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*Electronically submitted via PrivacyRegulations@samhsa.hhs.gov*

Feb. 28, 2018

Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
Attn. Mitchell Berger
5600 Fishers Lane, Room 18E89C
Rockville, MD 20852

**Re: Confidentiality of Substance Use Disorder Patient Records; Notice of Public Meeting (Docket no. 2018-00150)**

Dear Assistant Secretary McCance-Katz:

Magellan Health, Inc. (Magellan) appreciates the opportunity to respond to the Notice of Public Meeting published by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the Jan. 9, 2018 *Federal Register* concerning confidentiality of substance use disorder (SUD) patient records regulations, 42 C.F.R. Part 2 (Part 2 regulations), as noted in Section 11002 of the 21st Century Cures Act of 2016. We further appreciate the opportunity to have attended the Jan. 31, 2018 listening session and have incorporated herein the oral remarks made by Teresa Berman, Magellan's senior vice president and Deputy Compliance Officer, as requested in the course of that session.

Headquartered in Scottsdale, Ariz., Magellan helps millions of Americans live healthier, more vibrant lives. We are committed to connecting behavioral, physical, pharmacy, and social needs with high-impact, evidence-based clinical and community support programs to ensure the care and services provided to the members we serve[1] are individualized, coordinated, fully integrated, and cost effective. Magellan develops and supports innovative ways of accessing better health by combining advanced analytics, agile technology, and clinical excellence, while remaining focused on the critical personal relationships necessary to achieve a healthy, vibrant life.

In addition to Ms. Berman's remarks, our response to the Notice also includes Magellan's experience with Part 2; how Part 2 affects patient care and health outcomes; and recommendations for regulatory action for SAMHSA to consider related to the following, as described further on Pages 5-6:

- Aligning Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) of 1996,
- Relaxing the stringency of the consent requirements to permit a consent form be executed for HIPAA-like purposes, and

1. Included here also are individuals we serve whom are members of our customers' health plans.

- Indicating the permissability (in response to the opioid crisis) of coordinating SUD care between providers and with providers and clinicians working within managed care entities.

## I. Magellan Health's Experience with 42 C.F.R. Part 2

Much of what Magellan does on behalf of our members and our customers necessitates disclosing patient-identifying information within the healthcare system, interfacing and interacting with providers while protecting the privacy concerns of members with mental health conditions and, often, co-occurring SUDs receiving treatment. Indeed, the *Journal of the American Medical Association* found 50 percent of individuals living with serious mental illness (SMI) also have a substance use disorder.[2] Of those, more than half (53 percent) are a drug-related use disorder, such as opioid use disorder. **As a result of Part 2's restrictions, these members' access to whole-person, fully integrated healthcare can be hampered when providers are prevented from accessing all relevant information necessary to appropriately support individuals' healthcare needs.**

As an experienced specialty healthcare organization, Magellan provides a tailored spectrum of mental health and substance use disorder treatment and services and Employee Assistance Programs for health plans, employers, and various military and government agencies and public healthcare programs, including to active-duty service members and their families, the Medicare Advantage and state Medicaid programs, and individuals dually eligible for Medicare and Medicaid. Magellan also contracts with more than 80,000 credentialed behavioral health providers nationwide and provides behavioral healthcare services to approximately 1.6 million public-sector members through a range of innovative state programs, including the nation's first Medicaid specialty health plan for individuals living with SMI, Magellan Complete Care of Florida. Our subsidiary, Magellan Healthcare, contracts with health plans nationwide and some state Medicaid programs (including Florida, as noted) in order to perform case management and care coordination, utilization review, utilization management, and/or claims adjudication functions on their behalf, and thus has significant direct experience with the impact of the requirements under 42 C.F.R. Part 2. As a contractor and subcontractor, Magellan Healthcare is expected to perform case management and care coordination and related functions on behalf of its customers for its customers' members, including those living with a SUD.

In addition, our subsidiary, Magellan Rx Management, is a full-service pharmacy benefit manager that expands beyond traditional core services to help our customers and members solve complex pharmacy challenges, including through the use of targeted clinical programs, comprehensive member and provider engagement strategies, advanced analytics, and expert specialty pharmacy management capabilities. **Accordingly, much of what Magellan does on behalf of our customers and members – including members living with SUDs – necessitates disclosing Part 2-covered, patient-identifying information within the healthcare system, including interfacing and interacting with providers, while protecting the privacy concerns of individuals living with SUDs receiving treatment and services.**

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2. Darrel A. Regier, MD, MPH; Mary E. Farmer, MD, MPH; Donald S. Rae, MS; et al., "Comorbidity of Mental Disorders With Alcohol and Other Drug Abuse: Results From the Epidemiologic Catchment Area (ECA) Study," *Journal of the American Medical Association* (1990) 264, no. 19:2511-2518. doi:10.1001/jama.1990.03450190043026.

