors (if authorized under state law). Practitioners who are separately covered under Medicare, such as clinical social workers and psychologists, can deliver these services either “incident to” the physician’s care or separately at different billing rates. In contrast, licensed professional counselors and certified SUD and peer counselors, which are not covered Medicare provider-types, could **only** furnish these services as auxiliary personnel under the direct supervision of an on-premises Medicare-authorized physician. **These limitations reduce the availability of SUD treatment, interrupt established therapeutic relationships when a patient becomes eligible for Medicare, and prevent qualified practitioners from meeting the growing demand for SUD care.** Congress would need to amend the Social Security Act to authorize these practitioners to be reimbursed for providing services under Medicare. Application of the Parity Act to Medicare would further ensure that practitioners who are authorized to deliver and bill services independently under state law are also authorized to do so under Medicare.

Covered SUD Services

Part B offers at least some coverage for SUD-related services in ASAM Level 0.5 (early intervention), ASAM Level 1 (outpatient services), and ASAM Level 2 (intensive outpatient/partial hospitalization). These services include (a) screening and early intervention, (b) office-based outpatient SUD care, (c) outpatient hospital psychiatric services, (d) opioid treatment programs, (e) telehealth, and (f) partial hospitalization programs. However, not all of the services in the ASAM continuum of care are covered by Medicare, and some of the ones that are covered do not meet the ASAM standards for those programs.

²⁹ See also Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services* § 60.1 (Rev. 259, July 12, 2019), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>; National Council for Behavioral Health, *Medicare “Incident To” Toolkit* (Mar. 2020), https://www.thenationalcouncil.org/wp-content/uploads/2020/04/NCBH_IncidentTo_Toolkit.pdf?dof=375ateTbd56.

³⁰ Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services*, *supra* note 29, § 60.1(B).

Screening and Early Intervention

Medicare Part B covers various types of screening and early intervention (ASAM Level 0.5) in certified settings. For example, Medicare covers preventive screening for SUD. Alcohol Misuse Screening and Counseling is covered in primary care settings once per year and can include up to four counseling visits if the provider determines that the beneficiary is misusing alcohol.³¹ Additionally, as part of the SUPPORT Act, screening for potential substance use disorders and referral for treatment as appropriate is now included in a Medicare beneficiary's initial preventative physical examination and subsequent annual wellness visits. 42 U.S.C. §§ 1395x(ww)(2)(N), 1395x(hhh)(2)(G).

Medicare also covers more targeted screening and interventions for individuals with risky substance use. Screening, Brief Intervention, and Referral to Treatment (SBIRT) services are reimbursable when provided in physicians' offices and outpatient hospital settings.³² SBIRT is used as an early intervention service for individuals at risk of developing a SUD and targets those who have risky substance use but do not meet the diagnostic criteria for a SUD.³³ Patients must have signs or symptoms of a SUD for SBIRT to be considered medically necessary and thus covered by Medicare.³⁴ The "screening" must be for purposes of diagnosis in the context of an illness or injury, in contrast to a general screening service that is widely available to beneficiaries (regardless of symptomology) or the specific screening services covered by Medicare under statutory authority, including those for mammography, diabetes, and colorectal cancer screening.³⁵ "Brief intervention" involves up to five counseling sessions aimed at engaging patients with risky substance use behaviors in short conversations to increase awareness and to give feedback, motivation, and advice.³⁶ Patients whose screening reveals a need for additional services are then referred to the appropriate specialty care.³⁷ Importantly, a Medicare recipient would face financial barriers to accessing those services if the practitioner or level of care to which the patient is referred is not covered by Medicare.

Medicare pays for SBIRT when providers are licensed or certified to perform mental health services by their state and qualified to perform the specific mental health services rendered, including physicians, physician assistants, nurse practitioners, clinical nurse specialists, clinical

³¹ Medicare Learning Network, *Alcohol Misuse Screening & Counseling*, ICN MLN006559, Centers for Medicare & Medicaid Services (June 2020), https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#ALC_MISUSE. The deductible, copayments, and coinsurance are waived for these services.

³² Medicare Learning Network, *Screening, Brief Intervention and Referral to Treatment (SBIRT) Services*, MLN Booklet (ICN MLN904084), Centers for Medicare & Medicaid Services 5 (Mar. 2020), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf [hereinafter *MLN904084*].

³³ *Id.* at 2-3.

³⁴ *Id.* at 7.

³⁵ See Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual, Chapter 4 – Part B Hospital* § 200.6 (Rev. 10186, June 19, 2020), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>.

³⁶ *MLN904084*, *supra* note 32, at 4.

³⁷ *Id.*

psychologists, clinical social workers, certified nurse-midwives, and independently practicing psychologists.³⁸

CMS has recently finalized a rule to improve interventions in hospital emergency departments for beneficiaries with OUD by reimbursing for services related to the initiation of OUD treatment starting in 2021.³⁹ The new billing code includes payment for assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services.⁴⁰ Initiation of medications for opioid use disorder (MOUD) in hospital emergency departments with linkage to treatment has been shown to increase enrollment in treatment⁴¹ and will help mitigate the increased costs to Medicare for inpatient care related to opioid overdose.

Office-Based Outpatient SUD Care

Office-Based Treatment

Medicare beneficiaries may receive treatment for a SUD in an outpatient office-based setting (ASAM Level 1) if services are delivered by a physician, psychiatrist, psychologist, or licensed clinical social worker, or by other SUD practitioners who are authorized to practice in a state as auxiliary personnel “incident to” a physician’s services. 42 U.S.C. §§ 1395u(b)(18)(C) – (D). Beneficiaries can also receive services and supplies in a “physician directed clinic,” where at least one physician is present to perform medical services at all times, each patient is under the care of a clinic physician, and all other services are furnished under physician supervision.⁴²

Office-Based Management and Counseling Treatment

Beginning in 2020, CMS created a new bundled episode of care payment for treatment of patients with OUD in an office-based setting.⁴³ This new bundled payment includes overall management, care coordination, individual and group psychotherapy, and counseling activities provided over the course of a month that would be similar to those services provided through the OTP benefit (described later in this section).⁴⁴ Billing for these codes is not limited to any particular physician or non-physician practitioner specialty and does not require consultation with a specialist, but the services must be furnished in a physician or other practitioner’s office.⁴⁵

³⁸ *Id.* at 5-7.

³⁹ CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84472, 84643-44 (Dec. 28, 2020).

⁴⁰ *Id.*

⁴¹ CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 50074, 50173 (proposed Aug. 17, 2020), citing Gail D’Onofrio et al., *Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence Randomized Clinical Trial*, JAMA 16, no. 313 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4527523/>.

⁴² Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services*, *supra* note 29, § 60.3.

⁴³ CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 84 Fed. Reg. 62568, 62673-77 (Nov. 15, 2019).

⁴⁴ *Id.* at 62673.

⁴⁵ *Id.* at 62674.

Medications for OUD, including buprenorphine and naltrexone in various formulations, are not covered in this bundle, but they can be reimbursed separately under Medicare Parts B or D if they are part of the patient's treatment plan.⁴⁶ CMS is expanding this bundled payment to cover all SUDs (not just OUD) starting in 2021.⁴⁷

Additional Office-Based Care Management and Service Coordination

Other models of care management and service coordination may be available to Medicare beneficiaries in certified settings, although the counseling and other behavioral health treatment are generally not bundled into the same payment. In all of these models, the care management may be provided by a Medicare-certified practitioner or by clinical staff who furnish services "incident to" to the physician's care.

Since 2017, Medicare has reimbursed care management for beneficiaries with behavioral health conditions, including SUD, as part of the psychiatric collaborative care model (CoCM) in an effort to integrate behavioral health care into the primary care setting.⁴⁸ Under this model, a behavioral health care manager must work in the same office as the treating physician and consult with a psychiatric specialist, although the specialist does not need to be located on site.⁴⁹ CoCM services include the initial assessment and care planning by the primary care team, proactive and systemic follow-up by the behavioral health care manager, and regular case load review with the psychiatric consultant.⁵⁰

In addition, chronic care management (CCM) services are available to Medicare beneficiaries with two or more chronic conditions, including SUDs,⁵¹ that are expected to last at least twelve months or until the death of the patient, when such services are furnished by a physician or other qualified health care professional or by clinical staff under the supervision of a physician or other qualified health care professional.⁵²

As of 2020, Medicare also reimburses for principal care management (PCM), which are similarly comprehensive care management services furnished for patients with a single high-risk disease

⁴⁶ *Id.* at 62673. CMS noted that the benefit sought to accommodate prescribing practices for long-acting medications for opioid use disorders (MOUD), such as implantable buprenorphine and injectable naltrexone.

⁴⁷ CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 39, 85 Fed. Reg. at 84642-43.

⁴⁸ Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017, 81 Fed. Reg. 80170, 80230-43 (Nov. 15, 2016).

⁴⁹ Medicare Learning Network, *Behavioral Health Integration Services, MLN Booklet (ICN MLN909432)*, Centers for Medicare & Medicaid Services 4-6 (May 2019), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/BehavioralHealthIntegration.pdf>.

⁵⁰ *Id.* at 2.

⁵¹ Centers for Medicare & Medicaid Services, *Connected Care Toolkit: Chronic Care Management Resources for Health Care Professionals and Communities* 8 (2017), <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/connected-hcptoolkit.pdf>.

⁵² Medicare Learning Network, *Chronic Care Management Services, MLN Booklet (ICN MLN909188)*, Centers for Medicare & Medicaid Services 3, 5 (July 2019), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf>.

or complex condition, including SUDs, expected to last between three months and one year, or until the death of the patient.⁵³ Under both of the CCM and PCM models, beneficiaries have disease specific care management, 24/7 access to a designated care team member through enhanced communication opportunities (such as secure email), referrals, and coordination with any home- and community-based clinical service providers.⁵⁴

Outpatient Hospital Psychiatric Services

Medicare beneficiaries may also receive outpatient SUD services (ASAM Level 1) in hospital settings when they are furnished by physicians, or incident to a physician's service, and reasonable and necessary for the diagnosis or treatment of the patient's condition.⁵⁵ The services must be prescribed by a physician under a written individualized treatment plan, supervised and periodically evaluated by the physician to assess progress in meeting treatment goals, and provided with a reasonable expectation of improvement.⁵⁶ Covered outpatient hospital psychiatric services include individual and group therapy with physicians, psychologists, or other state-authorized mental health professionals; occupational therapy; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes if they cannot be self-administered; activity therapies that are individualized and essential for the treatment of the patient's condition; family counseling; patient education; and diagnostic services.⁵⁷ A service is considered "diagnostic" when "it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease," which includes psychological testing.⁵⁸

Opioid Treatment Programs

Individuals with OUD may receive care in a federally accredited clinic-based setting designated as an Opioid Treatment Programs (OTPs). See 42 C.F.R. § 8.1 et seq. These programs involve the direct administration of opioid agonist medications (methadone and buprenorphine) on a daily or less frequent basis depending on the patient's treatment progress, in addition to other outpatient services. OTPs typically fall under ASAM Level 1 as an outpatient service, and they may be located in a range of settings, including freestanding clinics, community mental health centers, community health centers, or hospital medication units or satellite clinics, as long as the

⁵³ CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 43, 84 Fed. Reg. at 62692-96.

