

DESIGNATION AGREEMENT
Between
The Maryland Health Care Commission
And
The Maryland Patient Safety Center, Inc.

I. Parties

The Maryland Health Care Commission (“MHCC”) and the Maryland Patient Safety Center, Inc. (“MPSC”) (collectively “the parties”), recognizing that cooperation is critical to the goal of protecting patient safety, enter into this Designation Agreement (“Agreement”), which will be approved by MHCC as part of its decision to re-designate MPSC as Maryland’s patient safety center for an additional five years, through 2025.

MHCC is an independent regulatory agency whose mission is to plan for health system needs, promote informed decision-making, increase accountability, and improve access by providing timely and accurate information on the availability, cost, and quality of health services to residents, policy makers, purchasers, and providers of health care services in Maryland. MHCC has statutory responsibility for quality measurement and performance reporting regarding health care facilities and, therefore, has a keen interest in patient safety and quality improvement in hospitals, nursing homes, and ambulatory care settings.

The entity that later became MPSC was first designated by MHCC as Maryland’s patient safety center in 2004. MPSC is a not-for-profit entity, which became a corporation in 2007. MPSC’s goal is to make health care in Maryland the safest in the nation by fostering a shared culture of safety among patient care providers. MPSC’s approach combines limited mandatory reporting of serious adverse events to the Maryland Department of Health and encourages voluntary reporting of other patient safety events. It also offers education and training on quality and facilitates patient safety collaborative arrangements.

II. Background

In 2001, the Maryland General Assembly passed the Patient Safety Improvement Act, charging MHCC with studying the feasibility of developing a system for reducing the number of preventable adverse medical events in Maryland, including a system for reporting such incidents. MHCC subsequently recommended the establishment of a Maryland Patient Safety Center to improve patient safety in Maryland. The General Assembly endorsed this concept in 2003 by adopting legislation that gives medical review committee status to an entity designated by MHCC as the Maryland Patient Safety Center, thereby making the proceedings, records, and files of the designated patient safety center confidential and not discoverable or admissible as evidence in civil actions. Md. Code Ann., Health Occ. § 1-401(d)(1).

In 2005, Congress passed the Patient Safety and Quality Improvement Act (“Patient Safety Act”), which authorized the creation of Patient Safety Organizations (“PSOs”) to improve quality and safety by reducing the incidence of events that adversely affect patients. Pub. L. 109-41 (codified at 42 USC 299b-21 through 299b-26). To implement the Patient Safety Act, the Agency for Healthcare Research and Quality (“AHRQ”) later adopted and published the Patient Safety and Quality Improvement Final Rule (“Patient Safety Rule”). 42 CFR Part 3. Mid-Atlantic Patient Safety Organization (“Mid-Atlantic”), a component of MPSC, has been recognized as a PSO by AHRQ.

In January 2020, MHCC issued a Public Notice and Request for Expressions of Interest (RFI) in Designation of the Maryland Patient Safety Center from entities that wished to be considered for the five -year designation period beginning April 1, 2020, to December 31, 2025. *See*, Attachment A. MHCC approved the redesignation of the MPSC in response to MPSC’s January 13, 2020, submission to the RFI. *See*, Attachment B.

In 2022, Maryland General Assembly passed Senate Bill 591, which requires MHCC to designate a Maryland patient safety center in accordance with specified requirements and objectives and establishes the Patient Safety Center Fund as a special non-lapsing fund to subsidize a portion of the costs of the designated center. 2022 Md. Laws Ch. 529 (to be codified at Md. Code Ann., Health-Gen § 19-112 & State Fin. & Proc. § 6-226.) Beginning in FY2023 and each year thereafter, the legislation requires the Governor to include in the annual budget bill an appropriation of \$1,000,000 for the fund. MHCC shall administer the fund.

III. Performance Requirements and Standards

- A. Under this Agreement, MPSC agrees to the following performance requirements to maintain the five-year patient safety center redesignation:
 - a. MPSC shall implement and continue the strategies, programs, and activities identified in MPSC’s January 13, 2020 response to MHCC RFI, which is incorporated into this Agreement as Attachment C, and shall
 - i. develop, coordinate, and implement patient safety initiatives across the state;
 - ii. be a model for patient safety innovation and implementation in the state; and
 - iii. convene health care providers, patients, and families to
 - 1. improve the quality of health care and reduce preventable and avoidable harm
 - 2. Provide safe and equitable health care for state citizens

3. Share information relating to best practices among providers and patients in the state.
- b. MPSC shall ensure that all projects and initiatives it undertakes under this Agreement are not inconsistent with the priorities identified in MHCC's 2020 RFI document, incorporated into this Agreement and Maryland's Total Cost of Care Model including the priorities and goals identified in Maryland's Statewide Integrated Health Improvement Strategy.

B. Annual Performance Requirements and Standards

- a. Prior to the start of the MPSC Fiscal Year 2024 and every year thereafter, MPSC shall submit an Annual Plan ("Annual Plan") to maintain its designation as the Maryland patient safety center and continue state funding. The Annual Plan shall contain at least the following information:
 - i. MPSC priorities for the year;
 - ii. specific and measurable goals to meet the priorities and performance requirements and standards identified in this Agreement;
 - iii. current and proposed collaborations, programs, and education initiatives for the next year and timelines for attaining annual goals;
 - iv. Proposed project budget detailing MPSC's proposed use of Patient Safety Center funds including funding provided under Chapter 529, 2022 Laws of Maryland (SB 591 Maryland Health Care Commission – Patient Safety Center – Designation and Fund); and
 - v. Most recent annual organization budget approved by MPSC's board of directors;
- b. MHCC may approve the Annual Plan, approve the Annual Plan with conditions, or deny the Annual Plan.
- c. If MHCC denies the Annual Plan, MHCC will specify the reasons for the denial and provide MPSC a reasonable opportunity to submit a revised plan. If MPSC does not submit revised plan or MHCC denies the revised plan, MHCC may terminate MPSC's designation as the Maryland patient safety center in accordance with Section XIIB.
- d. MHCC approval of the Annual Plan constitutes authority for the MPSC to invoice the MHCC for funding authorized under Chapter 529, 2022 Laws of Maryland.

IV. Reporting and Monitoring

- A. Interim Report. MPSC will annually submit a written interim report due 30 days after the six-month mid-point in MPSC's fiscal year. The interim report shall summarize MPSC's program activities and progress related to measurable performance goals defined in the Annual Plan, this Agreement and specified by the MPSC Board of Directors.
- B. Annual Report. Thirty days after end of the MPSC's fiscal year, MPSC shall submit an Annual Report to MHCC that summarizes its programs, activities, and expenditures for the preceding year and detail its progress in meeting the objectives outlined in its Annual Plan and this Agreement. MPSC shall also address how its initiatives align with state designated priorities.
 - a. MPSC's Annual Report shall be incorporated into the report that MHCC submits annually to the Senate Finance Committee and House Health and Government Operations Committee in accordance with § 19-112 of the Health-General Article of Maryland Code.
 - b. MPSC's failure to demonstrate sufficient progress in implementing its Annual Plan or this Agreement may result in loss of MPSC's designation in accordance with Section XIIB and loss of funding under Section VII.
- C. If requested, MPSC will attend MHCC meetings to present information on its programs, its progress in attaining goals, and other information that may be presented in its reports.

V. Data Sharing and Use

MHCC and MPSC each maintain a significant amount of data regarding the provision of health care services in Maryland and recognize that the goals of each party will be furthered by the sharing of such data. Each party agrees to exchange data that will enhance analysis, policy development, and reporting capabilities of either party. MPSC agrees to voluntarily share information on quality to the extent permitted under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41). The parties will execute a separate data use agreement that will contain terms to assure that the privacy and security of any exchanged data are fully protected, in accordance with federal and State law.

VI. Representation on the Board of MPSC

MHCC and MPSC affirm the importance of having MHCC, the organization responsible for designating Maryland's patient safety center, participate on MPSC's Board of Directors. MPSC shall amend its bylaws to add one *ex officio*, non-voting position on its board for a MHCC Commissioner or staff member. MHCC shall designate the person to fill the *ex officio* position, subject to MPSC's approval, which shall not be unreasonably denied.

