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Pilot: Automated EHR adverse event monitoring system PROSPECTUS FOR MASSACHUSETTS ACUTE CARE HOSPITALS

The opportunity

The Betsy Lehman Center is preparing to pilot automated adverse event monitoring (AAEM) in 6-8 Massachusetts acute care hospitals. Projected to start in summer 2025, this 18-month pilot is a foundational action step toward implementing the state's *Roadmap to Health Care Safety*. Its purpose is to demonstrate whether and how AAEM — which generates clinically validated adverse event outcomes data to measure patient harm and drive improvement initiatives — leads to sustained reductions in preventable patient harm and other benefits, including cost savings.

Application and more information

All Massachusetts acute care hospitals are eligible to apply to serve as a pilot site. Application materials are located here. The application deadline is January 17, 2025.

An FAQ is included in the Appendix to this Prospectus. Recordings from a series of information sessions for interested hospitals are available on the Betsy Lehman Center's website.

For the pilot, the Betsy Lehman Center has contracted with Pascal Metrics Inc., which hosts a federally listed Patient Safety Organization (PSO) and is a leader in the field of AAEM. The Center will cover the cost of Pascal Metrics' services for participating hospitals during the pilot period.

About automated adverse event monitoring

Automated adverse event monitoring is a new but established approach that detects harm in near real time by continuously analyzing EHR data and generating clinically validated safety outcomes data. AAEM uncovers a much higher volume of serious harm events than hospitals have been able to detect through reporting systems that rely upon staff or patients to recognize harm and report what they know. This harm identification also occurs while patients are receiving care. Despite considerable hospital investment in these manual systems, they have been shown to miss over 90 percent of serious harm, and often lack the levels of timeliness and actionability needed to improve safety.

Pascal Metrics' approach to AAEM:

 Integrates a software service with a hospital's EHR that streams data from patient charts into a PSO cloud-based application where evidence-based rules and algorithms, or "triggers," are applied continuously to detect a wide array of adverse events (see Appendix 1 for a partial listing).

- Provides hospitals with a daily feed of adverse event outcomes and analytics that have been clinically adjudicated by a remote team of trained physicians and nurses who also contribute insights on type, severity, preventability, and more.
- Offers expert training, consultation, and support to help hospitals make sense of the data and to set priorities in responding to identified risks that will prevent future harm.

Early-adopter hospitals across the country are using this approach to uncover around ten times more adverse events than they had been identifying through manual reporting. Their ability to access timely, robust information about events affecting current patients has allowed these hospitals to respond to underlying risks and achieve unprecedented reductions in preventable harm — 25 percent on average, and over 60 percent in some cases. These hospitals also have experienced an average 3-to-1 annual return on investment, much of it attributable to a reduced need to provide non-revenue generating services, particularly extended lengths of stay. Leveraging AAEM to improve risk management also has driven down costs.

First-in-nation pilot

Goals

Although several early-adopter hospital systems have shared their results with the Betsy Lehman Center on a confidential basis, a rigorous evaluation of AAEM is needed to better understand whether and how this approach:

- Provides hospitals with daily validated data on a wide range of safety events that leadership and staff can use to inform and drive their current quality and safety improvement systems;
- Helps hospitals achieve significant and sustained reductions in preventable harm that:
 - Improve patient experience and outcomes
 - Reduce non-revenue generating services tied to extended lengths of stay
 - Accelerate patient throughput
 - Prevent a leading cause of burnout for frontline staff
 - Facilitate risk management and reduces liability claims and payouts
 - Align with the new Center for Medicare and Medicaid Services EHR-based hospital harm measures
- Yields cost savings for private and state health care payers by reducing excess claims to commercial health plans and MassHealth; and
- Could deliver timely, actionable information on system-level patient safety risks and trends.

Evaluation

An independent evaluation by a leading research team will examine these questions and measure the return on investment to the state and to the pilot hospitals. It also will project the potential ROI to payers if AAEM were to be implemented by all Massachusetts hospitals or by ambulatory and long-term care provider organizations that use EHRs.

Data security and confidentiality

Pascal Metrics is a Patient Safety Organization (PSO). Under federal law, <u>42 U.S.C. § 299b-22</u> and <u>42 C.F.R. § 3.204</u>, the clinically validated adverse event outcomes based on real-time EHR data generated by Pascal is considered Patient Safety Work Product and is protected from disclosure.

Under Massachusetts law, M.G.L. c. 12C, section 15(e), information received by the Betsy Lehman Center is confidential. It is not public record and is not subject to subpoena or discovery or introduction into evidence in any judicial or administrative proceeding except as otherwise specifically provided by law. This protection applies to the data that the Center will receive during the pilot.

The confidentiality of hospital data will be assured through data-sharing agreements between Pascal Metrics and each pilot hospital and between the Betsy Lehman Center and each pilot hospital.

Roles and responsibilities

Betsy Lehman Center

The Center will:

- Provide general oversight of Pascal Metrics;
- Cover the costs of Pascal Metrics' services to pilot hospitals;
- Conduct the hospital outreach and selection process in consultation with its <u>Advisory Committee</u> and Pascal Metrics;
- Facilitate a monthly learning collaborative exclusively for participating pilot hospitals;
- Receive and securely manage monthly deidentified hospital-level data from Pascal Metrics;
- Participate in an evaluation of the pilot by an independent research team; and
- Publish pilot findings, including in peer reviewed journals.

Pascal Metrics

Pascal Metrics is contracted with the Betsy Lehman Center to:

- Technically integrate pilot hospitals' EHR data feeds with Pascal's cloud-based
 Virtual Patient Safety platform to use automated triggers to identify patient harm events;
- Stream data into a Patient Safety Organization-protected environment where trained physicians and nurses validate safety outcomes and generate other insights at least once every 24 hours;
- Provide clinically validated adverse event outcomes based on real-time EHR data ("AE Outcomes") and other documentation to authorized hospital personnel on a daily basis through an interactive dashboard;
- Provide individualized consultations to help each pilot hospital understand the data and use it to support their existing safety improvement systems, enabling concurrent

- interventions and high frequency cycles of improvement as needed; and
- Confidentially share data and analytics with the Betsy Lehman Center and a third-party research team for evaluation purposes.

Pilot hospitals

Pilot hospitals will enter into memoranda of understanding with the Betsy Lehman Center that define the parties' respective commitments and responsibilities and address how the data and analyses will be shared and used. Hospitals also will enter into business agreements with Pascal Metrics that describe Pascal's services to the hospital, system implementation, and data use. In these agreements, each pilot hospital will commit to:

Start up and implementation

- 1. Collaborate with Pascal Metrics on integrating data feeds from the hospital's EHR to Pascal's cloud service;
- 2. Collaborate with Pascal Metrics to use the outcomes-based analytics and insight in its safety improvement structures within a culture of safety;
- 3. Conduct internal communication activities to inform staff about participation in the pilot and affirm executive and clinical leadership support;

Staffing and leadership sponsorship

- 4. Ensure that appropriate leaders and staff are available and prepared for each phase of the pilot and that they engage with Pascal Metrics' clinical leaders, team, and data analytics as needed. This includes:
 - Designating an Executive Sponsor with appropriate executive and operational span of influence and control to facilitate hospital engagement on the part of executives, quality and safety leaders, IT staff, and clinicians;
 - Designating a Clinical Sponsor who has responsibility for patient safety, both strategies and methodologies of delivering care as well as daily operations (or multiple Clinical Sponsors if this responsibility is split);
 - c. Designating a part-time (estimated 1-hour per day) Patient Safety Liaison with dedicated time to interact with Pascal Metrics;
 - d. Ensuring that executive leadership has access to the Pascal Metrics' dashboard and receives
 - regular notifications, escalations if necessary, and reports on patient harm events;
 - e. Presenting pilot progress updates to the full Board at least quarterly, and including details on the pilot progress and how the data and analytics are being applied for improvement;
 - f. Designating sponsors and staff to participate in monthly virtual meetings of a learning collaborative that will facilitate information exchange among the pilot hospitals, Pascal Metrics, and the Betsy Lehman Center;
- 5. Ensure that senior leaders in addition to the patient safety liaison participate in the pilot learning collaborative;

Data sharing and dissemination

- 6. Authorize Pascal Metrics to share de-identified hospital-level safety event data with the Betsy Lehman Center for the Center's use in understanding progress over the course of the pilot (data confidentiality will be maintained as described below);
- 7. Acknowledge participation as a pilot site, and to having the hospital's name included on the Betsy Lehman Center project website and in publications resulting from the pilot;
- 8. Participate in pilot evaluation activities such as key informant interviews and surveys to provide context on the continuous improvement methods, resources used, and lessons learned before, during, and after the pilot; and
- Agree that the Center may publish and communicate pilot evaluation results that use nonidentifiable aggregate data, including in academic journals. Confidentiality regarding individual pilot hospital experience will be maintained in any public communications or publications.

Benefits to pilot hospitals

In addition to playing a leading role in a novel demonstration that could advance the field of health care safety, pilot hospitals will have the opportunity to:

- Receive technical integration and the first year of Pascal Metrics' services at no charge;
- Boost performance on EHR-based patient safety outcome and structural measures recently implemented by the Centers for Medicare and Medicaid Services;
- Reduce the burden of manual reporting on frontline staff;
- Initiate risk management and communication and resolution while a patient is still receiving care in the hospital; and
- Benefit from participation in a learning collaborative with other pilot hospitals that are working to embed safety improvement as a strategic priority.

Hospital eligibility and selection

All acute care hospitals in Massachusetts are eligible to apply for the pilot. Pascal Metrics' system can be integrated with any commercial EHR that conforms to industry standards.

A committee comprising Betsy Lehman Center staff, members of the Advisory Committee, and Pascal Metrics will select a diverse cohort of 6-8 hospitals, assessing each interested hospital's readiness to participate. Considerations will include:

- Hospital executive leadership's support for and level of engagement in the pilot;
- Hospital preparedness to follow through on its commitments during each phase of the
 pilot (see below), including availability of essential executive leadership, clinical leaders
 and managers, and IT staff;
- Hospital capacity to engage in safety improvement, including established systems for continuous improvement within a culture of safety;
- Hospital size, region, type, and EHR system contributes to pilot site diversity; and

- EHR implementation maturity
 - Hospitals transitioning to a new EHR (or planning to do so during the pilot period) are unlikely to qualify.
 - Hospitals that have recently implemented a new EHR will be considered on a caseby-case basis.

Timeline

Phase 1: Readiness	
Applications due	January 17, 2025
Follow-up interviews	January – March 2025
Pilot hospital selection and notification	Completed by March 31, 2025
Contracts with the Betsy Lehman Center and Pascal Metrics	Completed by June 30, 2025
Phase 2: Implementation	
Software integration and data validation	August – December 2025
Go-live	January 2026
Monthly meeting of pilot hospital learning collaborative	July 2025 – December 2026
Daily adverse event analytics posted to hospital dashboards; technical and consulting support	January – December 2026
Pascal Metrics consultation with hospitals on using the analytics in their safety improvement systems	January – December 2026
Monthly deidentified hospital-level event data from Pascal to the Betsy Lehman Center	January – December 2026
Monthly deidentified hospital-level event data from Pascal to the Betsy Lehman Center	January – December 2026
Phase 3: Evaluation and wrap-up	
Final evaluation activities	
Betsy Lehman Center findings and recommendations	
Academic publications	
Expand pilot activities to more hospitals and other clinical settings, as appropriate	

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