⁵⁴ *Id.* at 62695-96.

⁵⁵ See Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 6 – Hospital Services Covered Under Part B* § 70.1 (Rev. 267, Feb. 4, 2020), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c06.pdf>.

⁵⁶ *Id.* § 70.1(A).

⁵⁷ *Id.* § 70.1(C)(1).

⁵⁸ *Id.* § 20.4.1.

entity satisfies federal accreditation standards.⁵⁹ OTP services are “delivered by a team of personnel trained in the treatment of opioid use disorder, which includes, at a minimum, physicians, nurses, licensed or certified addiction counselors, and mental health therapists who provide patient-centered and recovery-oriented individualized treatment, case management, and health education.”⁶⁰

As of January 2020, Medicare Part B covers OUD services in an OTP and reimburses those services at a bundled facility rate for weekly episodes of care. 42 U.S.C. §§ 1395x(s)(2)(HH), 1395m(w), 1395cc(e)(3). The bundled payment to OTPs includes oral, injected, and implanted Food and Drug Administration (FDA)-approved opioid agonist and antagonist treatment medications (methadone, buprenorphine, and naltrexone);⁶¹ dispensing and administration of such drugs; substance use counseling by professionals authorized under state law to provide such services; individual and group therapy with a physician, psychologist, or other state-authorized mental health professional; toxicology testing; intake activities; and periodic assessments. § 1395x(jjj)(1); 42 C.F.R. §§ 410.67(b), 8.12(f). Starting in 2021, Medicare’s OTP benefit will also include the coverage and dispensing of naloxone (an FDA-approved opioid overdose reversal medication) and overdose education for patients and caregivers.⁶² Professionals who can provide the substance use counseling and individual and group therapy include licensed clinical social workers, licensed professional counselors, licensed clinical alcohol and drug counselors, certified peer specialists, and others who are permitted to furnish this type of therapy or counseling by state law and scope of practice.⁶³ **As such, practitioners who are not otherwise authorized under Medicare to furnish services to Medicare beneficiaries can provide some OTP services through the bundled payment.**

Unique cost-sharing rules also apply to Medicare beneficiaries who receive OTP services. While Medicare reimburses most Part B services at 80 percent of the billable rate, with beneficiaries paying 20 percent of the cost as coinsurance, CMS has waived the cost-sharing requirement for OTP services, for a time-limited period, to minimize barriers to OUD treatment services during the opioid crisis.⁶⁴ Outside of an OTP, beneficiaries who receive OUD services, including the prescription of buprenorphine in office-based settings, continue to pay the standard 20 percent coinsurance.⁶⁵

⁵⁹ *The ASAM Criteria*, *supra* note 10, at 291-95.

⁶⁰ *Id.* at 293.

⁶¹ CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 43, 84 Fed. Reg. at 62631-35; Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 17 – Opioid Treatment Programs (OTPs)* § 40.1.1(B)(1) (Rev. 268, Feb. 4, 2020), <https://www.cms.gov/files/document/chapter-17-opioid-treatment-programs-otps.pdf>.

⁶² CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 39, 85 Fed. Reg. at 84682-88.

⁶³ Medicare Learning Network, *Opioid Treatment Programs (OTPs): Medicare Billing and Payment Fact Sheet, MLN 8296732*, Centers for Medicare & Medicaid Services (May 2020), <https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf>.

⁶⁴ CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 43, 84 Fed. Reg. at 62664-65.

⁶⁵ *Id.* at 62665.

Telehealth

Medicare will pay for certain services that are furnished via telehealth communications: an audio-visual interactive telecommunications system by a physician or authorized practitioner who is located in a different setting from the Medicare beneficiary. 42 U.S.C. § 1395m(m). Medicare only covers services via telehealth that are specified in the annual physician fee schedule rulemaking and added to the Medicare telehealth services list. 42 C.F.R. § 410.78(f).⁶⁶ These services currently include office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, and pharmacologic management services. § 410.78(b). In addition, the substance use disorder counseling, individual and group therapy services, and periodic assessments in Medicare's OTP benefit are covered when furnished via telehealth. §§ 410.67(b)(3), (4), (7).⁶⁷

For Medicare to reimburse services delivered via telehealth, the beneficiary must be located at one of an enumerated list of originating sites when receiving the telehealth-authorized services, which can include a beneficiary's home when the individual has a SUD diagnosis and is receiving treatment of such disorder or co-occurring mental health disorder. 42 U.S.C. §§ 1395m(m)(4)(C)(ii), 1395m(m)(7); 42 C.F.R. § 410.78(b)(3)(xii). Generally, the originating site must be located in an area that is designated as a rural health professional shortage area or in a county that is not included in a Metropolitan Statistical Area, although these geographic requirements also do not apply for the purposes of providing SUD treatment to a beneficiary with a SUD diagnosis. 42 U.S.C. §§ 1395m(m)(4)(C)(i), 1395m(m)(7); 42 C.F.R. § 410.78(b)(4)(iv)(C). During the COVID-19 Public Health Emergency (PHE), Medicare can reimburse for a wider range of services delivered via telehealth to patients located anywhere in the country, including in a patient's place of residence even when their treatment is not related to SUD care.⁶⁸

Practitioners at the distant site who can deliver telehealth services are limited to physicians, physician assistants, nurse practitioners, clinical nurse specialists, nurse-midwives, clinical psychologists, clinical social workers, registered dietitians or nutrition professionals, and certified registered nurse anesthetists. 42 C.F.R. § 410.78(b)(2). During the COVID-19 PHE, CMS has authorized practitioners and auxiliary personnel to receive supervision via interactive telecommunications technology as well, when such practitioners or the services they are furnishing require direct supervision.⁶⁹

⁶⁶ Centers for Medicare & Medicaid Services, *List of Telehealth Services*, <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes> (last visited Oct. 28, 2020).

⁶⁷ CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 39, 85 Fed. Reg. at 84690-91.

⁶⁸ Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 19230, 19232 (Apr. 6, 2020).

⁶⁹ CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 41, 85 Fed. Reg. at 50115-16. This temporary change lasts through the end of the PHE or December 31, 2021, whichever is later.

Generally, Medicare requires that telehealth services be delivered through multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. § 410.78(a)(3). When audio-video communication technology is not available to the beneficiary during the COVID-19 PHE, certain services may be furnished using audio-only telephone calls if all other applicable requirements are met, including OTP-based substance use counseling, individual and group therapy, and periodic assessment services. §§ 410.67(b)(3), (4), (7).⁷⁰ During the COVID-19 PHE, CMS also used waiver authority to cover, and then increase payment rates for, audio-only evaluation and management services, because those codes were being used more frequently and to manage more complex care. CMS has stated that all of the flexibilities related to the use of audio-only telephone for purposes of telehealth services will end with the PHE.⁷¹

Partial Hospitalization Programs

ASAM Level 2 services cover two levels of care: intensive outpatient (IOP) and partial hospitalization programs (PHP). As described in detail in Section III, IOP (Level 2.1) and PHP (Level 2.5) services for SUD care are effectively not covered under Medicare Part B. A far narrower set of PHP services are covered under Part B when delivered in specific settings and for patients with serious psychiatric conditions who are at risk of hospitalization.

Part B covers PHP services when they are provided by a community mental health center (CMHC) or an outpatient hospital department and when an individual would require inpatient psychiatric care in the absence of such services. 42 U.S.C. §§ 1395n(a)(2)(F), 1395x(ff).⁷² PHP services closely resemble those of highly structured, short-term hospital inpatient programs, although patients do not reside at the treating facility.⁷³ Patients must require a minimum of 20 hours per week of therapeutic services, consistent with an individualized treatment plan, and they generally have “an acute onset or decompensation of a covered Axis I mental disorder” under the current edition of the Diagnostic and Statistical Manual (DSM) or the International Classification of Diseases (ICD).⁷⁴

⁷⁰ See also Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, *supra* note 68, 85 Fed. Reg. at 19258.

⁷¹ CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 39, 85 Fed. Reg. at 84533-35. CMS also recognizes and reimburses for brief communication technology-based services furnished via telephone or electronic messages, often called “virtual check-ins,” that do not meet the definition of telehealth because they are not provided via audio-visual communication systems and they are not deemed to be equivalent to in person services. See CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 41, 85 Fed. Reg. at 50112. CMS will continue to reimburse for virtual check-ins for established patients post-PHE. CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 39, 85 Fed. Reg. at 84535.

⁷² See Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 6 – Hospital Services Covered Under Part B*, *supra* note 55, § 70.3.

⁷³ *Id.*

⁷⁴ *Id.* While Axis I in the DSM-IV included substance-related disorders; the DSM-5, the most recent edition of the DSM, removed the multi-axial system, although it still includes substance-related and addictive disorders. See SAMHSA, *Impact of the DSM-IV to DSM-5 Changes on the National Survey on Drug Use and Health* (June 2016),

Medicare-covered services in PHPs include individual and group therapy with physicians, psychologists, or other state-authorized mental health professionals; occupational therapy; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes if they cannot be self-administered; individualized activity therapies that are not primarily recreational or diversionary; family counseling; patient training and education; and diagnostic services. 42 U.S.C. § 1395x(ff)(2); 42 C.F.R. § 410.43(a)(4). However, as discussed in Section III, the standards for PHP for SUD treatment (ASAM Level 2.5) do not align with Medicare’s existing coverage of partial hospitalization services.

Accordingly, Medicare Part B offers coverage of ASAM Level 0.5 by reimbursing for screening and early intervention for SUDs and much of ASAM Level 1 by reimbursing for a range of outpatient treatment services for SUDs that can also be delivered via in person visits or telehealth. Coverage of ASAM Level 2 is more limited, and nonexistent for ASAM Level 3, as discussed in Section III.

Medicare Part C: Medicare Advantage

Medicare beneficiaries can choose to receive their traditional Medicare benefits through an integrated model provided by private insurance companies, commonly known as Medicare Advantage Plans.⁷⁵ In 2020, nearly forty percent of Medicare beneficiaries – roughly 25 million people – enrolled in Medicare Advantage Plans.⁷⁶ These plans provide all Part A and Part B coverage and may also offer supplemental benefits and coverage, such as those available in Medicare Part D. 42 U.S.C. § 1395w-22. While these plans can set their own standards for how beneficiaries pay for and receive their benefits, they must still follow rules set by Medicare. *Id.* For example, Medicare Advantage Plans may establish their own provider networks and reimburse out-of-network providers at a lower rate than their in-network providers. See 42 C.F.R. §§ 422.4(a)(1)(ii), 422.112(a), 422.200 et seq. CMS must approve provider networks to ensure that all applicable requirements are met, including access and availability, service area, and quality. See §§ 422.4(a)(1), 422.112(a)(1). Medicare Advantage Plans may also use utilization management criteria for the delivery of certain benefits, such as requiring referrals from a gatekeeper or step therapy for medications before a patient can get coverage. See §§ 422.4(a)(1)(ii), 422.136.

