November 1, 2021

The Honorable, Ron Wyden
Chairman
Senate Finance Committee
United States Senate
Washington, DC 20510

The Honorable, Mike Crapo
Ranking Member
Senate Finance Committee
United States Senate
Washington, DC 20510

Re: Senate Finance Committee's September 21, 2021, RFI on Behavioral Health Package

Dear Chairman Wyden and Ranking Member Crapo:

There is a pressing need to establish a national infrastructure to monitor and prevent patient safety events in mental health care settings. While a growing set of patient safety measures, research, and evidence-based practices exist for medical errors, there are only a few measures and recommendations for safety events in mental health settings, despite the daily occurrence of diagnostic, medication, and harm-related events in mental health care. Our nation must increase the safety and reliability of mental health care to protect patients and providers, increase the public's trust in mental health providers, and help reduce the stigma associated with receiving mental health services.

The National Patient Safety Board (NPSB) Policy & Advocacy Coalition (https://npsb.org/join-the-coalition/) recommends establishing this national infrastructure by creating an independent National Patient Safety Board (NPSB) to reduce patient safety events in health care settings, including inpatient and outpatient mental health settings.

As a non-punitive, independent agency, the NPSB is modeled after the National Transportation Safety Board (NTSB). As such, the NPSB's primary functions would be to:

(a) identify significant harm;
(b) study the root causes of the patient safety events; and
(c) create recommendations, including autonomous solutions, to prevent patient safety events from re-occurring.

The NPSB is a critical component for advancing patient safety, but like the NTSB, it is not the sole solution. It would interface with Health and Human Services (HHS) agencies and offices,[1] the Veterans Affairs (VA),

[1]Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Medicare and Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology, Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), and National Institutes of Health (NIH)

and public and private entities at the state and local level by helping them adopt autonomous patient safety surveillance systems, working with these partners to conduct the studies, and sending recommendations to the agencies based on the findings of the studies. The NPSB is intended to augment the work of federal agencies and long-standing patient safety organizations without displacing them. For example, the NPSB's non-punitive functions are different than accreditation, certification, and licensure reviews and are not part of any federal or state agency's role.

This national infrastructure for monitoring, studying, and preventing patient safety events is especially needed for mental health care, which is often overlooked by patient safety efforts.[2] Only a few of the more than 70 patient safety event indicators (e.g., IHI Global Trigger Tool, Never Events, and AHRQ's Patient Safety Indicators) relate to safety events in mental health care settings. As a result, the majority of the patient safety recommendations and best practices[3] are not designed for preventing patient safety events in mental healthcare settings. Similarly, the Joint Commission only has four safety goals for behavioral health care: accurately identifying people served, medication safety, health care-associated infections, and suicide risk.[4]

The NPSB's three core functions would improve patient safety in mental health settings in the following ways.

Identifying Patient Safety Events

To address the lack of patient safety measures for mental healthcare settings, the NPSB would establish an interagency coordinating committee with SAMHSA, AHRQ, CDC, Veterans Affairs, Office of the National Coordinator for Health Information Technology, Indian Health Service, Office of Minority Health, HRSA, FDA, NIH, National Quality Forum, and the National Committee for Quality Assurance to review, update, and prioritize patient safety indicators for mental health care settings.

Medication errors, diagnostic errors, restrain and seclusion, suicide, falls, assault, and self-harm, among other measures, have been proposed for patient safety indicators in mental health settings.[5] For example, England & Wales has a National Learning and Reporting System that analyzes medication errors in mental hospitals. They found that omission of medication, wrong frequency, and wrong or unclear dosage were the most frequently reported medication incidents.[6]

Once the committee establishes these patient safety indicators, the NPSB would work with the agencies and offices to help them adopt patient safety data surveillance technologies to autonomously collect the data from electronic health records (EHRs) and other data sources to track the patient safety events.

