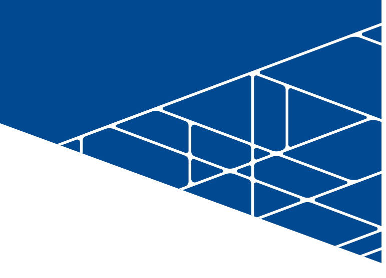


Healthcare

VANTAGE POINT®

A Healthcare Risk Management Resource | 2023 Issue 2

Evolving Models of Care: New Delivery Methods Present New Risks

In the wake of changing consumer preferences and payment systems, the healthcare industry is undergoing a fundamental transformation. (See "Alternative Payment Models" on page 8.) Care delivery is being restructured in order to reduce costs, improve outcomes and increase access.

The emerging delivery systems are known as evolving models of care (EMOC). While EMOC vary considerably, they typically include the following characteristics:

- **An emphasis on preventive care** and expanded availability of primary care providers.
- **A range of community care options** to better serve the needs of all patients, especially in rural areas.
- **Broad utilization of nontraditional care settings** – such as retail clinics and freestanding diagnostic centers – that operate in a more flexible, cost-effective manner.
- **Expansion of practice boundaries,** including services, procedures and tasks that different types of healthcare providers are authorized to perform.
- **Implementation of evidence-based practices and guidelines** to improve consistency and effectiveness of care.
- **Timely adoption of new technologies,** when appropriate, as well as a commitment to enhanced data connectivity and information sharing. (See "Six Innovative Technologies Enabling New Models of Care," page 3.)

For a description of some of these healthcare delivery innovations, see "New Care Delivery Models" on page 2.

In this issue…

- Understanding Evolving Models of Care… page 2.
- New Care Delivery Models… page 2.
- Six Innovative Technologies Enabling New Models of Care… page 3.
- Alternative Payment Models… page 8.
- Quick Links… page 8.

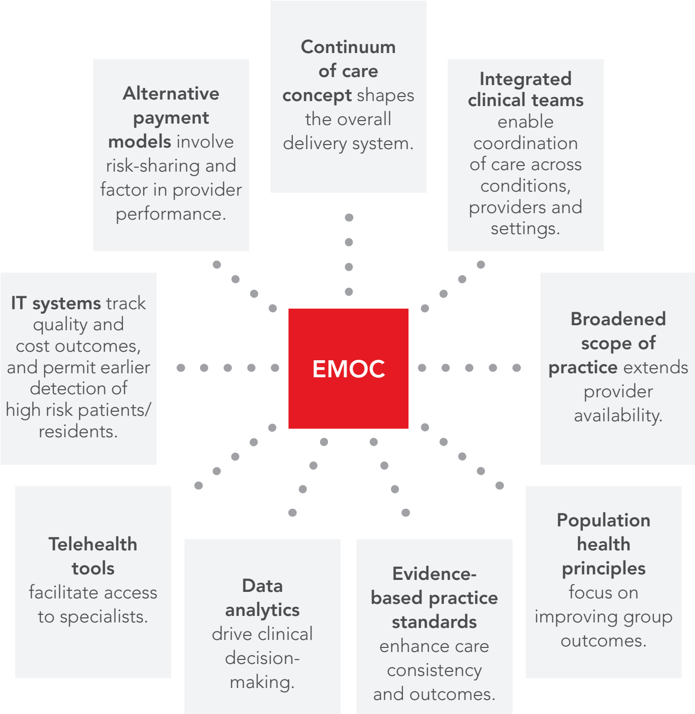
These seismic shifts in the healthcare landscape are intended to offer enhanced options to both medical consumers and society at large, including greater access to primary and specialty care at a lower cost. (See page 2 for more information on the advantages of EMOC.) At the same time, the expansion of services and changes in scope of practice associated with new models of care present challenges to facilities and providers, including but not limited to the following:

- New and unpredictable professional liability exposures.
- Staffing issues, including training and retention.
- Reimbursement questions.
- Potentially harmful overreliance on technology.

This edition of *Vantage Point®* identifies the elements of new healthcare delivery models, describes the benefits and risks of these innovations, and suggests strategies designed to protect patients/residents and reduce liability exposure.