<https://www.samhsa.gov/data/sites/default/files/NSDUH-DSM5ImpactAdultMI-2016.pdf>. Chapter 5 of the ICD also includes substance-related disorders. ICD-10-CM Section F10-F19, *supra* note 26.

⁷⁵ Dep’t. of Health & Human Services, *What is Medicare Part C?*, <https://www.hhs.gov/answers/medicare-and-medicaid/what-is-medicare-part-c/index.html> (last visited Oct. 28, 2020).

⁷⁶ Centers for Medicare & Medicaid Services, *CMS Fast Facts*, *supra* note 1.

Medicare Part D: Prescription Drug Coverage

An individual who is entitled to benefits under Part A or enrolled under Part B may elect to receive prescription drug coverage through a Medicare Part D plan. 42 U.S.C. §§ 1395w-101(a)(1), (a)(3)(A). As with Part B, beneficiaries enrolled in Part D plans are required to pay premiums, an annual deductible, and coinsurance. §§ 1395w-102(b)(1) – (2)(A). Part D plans must offer all covered Part D drugs, which are those that are dispensed only with a prescription and used for a medically accepted indication. § 1395w-102(e)(1); 42 C.F.R. § 423.100.

Medicare Part D plans must cover drugs that are medically necessary for the treatment of opioid dependence.⁷⁷ The three FDA-approved medications for opioid use disorder (MOUD) are methadone, buprenorphine, and naltrexone.⁷⁸ Part D also covers naloxone, an FDA-approved opioid antagonist indicated for the emergency treatment of opioid overdose.⁷⁹ Coverage under Part D must include both single entity products and combination products – buprenorphine monotherapy and buprenorphine-naloxone – when they are medically necessary.⁸⁰ Methadone is not covered under Part D when used for opioid dependence because it cannot be obtained from a pharmacy with a prescription, but it is covered as part of the OTP benefit.⁸¹ In addition, all Medicare Part D and Medicare Advantage plans cover the three FDA-approved medications for alcohol use disorder: acamprosate, disulfiram, and naltrexone.⁸²

Part D plans have the authority to impose restrictions and limitations on Part D drugs, including the use of prior authorizations and formulary benefit management tools, step therapy, and quantities per prescription or the number of refills.⁸³ Part D plans typically place drugs on different tiers in their formularies, such that beneficiaries would be required to pay more to get non-preferred brand-name prescription drugs or very high cost prescription drugs than for most generic prescription drugs. 42 U.S.C. § 1395w-102(b)(2)(B); 42 C.F.R. § 423.104(d)(2).⁸⁴

⁷⁷ Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements* § 10.8 (Rev. 18, Jan. 15, 2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

⁷⁸ SAMHSA, *Medications for Opioid Use Disorder, Treatment Improvement Protocol (TIP) 63 ES-1, 1-3 – 4* (2020), <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006>.

⁷⁹ See CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 41, 85 Fed. Reg. at 50203.

⁸⁰ Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements*, *supra* note 77, § 10.8.

⁸¹ *MLN Matters #SE1604*, *supra* note 8, at 4.

⁸² See SAMHSA, *Medications for Opioid Use Disorder, Treatment Improvement Protocol (TIP) 63*, *supra* note 78, 2-4; GoodRx, *Acamprosate Medicare Coverage*, <https://www.goodrx.com/acamprosate/medicare-coverage>; GoodRx, *Disulfiram Medicare Coverage*, <https://www.goodrx.com/disulfiram/medicare-coverage>; GoodRx, *Naltrexone Medicare Coverage*, <https://www.goodrx.com/naltrexone/medicare-coverage> (last visited Oct. 28, 2020).

⁸³ Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements*, *supra* note 77, § 30.2.2.

⁸⁴ *Id.* § 30.2.4

As part of its efforts to improve access to medications for the treatment of OUD, CMS closely scrutinizes Part D plans and Medicare Advantage Plans for formulary inclusion of MOUD treatment, utilization management criteria and cost-sharing for such medications and has informed plan sponsors that it will not approve benefit designs that would discourage enrollment by beneficiaries who needed such therapy.⁸⁵ In 2018, CMS specifically indicated that it would not approve plans that require authorization more than one time per year for buprenorphine medications and required plans to carry over previous authorizations.⁸⁶ In response, the overwhelming majority of Medicare Part D plans removed prior authorization requirements entirely for at least one formulation of both generic and brand buprenorphine-naloxone.⁸⁷ **As such, access to MOUD – both through the prescription drug benefit and OTP benefit coverage – has greatly improved in Medicare in recent years.**

Gaps in Medicare SUD Coverage

Although Medicare has begun to cover some discrete services for the prevention and treatment of SUD, the full scope of services and levels of care identified by ASAM – which are needed to meet the needs of individuals with SUD – are not covered by Medicare. Indeed, Medicare covers the most intensive and expensive level of care – services in hospitals – and the least intensive levels of care – certain screening, counseling, and care coordination services in office-based outpatient settings and OTPs. Patients who do not meet the medical necessity criteria for acute hospital care but are too ill to receive appropriate care in an office-based setting or OTP cannot access appropriate SUD services through Medicare, as freestanding SUD treatment facilities that deliver care for subacute SUDs are not covered as a Medicare provider type.⁸⁸ Current Medicare reimbursement standards make it virtually impossible for providers to bill for the required mix and intensity of services without a bundled rate. Additionally, many of the practitioners who provide these services are not authorized to be reimbursed under Medicare. As a result, **community-based options for SUD care under ASAM Levels 1, 2 and 3 are severely limited for Medicare beneficiaries.**

⁸⁵ *Id.* § 30.2; Centers for Medicare and Medicaid Services, *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter 253* (Apr. 2, 2018), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>.

⁸⁶ *Id.*

⁸⁷ *Id.*; see also Tami L. Mark, et al., *Association Between Medicare and FDA Policies and Prior Authorization Requirements for Buprenorphine Products in Medicare Part D Plans*, *JAMA* (July 9, 2019), <https://jamanetwork.com/journals/jama/fullarticle/2737670>; Ellen Weber, *State Medicaid Programs Should Follow the “Medicare Model”: Remove Prior Authorization Requirements for Buprenorphine and Other Medications to Treat Opioid Use Disorders*, *Legal Action Center* 3-4 (July 2019), <https://www.lac.org/resource/state-medicare-programs-should-follow-the-medicare-model-remove-prior-authorization-requirements-for-buprenorphine-and-other-medications-to-treat-opioid-use-disorders>.

⁸⁸ *The ASAM Criteria*, *supra* note 10, at 308.

Gaps in Levels of SUD Care

Outpatient Care

The ASAM Criteria designate levels of care by matching the patient’s risk, severity of illness and level of function with type and intensity of services,⁸⁹ and contemplate that a patient will move to a less or more intensive level of care depending upon treatment need. ASAM Level 1 – outpatient services – generally involve treatment services for less than 9 hours per week and “are tailored to each patient’s level of clinical severity and function and are designed to help the patient achieve changes in his or her alcohol, tobacco, and/or other drug use or addictive behaviors.”⁹⁰ Outpatient SUD services may be appropriate for patients whose conditions are of moderate severity but are able to maintain their daily activities, patients who are in early stages of readiness to change who need education about addiction or are not ready to commit to full recovery, patients who need monitoring to determine whether they have responded to more intensive levels of service, and patients who have achieved stability in recovery and need ongoing monitoring and disease management, as with other chronic diseases.⁹¹

ASAM Level 1 services “may be offered in any appropriate setting that meets state licensure or certification criteria,” which can include office practices, health clinics, mental health clinics, or addiction programs.⁹² The programs are staffed by “appropriately credentialed and/or licensed treatment professionals (including addiction-credentialed physicians, counselors, psychologists, social workers, and others),” and also often include licensed independent practitioners with prescribing authority such as generalist physicians, physician assistants, and advanced registered nurse practitioners.⁹³ The typical staff credentials and settings of care go beyond Medicare authorized provider-types.

Community-Based SUD Treatment Facilities

Medicare does not recognize substance abuse treatment facilities as a provider type for purposes of outpatient treatment.⁹⁴ Many of the freestanding SUD treatment facilities that offer outpatient SUD services also deliver intensive outpatient programs, partial hospitalization, or residential care. When other health plans cover these facility-based settings, patients have flexibility to move to more or less intensive services within a single setting as their needs change and as their recovery progresses. Patients can build trusting and lasting relationships with their treatment team and continue to receive care in the least restrictive setting. As described below, the practitioners in these community-based facilities have the unique training and skills to meet the needs of their patient populations and link their patients to additional support services to

⁸⁹ *Id.* at 69.

⁹⁰ *Id.* at 184.

⁹¹ *Id.* at 184-86.

⁹² *Id.* at 186-87.

⁹³ *Id.* at 187.

⁹⁴ *MLN Matters #SE1604, supra* note 8, at 2.

promote integration in their communities. When Medicare fails to recognize and reimburse these facilities, beneficiaries must seek care in a more restrictive and expensive setting than is clinically necessary or in an office-based setting in which their physician lacks expertise in addiction medicine and likely does not employ the full range of practitioners who are trained to support and counsel patients with SUDs.

Licensed or Certified SUD Practitioners

Apart from prescribing and medication management, “certified and/or licensed addiction counselors offer much of the counseling in Level 1 services.”⁹⁵ The counseling staff in SUD treatment facilities is composed of practitioners with varying levels of educational attainment, with a majority having a graduate degree (57%), a quarter having a bachelor’s degree, and a smaller portion (17%) with either an associate degree or no degree.⁹⁶ Individuals with the most expertise in SUDs and addiction are those with certification in addiction treatment, which is “available for different levels of staff and requires education/training, work experience, and an exam focused on SUDs and addiction.”⁹⁷ Based on 2016 data, certification is more common among counselors with less educational attainment than those with graduate degrees: 59% of counselors with an associate or no degree and 49% of counselors with a bachelor’s degree are certified counselors, compared to only 40% of counselors with a master’s degree and 34% of those with a doctorate degree.⁹⁸

Several practitioners that provide much of the counseling in ASAM Level 1 programs and make up a significant part of the SUD treatment workforce are not authorized as a provider type that may bill and receive reimbursement under Medicare. These practitioners include Licensed or Certified Professional Counselors, Licensed or Certified Clinical Alcohol and Drug Counselors, and Marriage and Family Therapists.⁹⁹

Their services may be covered as auxiliary personnel when furnished “incident to” a physician’s services, consistent with Medicare requirements.¹⁰⁰ Because of this limitation, outpatient therapy services are only covered by Medicare when furnished by physicians, enrolled licensed clinical social workers, psychologists, or psychiatrists.¹⁰¹ This may account for why, among beneficiaries who are the highest users of behavioral health services, those with SUDs receive only 20% of their services from behavioral health specialists, compared to those with mental health diagnoses who receive 78% of services from behavioral health specialists.¹⁰² Medicare’s current

⁹⁵ *The ASAM Criteria*, *supra* note 10, at 187.