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For our members and our customers, as well as our customer's members, Magellan performs case management, care coordination, discharge planning, utilization review, claims adjudication, and other related functions, affording us significant direct experience with the impact of Part 2. **This extensive experience informs our perspective on confidentiality and disclosure of substance use disorder patient records, and our response to the Notice.**

## II. How 42 C.F.R. Part 2 Affects Patient Care and Health Outcomes

The vast majority of today's integrated care models rely on HIPAA-permissible disclosures and information sharing to support care coordination—that is, without the need for the individual's written consent to share relevant treatment details, provider by provider. **Magellan believes it is critical for health plans to be able to assist their members' recovery and relapse prevention by sharing valuable substance use disorder information with members' providers** when arranging for pre-authorization, referrals, step-down services, residential treatment, and other care coordination activities without the need to obtain written consent for each individual provider.

The same is true for the modern electronic infrastructure for information exchange. In an era of electronic medical records (EMRs), having incomplete records available for providers—because substance use disorder information cannot be included without individualized consent—disallows providers from supporting their patients holistically. **In facIn some case, providers may believe the EMR (to which they have access) reflects the individual's full medical record.** In such situations, a provider may, for example, prescribe opiates for back pain for a member with prior history of opioid misuse, which could lead to relapse. Access to complete medical information is critical for providers to ensure members' access to care is appropriate to their needs and clinical histories.

While having to obtain any written consent is a barrier to achieving care coordination, **the ability to obtain a more broad consent would certainly permit member information to more easily be shared for care coordination and treatment purposes. It would also make it easier to include information in EMR systems noting whether the consent was constrained to individual providers.** Consents having to list individual providers often have to be obtained over and over again as members move through the system of care, leading to delays or barriers in coordinating a member's care. These hurdles are extremely problematic for health plan entities who are responsible for coordinating the care received by their members to make certain it is optimally suited for each member; any change of provider by the member necessitates a new written consent. In the event a member changes their primary care provider, or switches psychiatrists, or begins a new course of treatment with a cardiologist – all of whom need to know about the member's substance use disorder treatment history to ensure patient safety and proper treatment approaches – a new written consent must be obtained. Doing so is not always easy, particularly if the member is in denial about their SUD; is unable to effectively understand or communicate due to their condition; or has other co-occurring conditions (such as SMI) which stymie the consent-collection process.

**The national opioid crisis is not being addressed nearly as effectively as it could be given the limitations posed by Part 2 on effectively coordinating care.** For example, when a health plan is

coordinating a member's discharge from an inpatient detox facility and attempting to locate an appropriate outpatient therapist in the community, the health plan is prohibited from informing the outpatient therapist that their new patient has a SUD diagnosis and was discharged from detox, and must hope that either the:

- Detox facility notifies the therapist of the treatment directly (although they too would first need to obtain written consent to do so as well),
- Therapist asks the member about any SUD history (and that the member responds truthfully), or
- Member is forthcoming enough to inform the therapist proactively.

If none of these occur, the therapist's treatment plan will not address the crux of the member's healthcare needs – their substance use disorder – potentially leaving the member at greater risk of relapse, re-admission, or worse.

Similarly, when a detox facility calls the member's health plan for pre-authorization, the health plan is prohibited from advising the facility that this member could have been in detox multiple times in the past year and – as a result – may need their treatment approach adjusted accordingly to improve the member's quality of care and overall outcome. A member with a SUD may not provide the health plan with written consent and may not share his or her treatment history with the facility, leaving the facility in the position of being unaware of this critical information and providing treatment or treatment recommendations in the dark.

Other effects on patient care and health outcomes Magellan has encountered in attempting to manage the behavioral healthcare and services of members in compliance with Part 2 include:

- Due to the need to exclude SUD data from the information sharing necessary to successfully coordinate a patient's care, **the regulations result in fragmentation in treatment, less than optimal patient assessments, and treatment plans often created in a vacuum because the complete clinical picture is not available to the current provider, which can lead to adverse drug reactions, accidental overdose, inappropriate diagnosis, and ineffective treatment** which targets the incorrect condition.
- **The need to single out specific patient written consent for each individual provider prior to any disclosure of SUD information slows the treatment process considerably, creates great inefficiencies, and may actually result in reinforcement of stigma** associated with SUD treatment and services instead of overcoming it.
- **The inability to share substance use patient information between providers without the express, written consent of the patient has created perceived liability situations for many physicians and other clinicians to the point that they may opt to refuse to treat any patient with a suspected history of substance use,** particularly in primary care, which is most unfortunate since primary care providers often are in the most advantageous position to screen

for and treat substance use disorders.