Understanding Evolving Models of Care

Multiple factors are leading the movement away from traditional healthcare delivery methods, ranging from increasing healthcare costs, persistent access challenges and service inequities to rapid advances in technology, a generational shift in consumer expectations, and the entry of well-funded, nontraditional players into the healthcare sector. The new models that have emerged to meet these changes and challenges tend to share the following common features:



Benefits of EMOC

The shift of the healthcare industry toward EMOC is designed to achieve the following goals, among others:

- **Emphasizing disease prevention** and population health management.
- **Maximizing consumer access to healthcare** by enlarging delivery system capacity.
- **Increasing provider productivity** by updating scope of practice arrangements.
- **Attracting new patient/resident populations** through augmented service offerings.
- **Lowering costs** by shifting care from traditional inpatient or outpatient facilities to less expensive settings, including home care and retail sites.
- **Strengthening service networks** by partnering with nontraditional care providers, including nationwide telehealth services and retail settings that provide routine care to walk-in clientele.
- **Enhancing efficiency and accountability** through shared-risk and value-based payment models.

New Care Delivery Models

The following innovative care models, among others, attempt to better meet consumer needs by reorganizing and integrating service delivery across the healthcare continuum:

Inpatient: Specialist centers of excellence; neighborhood medical centers for chronic care admissions; smaller, community-based hospitals for elective care; and hospital-at-home programs.

Outpatient: Diagnostic and testing sites that combine primary care with a range of specialty providers, 24-hour mental health crisis centers, urgent care facilities, expanded telehealth offerings and freestanding emergency departments for acute care.

Primary care: Adoption of the "Medical Home Model," which employs a patient-centered, team-based approach to care and coordinates services across a healthcare system.

Ambulatory care: Retail and worksite health clinics, as well as conveniently located urgent care and pediatric care sites.

Home care: Remote care services, self-diagnostic tools, wearable monitoring devices and online pharmaceutical retailers.

Aging services: Use of artificial intelligence-powered clinical and remote monitoring tools, increased home-based care options, and inclusive care models that cover Medicare- and Medicaid-funded clinical services.

Risk Factors and Strategies

The following strategies seek to mitigate risk exposures commonly associated with EMOC:

Changes in Scope of Practice

Scope of practice (SOP) is evolving toward greater flexibility for all direct care providers, including nurse practitioners, physician assistants, nurses, certified nurse assistants, dentists, pharmacists and physical therapists. To minimize liability exposure, administrative and clinical leaders and office practice managers should address the following risks associated with changing SOP and delegation standards:

Risk Factors	Strategies
1. Unauthorized expansion of practice for direct care staff.	• **Create an oversight mechanism** to verify that job duty changes comply with state practice laws and regulations, as well as professional association guidelines. • **Draft a delegation protocol,** guided by scope of practice statutes, to ensure that assigned tasks are consistent with the caregiver's level of knowledge and skill. • **Establish a formal process for authorizing expansion of job duties,** with written criteria associated with the specific provider type and task. • **Define, in writing, the nature and extent of practice changes** for all direct care providers. • **Update policies and procedures** to reflect the new clinical responsibilities. • **Revise certification requirements** for direct care providers in accordance with relevant laws and regulations. • **Review job descriptions** to ensure that they are aligned with changing expectations.
2. Lack of specific policies or outdated protocols.	• **Implement written protocols** that clearly define the activity to be performed, as well as the requisite supervision required of the delegating provider, if applicable. • **Update practice agreements** for independent practitioners in new areas of care and have them reviewed and approved by governing boards, executive leadership and legal counsel.
3. Miscommunication within treatment teams.	• **Develop a framework for collaborative decision-making** within each integrated care team. • **Implement set communication checkpoints,** including team rounds, case conferences and huddles. • **Formalize two-way communication** between delegating providers and assistive personnel.
4. Inadequate examinations, consultations, diagnoses and treatments.	• **Develop medically reviewed pathways** that reflect evidence-based standards of care. • **Create written guidelines regarding authority to prescribe drugs and medical devices,** as well as to perform diagnostic tests and surgical procedures. • **Review processes for tracking diagnostic and laboratory tests,** including receipt of results, patient notification and follow-up actions, in order to avoid costly diagnosis- and treatment-related failures. • **Periodically audit healthcare information records** to measure compliance with practice directives and standards of care in evolving areas of practice. • **Implement a formal Quality Improvement/Risk Management program** comprising key clinical and outcomes measures, regular audits to assess performance and quality of care, and process improvements.