⁹⁶ U.S. Dep’t. of Health & Human Services, Assistant Secretary for Planning & Evaluation, Office of Disability, Aging, and Long-Term Care Policy, *Examining Substance Use Disorder Treatment Demand and Provider Capacity in a Changing Health Care System: Final Report 22* (Dec. 2017), <https://aspe.hhs.gov/system/files/pdf/259356/ExamSUDfr.pdf>.

⁹⁷ *Id.* at 23.

⁹⁸ *Id.*

⁹⁹ See 42 U.S.C. § 1395u(b)(18)(C); 42 C.F.R. § 410.10; *The ASAM Criteria*, *supra* note 10, at 308.

¹⁰⁰ See National Council for Behavioral Health, *Medicare “Incident To” Toolkit*, *supra* note 29; *MLN Matters #SE1604*, *supra* note 8, at 2.

¹⁰¹ *MLN Matters #SE1604*, *supra* note 8, at 2; *The ASAM Criteria*, *supra* note 10, at 308.

¹⁰² GAO-20-408, *supra* note 9, at 18.

provider-type structure is not aligned sufficiently with the mix of providers that deliver SUD services in community-based settings.

Congress has recognized these limitations in current Medicare rules and established, under the SUPPORT Act,¹⁰³ the Value in Opioid Use Disorder Treatment demonstration project that will allow for reimbursement of services delivered by behavioral health practitioners who are not Medicare-certified providers, including licensed clinical professional counselors and licensed clinical alcohol and drug counselors.¹⁰⁴ Value in Treatment highlights the need to cover these providers, recognizing that increasing access to more community-based providers and services could “result in improved health outcomes and cost savings among beneficiaries who have health and social needs that go beyond the clinical services currently covered by Medicare.”¹⁰⁵

The SUD provider workforce could be expanded significantly in Medicare if these providers were authorized under Medicare law to practice independently and permitted to furnish services in authorized facilities and offices, rather than function only as auxiliary personnel who are subject to “incident to” coverage rules.¹⁰⁶

Certified Peer Counselors

Generally, peer specialists are individuals recovering from a behavioral health condition who have obtained specific training and certification requirements defined by the state that allow them to advocate for people in recovery, lead recovery groups, and mentor patients or help set treatment goals.¹⁰⁷ While certified peer specialists can be authorized by the state to work with patients with SUD, Medicare does not authorize them to furnish services to beneficiaries nor does it reimburse for these services.¹⁰⁸ **In contrast, most state Medicaid programs have begun to cover peer support services for behavioral health conditions, and 38 states cover some type of peer support for persons with SUD.**¹⁰⁹

¹⁰³ SUPPORT for Patients and Communities Act, 115th Congress, Pub. L. 115-271 § 6042 (enacted Oct. 24, 2018).

¹⁰⁴ Centers for Medicare & Medicaid Services, *Value in Opioid Use Disorder Treatment Demonstration Program: Request for Applications (RFA) 7* (May 1, 2020), available for download at <https://innovation.cms.gov/innovation-models/value-in-treatment-demonstration>.

¹⁰⁵ *Id.* at 4.

¹⁰⁶ See *Medicare Reimbursement*, American Counseling Association, <https://www.counseling.org/government-affairs/federal-issues/medicare-reimbursement> (last visited Oct. 2, 2020). There is currently a bill pending before Congress that would allow Medicare to authorize and reimburse licensed professional counselors and marriage and family therapists. Mental Health Access Improvement Act, H.R.945 (116th Congress) (2019).

¹⁰⁷ *Issue Brief: Recovery Support Services for Medicaid Beneficiaries with a Substance Use Disorder*, MACPAC 9 (July 2019), <https://www.macpac.gov/wp-content/uploads/2019/07/Recovery-Support-Services-for-Medicaid-Beneficiaries-with-a-Substance-Use-Disorder.pdf>.

¹⁰⁸ PEERS Act of 2020, H.R.8206 (116th Congress), <https://www.congress.gov/bill/116th-congress/house-bill/8206/text>; *Older Adults Peer Support: Finding a Source for Funding*, National Association of State Mental Health Program Directors 6 (Aug. 2017), https://www.nasmhpd.org/sites/default/files/TAC.Paper_.8.Older_Adults_Peer_Support-Finding_a_Funding_Source.pdf.

¹⁰⁹ *Issue Brief: Recovery Support Services for Medicaid Beneficiaries with a Substance Use Disorder*, MACPAC, *supra* note 107, at 6-9.

Certified peer specialists, authorized by a state, could theoretically provide counseling and other “incident to” services as auxiliary personnel as part of a bundled payment for an inpatient stay under Part A or outpatient treatment in Part B covered settings.¹¹⁰ Yet, many of the settings in which peer specialists are practicing are not eligible for coverage because Medicare does not recognize SUD treatment facilities as an independent provider type.¹¹¹ CMS has begun to encourage Medicare Part C plans to consider covering peer support services to help facilitate recovery and assist in navigating health care resources,¹¹² although it does not appear that plans have begun to cover these services to date.¹¹³

The lack of coverage for outpatient community-based SUD facilities and providers – including licensed or certified SUD practitioners and peer counselors – prevents many Medicare beneficiaries from accessing ASAM Level 1 outpatient SUD care. There is an urgent need to combat the significant and growing workforce shortage of SUD professionals, especially those who are trained to work with the aging U.S. population and share the same racial and cultural background of an increasingly diverse aging population.¹¹⁴

Care Management

Limited care management is now available for Medicare beneficiaries with SUD as PCM or CCM, and it is also available as part of bundled payments under the psychiatric CoCM¹¹⁵ and office-based SUD management and counseling.¹¹⁶ However, these services are still only available in office-based settings, which excludes freestanding SUD treatment facilities and other community-based settings where patients typically access SUD care. Only physicians and non-physician practitioners who are authorized to furnish services under Medicare may be reimbursed for care management, which excludes most clinical staff, such as licensed and certified SUD practitioners, who would typically provide these services in the community,¹¹⁷

¹¹⁰ *MLN Matters #SE1604*, *supra* note 8, at 2.

¹¹¹ *Id.*

¹¹² Centers for Medicare & Medicaid Services, *Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter 159* (Jan. 30, 2019), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf>.

¹¹³ See Beth McGinty, *Medicare’s Mental Health Coverage: How COVID-19 Highlights Gaps and Opportunities for Improvement*, The Commonwealth Fund (July 9, 2020), <https://www.commonwealthfund.org/publications/issue-briefs/2020/jul/medicare-mental-health-coverage-covid-19-gaps-opportunities>.

¹¹⁴ Michael A. Hoge et al., *Mental Health and Addiction Workforce Development: Federal Leadership is Needed to Address the Growing Crisis*, *Health Affairs* (Nov. 2013), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2013.0541>.

¹¹⁵ Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017, *supra* note 48, 81 Fed. Reg. at 80230-43; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018, 82 Fed. Reg. 52976, 53169-80 (Nov. 15, 2017).

¹¹⁶ CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, *supra* note 39, 85 Fed. Reg. at 84642-43.

¹¹⁷ See 42 U.S.C. § 1395u(b)(18)(C); 42 C.F.R. § 410.10; Centers for Medicare & Medicaid Services, *Value in Opioid Use Disorder Treatment Demonstration Program: Request for Applications (RFA)*, *supra* note 104, at 7.

unless they have direct supervision and work on-site with the physician to meet Medicare's standards for "incident to" services.

Intensive Outpatient Programs (IOPs)

SUD programs that offer intensive outpatient services (ASAM Level 2.1) treat patients who have biomedical conditions that are stable or are being addressed concurrently, are experiencing greater intensity of SUD-related symptoms or are unable to stabilize at a lower level of care, and who require close monitoring and structured therapy to promote treatment progress and prevent further deterioration.¹¹⁸ Patients in IOPs generally require at least 9 hours of skilled treatment services per week, including individual and group counseling, medication management, family therapy, education groups, occupational and recreational therapy, and other therapies.¹¹⁹ ASAM Level 2.1 programs "may be offered in any appropriate setting that meets state licensure or certification criteria," but they are primarily delivered by SUD outpatient specialty providers.¹²⁰ IOPs must be "staffed by an interdisciplinary team of appropriately credentialed addiction treatment professionals," and any "physicians treating patients in this level should have specialty training and/or experience in addiction medicine or addiction psychiatry."¹²¹

Medicare regulatory requirements and billing standards render this benefit effectively unavailable for patients with a primary SUD diagnosis and, more importantly, Medicare does not cover the settings of care that provide IOP for patients with SUD.¹²² In authorized facility-based settings, Medicare covers outpatient SUD services and may reimburse the facility for multiple services even if delivered on the same date of service, including individual, group, and family counseling; client education and training; drugs and biologicals that cannot be self-administered; occupational therapy and individualized therapeutic activity services; and diagnostic services.¹²³ As such, Medicare certified providers could likely bill for the majority of these services as individual outpatient psychiatric services in authorized settings. In contrast, Medicare does not have a daily, weekly, or monthly payment for the full bundle of services provided to patients in IOPs to facilitate billing or ensure that their claims are not denied as duplicative.¹²⁴ When authorizing other levels of care or bundled services, Medicare can develop

¹¹⁸ *The ASAM Criteria*, *supra* note 10, at 202-04.

¹¹⁹ *Id.* at 199.

¹²⁰ *Id.* at 198; *see also Overview of Substance Use Disorder (SUD) Care Clinical Guidelines: A Resource for States Developing SUD Delivery System Reforms*, Medicaid Innovation Accelerator Program 6-7 (Apr. 2017), <https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/iap-downloads/reducing-substance-use-disorders/asam-resource-guide.pdf>.

¹²¹ *The ASAM Criteria*, *supra* note 10, at 198-99.

¹²² *Id.* at 308.

¹²³ *See* 42 C.F.R. § 485.918(b)(1) (services provided by Community Mental Health Centers); § 410.43(a)(4) (services provided in partial hospitalization programs); § 410.67(b) (services provided in Opioid Treatment Programs).

¹²⁴ *See* Wyn Staheli, *Intensive Outpatient Treatment*, Find-A-Code (Jan, 11, 2018),

<https://www.findacode.com/articles/intensive-outpatient-treatment-iop-32825.html>; *see also* Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 6 – Hospital Services Covered Under Part B*, *supra* note 55, § 70.1; *The ASAM Criteria*, *supra* note 10, at 308. The office-based care coordination management and counseling treatment benefit going into effect in 2021 for all SUDs is designed to address the gap

policies that allow for certified providers – such as OTPs or PHPs – to bill for add-on codes or additional services beyond what may be permitted otherwise in a given timeframe (e.g. same date of service).¹²⁵ In failing to cover IOP services, Medicare does not authorize these providers, or the settings that offer these programs, to bill in the same way to cover the mix and number of services a patient in an IOP would need. By contrast, most state Medicaid programs cover IOP for people with SUD.¹²⁶ This gap in Medicare coverage means that beneficiaries will not have access to a more intensive outpatient service if they resume substance use and need additional clinical support, or if they are eligible to step down from a higher level of care but are not ready for ASAM Level 1 outpatient services.

