

Dr. Mehmet Oz

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Dear Dr. Oz and staff,

Thank you for the opportunity to provide input regarding the Center for Medicare and Medicaid Services' efforts to improve health through digital transformation. Mental Health America (MHA)'s comments will focus on the unique challenges and opportunities for improving behavioral health through increased investment in technology.

Mental Health America – founded in 1909 – is the nation's leading community-based nonprofit dedicated to addressing the needs of those living with mental illness and to promoting the mental health of all. With approximately 140 affiliate organizations in 38 states, our work is driven by our commitment to promote mental health as a critical part of overall wellness, including prevention services, early identification, integrated care, behavioral health services, and supports.

MHA has led the mental health field in leveraging technology to provide mental health screenings and support, operating a no-cost [online screening program](#) that has served over 31 million individuals since its launch in 2014. The program also offers digital support, including information and tools to people with mental health and substance use conditions. MHA was founded by Clifford Beers, who experienced abuse in psychiatric facilities, and has always been committed to transforming mental health care. Today, we continue that mission by centering patient empowerment and experience, including through the use of technology and innovation.

MHA fully supports technological advances to improve education, experience, empowerment, and outcomes for people who have mental health and substance use conditions and is grateful to CMS for initiating this transformation. We strongly recommend that CMS carefully consider the unique opportunities and challenges that arise for people with mental health and substance use disorders. One challenge is the accuracy and patient knowledge of mental health diagnoses and treatment options. Unlike many physical health conditions, there are no blood tests or imaging techniques that can diagnose a mental health condition. However, the field of digital health has a tremendous opportunity to begin to close this gap.

The sharing of patient information also presents challenges. Although it is often necessary to share relevant patient mental health information between providers in order to provide the highest quality care, negative bias regarding certain mental health and substance use conditions can end up harming patients if they are denied physical health treatment or have their symptoms dismissed due to their behavioral health condition. Additionally, the historical exclusion of mental health providers from resources to develop electronic health records has resulted in large disparities between the fields of physical and mental health regarding advancements in electronic

record keeping. Because of the exclusion of mental health providers from grant funding, EHRs were not developed to include open notes and other critical features in behavioral healthcare. Several enacted laws and regulations related to information technology and data sharing have excluded mental health and substance use providers and patients or considered them as an afterthought (HITECH Act, 42 CFR Part 2, which has been revised to allow sharing information on substance use). Accordingly, our primary recommendations are for CMS to ensure that mental health and substance use concerns are front and center in the transformation effort and to recognize that strategies that may be effective for other medical conditions may not work for behavioral health.

1. Patient Needs

- b. What are the top things you would like to be able to do for your or your loved ones' health that can be enabled by digital health products?*

Unlike many physical health conditions, psychiatric diagnoses can't be confirmed through blood tests or imaging. As a result, people struggling with these conditions often receive brief screenings and are left with conflicting or unclear diagnoses, without sufficient explanation or information about treatment options.

Digital health products could improve the patient experience through:

1. **Enhanced mental health and substance use screening.** Currently, CMS requires depression and substance use screening in several programs. Generally, during a provider visit, individuals are given a paper or a tablet and told to answer questions. They receive very little information, both before and after they complete these questionnaires. Digital health products have the opportunity to better explain why the patient is receiving the screening, what will happen next should the patient screen positive for a mental health or substance use condition, and provide comprehensive information and tools following the screening to answer questions from and provide support for patients and their caregivers. MHA has found that most people who take our online screens want additional information about their condition and their options for digital tools to improve their symptoms.
2. **Providing more detailed and accessible information on diagnoses and treatment options.** People with mental health and substance use conditions and their caregivers often get insufficient information on their diagnoses— what they are, what they mean, and how to treat them effectively— and even when information is provided, it is often delivered in high-level, inaccessible ways. Digital health products have the opportunity to deliver this information in ways that are easier for patients and caregivers to understand, which would help to ensure more effective treatment. Digital information can be more comprehensive and allow people to navigate to information that is responsive to their needs. For example, peer support is a very effective service that is rarely discussed with people after diagnosis.
3. **Conducting proactive lifestyle and wellbeing assessments and recommendations to improve overall mental health and wellbeing.** Currently, physicians and mental health and addiction professionals often wait for conditions to reach a threshold of

symptoms before providing any support or care. Digital health tools such as digital lifestyle and wellbeing assessments could allow for more proactive identification of risk and protective factors that affect mental health and addiction, such as social connection, purpose, relationships, social media use, exercise, and nutrition. Following these assessments, digital health tools can help identify personalized recommendations that could improve wellbeing before problems arise or become more serious, and more costly to treat. This can include nudges and other ways to consistently encourage healthy behaviors.

- 4. Creating a clear and easy path to manage HIPAA compliance and information sharing.** One of the ongoing challenges in mental health and substance use care is the sharing of information between providers and caregivers. While people with mental health and substance use conditions often do not want their therapy notes or confidential conversations being revealed to family or caregivers, many would still like to have the option to share certain information, such as formal diagnoses or medication management, with the parties of their choosing.

Because most providers make HIPAA an all-or-nothing choice to ensure legal compliance, providers are constrained from sharing, families are frustrated, and patients are not able to receive the support they want. Digital health products should allow for more detailed customization of the patient information that can be shared in order to increase patient autonomy and strengthen relationships between patients, providers, and caregivers.

- 5. Care navigation applications that can identify readily available in-network, high-quality mental health and substance use providers.** Currently, ghost networks— lists of healthcare providers who are officially listed in an insurance plan’s directory but are not actually available to see patients— are a serious and widespread problem, particularly for those seeking behavioral health care. People with mental health and substance use conditions and their families often call down a list of providers and cannot find anyone taking new patients or with timely availability.

A recent [study](#) confirmed that people with mental health and substance use conditions more often receive treatment from out-of-network providers and incur higher costs than those seeking other types of medical care. The inability to navigate care networks does not just cost money- it can also cost people their lives. Recently, a [lawsuit](#) was filed on behalf of an Arizona man who tried desperately to access an in-network mental health provider and died by suicide after struggling for months and making 21 calls to his insurer trying to find a provider within a “ghost” provider directory. There is an urgent need for digital health solutions, particularly care navigation applications, that help individuals, families, and caregivers navigate care networks in order to find timely, in-network care.

Information on quality, patient experience, and treatment outcomes and results is also exceedingly hard to find, especially for those navigating the behavioral healthcare space. Patient experience and outcome information should be integrated into care navigation applications to empower those seeking care to find providers that they are

confident can help manage their conditions effectively. [Research](#) shows that better management of mental health conditions directly correlates to better management of co-occurring physical health conditions. For example, diabetes and depression are very bidirectional, with each raising the incidence of the other, and treatment of both conditions leading to optimal overall health outcomes.

6. Holding insurers accountable for adequate networks. Senate Finance Committee staff conducted a secret shopper [study](#) and found that the vast majority of mental health providers listed in Medicare Advantage plan directories were unreachable, unavailable, or not actually in-network, highlighting the widespread problem of ghost networks in mental health care. Medicare Advantage insurers also charge Medicare more for these same patients because they have been identified as having mental health and substance use conditions. A [review](#) of Oregon Medicaid managed care directories found that over half of mental health providers listed on provider networks were ghost providers.

Digital health products could allow patients to alert CMS when they are unable to locate timely, affordable mental health care. CMS can also require plans to use readily available claims data to determine which providers on a network are not billing that insurer and, therefore, need to be contacted and removed from the network if they are not seeing patients. High percentages of such providers could then trigger investigations and lower STAR ratings and bonus payments. More sophisticated tools could link diagnosed patients for whom the insurer is receiving higher payments to claims to see if they are getting more behavioral healthcare. The bipartisan [Real Providers Act](#), introduced in the last Congress (HR 7708, S.3059), would require CMS to ensure greater transparency of behavioral health networks. Digital health tools and care navigation applications could facilitate this transparency and allow adequate networks and timely appointments to be measured and rewarded.

The RFI asks what patients want to be able to do, and we also want to provide information on what people do NOT want from digital health products, as these products should do no harm.

We strongly advise that digital health products:

- 1. Do not lead to engagement with law enforcement.** [Data](#) show that, among cases of fatal police shootings, a significant percentage involved an individual experiencing a mental health crisis. If people believe that sharing information will lead to harmful interactions with law enforcement, they will be less likely to seek help. When digital health tools detect a risk of suicide, the tool should ensure a mental health response, such as the 988 Suicide and Mental Health Crisis Lifeline.
- 2. Do not initiate referral for investigation by child welfare agencies.** Behavioral health conditions, including suicide and overdoses, are the number one cause of maternal mortality. Mothers will not be willing to seek help to address these problems if doing so will put them at risk of a child welfare investigation. Digital health products should not share information with these agencies, and the use of these products should not lead to the initiation of child welfare investigations.

3. **Do not result in discrimination against individuals who have mental health and substance use conditions.** Many individuals with mental health and substance use conditions experience harmful and discriminatory medical care when their behavioral health information is shared with non-behavioral health professionals. For example, one individual told MHA staff that he came to an emergency room for stomach pain, and, as soon as his medications, and therefore his schizophrenia diagnosis, were revealed to the emergency room staff, a security officer was called, and he was treated as a danger, compromising his care. Others have had their symptoms discounted entirely. A research [study](#) recently found that people with mental health and substance use disorders reported that medical professionals dismissed physical symptoms, including pain, as being caused by their mental health or substance use disorder, and denied them needed treatment as a result. It is important to train providers so they do not use health information in a way that harms patients, and digital tools can help with that training. CMS also should have clear information readily available about how patients may file a complaint with the HHS Office for Civil Rights (OCR) if a health care provider treats them differently because of their mental health or substance use diagnosis. OCR should be a partner in the digital transformation rollout to ensure privacy and nondiscrimination laws are followed.

In addition, digital health tools will only be helpful if they are accessible.

We recommend the following to ensure accessibility:

- **Information should be delivered at a 5th-grade reading level and in engaging formats** such as videos, animations, and infographics.
- **Information should be available in users' primary languages** to maximize understanding.
- **Features should be intuitive**, and consumers and caregivers should be able to easily provide feedback on ease of use.
- **Training should be available to the patient on how to use the tools.** Ideally, this training would be available both from in-person support staff in provider settings, such as peer support specialists or nurses, as well as online. CMS should ensure that providers can bill for such training.
- **Cost should be addressed, and access to broadband and other technology should be provided** where needed for rural and low-income individuals.

- c. *If you had a personal assistant to support your health needs, what are the top things you would ask them to help with? In your response, please consider tasks that could be supported or facilitated by software solutions in the future.*

A personal assistant could be helpful with providing information on mental health diagnoses and effective treatment options, monitoring wellbeing and mental health (status or changes) and recommending appropriate screens, providing consistent encouragement for lifestyle changes, monitoring relevant indicators of wellbeing (such as voice and social connections), and finding in network, high quality care. See the above response to the previous question for more information.

In addition, it is very important to note that people are already using AI tools for companionship and therapy. A recent [study](#) found that this support was the number one reason people were using AI. At the same time, a [study](#) of a highly monitored large language model created specifically for mental health still found examples of the model providing incorrect information that needed to be corrected by mental health professionals. Recent [news reports](#) have indicated that the use of certain AI bots has actually led to the exacerbation of delusional thoughts in some individuals. CMS should ensure that any digital personal assistant is carefully monitored for mentions of or requests for companionship or therapeutic advice, and should connect users to crisis resources (such as using a button or other way to get to 988) in such cases, while continuing a safe conversation with the individual. Developers of such tools should be required to work with the FDA to develop safety standards.

Also, it is critical that a personal assistant does no harm and does not contact law enforcement or child welfare agencies in response to mental health and substance use information shared with the personal assistant, nor should any personal assistant tool reinforce stigma or stereotypes about mental health and substance use. See above.

PC-2. Do you have easy access to your own and all your loved ones' health information in one location (for example, in a single patient portal or another software system)?

- a. If so, what are some examples of benefits it has provided?*
- b. If not, in what contexts or for what workflows would it be most valuable to use one portal or system to access all such health information?*

Because of the exclusion of mental health providers from the HITECH Act resources, many people with mental health conditions cannot access mental health information in their overall patient portals. It would be helpful to have information about mental health diagnoses, treatment, progress, or lack of progress in one place, without compromising patient confidentiality.

PC-5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?

What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality, impact, or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process? What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example, enhancements to data access, reimbursement adjustments, or new beneficiary communications)?

There are several policy issues relevant to technology use to improve health outcomes for people with mental health and substance use conditions:

Medicare reimbursement policy that favors medical specialists over primary care and behavioral health professionals. The current RUC/RVU system values procedures over cognitive work. As a result, primary care and mental health care are undervalued. This is

particularly a problem for integrated behavioral health care in primary care, which combines two undervalued services. The shortages of mental health providers and primary care doctors accepting Medicare are ample evidence that the current system is not setting reimbursement rates correctly because it is not taking into account the needs of the population and demand, and it is not valuing overall health, wellness, and wellbeing. MHA urges CMS to consider the true value of cognitive work and weigh the demand and difficulty of obtaining in-network care to reassess primary care, behavioral healthcare, and integrated care codes.

Medicare reimbursement policy that does not reimburse for peer support specialists in community mental health and health settings. As CMS works to transform technology, it should ensure that the right workforce is in place to ensure that patients can use and benefit from the technology. Within healthcare, and especially for mental health and addiction care, trust is critical. Having peer support specialists, who share lived experience in mental health and addiction, explain the technology and help people use it will ensure trust and success. Some states have organizations that have developed curriculum for peer specialists on guiding people to use health apps and other technology, and it would be helpful for CMS to ensure that peers can be billed by community mental health and health centers, and then fund training specifically in technology use.

Lack of accountability for mental health and substance use outcomes. There are very few value-based measures of effective mental health and substance use services. Currently, screening and follow-up for depression are most widely used in CMS programs. ACOs are assumed to improve care, but in behavioral health, [studies](#) show this is not true, and people with depression and anxiety were more likely to get treatment if they were not participating in an ACO. Researchers recommended more incentives to improve behavioral health results. Accordingly, it is critical to include more process and outcome measures relevant to behavioral health. Some process measures used by NCQA for the [distinction in behavioral health integration](#) for health homes would be very helpful and are relevant to technological capacity, such as keeping a registry and tracking measurement-based outcomes using validated tools.

Inability to reimburse for education, screening, and tools that keep people mentally healthy, compared to treating people who are experiencing mental illness. As the Secretary of HHS has pointed out, health providers are incentivized to treat people who are already ill and not to prevent illness. This is true in behavioral health, where providers are incentivized to screen to find an issue, but not to prevent the problem from happening in the first place. CMS will need to develop codes and payment for lifestyle reviews and recommendations from peer support specialists, community health workers, and behavioral health professionals. Areas that are directly related to mental health include social media use, loneliness and isolation, and lack of purpose. Loneliness, in particular, is critical to address for older populations. Other areas that affect mental and physical health include sleep, stable housing, exercise, use of alcohol and other substances, and healthy eating. Most practices focus on measuring blood sugar, blood pressure, and PHQ-9 for depression, which asks about mood. These screens do not review lifestyle factors and recommend changes and psychosocial supports, which would be very impactful for better behavioral health, but are currently not reimbursed and not incentivized.

With respect to CMS's role in reviewing digital tools, MHA recommends the following:

CMS should work with FDA and stakeholders (especially people with mental health conditions) on safety criteria for mental health and health chatbots. Currently, there is no standardization of safety features for mental health and health chatbots. Given the risks of incorrect information and hallucinations, CMS could play a powerful role in working with FDA on safety assurances for any health-related chatbot reimbursed as part of digital transformation that could be used for companionship or therapeutic purposes and responds to such requests, even if that is not its intended use. The current risks are significant, with a [lawsuit](#) filed in response to a chatbot encouraging suicide and increasing [reports](#) of chatbots facilitating paranoia.

Efficacy of digital tools should include an assessment of continued patient engagement. Many digital tools are used for a brief period, and research studies incentivize participants to use technology so they can show efficacy that may not be replicated in clinical practice. It is critical that reimbursement policy takes into account whether patients are using the technology consistently so that resources are allocated appropriately, given that Medicare currently does not reimburse many important mental health services, such as crisis care and peer support specialists.

Require clear language on allowable data use and strong privacy protections. Many digital tools have broad privacy waivers that allow the use of patient data for many purposes. CMS should require that privacy language be written in plain language and that any digital tools reimbursed by CMS have strong privacy protections. This is especially important for mental health and substance use information, which has significant potential for discrimination if information is inappropriately released.

2. Data Access and Integration

PC-8. In your experience, what health data is readily available and valuable to patients or their caregivers, or both?

a) What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use (for example, claims data, clinical data, encounter notes, operative reports, appointment schedules, prices)?

The RFI envisions a digital ecosystem where patients have secure, electronic access to their personal health information with the aim of achieving access to their "complete health information", potentially in "one location". While this aspiration is critically important, realizing it effectively for individuals with mental health conditions poses significant challenges related to the nature of mental health data. Accessing different data formats presents challenges in the current system. This is particularly relevant for mental health records, which often contain extensive free-text notes from therapy sessions, psychiatric evaluations, and progress updates. Unlike structured data fields, these notes capture nuanced details, context, and qualitative information that are essential for understanding a person's mental health journey and treatment plan.

Ensuring that these less structured, but vital, data formats are accurately captured, integrated, and made available through digital health products is crucial. If digital tools primarily rely on structured data or fail to adequately process and present the information contained in free-text notes, individuals using these tools may receive an incomplete or potentially misleading picture of their mental health status and care. Such data limitations could lead to several negative outcomes for patients:

- Misinterpretations of their health information.
- Difficulty in coordinating care effectively, especially when seeing multiple providers (mental health and physical health).
- Reduced usefulness of digital health management or care navigation applications that depend on comprehensive data.
- Challenges in using the data for managing conditions or finding appropriate care.

The RFI appropriately asks about the importance of making all data in an EHR accessible for exchange, regardless of storage format. We believe it is extremely important that challenges in accessing different data formats, technical barriers to full data accessibility, and the potential impact on patient care quality are thoroughly addressed with the specific complexities of mental health information in mind. This would include provider training to ensure notes are carefully written and providers do not misuse the information to discount patient symptoms or otherwise discriminate against them, and should also include a notice to patients that they can file a complaint with the Office for Civil Rights if their information is misused.

c. Is there non-CMS data that should be included in the API?

It would be helpful to consider several non-CMS data sources in the API, such as SAMHSA's treatment locator and early treatment locator and HRSA's health center locator.

d. What is the ongoing role of HIEs amidst other entities facilitating data exchange and broader frameworks for data exchange (for example, vendor health information networks, TEFCA, private exchange networks, etc.)?

PC-12. What are the most valuable operational health data use cases for patients and caregivers that, if addressed, would create more efficient care navigation or eliminate barriers to competition among providers or both?

a. Examples may include the following:

- (1) Binding cost estimates for pre-defined periods.*
- (2) Viewing provider schedule availability.*
- (3) Using third-party apps for appointment management.*
- (4) Accessing patient-facing quality metrics.*
- (5) Finding the right provider for specific healthcare needs.*

- b. What use cases are possible today?*
- c. What should be possible in the near future?*
- d. What would be very valuable but may be very hard to achieve?*

Studies over decades have demonstrated the difficulty in finding in-network mental health and substance use providers, and individuals have to consult numerous sites to find any quality information. Having the ability to schedule appointments with in-network providers with some information on their qualifications, quality, and ability to treat specific populations would be very helpful. However, it is important to note that there have been many complaints filed against third parties for including therapists that have not agreed to be part of the network, taking all referrals from online sources for any therapist that is in their network such that the therapist must rely on the third party when they do not want to, and giving patients incorrect information on costs. If CMS works with third parties, it should address these troubling practices and require accurate patient information, given the complexity of deductibles and co-pays.

3. Information Blocking and Digital Identity

PC-13. How can CMS encourage patients and caregivers to submit information blocking complaints to ASTP/ONC's Information Blocking Portal? What would be the impact? Would increasing reporting of complaints advance or negatively impact data exchange?

CMS should also encourage information sharing complaints, especially when information is used to deny treatments or discount symptoms. This is a critical problem for mental health and substance use information that CMS should be concerned about, along with concerns about information blocking.

PC-14. Regarding digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800-63-3 IAL2/AAL2 credentialing service providers (CSP)):

- a. What are the challenges today in getting patients/caregivers to sign up and use digital identity credentials?*
- b. What could be the benefits to patients/caregivers if digital identity credentials were more widely used?*

Providers of mental health and substance use treatment were excluded from the resources provided in the HITECH Act, so it is difficult for them to share information. If the digital identity credentials were more widely used, this may be a way to ensure the sharing of information by the patient into their portal or other means of addressing this barrier to sharing information.

- c. What are the potential downsides?*

Please see the above description of how patients with mental health and substance use disorders have been harmed by disclosure, and report that their physical health symptoms are discounted when a provider becomes aware of their behavioral health diagnosis. People should be given options for customizing the sharing of information, so if they do not want certain information shared, it can be kept confidential, without barring them from sharing

information entirely. In addition, providers must be trained and held accountable for not using information to discount symptoms or withhold treatment, and patients must be notified of their rights to file a complaint if information is misused.

VB-1. What incentives could encourage APMs such as accountable care organizations (ACOs) or participants in Medicare Shared Savings Program (MSSP) to leverage digital health management and care navigation products more often and more effectively with their patients? What are the current obstacles preventing broader digital product adoption for patients in ACOs?

VB-4. What are the essential data types needed for successful participation in value-based care arrangements?

Value-based care arrangements often do not adequately include behavioral healthcare. Mental Health America strongly urges CMS to consider state examples of data collection to advance integrated behavioral healthcare in primary care. [Massachusetts](#) and [Colorado](#) have implemented [tiered](#) payment with more integration, allowing for greater payment. These models combine traditional outcome measurement with process changes to ensure integrated care, including technological changes. Colorado [provided](#) technical assistance and funding to modernize technology and electronic health records as part of its efforts to support advanced primary care with integrated behavioral healthcare. Models like collaborative care have shown strong outcomes in symptom reduction for anxiety and depression when provided through telehealth with remote monitoring.