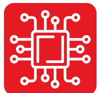
Six Innovative Technologies Enabling New Models of Care

- **Artificial intelligence,** which replicates human thought processes, can help enhance diagnostic, administrative and operational processes.
- **Three-dimensional (3D) printing,** which is a computerized manufacturing process used to produce experimental medical products and devices at a fraction of conventional costs, is potentially making products more accessible to patients.
- **Robotic surgery,** which helps physicians perform complex procedures with greater precision.
- **Digital health platforms and applications,** which facilitate information-sharing among clinical teams and patients/residents.
- **Wearable devices,** which permit ongoing patient/resident monitoring and generate treatment recommendations based upon data analysis.
- **Telehealth platforms,** which help facilitate monitoring, counseling and education of remotely located patients/residents.

Rapid Expansion of Services

As delivery systems evolve and consumer access points increase, organizations are likely to find themselves offering a wider range of services. The following strategies can help ensure that organizations change and grow in a safe, controlled manner:

Risk Factors	Strategies
1. Remote care options in new clinical environments.	• **Implement delegation requirements and documentation standards for licensed providers providing virtual services** in newly expanded settings, especially with respect to primary care and behavioral health. • **Draft policies and systems to track remotely located patients** within and across different settings, as well as to report adverse events and monitor equipment and supplies. • **Document patient response to remote care** and switch to in-person care if clinical conditions warrant.
2. Emerging therapies offered in non-traditional settings.	• **Designate a task force to research advanced medicine prospects, benefits, costs and risks**, and to create a strategic plan for emerging treatments that addresses ethical and liability considerations. • **Conduct risk assessments of all nontraditional settings** – e.g., urgent care, retail clinics, medi-spas, pharmacies and freestanding emergency departments – including liability exposures, statutory, regulatory and ethical implications, adequacy of insurance coverage and risk reduction measures. • **Revise competency and credentialing models for providers and other direct caregivers to include emerging technologies and therapies,** such as pharmacies providing medication-assisted treatment; medi-spas offering cosmetic procedures and intravenous therapies; and pharmacies, imaging centers and laboratory services performing targeted treatments based upon genetic profiling. • **Adapt informed consent policies to changing models of care,** taking into account consumer awareness of new technology and treatment modalities (see page 3), including artificial intelligence (AI) systems.
3. Changing statutory, regulatory and licensing board requirements.	• **Adopt a proactive stance regarding legal compliance,** including tracking statutory and regulatory changes related to evolving services or therapies; routinely reviewing treatment protocols in areas of high risk exposure; and maintaining comprehensive records of current and past policies and procedures. • **Digitally document compliance regarding new entity licensing,** as well as FDA approval for all new technologies and devices.
4. Fragmented care due to the wider range of services available over diverse care settings.	• **Advocate for treatment teams to collaborate on compiling data,** reviewing test results and integrating clinical information across the care continuum. • **Refine IT tools to enhance referrals and patient/resident transitions,** using closed-loop technology that streamlines workflows and ensures automatic patient data transfer. • **Digitize the flow of information across all settings** and present it in user-friendly formats, e.g., order sets, clinical pathway checklists, information tracking functions.
5. Multi-state patient/ resident populations and associated licensing issues.	• **In collaboration with legal counsel, develop a risk management approach for multi-state patient/ resident populations,** ensuring that liability considerations and insurance coverage issues are factored into organizational decisions. • **Review current licensing requirements in relevant jurisdictions** when verifying provider authorization to legally practice in multiple states via compacts, as well as telehealth-specific licenses.
6. Documentation deficiencies.	• **Audit patient/resident healthcare information records,** in order to identify gaps or omissions in documentation requirements created by new models of care and shifting expectations. • **Review record retention policies** to ensure continued compliance with statutory and regulatory requirements.