Although intensive outpatient services are not available for Medicare beneficiaries with SUD, Medicare Part B covers Comprehensive Outpatient Rehabilitation Facility (CORF) services when a referring physician certifies that a beneficiary needs skilled rehabilitation services for a medical health condition, those services are furnished while the individual is under the care of a physician, and the services are provided under a written plan of treatment. 42 U.S.C. §§ 1395k(a)(2)(E), 1395x(cc); 42 C.F.R. §§ 410.105(b), (c). Covered CORF benefits that are comparable to those in ASAM Level 2.1 include physician services, occupational therapy, social and psychological services, nursing care services, drugs and biologicals, and supplies and durable medical equipment. 42 C.F.R. § 410.100. However, the social and psychological services included in this benefit are covered only if physical therapy services represent the predominate rehabilitation services provided in the CORF, and they may not relate to a mental health diagnosis.¹²⁷ Thus, this Medicare benefit cannot be applied to patients with SUDs, even if the appropriate facilities were covered under the same rules and fee structures, because “CORFs do not provide services to treat mental, psychoneurotic and personality disorders.”¹²⁸ Even so, Medicare could establish an IOP benefit for beneficiaries with SUD that could be modeled after the CORF benefit to meet this treatment gap for ASAM Level 2.1.

in care management services, rather than higher intensity outpatient SUD services, and the requirement for such services to be provided in an office prevents this benefit for being sufficient in the IOP context. *See supra* notes 43-47 and accompanying text.

¹²⁵ *See, e.g.*, Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual, Chapter 39 – Opioid Treatment Programs (OTPs)* §§ 30.6, 30.6.1 (Rev. 4524, Feb. 14, 2020),

<https://www.cms.gov/files/document/chapter-39-opioid-treatment-programs-otps.pdf> (addressing coding exceptions for services provided by OTPs); Centers for Medicare & Medicaid Services, *Medicare NCCI 2020 Coding Policy Manual – Chap11-CPTcodes90000-99999* 8-10, 44-45 (Jan. 1, 2020), available for download at <https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd> (addressing coding exceptions for psychiatric services provided by PHPs).

¹²⁶ *Medicaid Behavioral Health Services: Intensive Outpatient Treatment for Substance Use Disorder*, Kaiser Family Foundation (2018), <https://www.kff.org/other/state-indicator/medicaid-behavioral-health-services-intensive-outpatient-treatment-for-substance-use-disorder/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

¹²⁷ Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 12 – Comprehensive Outpatient Rehabilitation Facility (CORF) Coverage* § 40.7 (Rev. 255, Jan. 25, 2019),

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c12.pdf>; *see also* 42 C.F.R. § 410.100(h).

¹²⁸ Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual, Chapter 5 – Part B Outpatient Rehabilitation and CORF/OPT Services* § 100.4 (Rev. 4440, Nov. 1, 2019), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c05.pdf>.

Partial Hospitalization Programs (PHPs)

Under the ASAM Criteria, PHPs (ASAM Level 2.5) are medically necessary for patients with SUD whose biomedical conditions and problems are severe enough to distract from recovery efforts and require medical monitoring, who have mild to moderate psychiatric decompensation with discontinuation of drug use, who are unable to achieve behavioral change at a lower level of care, and who require close monitoring and structured therapy to promote treatment progress and prevent further deterioration.¹²⁹ Patients in PHPs receive at least 20 hours of skilled treatment services each week, including individual and group counseling, medication management, family therapy, education groups, occupational and recreational therapy, and other therapies.¹³⁰ ASAM Level 2.5 programs “may be offered in any appropriate setting that meets state licensure or certification criteria,”¹³¹ which may be freestanding or part of a larger health care system and typically offer direct access to psychiatric, medical, and laboratory services to address the severity of the patient’s medical conditions.¹³²

As noted above, Medicare covers partial hospitalization services in only two settings – outpatient hospitals and Medicare-certified community mental health centers – for patients with serious mental health conditions who would otherwise need inpatient treatment.¹³³ A 2009 report prepared for CMS found that, while 30-80% of PHP patients have a diagnosis of SUD in addition to their mental health diagnosis, SUD was never the primary diagnosis for admission to the PHP.¹³⁴ **Medicare regulatory requirements and billing standards render this benefit inadequate to cover patients with a primary SUD diagnosis and, more importantly, Medicare does not cover the settings of care that provide PHP for patients with SUD.**¹³⁵

Under the ASAM Criteria, PHPs for SUD must be “staffed by an interdisciplinary team of appropriately credentialed addiction treatment professionals,” and any “physicians treating patients in this level should have specialty training and/or experience in addiction medicine or addiction psychiatry.”¹³⁶ While CMHCs are required to have medical staff that have psychiatric training or experience, there is no requirement that such personnel have any addiction treatment training or experience. 42 C.F.R. § 485.904(b). Thus, while it is possible that outpatient hospital units or CMHCs have staff that meet the ASAM Criteria for a Level 2.5 program, it is not required, as this service is directed to patients with severe psychiatric conditions and not aligned with care for patients with primary SUD conditions. Furthermore, since freestanding SUD

¹²⁹ *The ASAM Criteria*, *supra* note 10, at 213-15.

¹³⁰ *Id.* at 210.

¹³¹ *Id.* at 208.

¹³² *Overview of Substance Use Disorder (SUD) Care Clinical Guidelines: A Resource for States Developing SUD Delivery System Reforms*, Medicaid Innovation Accelerator Program, *supra* note 120, at 7.

¹³³ Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 6 – Hospital Services Covered Under Part B*, *supra* note 55, § 70.3(A) – (B)(1).

¹³⁴ Musetta Y. Leung et al., *Impacts Associated with the Medicare Psychiatric PPS: A Study of Partial Hospitalization Programs*, RTI International 21 (Feb. 2009), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Leung_PHP_PPS_2010.pdf.

¹³⁵ *The ASAM Criteria*, *supra* note 10, at 308.

¹³⁶ *Id.* at 209.

treatment facilities are not authorized to be Medicare-approved facilities, any program with the targeted resources and personnel to treat individuals with SUD as a primary diagnosis would not be covered by Medicare.¹³⁷

Residential Treatment

Under the ASAM Criteria, patients with SUDs who, “because of specific functional limitations, need safe and stable living environments and 24-hour care” are best served in residential treatment programs (ASAM Level 3).¹³⁸ These community-based programs allow patients to develop, practice, and demonstrate the recovery skills that are necessary to prevent relapse and allow them to transition into lower levels of care.¹³⁹

Residential programs range in intensity, based on the “functional limitations of the patient and services provided to respond to those limitations,”¹⁴⁰ from clinically managed low-intensity residential services (ASAM Level 3.1) to medically monitored high-intensity inpatient services (ASAM Level 3.7).¹⁴¹ These programs can include withdrawal management; individual, group, and family therapy; medication management; psychoeducation; daily clinical services including physician monitoring, nursing care, and observation; and other support services for building the skills and tools necessary for maintaining recovery upon discharge from the program.¹⁴²

Residential treatment programs are provided in facilities where patients can reside safely, and they are staffed 24 hours a day to provide clinical services by addiction treatment, mental health, and general medical personnel.¹⁴³ In addition, mutual and self-help group meetings are generally available on-site at these programs for further support.¹⁴⁴

In contrast to the lack of coverage under Medicare for residential treatment for SUDs, Medicare Part A does cover post-hospital subacute services in two settings: Skilled Nursing Facilities (SNFs) and Inpatient Rehabilitation Facilities (IRFs). See 42 U.S.C. § 1395d(a)(2); 42 C.F.R. §§ 409.5, 409.30, 412.622(a)(3). Post-hospital SNF benefits are available to beneficiaries who have been hospitalized in a hospital or critical access hospital (CAH) for at least three consecutive calendar days and require skilled nursing or skilled rehabilitation services on a daily basis for the condition treated in the hospital. 42 C.F.R. §§ 409.30(a)(1), 409.31. While some SNF services are tailored to physical rehabilitation, post-hospital SNF benefits also include care that is similar to SUD treatment in a residential setting: nursing care and bed and board in

¹³⁷ *MLN Matters #SE1604*, *supra* note 8, at 2.

¹³⁸ *The ASAM Criteria*, *supra* note 10, at 219.

¹³⁹ *Id.*

¹⁴⁰ *Id.* at 220.

¹⁴¹ *Id.* at 219-79.

¹⁴² *Id.*; see also Mauren T. Stewart et al., *State Residential Treatment for Behavioral Health Conditions: Regulation and Policy Environmental Scan*, prepared for the U.S. Dep’t. of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Disability, Aging and Long-Term Care Policy 13-14 (Nov. 2019), <https://aspe.hhs.gov/system/files/pdf/262961/BehHeaConLR.pdf>.

¹⁴³ *The ASAM Criteria*, *supra* note 10, at 219.

¹⁴⁴ *Id.*

connection with that nursing care; occupational therapy; medical social services; and drugs, biological, supplies, appliances, and equipment. § 409.20(a).

Similarly, a patient who requires intensive rehabilitation in an inpatient hospital environment following hospital treatment is eligible for the Medicare Inpatient Rehabilitation Facility (IRF) benefit in appropriately credentialed facilities.¹⁴⁵ The IRF benefit under Part A provides intensive rehabilitation therapy in an “inpatient hospital environment for patients who, due to the complexity of their nursing, medical management, and rehabilitation needs, require and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to the delivery of rehabilitation care.”¹⁴⁶ To qualify for the IRF benefit, a patient must need at least two disciplines of therapy, one of which must be physical or occupational therapy. 42 C.F.R. § 412.622(a)(3)(i). The program typically consists of at least three hours of intensive rehabilitation therapy per day for at least five days a week. § 412.622(a)(3)(ii). Furthermore, the patient must reasonably be expected to actively participate in and significantly benefit from the intensive rehabilitation therapy program. *Id.*

Medicare coverage for SUD residential treatment facilities could be modeled on either the SNF or IRF benefit. Although existing SNF requirements, such as the 3-day inpatient stay rule,¹⁴⁷ do not align entirely with the typical process for SUD residential treatment referral and admission,¹⁴⁸ the treatment goals of delivering subacute inpatient treatment and the care delivery model are quite similar. Nonetheless, neither SNFs or IRFs meet the ASAM Criteria for Level 3 residential treatment programs because they lack the requisite staffing, clinical and social services, and other resources to appropriately treat patients with SUD.¹⁴⁹ SNFs in many states have been found to exclude patients on MOUD, frequently citing their lack of capacity to provide this “specialty care.”¹⁵⁰

¹⁴⁵ Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 1 – Inpatient Hospital Services Covered Under Medicare Part A*, *supra* note 21, § 110.