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[2] Shields, M. C., Stewart, M. T., & Delaney, K. R. (2018). Patient safety in inpatient psychiatry: a remaining frontier for health policy. Health Affairs, 37(11), 1853-1861. https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0718

[3] Comparison Tables for Making Healthcare Safer Reports. Content last reviewed April 2020. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/research/findings/making-healthcare-safer/comparison.html

[4] The Joint Commission. (2021). *Behavioral Health Care and Human Services: 2021 National Patient Safety Goals*. Retrieved from https://www.jointcommission.org/standards/national-patient-safety-goals/behavioral-health-care-national-patient-safety-goals/

[5] Marchus et al. Defining Patient Safety Events in Inpatient Psychiatry. J Patient Safety. Jan 2020. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6336525/
Cuomo, A et al. Patient Safety and Risk Management in Mental Health. Dec 2020. https://link.springer.com/chapter/10.1007/978-3-030-59403-9_20

[6] Alshehri, Ghadah H et al. Medication Safety in Mental Health Hospitals: A Mixed-Methods Analysis of Incidents Reported to the National Reporting and Learning System, Journal of Patient Safety: August 2021 - Volume 17 - Issue 5 - p 341-351
https://journals.lww.com/journalpatientsafety/Citation/2021/08000/Medication_Safety_in_Mental_Health_Hospitals__A.2.aspx

The NPSB would then be able to view de-identified data by race, ethnicity, gender, facility, and location, looking for disparities, abnormal patterns, or clusters of mental health safety events. These findings would then trigger the NPSB's Study Division to determine the appropriate type of study.

Studying the Root Causes of the Patient Safety Events

The NPSB's Study Division would determine the type of study to conduct by taking into account the impact of the patient safety event, whether there is systemic risk, and the potential of learning from the studies. For re-occurring events that lead to significant harm and pose systemic risk, the NPSB would conduct a major study with a "Go Team" of multidisciplinary experts, including a clinically-informed Human Factors Engineer, to gather additional data onsite (e.g., including but not limited to interviews, surveys, incident reports, imaging data, and additional EHR data). These studies would have one sole purpose: to establish facts, circumstances, and causes or probable causes of patient safety events.

The NPSB's study team would then submit a report to the NPSB's five-member Board, documenting factual information, an analysis of what went wrong, findings, probable causes, safety issues, and recommendations.

Issuing Recommendations to Prevent Patient Safety Events

Based on the study's findings, the NPSB would create recommendations for the industry, HHS agencies, and the VA to design a safer system for all providers to achieve optimal results and for all patients to receive safe and equitable mental health care.

The HHS agencies and the VA would be required to respond to the NPSB's recommendations within 90 days in terms of whether and how agencies will use their existing authorities and policy levers to help the industry adopt the recommendations.

While CMS has already added seclusion and restraint use that leads to injury to their list of Never Events, little to no action has been taken on the other types of patient safety events in mental health care settings. For example, in other countries, the United Kingdom's Healthcare Safety Investigations Branch (HSIB) has issued recommendations related to mental health emergency room staffing and transitioning young adults from youth to adult mental health care.

Where possible, the NPSB's recommendations would draw on autonomous technologies and fail-safe solutions. Using technology to examine EHRs can help to improve diagnostic instruments and find errors.[7] For example, a machine learning algorithm that uses data from mental health questionnaires and blood biomarker data can help to differentiate between bipolar disorder and major depression disorder.[8]

[7] Terri L Fletcher, Ashley Helm, Viralkumar Vaghani, Mark E Kunik, Melinda A Stanley, Hardeep Singh, Identifying psychiatric diagnostic errors with the Safer Dx Instrument, International Journal for Quality in Health Care, Volume 32, Issue 6, July 2020, Pages 405–411, https://academic.oup.com/intqhc/article/32/6/405/5871955

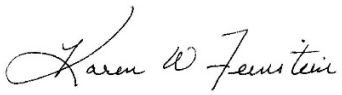
[8] Tomasik, J., Han, S.Y.S., Barton-Owen, G. et al. A machine learning algorithm to differentiate bipolar disorder from major depressive disorder using an online mental health questionnaire and blood biomarker data. Transl Psychiatry 11, 41 (2021). https://www.nature.com/articles/s41398-020-01181-x#citeas

Thank you for your interest in addressing the mental health crisis in our country, and we appreciate the opportunity to provide feedback in response to your Request for Information.

An essential, fundamental step for improving mental health care is to establish an independent agency to monitor the safety events, study the causes, and issues autonomous, fail-safe solutions. This work has never been more important.

If you have any questions, please contact Robert Ferguson, Chief Policy Officer at Jewish Healthcare Foundation, at ferguson@jhf.org who can also provide the legislative specifications for the NPSB. We look forward to working with your Committee to meet the critical mental health needs across the country.

Sincerely,



Karen Wolk Feinstein, PhD

Chair, National Patient Safety Board Policy & Advocacy Coalition
President and CEO, Pittsburgh Regional Health Initiative