Overdependence on Technology

The emergence of AI technologies threatens to create an overreliance on tools designed to replicate human mental functions and decision-making processes. The following chart summarizes some of the risk factors associated with data analytics and AI, and suggests measures to evaluate the safety and effectiveness of specific applications:

Risk Factors	Strategies
1. Privacy and HIPAA concerns stemming from increased information exchange and data storage.	• **Ensure that interconnected electronic health information and telecommunication platforms have adequate technical safeguards** – such as encryption capabilities, passwords and security codes – to protect patient/resident health information from improper disclosure. • **Identify websites or software apps that use online tracking technology** - i.e., script or code that is designed to collect information about users - and prohibit their use, as this practice may lead to impermissible disclosure of patient/resident protected health information (PHI). • **Develop and enforce virtual care security protocols** for providers working from remote locations. • **Utilize encrypted chat features** and other privacy safeguards when delivering virtual care. • **Perform routine assessments of AI systems and IT databases** to detect potential cybersecurity threats. • **Acknowledge the potential of AI technology to "re-identify" previously anonymized PHI when combining multiple datasets,** and revise informed consent processes to alert patients that de-identified PHI may appear in research databases and be utilized in the development of AI technology.
2. Unchecked acceleration in the adoption of AI technology.	• **Appoint a task force to undertake a prospective AI risk analysis** – including the uses, benefits, limitations and hazards of AI tools – in order to assess the extent of enterprise liability. • **Retain medical experts to help develop AI algorithms** and evaluate system outcomes. • **Consult with vendor representatives when drafting AI-related policy,** in order to better understand the limits of AI tools and enable their safe and appropriate use. • **Confer with legal counsel regarding vendor-related contractual protections,** including hold harmless and indemnity provisions.
3. AI tools driving clinical care without proper oversight.	• **Draft a strategic plan for AI adoption,** including training opportunities and performance expectations. • **Review AI systems** to ensure that data in AI algorithms are accurate, up-to-date, unbiased and extracted from identifiable sources. • **Assign responsibility for managing and evaluating AI systems,** in order to detect possible programming flaws that may lead to diagnostic and treatment lapses by providers. • **Develop transparency requirements for data used to train AI systems** and encourage providers to work with data analysts in the annotation, publication and presentation of data. • **Educate providers about the risks of "automation bias"** and suggest error avoidance strategies, using simulated scenarios of faulty decisions. • **Create an audit process for reviewing AI-generated decisions** to ensure decision-making criteria are valid and consistent, and that providers rely upon professional judgment when accepting or rejecting AI-generated recommendations.
4. Big data analytics and the risk of improperly disclosing clinical data.	• **Identify "big data" databases within the organization,** i.e., large-volume databases that are unmanageable using traditional software or Internet-based platforms. • **Develop a strategic plan for generating and analyzing "big data,"** using technically advanced AI and robotic process automation tools capable of processing vast amounts of miscellaneous data. • **Employ natural language processing or related technologies** to extract information from electronic healthcare records (EHRs). • **Develop guidelines for sharing sensitive health data with third parties,** including strict internal controls to protect patient/resident privacy, as well as data integrity and security. • **Incorporate closed-loop data platforms** to better visualize who is accessing data and for what purposes. • **Ensure that healthcare data transactions are transparent and traceable,** utilizing blockchain technology.

Staff and Provider Turnover

For organizations seeking to adopt new models of care, enhanced staffing flexibility is necessary but may not be feasible. Therefore, the chronic problem of high provider and staff turnover should be addressed, utilizing the following additional strategies, among others:

Risk Factors	Strategies
1. Burnout due to overwork, cost-cutting pressures, increased documentation demands and other factors.	• **Perform a comprehensive review of temporary staffing arrangements** and their effect on organizational functioning and morale. • **Ensure that workloads are balanced and safe** through the use of agency staff, float pools, medical assistants and flexible scheduling systems. • **Implement principles of advanced team-based care,** in order to enhance office practice workflow efficiencies. • **Monitor staff absenteeism rates and work satisfaction levels,** as well as overtime hours, average workloads and time spent on EHR data input. • **Institute wellness programs** for all direct care providers. • **Include staff wellness scores in supervisory and management reviews** to encourage implementation of burnout-reduction strategies and action plans. • **Consider updating EHR systems,** in order to improve efficiencies related to the documentation of workflow processes and practices.
2. Perception that technology is diminishing provider autonomy and creating uncertainty.	• **Introduce AI technology as a complement to diagnostic and treatment skills of providers,** thus diminishing anxiety, as well as enhancing morale and retention. • **Create a communication plan for adoption of AI and other new technologies,** covering such issues as process changes, timelines, training opportunities and performance expectations.