¹⁴⁶ *Id.*

¹⁴⁷ Medicare beneficiaries are only eligible for SNF services after they have been treated in the hospital for at least three days, which does not include the day of discharge from the hospital or any pre-admission time the patient spends in the emergency room or in outpatient observation. Medicare Learning Network, *Skilled Nursing Facility 3-Day Rule Billing, ICN MLN9730256*, Centers for Medicare & Medicaid Services (July 2019), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/SNF3DayRule-MLN9730256.pdf>.

¹⁴⁸ Unlike patients requiring skilled rehabilitation, many individuals with SUD do not begin residential treatment following an inpatient hospital stay, let alone one that lasts three days, in part because there are few hospital-based SUD treatment services and medically supervised 24-hour care is generally provided in community based settings. Other individuals may require residential treatment after entering the continuum of care at a lower level that is insufficient to meet their clinical needs.

¹⁴⁹ See *The ASAM Criteria*, *supra* note 10, at 219-20.

¹⁵⁰ See Allison Bond, *Nursing homes routinely refuse people on addiction treatment – which some experts say is illegal*, Stat News (April 7, 2018), <https://www.statnews.com/2018/04/17/nursing-homes-addiction-treatment/>; Boston Medical Center, *Patients with substance use disorder discriminated against by post-acute care facilities*, Eureka Alert! (July 16, 2020), https://www.eurekaalert.org/pub_releases/2020-07/bmc-pws071620.php; U.S. Attorney’s Office, District of Massachusetts, *U.S. Attorney’s Office settles disability discrimination allegations with operator of skilled nursing facilities* [Press Release] (Sept. 17, 2019), <https://www.justice.gov/usao-ma/pr/us-attorney-s-office-settles-disability-discrimination-allegations-operator-skilled>.

More state Medicaid programs are incorporating SUD residential treatment providers in their networks through Section 1115 waiver programs to expand and strengthen their SUD service system consistent with the ASAM criteria.¹⁵¹ Yet Medicare's lack of coverage of residential services means that these providers cannot be certified under Medicare, such that beneficiaries with SUD must pay out-of-pocket to access an appropriate level of care, absent secondary insurance that covers this benefit. Furthermore, even if individually certified providers who work in residential treatment settings were to bill Medicare for the specific services they furnish, the lack of a bundled payment for any ASAM Level 3 SUD treatment program prevents beneficiaries from receiving the full scope of services that they would need in these settings.

Withdrawal Management

Initiation of SUD treatment often begins with withdrawal management (frequently referred to as detoxification) that addresses the physiological and psychological symptoms that occur when a patient stops using a substance on which they are physically dependent. Counseling and other therapy are also provided as part of withdrawal management to engage the patient in the recovery process.¹⁵² ASAM identifies five different levels of care – both ambulatory and with 24-hour supervision – for withdrawal management depending on the severity of the patient's condition.¹⁵³ Those services may be delivered in multiple settings: offices, more structured outpatient settings, residential settings, and acute or inpatient hospital settings.¹⁵⁴

In most cases, withdrawal management is delivered and reimbursed in inpatient settings, which are the most intensive and expensive levels of care,¹⁵⁵ even though addiction medicine, like other specialties, seeks to treat a patient in the least restrictive and most cost-effective setting.¹⁵⁶ Under current Medicare standards, withdrawal management can be furnished in an office-based outpatient setting, as long as the medical staff have the required skills and knowledge to carry out the clinical care related to withdrawal, are readily available for medical consultation in emergencies, and have the ability to facilitate the patient's entry into treatment.¹⁵⁷ **Because Medicare does not cover freestanding SUD treatment facilities that provide the range of less intensive and intermediate levels of care,¹⁵⁸ the only settings outside of an office-based practice in which Medicare effectively reimburses for withdrawal management are in licensed acute care or psychiatric hospitals.¹⁵⁹**

¹⁵¹ John O'Brien et al., *State Approaches to Developing the Residential Treatment Continuum for Substance Use Disorders*, Technical Assistance Collaborative (March 2019), http://www.tacinc.org/media/90946/arnold_state-approaches-to-residential-sud-care-continuum_2019.pdf.

¹⁵² *The ASAM Criteria*, *supra* note 10, at 127-29.

¹⁵³ *Id.* at 131.

¹⁵⁴ *Id.* at 107.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 129; SAMHSA, *Detoxification and Substance Abuse Treatment, Treatment Improvement Protocol (TIP) 45 11-12* (2015), <https://store.samhsa.gov/sites/default/files/d7/priv/sma15-4131.pdf>.

¹⁵⁷ *Id.* at 14.

¹⁵⁸ *See id.* at 13-20; *see also MLN Matters #SE1604*, *supra* note 8, at 2.

¹⁵⁹ *The ASAM Criteria*, *supra* note 10, at 308.

Other Restrictions/Barriers to SUD Care

Utilization Management Practices

Utilization Management of Medications for SUD

As noted above, Part D drug plans impose utilization management (UM) requirements on medications to control prescription drug costs and conduct medical necessity reviews. Such requirements often pose barriers to accessing medically necessary treatment, and CMS has taken important steps to ensure that access to buprenorphine medications is not restricted by a drug plan's use of prior authorization. Research shows that the removal of prior authorizations for buprenorphine-naloxone in the Medicare program is associated with greater access to this medication and a reduction in emergency department visits and hospitalizations for all health conditions by individuals with an OUD diagnosis.¹⁶⁰ The savings in health expenditures for hospital services far exceeds the cost of increased medication use.¹⁶¹

Other types of utilization management – such as formulary design, step therapy, quantity limits per prescription or the number of refills, and requirements that patients simultaneously receive behavioral therapy – are permitted under Medicare and may further limit access to MOUD.¹⁶² As with prior authorizations, these practices should be examined for their cost effectiveness in the Medicare program, especially when considering the high costs of emergency department visits and hospitalizations when treatment is deterred or delayed. A review of these utilization management tools for SUD medications in the Medicaid program has begun.¹⁶³ The application of the Parity Act to Medicare would also ensure that a plan sponsor adopt and apply utilization management requirements to SUD medications in a manner comparable to UM requirements for medications for medical conditions.¹⁶⁴

¹⁶⁰ Tami L. Mark, et al., *Association of Formulary Prior Authorization Policies with Buprenorphine-Naloxone Prescriptions and Hospital and Emergency Department Use Among Medicare Beneficiaries*, JAMA (Apr. 20, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764598>.

¹⁶¹ *Id.*

¹⁶² Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements*, *supra* note 77, § 30.2.2.

¹⁶³ *Report to Congress: Utilization Management of Medication-Assisted Treatment in Medicaid*, MACPAC 18-31 (Oct. 2019), <https://www.macpac.gov/wp-content/uploads/2019/10/Report-to-Congress-Utilization-Management-of-Medication-Assisted-Treatment-in-Medicaid.pdf>.

¹⁶⁴ *See* 42 C.F.R. §§ 438.910(b)(2), (c)(2), and (d) (certain Medicaid plans); 45 C.F.R. § 146.136(c)(2), (c)(3)(iii), (c)(4) (private health plans).

Utilization Management of SUD Services

Medicare Advantage Plans may also impose similar UM requirements on services. For example, many Medicare Advantage Plans require enrollees to get a referral to see a specialist, such as a psychiatrist.¹⁶⁵ As of 2018, the majority of Medicare Advantage beneficiaries were enrolled in plans that imposed prior authorization requirements on mental health services.¹⁶⁶ These types of practices limit access to care for beneficiaries in these plans, and research suggests that they also have more systemic consequences of decreasing the number and type of services offered by SUD treatment facilities.¹⁶⁷

Telehealth

Although Medicare covers telehealth for SUD services in the beneficiary's home without any geographical restrictions, the limitations on how telehealth services can be delivered and who can provide these services create significant barriers for patients who need or want to use telehealth. See 42 U.S.C. § 1395m(m)(7). The most problematic barrier, especially for patients who are utilizing telehealth from their homes, is the requirement that telehealth service be furnished through audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. 42 C.F.R. § 410.78(a)(3). Many Medicare beneficiaries, as well as clinical originating sites, lack the requisite technology.

During the COVID-19 pandemic, providers and patients have relied heavily on CMS's flexibilities to permit audio-only telehealth, but they will no longer have access to this mode of service delivery at the end of the PHE.¹⁶⁸ **The lack of coverage of audio-only telehealth service delivery outside of the COVID-19 PHE exacerbates health disparities among beneficiaries with SUD whose disability, income, language, geographic location, and technological literacy prevent them from using audio-visual telehealth communication technologies.**

Additionally, the practitioners eligible to provide telehealth services must be included in the enumerated list in the regulations, which excludes any providers that would otherwise be covered under bundled payments or as auxiliary personnel in covered settings under Medicare Parts A and B. See § 410.78(b)(2). Clinical psychologists and clinical social workers may be reimbursed for individual psychotherapy furnished by telehealth, but they may not be

¹⁶⁵ *Specialists & Referrals in Medicare Advantage Plans*, Medicare.gov, <https://www.medicare.gov/sign-up-change-plans/types-of-medicare-health-plans/specialists-referrals-in-medicare-advantage-plans> (last visited Nov. 3, 2020).

¹⁶⁶ Gretchen Jacobson & Tricia Neuman, *Prior Authorization in Medicare Advantage Plans: How Often Is It Used?*, Kaiser Family Foundation (Oct. 24, 2018), <https://www.kff.org/medicare/issue-brief/prior-authorization-in-medicare-advantage-plans-how-often-is-it-used/>.

¹⁶⁷ Todd Olmstead, William D. White & Jody Sindelar, *The Impact of Managed Care on Substance Abuse Treatment Services*, 39(2) *Health Services Research* 339 (2004), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361010/>.

¹⁶⁸ See *supra* note 71 and accompanying text.

reimbursed for medical evaluation and management services, (§ 410.78(e)(1)), which, as noted above, have been expanded significantly during the COVID PHE. To effectuate the SUPPORT Act in authorizing greater usage of telehealth among beneficiaries with SUD, Medicare must also authorize the full range of providers that furnish SUD services to be reimbursed for delivering care via telehealth.

Custody Exclusion

Medicare prohibits payment for services for which it has no legal obligation to pay. 42 U.S.C. § 1395y(a)(2). Under this authority, CMS excludes individuals who are “in custody under a penal authority” from receiving Medicare reimbursed services, based on the assumption that the correctional entity is responsible for their health services.¹⁶⁹ The only exception to this rule is if state or local law requires the individual to repay the costs of those health services and the government entity enforces the repayment obligation. 42 C.F.R. § 411.4(b). The reach of this exclusion, however, goes far beyond those who are incarcerated and presumably receiving health care in the correctional setting. According to Medicare regulations:

Individuals who are in custody include, but are not limited to, individuals who are under arrest, incarcerated, imprisoned, escaped from confinement, under supervised release, on medical furlough, required to reside in mental health facilities, required to reside in halfway houses, required to live under home detention, or confined completely or partially in any way under a penal statute or rule. *Id.*¹⁷⁰

Medicare has adopted this broad definition based on federal court case law, developed outside the Medicare context, that has found that “custody” is not limited to those who are physically confined.¹⁷¹ Thus, “individuals on parole, probation, bail, or supervised release may be ‘in custody’” for purposes of the Medicare exclusion,¹⁷² even if they live outside of a correctional facility and, therefore, receive no correctional health services.

