



PhRMA and its member companies are committed to addressing the stigma of mental illness and substance use disorders, including addiction, and supporting access to the full spectrum of care that individuals with these conditions need. America's biopharmaceutical research companies are also focused on continuing to advance new treatments to improve the health and wellbeing of those with a mental illness, with nearly 140 medicines in development to treat these conditions.<sup>1</sup>

Mental illness refers to a wide range of mental health conditions that can affect mood, thinking and behavior. These illnesses include substance use disorders and such conditions as depression, anxiety disorders, schizophrenia, bipolar disorder and eating disorders. The United States is facing a crisis of mental health and addiction that has left few Americans and families unimpacted by these illnesses and the devastating consequences that are often associated with them.

Unfortunately, the COVID-19 pandemic has exacerbated these trends as Americans of all ages and socioeconomic backgrounds have faced unprecedented levels of isolation, grief, trauma and economic insecurity. But our under-resourced and fragmented American health care system has been poorly equipped to handle the alarming increase in mental illness and addiction and ensure patients can access the care they need. Marginalized and medically underserved populations are facing some of the worst outcomes as a result of these challenges.

This paper highlights key trends in mental illness and substance use disorders and discusses critical barriers and opportunities to implement policy reforms to overcome these challenges.

# TRENDS IN MENTAL ILLNESS, SUBSTANCE USE DISORDERS AND RISK OF SUICIDE

One in five American adults experience a form of mental illness each year and one in 20 adults experience serious mental illness. Serious mental illnesses are those that result in functional impairment and include diagnoses such as severe depression, bipolar disorder or schizophrenia. These illnesses are estimated to cost society more than \$317 billion each year in lost wages, health care expenditures and disability benefits.<sup>2</sup> Having a serious mental illness reduces average life expectancy by 10 years and the average expected lifetime societal costs associated with having one of these illnesses by the age of 25 is \$1.85 million.<sup>3,4</sup>

Low-income individuals or those living in under-resourced areas experience higher rates of mental illness. Though prevalence of these illnesses does not affect specific racial or ethnic groups disproportionately, mixed race and lesbian, gay, bisexual, transgender and queer (LGBTQ) youth experience much higher rates of mental illness-36% and 47%, respectively.5

Substance use disorders represent significant lifetime challenges facing many Americans. And unfortunately, too often, addiction and other mental health conditions go hand in hand. In 2020 alone6:

- 15%-or 40 million Americans aged 12 years or older-reported having a substance use disorder—including alcohol use disorder and illicit drug use disorder.
- More than 18 million Americans have an illicit drug use disorder. 17 million American adults reported having both a mental illness and a substance use disorder.
- Nearly 6 million had both a serious mental illness and a substance use disorder. Those with mental illness are significantly more likely to be users of illicit drugs.

### The COVID-19 pandemic has exacerbated all of these trends.

- · Two out of five adults report symptoms of anxiety or depression. This is up from one in 10 prior to the pandemic.7
- More than half of adults in the United States report their mental health has been negatively impacted by the pandemic, due to worry and stress over the virus-resulting in difficulty sleeping or eating and increases in alcohol consumption or substance use.8
- Emergency room visits for drug overdoses and suicide attempts were 36% and 26% higher, respectively, compared to prior to the pandemic.9

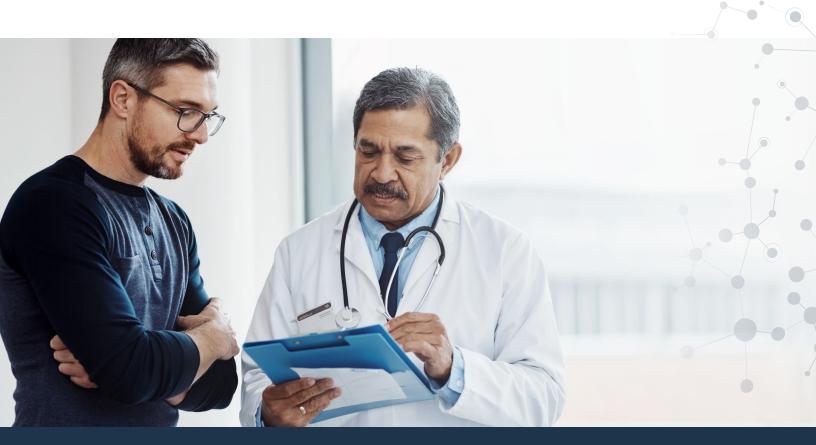


Due to the ongoing burden of these illnesses, severe complications, most notably suicide, have also been increasing among adults. In fact, suicide trends have seen a dramatic rise well before the onset of the pandemic.

- In 2019, 5% of adults (more than 12 million) had serious thoughts of suicide. 10 The national rate of adults experiencing suicidal ideation has increased every year since 2011.11
- The rate of suicides among adults also increased from 2000 through 2018. Though there have been some recent declines in adult suicide rates, today, suicide remains the 12th leading cause of death in the United States.12

The burden of addiction and its consequences are also contributing to increases in mortality. The ongoing opioid crisis continues to drive increases in overdose deaths, but use of other illicit substances are also now driving alarming increases in overdose mortality.

- In 2021, there were an estimated 107,622 drug overdose deaths in the United States-a 15% increase over the previous year.13
- Illicit synthetic opioids such as fentanyl and fentanyl analogues have contributed to significant increases in overdose deaths since 2015.
- More recently, use of methamphetamines and cocaine have contributed to a significant increase in overdose deaths—both independently and in combination with synthetic opioids. 14, 15 In 2021, synthetic opioids such as fentanyl were involved in 64% of drug overdose deaths, and methamphetamine and cocaine in more than half. 16
- Dangerous psychoactive substances also continue to emerge in the illicit drug supply often in the form of counterfeit prescription pills-increasingly contributing to overdoses and deaths among those struggling with addiction.



### **Youth Trends**

Some of the most alarming trends in mental health are among our nation's youth.

- Prior to the pandemic, one in three high school students reported persistent feelings of sadness in 2019-a 40% increase since 2009. Almost half of female high school students reported these feelings.17
- A growing percentage of youth in the United States are also living with major depression. Rates of depressive episodes increased 63% between 2009 and 2017.18
- These trends are particularly acute among socioeconomically disadvantaged children and adolescents. For example, those growing up in poverty are 2-3 times more likely to develop a mental health condition than peers with higher socioeconomic status. 19

Evidence suggests more adolescents and young adults are experiencing serious psychological distress, major depression and suicidal thoughts and behaviors relative to the mid-2000s.

- In 2019, about one in six students reported making a suicide plan in the past year, a 44% increase since 2009.
- Female students are more likely to report suicide-related behaviors than males.
- Cultural trends, such as the rise of electronic communication and digital media and declines in sleep duration, are thought to be having a significant impact on younger people and contributing to these troubling trends.<sup>20</sup>

The most recent data assessing the impact of COVID-19 document how youth mental health and suicidal behaviors have worsened during the pandemic.

- During the first year of the pandemic, more than 17% of youth experienced a major depressive episode.<sup>21</sup>
- ER visits due to suicide attempts among teenagers increased significantly during the pandemic. Though the impact was seen across boys and girls, attempted suicides among girls increased more than 50%.22
- In recent years suicide rates among black children under the age of 13 have been increasing rapidly, with black children nearly twice as likely to die by suicide than non-black children.23

As a result of these alarming trends and the worsening impact of the pandemic, at the end of 2021 the U.S. Surgeon General issued an advisory, Protecting Youth Mental Health, detailing the widespread mental health challenges experienced by American youth and offering recommendations to address these challenges.24



### Co-occurring mental illness and substance use disorders are also resulting in particularly concerning trends in younger Americans:

- Though substance use has generally declined among American youth between 2009 and 2019, youth who have a mental illness continue to be more likely to use substances than those who did not have a mental illness.<sup>25, 26</sup> For example, nearly 30% of adolescents who experienced a major depressive episode were illicit drug users in 2020 relative to just 11% of those that did not experience such an episode.27
- Given the continued increase in deadly illicitly manufactured fentanyl, fentanyl analogs and other dangerous synthetics in the illicit drug supply that are widely available to youth online and elsewhere, the mental health trends facing our nation's youth is particularly troubling. Last year, three quarters of teen overdose deaths in 2021 involved illicit fentanyl.<sup>28</sup>

# CHALLENGES AND OPPORTUNITIES TO ADDRESS MENTAL HEALTH AND SUBSTANCE USE DISORDERS AND IMPROVE OUTCOMES

The alarming pace by which rates of mental illness, addiction and suicide are increasing across the country demands a comprehensive and multifaceted strategy to stem the tide of these crises. Unfortunately, our health care system is not equipped to handle these increasing trends and ensure patients can access the care that they need. The following areas, discussed in more detail below, represent key barriers that impede progress against mental health and addiction in the United States. These barriers also present opportunities to target policy reforms and improve health outcomes for the millions of Americans struggling with these conditions.

#### The biopharmaceutical industry supports policies to:

- Reduce the stigma of mental illness and substance use disorders and bolster our behavioral health workforce.
- Improve access to the comprehensive range of treatment services needed to successfully manage these conditions and make insurance work more like insurance.
- Enforce mental health and substance use disorder parity.
- Leverage and expand the appropriate use of telehealth, while ensuring safeguards to protect the quality of patient care.
- Improve care coordination and delivery through evidence-based care integration models

Together, these policies can represent meaningful steps towards curbing the mental health and addiction crises facing Americans today.



### **Behavioral Health Treatment Access**

Patients with mental illnesses and substance use disorders already face significant hurdles to receiving care, due in large part to the nature of their illnesses, the stigma associated with these illnesses, and a lack of adequate screening. These challenges are compounded by a poorly resourced behavioral health workforce, particularly for patients living in rural areas. Disparities in accessing treatment are also more pronounced in racial and ethnic minority groups.

### Despite the significant burden of mental illnesses few actually receive treatment.

- In 2020, less than half of adults with mental illness received treatment and among those with serious mental illness just about three quarters received treatment.
- Only over half of youth aged six to 17 years old with mental health disorders receive treatment.
- The average delay between the onset of mental illness symptoms and treatment is 11 years.<sup>29</sup>

Although prevalence of certain mental health disorders and substance use disorders are not generally higher among racial and ethnic minority groups, these groups are often less likely to receive treatment services.30

- Asian American, Black or African American, Hispanic or Latin American and multiracial individuals all have lower annual treatment rates.31
- As a result of these inequities, between 2016 and 2020, there have been an estimated 116,722 excess premature mental and behavioral health-related deaths among racial and ethnically minoritized groups and indigenous populations-amounting to \$278 billion in excess cost burden to society.32





Similarly, treatment rates remain low for substance use disorders despite the high prevalence of these illnesses.33

- In 2020, 6.5% of those with a substance use disorder received any treatment.
- Among those with co-occurring substance use disorder and mental health disorders, nearly half did not receive mental health treatment or substance use treatment in the previous year.
- Medication-assisted treatment (MAT) is an evidence-based approach that pairs behavioral therapy with medications for the treatment of opioid use disorder. Despite the availability and proven efficacy of MAT, just 11.2% of the 2.5 million Americans aged 12 years or older with an opioid use disorder received MAT in 2020.
- Unfortunately, despite the significant need for treatment, our behavioral health workforce is severely limited which can pose significant challenges to patients in accessing the care they need. The United States needs 4.4 million more behavioral health practitioners than is currently available in order to meet current needs for those diagnosed with serious mental illness, substance use disorder, and serious emotional disturbance.34

While workforce shortages impact both urban and rural communities, the distribution of behavioral health professionals predominately in urban areas exacerbates barriers to access in rural communities.

- Nearly one-third of Americans currently live in a mental health care professional shortage area, where communities have fewer mental health providers than the minimum their level of population would need.35
- In fact, more than 60% of all U.S. counties-including 80% of rural counties-do not have access to a single psychiatrist. Only 1.6% of licensed psychiatrists live in rural areas.36

Similar workforce shortages exist for treatment providers capable of prescribing certain medications involved in MAT for opioid use disorder.

- 80% of counties do not have a facility available to dispense methadone and one state lacked one entirely (WY).37
- Nearly 40% of counties in the United States do not have a single provider capable of prescribing buprenorphine.38
- 38% of counties have neither a facility nor a provider capable of prescribing either of these medications.39
- Rural communities are among those with the most limited capacity.<sup>40</sup>

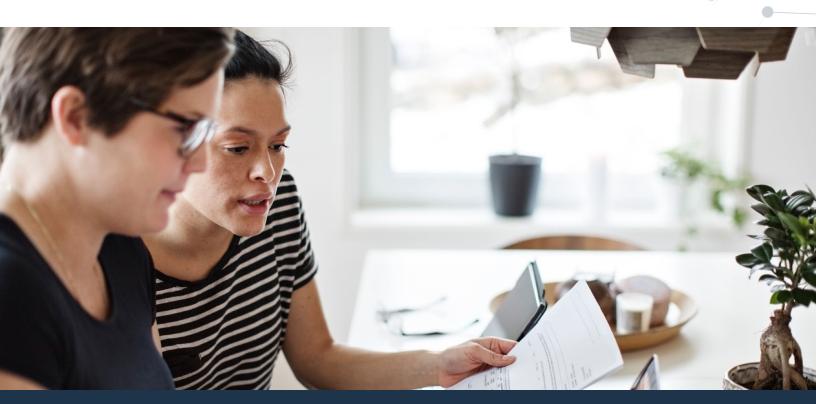


COVID-19 further stretched already limited behavioral health services with a greater number of Americans struggling to manage the mental health and addiction challenges that were worsened by the pandemic.

More than two-thirds of behavioral health providers reported having to cancel, reschedule or turn away patients in the last 3 months during the public health crisis.41

The lack of treatment providers available to meet the significant demand for behavioral health services is unparalleled in other areas of health care. More needs to be done to address the stigma of mental illness and substance use disorders and develop broader recognition of these illnesses as chronic diseases, improve screening for these illnesses, bolster our behavioral health workforce and ensure patients can access the care they need. The following policy solutions can help achieve these goals:42,43

- Integrate behavioral health expertise into general health care settings to improve screening and improve linkages to care.
- Expand qualified behavioral health workers through recruitment programs, scholarships, loan repayment and other incentives to encourage entry into the field and work in rural areas and historically under-resourced communities.
- Develop and maintain a diverse and culturally competent workforce that can be responsive to the populations they serve. This will be critical to closing gaps in health disparities and reducing the stigma associated with seeking help among certain racial and ethnic groups.



### **Insurance Coverage and Access**

Individuals with mental health and substance use disorders already face significant stigma and barriers to accessing care. But coverage challenges are also a key barrier to accessing treatment. About 11% of adults with mental illness and serious mental illness had no health insurance coverage in 2020.44 Affordability challenges also exist for the insured due to high outof-pocket costs for mental health and substance use disorder treatments, services and providers.

### Having health insurance coverage is not always sufficient to ensure access to treatment and related services and support:

- 30% of insured Americans still face a financial barrier to care, like having trouble paying medical bills or having out-of-pocket costs that are more than they can afford.
- Americans with mental health challenges face a high proportion of this burden-with 56% reporting a financial barrier to care.
- These patients also face higher rates of having difficulty understanding and navigating their health insurance coverage with 54% reporting they don't understand what's covered by their insurance company.45

Health care access insecurity for patients with mental health and substance disorders can sometimes be driven by high out-of-pocket costs for needed medicines. Unfortunately, too often health insurance isn't working like it should. Through an endless web of high deductibles, expanded cost sharing obligations and coverage exclusions, insurers are increasingly standing between patients and the care they need. In fact, insurers and intermediaries known as pharmacy benefit managers have shifted more health care costs onto patients through the use of deductibles and coinsurance. As a result, today's patients are paying more for their insurance and getting less.

### Insured patients with mental health conditions also face significant access restrictions to the medicines they need:

- For example, among commercial health insurance plans, utilization management restrictions for brand depression medications were applied nearly 40% of the time in 2020. These restrictions include prior authorization and step therapy requirements, where patients must try and fail on one or more medicines before the originally prescribed medicine is covered.
- Between 2014 and 2020, use of step therapy for depression medicines increased 125%.46

To make matters worse, insured patients with mental health disorders often face difficulty in accessing in-network treatment providers, thereby imposing a higher financial burden for these patients.

Out-of-network care is particularly common in behavioral health care as these providers are less likely to participate in insurer networks.<sup>47, 48</sup>



- Mental health providers often cite low reimbursement rates, heavy administrative burden and high demand as reasons they have chosen not to participate in health plan networks. 49,50
- Privately insured patients seeking outpatient and inpatient mental health care are significantly more likely to report their mental health provider network as inadequate as compared to their medical provider network. Outpatient and inpatient out-of-pocket costs imposed on these individuals were also significantly more costly than other types of medical care.51

Health care access insecurity for patients with mental health and substance use disorders is too often driven by coverage and access restrictions. The following policy solutions can help achieve these goals:52



Increase access to the comprehensive range of treatment options necessary to successfully treat and improve health outcomes for patients with these disorders including inpatient and outpatient treatment options, peer-support specialists and recovery support services.



Make insurance work more like insurance. We need to ensure more medicines are covered from day one and out-of-pocket costs are more predictable. People managing chronic conditions such as mental health and substance use disorders should not have to pay a deductible at the pharmacy counter. Sharing more of the negotiated rebates, discounts and other price concessions that insurers and pharmacy benefit managers receive on medicines from biopharmaceutical companies with patients at the pharmacy counter can also improve affordability for patients with these conditions.

## Mental Health and Substance Use Disorder Parity

Many of the barriers in accessing behavioral health treatment underscore the continued challenges in equitable access to coverage for treatment of mental health and substance use disorders and the stigma associated with these conditions. Various parity laws have been implemented over the years to address inequitable coverage and access and ensure that health plans offering mental health and substance use disorder benefits offer those benefits at the same level as benefits for medical and surgical benefits.53

Unfortunately, parity requirements do not exist for Medicare or Medicaid fee-for-service, which can impose significant barriers to patients in these programs seeking mental health and substance use disorder treatment. For example, Medicare coverage policies impose a 190-day lifetime limit on inpatient psychiatric facility stays, a limit that does not exist for inpatient care in other settings. Medicare also excludes coverage of certain types of behavioral health providers.

Additionally, there are continued challenges in enforcing existing parity requirements. A recent Department of Labor (DOL), Health and Human Services and Treasury report to Congress found numerous mental health parity violations, including unequal treatment limitations, prior authorization requirements and treatment exclusions.54 While the Treasury Department has authority to levy an excise tax on non-compliant health plans, a 2019 Government Accountability Office report had noted that the DOL had not referred a noncompliant employer-sponsored health plan to Treasury.55



Despite the continued challenges in enforcing mental health and substance use disorder parity, evidence shows improving parity leads to improved outcomes-including among marginalized and medically underserved populations.56

- Parity provisions contained in law which reduced cost sharing have led to greater utilization of mental health services and psychotropic medications for mental health disorders.57
- State parity laws and coverage mandates have been shown to be associated with increased alcohol treatment rates for a diverse set of racial and ethnic groups.58 They were also shown to narrow differences in outcomes by racial and socioeconomic subgroups in adolescents.59

Greater enforcement of mental health and substance use disorder parity laws is critical to ensure patients can access the care they need-including the full range of outpatient and inpatient treatment options that are needed to successfully treat these disorders. Too often patients face greater hurdles relative to other medical services in terms of benefit management processes, quantitative and non-quantitative treatment limitations, cost-sharing obligations and out-of-pocket costs. The following policy solutions can help strengthen mental health parity regulation and enforcement: 60,61



States can take actions that set clear standards for parity compliance to strengthen enforcement under existing state and federal laws.