VII. Funding of MPSC

- A. Beginning in FY2023, the entity that is designated by MHCC as the patient safety center for Maryland shall receive funding support from the Maryland General Assembly for \$1 million annually through the Maryland Patient Safety Fund (“Fund”). The money expended from the Fund for the center is supplemental to, and not intended to take the place of, funding that otherwise would be appropriated for the center.
- B. Beginning Fiscal Year 2024, funds will only be released to MPSC upon approval of an Annual Plan, in accordance with Section IIIB, and its demonstration of satisfactory progress in implementing its prior year’s objectives, in accordance with Section IV.
- C. Upon approval of MPSC’s Annual Plan and Report, MPSC may submit an invoice to MHCC for the next year’s funding. MHCC shall work with MPSC to arrange for the disbursement of funds in a manner that is compliant with the requirements of the State Treasurer and Office of the Comptroller.
- D. Funds provided to MPSC from the Fund shall be used only for the initiatives outlined in its Annual Plan as approved by MHCC. A budget revision of more than a 10% increase or decrease of expenditures from the Fund must be approved by MHCC.
- E. MPSC, as an independent entity, may undertake other projects that are consistent with its duties as the state-designated patient safety center and may seek funding for any such projects from other sources, so long as MPSC does not use the funding provided through the Fund for projects not approved by MHCC.

VIII. Compliance with Requests for Information

MPSC shall comply with all state requests for information including requests from the MHCC, MDH, the Office of Legislative Audits, the Office of the Comptroller, and the Department of Budget Management.

IX. Governing Law

This Agreement shall be construed in accordance with and governed by the laws of the State of Maryland.

X. Non-Assignment

MPSC may not assign its designation as the Maryland patient safety center nor any rights or responsibilities under this Agreement to any other person. MPSC shall notify MHCC within 30 days of any change of control of the organization, including change in the CEO/President.

XI. Modifications and Amendments

This Agreement may be modified or amended only with the express written agreement of both parties, and all amendments shall be incorporated into this Agreement.

XII. Effective Date and Termination

- A. This Agreement is effective from July 1, 2022, to December 31, 2025, and is conditioned on MPSC remaining in good standing and designated as Maryland's patient safety center.
- B. **Loss of Designation.** MHCC may terminate MSPC's designation as the Maryland patient safety center if MSPC fails to substantially comply with the requirements of this Agreement.
 - a. Prior to terminating MSPC's designation, MHCC shall provide MSPC written notice that specifies the reasons that MHCC has failed to comply with this Agreement. MSPC may dispute the notice in writing within 90 days of receipt.
 - b. MHCC and MSPC may agree to a plan of correction to address any deficiencies.
 - c. If MHCC and MSPC fail to enter into a plan of correction or MSPC fails to abide with the plan, MHCC shall form an independent review committee to determine whether MSPC's designation as the Maryland patient safety center should be terminated. The independent review committee shall submit its written recommendation to MHCC for review by the full Commission.
 - i. MSPC shall be granted the opportunity to present oral argument to the Commission upon request.
 - ii. After oral argument, if any, the Commission shall vote to:
 1. Continue MSPC's designation as the Maryland patient safety center;
 2. Continue MSPC's designation with conditions;
 3. Or terminate MSPC's designation.

XIII. Notices

Any notice or report given pursuant to this Agreement shall be made in writing and, in addition to being given by email, shall be given by U.S. Postal Service or other carrier:

If to MHCC: Ben Steffen
 Executive Director
 Maryland Health Care Commission
 4160 Patterson Avenue
 Baltimore, Maryland 21215

Ben.Steffen@maryland.gov
410-764-3566

If to MPSC:

Dr. Blair Eig
President & CEO
Maryland Patient Safety Center, Inc.
6820 Deerpath Road
Elkridge, Maryland 21075
rimhoff@marylandpatientsafety.org
410-540-5076

IN WITNESS WHEREOF, the duly authorized representative of the parties has executed this Agreement this _____ day of ____ 2022.

Maryland Health Care Commission

Maryland Patient Safety Center, Inc.

BY: Ben Steffen
Ben Steffen
Executive Director

BY: Blair Eig
Blair Eig
President & CEO

Date: 09/06/2022

Date: August 9, 2022