- Denial is an important dynamic in substance use disorders. Individuals living with a SUD may inadvertently rely on denial and not appreciate their own chronic health condition, allowing him or her to hide their condition from clinicians who are attempting to ensure appropriate treatment and services. **Without an easier, more effective way to facilitate transfer of SUD information between providers and health plans, the clinician is left naïve concerning the patient's true healthcare condition, and the SUD diagnosis can go unaddressed and untreated**, further feeding into this difficult, unintended pattern.

In our experience, we have seen multiple member situations and dynamics adversely impacted by Part 2 (as we note above). In further response to the listening session, we would like to share the story of one of our members, and how their care and health outcomes were affected by Part 2:

> An adult member was brought to the emergency department by relatives concerned by their loved one's depression and suicidal statements. The member received a complete evaluation, including a physical examination and a psychiatric evaluation. Records from a previous psychiatric hospitalization were obtained from another facility in the community without patient written consent, as permitted by HIPAA.
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> Three days after admission, the patient experienced a grand mal seizure; it was only then the member shared several years of barbiturate misuse. The member shared they had not wanted the hospital's treatment team to know about this, and thus had denied any history of substance use to staff.
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> At the previous admission to the other psychiatric facility, the member had been forthcoming about the barbiturate misuse, and had received appropriate detox treatment; however, since a release specifically for SUD information had not been signed by the member, pages of their medical record concerning this previous SUD history had been omitted when the facility provided the patient's records to the emergency department. Since the emergency department's treatment team was deprived of this knowledge, the hospital's inability to correctly diagnose and treat their patient led to a serious adverse incident for this member.

## III. Recommended Regulatory Action for SAMHSA to Consider

While we appreciate recent efforts to revisit the regulations, **Magellan continues to urge SAMHSA to update Part 2 to align with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 by adopting a care coordination exception to the consent requirement. While HIPAA permits such information sharing for treatment and healthcare operations, Part 2 does not**—presenting an unnecessary and sometimes even insurmountable barrier and marginalizing this crucial tool for individuals living with SUDs. This meaningful change would retain sufficient protection and confidentiality of individuals' substance use disorder records while also bringing Part 2 into the modern era. Part 2 was created before HIPAA existed and these stringent requirements are incompatible with contemporary advancements in care coordination and electronic information sharing which can

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currently be afforded to all health plan members, except those with substance use disorders.

Alternatively, while SAMHSA may be constrained somewhat by 42 U.S.C. §290dd-2, **Magellan believes there is some latitude afforded both in relaxing the stringency of the consent requirements in 42 U.S.C. §290dd-2 (1) and in the exception in section (2) for disclosures** "to medical personnel to the extent necessary to meet a bona fide medical emergency." 42 U.S.C. §290dd-2(1) notes the content of records "may be disclosed in accordance with the prior written consent of the patient with respect to whom such records are maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g)." **The regulations could be modified to permit a consent form to be executed that allows for the use of the member's information for treatment, payment and healthcare operations – including care coordination – rather than the current requirements** to obtain consents specific to each and every provider who is involved in the member's care in order to coordinate all the various treatments and services the member receives.

We also believe that, given the significant opioid crisis in our country, which has been declared a public health emergency[3], **SAMHSA could indicate in regulation that the coordination of substance use disorder care between providers and with providers and clinicians working at managed care entities and pharmacies would be permissible in response to addressing a bona fide medical emergency.**

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To ensure individuals with substance use disorder s receive the full benefits of integrated care, Magellan respectfully requests that SAMHSA consider pursuing the proposals discussed above, including either permitting coordination of care without an authorization, or, in the alternative, permitting a member to sign one consent authorizing their information to be used for treatment and healthcare operations purposes, including care coordination, without the burden of naming individual providers.

Magellan would be glad to answer questions or provide further information. Please contact Brian Coyne, vice president of federal affairs, at (804) 548-0248 or bcoyne@magellanhealth.com; or, Claire Wulf Winiarek, vice president of public policy, at (860) 507-1918 or cwulfwiniarek@magellanhealth.com.

Thank you for the opportunity to share our experience and recommendations on this important issue.

Sincerely,

Meredith A. Delk, Ph.D., MSW
Senior Vice President, Government Affairs

3. Office of the Secretary, U.S. Department of Health and Human Services, "Determination that a Public Health Emergency Exists" (Oct. 26, 2017), https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf.