

Via online submission to <https://www.regulations.gov>

October 5, 2020

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1734-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

**RE: Medicare Program; CY2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy (CMS-1734-P)**

On behalf of the National Council for Behavioral Health (National Council), thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed CY 2021 Physician Fee Schedule (PFS) rule and other policy changes. The National Council serves as the unifying voice of America's health care organizations that deliver mental health and addiction treatment services. Together with our 3,326 member organizations serving over 10 million adults, children and families living with mental illnesses and addictions, the National Council is committed to all Americans having access to comprehensive, high-quality care that affords every opportunity for recovery.

## **II. Provisions of the Proposed Rule for the PFS**

### ***D. Telehealth and Other Services Involving Communications Technology***

National Council members have relied heavily upon telehealth for the provision of mental health and substance use disorder services in an effort to maintain therapeutic relationships with their patients throughout the COVID-19 public health emergency (PHE). In May 2020 National Council, in partnership with Qualifacts, conducted a survey of behavioral health providers that found prior to the PHE, 93% of survey respondents indicated they provided less

than 20% of their care in a virtual setting.<sup>1</sup> The same survey demonstrated that in the span of just weeks the figure soared, with 60% of respondents indicating they were offering up to 80% of care virtually.<sup>2</sup> Additionally, survey respondents cited the expansion of services that may be delivered via telehealth as one of the most impactful policy changes in facilitating the transition to virtual care.<sup>3</sup> According to the American Psychiatric Association, “[telepsychiatry’s] effectiveness is comparable to in-person care in terms of therapeutic engagement, quality of care, validity/reliability of assessment, and clinical outcomes.”<sup>4</sup> Additionally, “the experience of other mental health clinicians using telemedicine (i.e., telemental health), is consistent with, and further substantiates the diagnostic, therapeutic and outcome evidence base”.<sup>5</sup>

The National Council appreciates CMS’s continued efforts to adjust telehealth flexibilities for providers and patients throughout the PHE and to maintain a number of flexibilities both in the short term and permanently. The current flexibilities are critical to allowing providers and patients to collaboratively determine which treatment modality best meets their needs, and so long as the provider/patient shared decision on the best treatment plan is protected and prioritized, we support making these flexibilities permanent.

#### **b. Requests to Add Services to the Medicare Telehealth Services List for CY 2021**

The National Council commends CMS for adding a number of crucial services to the Medicare telehealth services list, including reimbursement codes for group psychotherapy, neurobehavioral status exams, and assessments and care planning for patients with cognitive impairments. The National Council particularly appreciates the SUPPORT for Patients Act’s elimination of geographic limitations imposed by originating site requirements for purposes of the treatment of a substance use disorder or co-occurring mental health disorder, and applauds CMS’s recognition that sufficient justification exists to add these services to the Medicare Category 1 Telehealth Services list. Concurring with CMS’s proposal, the National Council believes that allowing clinicians to provide services to patients in their own homes reduces barriers to access for some of the nation’s most vulnerable individuals. The National Council agrees with CMS that the service codes added to the Medicare Category 1 Telehealth Services list are sufficiently similar to services currently on the list and therefore should be made

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<sup>1</sup> <https://www.thenationalcouncil.org/wp-content/uploads/2020/08/The-New-Role-Of-Virtual-Care-In-Behavioral-Healthcare.pdf?dof=375ateTbd56>.

<sup>2</sup> [Id.](#)

<sup>3</sup> [Id.](#)

<sup>4</sup> <https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/toolkit/evidence-base>

<sup>5</sup> [Id.](#)

permanent. These changes will serve communities by increasing access to desperately needed telehealth services that have been demonstrated to be as effective as in-person care.<sup>6</sup>

### **c. Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services from the Medicare Telehealth Services List**

The National Council supports the creation of Category 3 Telehealth Services criteria that provide for temporary additions to the list of Medicare telehealth services to allow for further evaluation of the merits of each code. The proposed rule stresses the importance of maintaining the high quality of care that patients deserve as more services are added to the qualifying telehealth list. As mentioned previously, there is a sufficient evidence base to support that telemental health is not only more accessible, but as effective as in-person services. The National Council concurs that decisions regarding additions to the telehealth list should be made with as much high-quality and reliable data as possible, and intends to continue relaying new information from our members regarding their adoption of telehealth services as it becomes available.

### **6. Comment Solicitation on Continuation of Payment for Audio-Only Visits**

In the survey of National Council members cited previously, respondents ranked expansion of telehealth services that may be delivered via audio-only communication as the third most impactful policy change in facilitating their transition to virtual care.<sup>7</sup> This has been an incredibly valuable treatment modality that has allowed more providers and patients to maintain their therapeutic relationships remotely while simultaneously avoiding additional exposure to COVID-19. It has particularly benefited older patients and those in low-income communities who may have limited access to the technology required for video-based telehealth.

We recognize, as outlined in the proposed rule, CMS may not have the authority to permanently allow for audio-only telehealth delivery. The National Council does, however, thank CMS for recognizing the inherent value of audio-only visits and supports CMS's approach of developing reimbursement for longer virtual check-ins for providers and patients to determine collaboratively if an in-person visit is necessary to best serve the patients' needs and assist them in meeting their treatment goals. While audio-only visits may not be a suitable alternative for in-person or telehealth services for all beneficiaries, CMS' approach to

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<sup>6</sup> Id.

<sup>7</sup> <https://www.thenationalcouncil.org/wp-content/uploads/2020/08/The-New-Role-Of-Virtual-Care-In-Behavioral-Healthcare.pdf?daf=375ateTbd56>.

reimbursement support for longer audio-only visits allows for comprehensive collaboration between the provider and patient to determine the ideal treatment approach when a patients' circumstances require a reasonable alternative to in-person care. This expansion would facilitate access for the purpose of collaborative development of treatment plans, especially in urban communities experiencing clinic capacity limitations and workforce shortages, as well as for individuals who may not otherwise be able to consistently receive services in an in-person setting, such as patients with limited access to the transportation necessary to receive treatment in-person, and patients located in rural settings who may live an unmanageable distance from their provider's clinical location.

## **8. Proposed Clarification of Existing PFS Policies for Telehealth Services**

The National Council strongly supports CMS's proposal to clarify that services may be billed "incident-to" via telehealth and under supervision of the billing professional. Allowing behavioral health providers to bill incident-to remote supervisors will greatly increase access to quality care. According to the Health Resources and Services Administration, roughly 119 million Americans live in a mental health care health professional shortage area, with over 6,400 more practitioners needed nationwide to fill these gaps in care.<sup>8</sup> The majority of these shortage areas are rural locations with significantly less access to behavioral health care than urban areas. Only 12% of the nation's psychiatric hospitals and 20% of the nation's substance use disorder treatment facilities are located in rural areas. By allowing behavioral health clinicians to bill incident-to remote clinicians, CMS will greatly increase access to services for underserved communities who may otherwise be unable to access a full array of treatment services. Expanded access to service will not only support the nation's behavioral health needs, but will produce cost savings across the board. According to the World Health Organization, every \$1 invested in scaling up treatment for various mental health disorders returns \$4 in better health and ability to work.<sup>9</sup>

## **9. Direct Supervision by Interactive Telecommunications Technology**

The National Council applauds CMS's proposal to extend flexibilities for clinicians to provide direct supervision through audio/video real-time communications technology on a temporary basis and urges the agency to consider extending these flexibilities permanently, as it would drastically increase access to desperately needed mental health and substance use disorder services across the country. Our support for this policy change follows the previous justification

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<sup>8</sup> <https://data.hrsa.gov/topics/health-workforce/shortage-areas>

<sup>9</sup> <https://www.who.int/en/news-room/detail/13-04-2016-investing-in-treatment-for-depression-and-anxiety-leads-to-fourfold-return>

for our support of clarifying incident-to-billing practices in that both changes will fill gaps in care in some of the most underserved communities in the nation.

We recognize CMS's concern that permanent virtual supervision may impact patient safety in the case of a crisis during which the supervising clinician cannot be physically available to respond. However, the National Council believes that, while this is a legitimate concern in the case of many physical health disciplines, behavioral health providers can be successfully supervised remotely without impact to patient safety.

***1. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)***  
**2. Definition of OUD Treatment Services**

The National Council strongly supports CMS's proposal to add naloxone to the definition of OUD treatment services. Naloxone is invaluable to the nation's opioid epidemic response, which has only been exacerbated by the COVID-19 PHE. According to the Centers for Disease Control and Prevention, 13.3% of U.S. adults reported starting or increasing substance use during the PHE, with individuals from ages 18 – 24 reporting the highest rates of new or increased substance use at 24.7%.<sup>10</sup> Substance use overdoses, including opioid overdoses, during the COVID-19 PHE have risen dramatically. In a study conducted by the Washington/Baltimore High Intensity Drug Trafficking Area, almost 62% of participating counties experienced an increase in overdose submissions after March 19, 2020.<sup>11</sup> The evidence base for increasing access to naloxone is a compelling one. Statistical models have found that wide-scale distribution of naloxone to supportive friends and family of people with OUD as well as emergency personnel could reduce opioid overdose deaths by 21%.<sup>12</sup> As a nation we realized the immense loss of life to overdose and delivered unprecedented investment through the SUPPORT Act to help curb the opioid epidemic and yet we now face an overdose resurgence as a horrible accompaniment to the COVID-19 pandemic. We must ensure we are not taking our nation backwards and try to prevent unneeded loss of life to overdose. Adding naloxone to the OUD treatment services definition will ensure greater access to this life-saving medication.

Additionally, the National Council supports CMS's proposal to create an add-on payment for OTPs to furnish opioid overdose prevention education. As noted in the proposed rule, we concur with U.S. Surgeon General Jerome M. Adams, M.D., M.P.H. when he stated, "Research shows that when naloxone and overdose education are available to community members,

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<sup>10</sup> <https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm>

<sup>11</sup> <http://www.odmap.org/Content/docs/news/2020/ODMAP-Report-June-2020.pdf>

<sup>12</sup> <https://www.drugabuse.gov/publications/naloxone-opioid-overdose-life-saving-science#ref>

overdose deaths decrease in those communities.” This not only supports the need to add naloxone to the definition of OUD services, but highlights the critical role that overdose prevention education plays in addressing the opioid crisis. OTPs are an ideal setting in which to deliver this education as they have high touch points with the patients and families most impacted by opioid use and overdose. Additionally, OTPs have access to all three FDA-approved medications for OUD, whereas other settings are unable to provide access to methadone. By creating an add-on code for overdose prevention education, CMS will add financial support for a critical life-saving tool in the nation’s opioid epidemic response.

### **a. Proposed Adjustment Made to the Bundled Payments for OUD Treatment Services Frequency Limit**

The National Council strongly opposes CMS’s proposal to impose a frequency limit for OTPs’ use of the naloxone add-on code to once every 30 days. Data from the Centers for Disease Control and Prevention state that the nation is currently in the grips of the “third wave” of opioid overdose deaths, largely characterized by significant increase in overdose deaths involving synthetic opioids, such as illicitly-manufactured and/or pharmaceutical grade fentanyl. Although opioid-involved death rates decreased overall by 2% between 2017 and 2018, synthetic opioid-involved death rates increased by 10%.<sup>13</sup> As you know, pharmaceutical grade fentanyl specifically is often 80 – 100 times more potent than morphine, leading to opioid overdoses and overdose deaths at lower doses than other opioids.<sup>14</sup>

Currently, Intranasal naloxone typically comes packaged in a box of two four-milligram doses.<sup>15</sup> In one study looking at the rates of fentanyl overdose in Chicago and the surrounding Cook County, naloxone was administered during 47.3% of emergency department visits with doses ranging from 0.4 milligrams to 12 milligrams.<sup>16</sup> For individuals experiencing overdose from the highest amounts of fentanyl, one would require 3 full doses of naloxone nasal spray to reverse the overdose. In the most serious cases of overdose, one box every thirty days may not be enough to meet the intention of saving lives. Moreover, reversing an opioid overdose with naloxone may result in the recipient experiencing immediate symptoms of withdrawal such as vomiting, diarrhea, and severe body aches.<sup>17</sup> The potential side-effects associated with naloxone, information that is shared with patients at OTPs, create an obvious natural deterrent to misuse.

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<sup>13</sup> <https://www.cdc.gov/drugoverdose/epidemic/index.html>

<sup>14</sup> <https://www.dea.gov/factsheets/fentanyl>

<sup>15</sup> <https://reference.medscape.com/drug/narcan-nasal-spray-naloxone-intranasal-1000057>

<sup>16</sup> <https://www.tandfonline.com/doi/full/10.1080/15563650701877374>

<sup>17</sup> <https://www.ncbi.nlm.nih.gov/books/NBK310652/>

Therefore, the proposal to limit how often OTPs may dispense naloxone on the basis of enhancing patient safety and discouraging misuse, waste and abuse, while a commendable aim, is misplaced. Instead, the National Council recommends forgoing a frequency limit and instead allowing treatment providers and patients to collaboratively determine the correct frequency of naloxone distribution.

The National Council appreciates the opportunity to provide these comments. We welcome any questions or further discussion about the recommendations described here. Please contact Reyna Taylor at [ReynaT@thenationalcouncil.org](mailto:ReynaT@thenationalcouncil.org). Thank you for your time and consideration.

Sincerely,



Charles Ingoglia, MSW  
President & CEO  
National Council for Behavioral Health