The “custody exclusion” imposes additional financial burdens on Medicare beneficiaries. To avoid significant penalties associated with Medicare’s late enrollment rules, individuals who are

¹⁶⁹ Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 16 – General Exclusions from Coverage* § 50.3.3(3) (Rev. 198, Nov. 6, 2014), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf>; Medicare Learning Network, *Beneficiaries in Custody Under a Penal Authority*, ICN 908084, Centers for Medicare & Medicaid Services 3 (Mar. 2018), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Items-Services-Furnished-to-Beneficiaries-in-Custody-Under-Penal-Authority-Fact-Sheet-ICN908084.pdf> [hereinafter *MLN Fact Sheet ICN 908084*].

¹⁷⁰ See also *MLN Fact Sheet ICN 908084*, *supra* note 169, at 3.

¹⁷¹ Changes to the Hospital Inpatient Prospective Payment System and Fiscal year 2008 Rates, 72 Fed. Reg. 47130, 47405 (Aug. 22, 2007) (“custody” definition adopted from habeas corpus protections, which are likely based on the broadest definition of “custody” to extend the greatest protections possible); Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 16 – General Exclusions from Coverage*, *supra* note 169, § 50.3.3(3).

¹⁷² Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual, Chapter 16 – General Exclusions from Coverage*, *supra* note 169, § 50.3.3(3).

taken into custody would still be required to pay their monthly premiums for Part B to prevent termination from coverage.¹⁷³ Those who are terminated for failure to pay premiums would need to reenroll in Medicare and would be required to pay a “late enrollment penalty” every month for as long as they have Part B coverage.¹⁷⁴

The Medicare custody exclusion has a significant impact on individuals with SUDs. Approximately 65% of the United States prison population has an active SUD and another 20% were under the influence of alcohol or drugs at the time of their crime.¹⁷⁵ Over 3% of those living in state or federal correctional facilities are 65 years or older and 3.6% are individuals between 60 and 64 years of age.¹⁷⁶ When these individuals are released from custody, it is critical that they have insurance to pay for care so that they can continue treatment they received while incarcerated or initiate treatment. **With Medicare Part B denying reimbursement for services pending the completion of community supervision, most formerly incarcerated individuals will face insurmountable financial barriers to care at the time they need it most.** Those who could not afford to pay the monthly Part B premiums while incarcerated and under community supervision (and thereby pay for insurance coverage while getting no benefits) will also pay a higher price for their insurance coverage for the remainder of their Part B enrollment. These financial and administrative barriers to community-based SUD treatment do not exist in Medicaid¹⁷⁷ or commercial insurance for individuals upon release from jails and prisons.

¹⁷³ *MLN Fact Sheet ICN 908084*, *supra* note 169, at 6.

¹⁷⁴ *Id.*

¹⁷⁵ *Criminal Justice DrugFacts*, National Institute on Drug Abuse (June 1, 2020), <https://www.drugabuse.gov/publications/drugfacts/criminal-justice>.

¹⁷⁶ E. Ann Carson, *Prisoners in 2019*, U.S. Dep’t. of Justice, Office of Justice Programs, Bureau of Justice Statistics 15 (Oct. 2020), <https://www.bjs.gov/content/pub/pdf/p19.pdf>.

¹⁷⁷ CMS addressed similar reimbursement restrictions in the Medicaid program in 2016, clarifying that individuals who are on parole or probation or have been released to the community pending trial are not considered inmates and are, therefore, eligible for Medicaid-reimbursed services. Centers for Medicare & Medicaid Services, *SHO # 16-007 Re: To Facilitate Successful Re-entry for Individuals Transitioning from Incarceration to Their Communities*, Q2 and Q3 (April 28, 2016), <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/sho16007.pdf>. CMS noted that the key consideration in determining an individual’s “custody” status is the individual’s “legal ability to exercise personal freedom.” *Id.* at Q1.

Discussion

The Need for Medicare Coverage of SUD Care is Growing and Program Barriers Limit Access to Care.

Less than one in four older adults with a SUD diagnosis are receiving treatment: over 1.2 million adults ages 65 and older reported a SUD diagnosis in 2019,¹⁷⁸ while only 284,000 individuals in this age group received treatment for a SUD.¹⁷⁹ The number of Medicare beneficiaries receiving MOUD under Part D plans has been steadily increasing since 2006, even before Medicare expanded coverage for OTP services.¹⁸⁰ Nonetheless, hospitalizations and deaths related to opioid overdoses are continuing to rise among older adults, even while overdose death rates are decreasing across the overall population.¹⁸¹

Despite the growing need for SUD treatment among Medicare beneficiaries, “Medicare’s coverage of services for mental health, behavioral health and substance abuse disorders is not as extensive as its coverage for other services.”¹⁸² Medicare beneficiaries with SUDs received only 20% of their behavioral health services from behavioral health specialists in 2018.¹⁸³ In 2016, only 13.8% of all substance use disorder treatment programs accepted Medicare and offered any medication treatment.¹⁸⁴

The data are not surprising; Medicare does not cover the SUD treatment facilities and specialists who would be able to provide this care appropriately to beneficiaries, and who do so under all other reimbursement models. Inadequate Medicare reimbursement rates for covered providers, such as psychiatrists and psychologists,¹⁸⁵ likely also contribute to professional shortages and limited access to care for beneficiaries. According to a 2014 study, just 55% of psychiatrists accepted Medicare reimbursement, compared with 86% of physicians in other specialties.¹⁸⁶ Nearly one third of all providers opting out of Medicare in 2017-18 were mental

¹⁷⁸ 2019 National Survey on Drug Use and Health, *supra* note 2, at Table 5.2A.

¹⁷⁹ *Id.* at Table 5.9A.

¹⁸⁰ U.S. Dep’t. of Health & Human Services, Office of Inspector General, *HHS OIG Data Brief: Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased 3-4* (July 2019), <https://oig.hhs.gov/oei/reports/oei-02-19-00390.pdf>.

¹⁸¹ See Leigh Wedenoja, *supra* note 6; Pamela L. Owens et al., *supra* note 4.

¹⁸² *Medicare Coverage of Mental Health and Substance Abuse Services*, Center for Medicare Advocacy, *supra* note 14.

¹⁸³ GAO-20-408, *supra* note 9, at 18.

¹⁸⁴ Samantha J. Harris et al., *Gaps in Access to Opioid Use Disorder Treatment for Medicare Beneficiaries*, Health Affairs, 233 (Feb. 2020), <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2019.00309>.

¹⁸⁵ *Medicare’s Shrinking Psychologist Reimbursement Rates*, American Psychological Association, (Mar. 2015), <https://www.apaservices.org/practice/advocacy/state/leadership/medicare-payment> (finding that, since 2001, Medicare reimbursement for the most common code billed by psychologists has dropped by more than 30% (adjusted for inflation)).

¹⁸⁶ Tara F. Bishop et al., *Acceptance of Insurance by Psychiatrists and the Implications for Access to Mental Health Care*, 71(2) JAMA Psychiatry 176 (Feb. 2014), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1785174>.

health and SUD practitioners—a total of over 7,000 psychiatrists, psychologists, and licensed clinical social workers.¹⁸⁷

Gaps in benefit coverage and shortages of Medicare providers translate into higher costs for Medicare beneficiaries who need SUD treatment. Premiums for Parts B and D (or Part C) and coinsurance for covered services make up less than half of total out-of-pocket spending for Medicare beneficiaries,¹⁸⁸ who must pay in full for services that are not covered by their Medicare plans or any supplemental insurance they may have.¹⁸⁹ With median out-of-pocket spending accounting for 12% of a beneficiary's total income, coverage gaps in Medicare can pose a significant hardship which can lead to decreased economic security and poverty.¹⁹⁰

These service and provider gaps in Medicare are particularly problematic because commercial insurance plans and Medicaid generally cover and reimburse for most ASAM levels of care, delivered in a wider range of settings and by a broader set of practitioners. Accordingly, individuals who become newly eligible for Medicare will no longer have access to the same treatment options, absent secondary coverage, and they may also need to terminate relationships with their providers. This problem applies both to individuals who age into Medicare as well as those who become eligible based on disability. While low-income Medicare beneficiaries may have some reduced costs and access to a wider range of services through their state's Medicaid program, many individuals are not eligible to become dually enrolled because their state has not elected to expand the Medicaid program under the Affordable Care Act or because their state's income threshold for Medicaid is so low.

Medicare's current coverage of SUD care also exacerbates health disparities for Black and brown beneficiaries. While an examination of the unique barriers that older adults in communities of color face in accessing SUD treatment is beyond the scope of this report, data clearly demonstrate that, for OUDs, the uptake in prescribing and administering buprenorphine has been significantly higher for white patients than Black patients.¹⁹¹ This disparity can be partly attributed to the high cost of treatment, shortage of providers who are authorized to prescribe opioid agonists, and the limited number of facilities providing opioid buprenorphine in Black and Latinx neighborhoods.¹⁹² By covering more SUD services in a greater number of settings and expanding the types of providers who are authorized to furnish SUD care to Medicare beneficiaries and receive reimbursement, Medicare can help to reduce health disparities among Black and brown beneficiaries who are living with SUDs.

¹⁸⁷ GAO-20-408, *supra* note 9, at 6.

¹⁸⁸ Juliette Cubsanski et al., *How Much Do Medicare Beneficiaries Spend Out of Pocket on Health Care?*, Kaiser Family Foundation (Nov. 4, 2019), <https://www.kff.org/medicare/issue-brief/how-much-do-medicare-beneficiaries-spend-out-of-pocket-on-health-care/>.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ Martha Bebinger, *Addiction Medicine Mostly Prescribed to Whites, Even as Opioid Deaths Rose Among Blacks*, Kaiser Health News (May 8, 2019), <https://khn.org/news/addiction-medicine-mostly-prescribed-to-whites-even-as-opioid-deaths-rose-among-blacks/>.

¹⁹² *Between the Lines: Understanding Our Country's Racialized Response to the Opioid Overdose Epidemic*, CLASP 8 (Feb. 2020), <https://www.clasp.org/sites/default/files/publications/2020/02/2020betweenthelines.pdf>.

Application of the Parity Act to Medicare Would Ensure More Comprehensive Coverage of SUD Care and Eliminate Discriminatory Policies.

Comprehensive coverage of SUD care in the Medicare program would have significant health benefits. It would ensure continuity of care for individuals who have accessed treatment prior to enrolling in Medicare; increase access to care for the hundreds of thousands of people who are newly diagnosed with a SUD each year; reduce health disparities; protect the financial security of beneficiaries who need these services; and prevent unnecessary high-cost hospitalizations and overdose deaths by getting more people into evidence-based treatment earlier. Medicare can start to address these gaps by:

- Covering services at all ASAM levels of care, including intensive outpatient programs, partial hospitalization programs delivered by SUD facilities, residential treatment, and withdrawal management in all levels of care;
- Authorizing freestanding licensed SUD treatment facilities, licensed professional counselors, and other licensed and certified addiction specialists as covered Medicare providers; and
- Establishing adequate reimbursement rates and bundled payments, for each ASAM level of care network adequacy standards to ensure sufficient numbers of providers for each level of care.

To address each gap systematically, Congress should address these gaps through, first, the inclusion of these provider types and coverage of all ASAM levels of care in the Medicare statute; and second, require traditional Medicare and Medicare Advantage Plans to comply with the Mental Health Parity and Addiction Equity Act (Parity Act).¹⁹³ The Parity Act requires health plans to cover SUD and mental health services at the same level as medical/surgical services and regulates virtually every design feature, including financial requirements, quantitative treatment limitations, and non-quantitative treatment limitations. Non-quantitative treatment limitations (NQTLs) encompass all plan features that limit the scope or duration of treatment but are not expressed numerically, including the Medicare coverage standards that have created gaps for SUD care: benefit and service exclusions, restrictions on facility type and provider specialty that may deliver and be reimbursed for care, and reimbursement policies and rate setting.¹⁹⁴ Under the Parity Act, financial requirements and quantitative treatment limitations for SUD and mental health benefits can be no more restrictive than those applied to medical/surgical benefits based on a mathematical calculation established in regulation.¹⁹⁵ For NQTLs, the “rules” that are used to develop and implement the design features for SUD and

¹⁹³ *The Mental Health Parity and Addiction Equity Act (MHPAEA)*, Centers for Medicare & Medicaid Services, *supra* note 20.

¹⁹⁴ See 42 C.F.R. § 438.910(d)(2) (certain Medicaid plans); 45 C.F.R. § 146.136(c)(4)(ii) (private health plans).

¹⁹⁵ 42 C.F.R. § 438.910(b) – (c) (certain Medicaid plans); 45 C.F.R. § 146.136(c)(3) (private health plans).

mental health benefits must be comparable to and no more stringently applied than the rules for medical/surgical benefits, both as written and in operation.¹⁹⁶

The Medicare program's structure would lend itself neatly to the Parity Act's analytical framework. To assess compliance, SUD and mental health benefits are compared to medical/surgical benefits in six different categories: inpatient, inpatient out-of-network, outpatient, outpatient out-of-network, emergency care, and prescription drugs. Any financial requirements, quantitative treatment limitations, or non-quantitative treatment limitations that apply to SUD benefits would be compared to those same features for medical/surgical benefits, using the applicable test for discrimination under the Parity Act.

- For traditional Medicare, inpatient SUD benefits could be compared to inpatient medical/surgical benefits in Part A; outpatient and emergency SUD benefits could be compared to medical/surgical benefits in Part B; and prescription drug benefits for SUD and medical conditions could be compared in Part D.
- For Medicare Advantage Plans – health insurance plans that integrate coverage for inpatient, outpatient, and often prescription drug benefits – SUD benefits would be compared based on the same six classifications, as they are currently evaluated by private health insurance plans.

Under this framework, Parity Act standards, if applied to Medicare, would call into question many of the Medicare coverage and reimbursement policies noted above and provide a framework for Medicare reform.

- **Benefit coverage exclusion for intensive outpatient and residential services.**

The scope of benefit coverage for SUD benefits must be comparable to the scope of coverage for medical/surgical benefits, under the Parity Act.¹⁹⁷ The lack of coverage for intermediate levels of care for SUD services – intensive outpatient programs and residential care – is not comparable to the CORF benefits and the services delivered in SNFs and IRFs.¹⁹⁸ Medicare clearly covers treatment options for medical conditions that require subacute care while not covering comparable treatment services for SUD care.

- **Failure to authorize care delivery and reimbursement to SUD treatment facilities that deliver intensive outpatient, partial hospitalization, residential treatment, and other community-based care**

Medicare's prescriptive list of authorized facilities and settings of care would likely violate the Parity Act by establishing more stringent limitations on facility types that deliver SUD care than

¹⁹⁶ 42 C.F.R. § 438.910(d)(1) (certain Medicaid plans); 45 C.F.R. § 146.136(c)(4)(i) (private health plans).

¹⁹⁷ Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 78 Fed. Reg. 68240, 68246-47 (Nov. 13, 2013).

¹⁹⁸ *Id.*

medical/surgical care.¹⁹⁹ Indeed, Medicare does not authorize any licensed SUD facility to deliver partial hospitalization services, in contrast to the coverage for outpatient hospital settings.²⁰⁰ Similarly, licensed community-based settings that deliver outpatient, intensive outpatient, and residential treatment are not authorized Medicare providers in contrast to CORFs, SNFs, IRFs, and freestanding facilities for other types of conditions such as End Stage Renal Disease.

- **Failure to authorize care delivery by SUD practitioners and inadequate networks of SUD providers and facilities.**

Medicare's failure to authorize the full range of practitioners who provide SUD services under state law, like its failure to authorize a range of SUD facilities, would likely violate the Parity Act because Medicare authorizes a full range of medical practitioners, including registered dietitians and nutrition professionals, occupational therapists, physical therapists and speech-language pathologists, to bill for medical care. If the Parity Act applied, Medicare could not exclude SUD practitioners on the basis of different or more stringently applied rules for SUD providers compared to medical care providers.

Additionally, network adequacy is a non-quantitative treatment limitation.²⁰¹ Medicare Advantage Plans are required to ensure access to essential services, which includes contracting with a sufficient number of providers to meet standards set by CMS for the time and distance it takes beneficiaries to get care. If the Parity Act is applied, Medicare would need to use the same standards to build its network of SUD providers as it uses in building its network of medical/surgical providers, thereby ensuring adequate access for beneficiaries.

- **Lifetime treatment limitation on inpatient psychiatric hospital services.**

Medicare Part A imposes a 190-day lifetime limit on the number of inpatient psychiatric hospital days to which a beneficiary is entitled, but does not impose any lifetime limit on inpatient care for medical/surgical benefits. This cumulative treatment limitation would violate the Parity Act because it applies only to SUD and mental health benefits.²⁰²

¹⁹⁹ Dep't. of Labor, *FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century CURES Act Part 39*, Q8 (Sept. 5, 2019), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-39-final.pdf>; see also Centers for Medicare & Medicaid Services, *Parity Compliance Toolkit Applying Mental Health and Substance Use Disorder Parity Requirements to Medicaid and Children's Health Insurance Program 50* (Jan. 17, 2017), https://www.apna.org/files/parity_toolkit_CMS.pdf. (requiring analysis of whether any practitioner types, facility types, including chemical dependency facilities, or specialty providers are excluded from providing covered benefits).

²⁰⁰ Medicare coverage of partial hospitalization services in community mental health centers (CMHCs) does not remedy the Parity Act violation, as an assessment of parity compliance is conducted for SUD benefits separate and apart from mental health benefits.

²⁰¹ Final Parity Act Rules, *supra* note 197, 78 Fed. Reg. at 68246.

²⁰² Dep't. of Labor, *Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA)* 18 (Oct. 23, 2020), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

- **Utilization management practices that are more restrictive for SUD services and medications than for medical conditions.**

Although most Medicare Part C prescription drug and Part D Plans have recently removed prior authorization requirements for at least one brand and generic buprenorphine-naloxone product, other types of utilization management practices are imposed on medications for SUDs and may limit access to care. If the Parity Act applied, such limitations would have to be comparable to and no more stringently applied than utilization management practices for medications that treat medical conditions. Requirements for formulary design, step therapy, quantities per prescription or the number of refills, and requirements that patients simultaneously receive behavioral therapy would also be subject to review.²⁰³ Any utilization management practices in Medicare Advantage Plans for SUD services would also be required to be comparable to and no more stringently applied than those practices for medical/surgical services, such as referral and prior authorization requirements.

- **Reimbursement rates for SUD and mental health providers.**

The limited number of SUD and mental health providers, and the high rate at which psychiatrists and psychologists are leaving the Medicare program compared to medical/surgical providers, suggests that Medicare or Part C plans may use different standards to set reimbursement rates for covered practitioners or may provide different incentives to ensure provider participation across these disciplines.²⁰⁴ Using different rules to establish reimbursement rates for psychologists or other SUD practitioners as compared to medical providers violates the Parity Act.²⁰⁵ To the extent that Medicare increases rates or provides incentives for primary care providers or medical specialists to enter their networks or become enrolled in Medicare, the same standards must apply to SUD and mental health providers.²⁰⁶

- **Reimbursement policies for SUD services.**

With the exception of Medicare's recent expansion to cover opioid treatment programs and services and office-based opioid use disorder services, Medicare reimburses SUD services based on individual codes and does not have bundled rates that could support care delivery in a community-based setting for intermediate levels of care (ASAM Levels 2 and 3). The establishment and use of a bundled rate for medical services in various settings raises Parity

²⁰³ Dep't. of Labor, *FAQs Part 39*, *supra* note 199, Q3 and 5; Dep't. of Labor, *FAQs About Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation*, Q7 and 8 (Oct. 27, 2016), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf>.

²⁰⁴ See American Psychological Association, *Medicare's Shrinking Psychologist Reimbursement Rates*, *supra* note 185 (identifying several factors that Medicare uses in setting reimbursement rates and effect on reimbursement rates for psychologists).

²⁰⁵ Dep't. of Labor, *Self-Compliance Tool*, *supra* note 202, at 20 and App. II at 38-39.

²⁰⁶ See Dep't. of Labor, *FAQs Part 39*, *supra* note 199, Q7; Dep't. of Labor, *Self-Compliance Tool*, *supra* note 202, at 20.

Act concerns to the extent those same practices are not available for reimbursement in SUD facility settings.

Conclusion

Current Medicare coverage of SUD treatment prevents beneficiaries from accessing the full scope of services and providers that are necessary to respond to the opioid and substance use disorder crisis among older adults and people with disabilities. In many ways, SUD coverage in Medicare is less generous than that offered by private and employer-sponsored health plans and Medicaid. As a result, beneficiaries who become eligible for Medicare lose access to the services and providers on which they previously depended. Medicare has begun to fill some coverage gaps, particularly with regard to opioid use disorder care. Yet comprehensive change is needed to ensure that all ASAM levels of care are covered and SUD specialty providers and facilities are authorized to deliver and be reimbursed for SUD treatment. Additionally, Medicare reimbursement rates and coverage policies are often used as a baseline for other insurance programs, even though Medicare reimbursement standards are not subject to non-discrimination standards. Using the Medicare “benchmarks” in other financing systems undermines the development of adequate networks and appropriate standards of care for the delivery of SUD services across all insurance programs.

The opioid epidemic has highlighted the significant limitations in Medicare coverage for persons with SUDs. Congress can remedy this long-standing problem by requiring Medicare to comply with the Parity Act.

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