Require insurance carriers to submit annual reports on their compliance with parity requirements to help facilitate regulatory agency enforcement of parity laws.

### **Telehealth**

Telehealth, when used appropriately, can play an important role in supporting access to health care when in-person routine visits are not feasible. The expanded use of telehealth provides a tremendous opportunity to not only reduce the access barriers driven by the limited distribution of behavioral health providers in rural areas, but it may also reduce the stigma that many experience in accessing an in-person treatment provider. While significant progress has been made in reducing barriers to telehealth access, safeguards are needed to ensure patient care and quality are maintained.

The public health emergency required the health care system to adapt quickly and expand the use of telehealth to address not only COVID-19 but increasing rates of mental health issues and substance use disorders. Federal agencies made significant changes to allow for more pragmatic behavioral health treatment guidelines. These included allowing initiation of MAT for opioid use disorder via telehealth and waiving in-person requirements. State Medicaid programs also significantly expanded their telehealth flexibilities through state plan amendments and waivers during the public health emergency. 62



As a result of these increased flexibilities and continued expanded use of these technologies, the use of telehealth for mental health and substance use disorder saw a marked increase during the pandemic.

- For example, Medicare visits conducted through telehealth increased 63-fold, from 840,000 visits in 2019 to 52.7 million in 2020, during the first year of the public health emergency.
- One-third of telehealth visits were for behavioral health providers.
- These trends were also apparent across both urban and rural areas.63

While expanded use of telehealth is critically valuable to reducing barriers to mental health and substance use disorder treatment, with increased use of telehealth and greater regulatory flexibility, there are also increased risks of diminished quality of care. It is important to keep in mind that remote contact is not always appropriate for every doctor and patient interaction. For example, a provider may not be able to observe a patient's physical behaviors that may aid in the assessment of a patient's overall physical and mental health.

#### The biopharmaceutical industry supports policies to:



Expand access to digital and telehealth services, especially in rural areas where there are shortages of providers.64



Ensure maintenance of quality care in telehealth services. As telehealth continues to expand in use and there is consideration of making certain telehealth flexibilities more permanent, it is important that periodic in-person visits occur and there is evidence of ongoing provider responsibility for the patient to ensure appropriate patient safeguards are maintained.

## **Care Coordination and Integration**

Access to the right behavioral health treatment at the right time requires not just access to treatment providers, but better access to information and coordinated care delivery. A multi-disciplinary, holistic approach is needed to appropriately address the mental, physical and addiction challenges that face so many Americans today. Unfortunately, too often care is delivered in siloed settings allowing for patient information to fall through the cracksparticularly for those with co-occurring mental illnesses, substance use disorders and other chronic illnesses. Behavioral health providers have adopted electronic health records at a much lower rate than other medical professions, which can contribute to these challenges.65

The current mental health and addiction crisis demands a more coordinated and integrated health care system across behavioral health care and primary health care settings to ensure important patient information and care plans can appropriately follow patients through the care continuum. There is increasing evidence supporting the effectiveness of programs that deliver coordinated and integrated care services.66



#### The biopharmaceutical industry supports policies to:



Improve care coordination and integrated delivery of mental health and addiction treatment. Evidence-based care integration models, such as patient-centered medical homes and the hub-and-spoke approach employed for the treatment of opioid use disorder in many states, are examples of integrated care delivery approaches that have the potential to significantly improve outcomes for Americans struggling with mental health and substance use disorders.<sup>67</sup>

America's biopharmaceutical research companies are committed to addressing the stigma of mental illness and substance use disorders and researching and developing medicines to improve the health and wellbeing of those struggling with these illnesses. But additional policy reforms are needed to address the significant barriers to accessing quality care for patients with these devastating diseases. The policy solutions to address key barriers and challenges identified here provide the opportunity to meaningfully curb the mental health and addiction crises facing Americans today and ensure patients can access the care they need.



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