Private Equity Acquisition

Private equity (PE) firms often have ready access to the investment capital needed to change and grow healthcare organizations, making them desirable partners for those that are struggling financially or seeking to move in new directions. However, their focus on maximizing profits can lead to an array of potential risk factors. For this reason, the following exposures, among others, should be considered during a merger or acquisition with a PE-backed firm:

Risk Factors	Strategies

1. Questionable business practices or unsustainable expansion of services following acquisition.	• **Closely examine the business model of potential PE partners for red flags,** such as:
	  • Use of borrowed money to purchase facilities/practices and expand the service territory.
	  • Transfer of debts onto the balance sheet of newly acquired entities and/or a rapid sell-off of assets.
	  • Opaque disclosure reports lacking a clear statement of ownership.
	  • Insufficient disclosure of vendor affiliations, such as ownership of diagnostic and imaging centers.
	  • Unduly high management fees and/or a sudden reduction in labor costs at acquired organizations.
	• **Appoint flexible and transformational leadership,** which is able to clearly communicate integration-related objectives to frontline providers and manage market growth in a transparent and open manner.
	• **Invest adequately in new or expanded service lines** and recruit additional staff, if necessary.

2. Consolidation of care sites and staff post-acquisition.	• **Engage in realistic strategic planning** with clear objectives for organizational restructuring and reallocation of human and physical resources. • **Establish communication forums** to share important news and updates with providers and staff, explain and discuss business and expansion plans, and resolve questions regarding organizational values and goals.

3. Noncompliance and unlawful activity.	• **Review PE investors' short- and long-term business goals,** as well as their history and corporate governance structure. • **Insist on full disclosure of PE partners' compliance with state/federal laws and regulatory requirements** that apply to new business models. • **Be alert for fraudulent billing schemes** involving claims for services provided by unlicensed, unqualified and/or improperly supervised staff. • **Monitor portfolio updates by PE partners to investors** for insight into business plans, operating strategies and timelines for return on investment.
4. Incompatibilities among merged entities.	• **Utilize accountability and process flow maps to detect core differences between acquired organizations,** as well as new reporting relationships and decision-making processes in the evolving service model. • **Review clinical policies and protocols** to ensure consistency of expectations regarding communication and documentation. • **Identify potential technology platform incompatibilities** that may lead to loss, corruption or improper disclosure of data. • **Ensure that transferred or new personnel complete a formal orientation** and an onboarding process, in order to avoid potential interpersonal conflicts and patient/resident safety lapses in newly merged settings.

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Reimbursement Uncertainties

Various payment concepts have been introduced to better manage healthcare utilization and reduce unnecessary spending. Most involve some sharing of risk, leading to uncertainty among some providers that reimbursement levels will offset the rising operational costs associated with new delivery models. The following strategies can help ease uncertainties associated with an evolving payment landscape:

Risk Factors	Strategies
1. Alternative payment models that shift financial risk to providers.	• **Redesign service lines based upon specific disease states or care episodes,** rather than medical specialties. • **Assist medical providers in shifting their role from individual decision-makers** to leaders of an integrated medical team. • **Reorganize primary care delivery** using an integrated care team model. • **Design effective care management programs** focusing on specific high-cost disease states.
2. Stagnant reimbursement levels associated with shared-risk payment models.	• **Look for promising service expansion possibilities,** in order to augment capacity and thrive under shared-risk payment models. • **Create diversified provider networks** – including combinations of provider groups, behavioral health organizations, ambulatory clinics and acute care hospitals – and assign them direct responsibility for improving patient/resident outcomes and reducing operating costs. • **Update clinical care protocols,** relying upon evidence-based population-health and disease-management principles.
3. Post-COVID changes to reimbursement policies.	• **Review and comply with the Consolidated Appropriations Act of 2023**, which extends many of the telehealth waivers authorized during the COVID-19 public health emergency through December 31, 2024. • **Monitor the status of pandemic-era waivers and flexibilities** relating to telehealth practice and reimbursement policies, as promulgated by the Centers for Medicare & Medicaid Services.
4. Provider resistance to alternative payment models.	• **Draft a "platform of change"** to inform providers of changes in payment methodologies, and encourage ongoing dialogue to bolster provider collaboration. • **Utilize population-health management and predictive modeling tools** to aid providers in identifying at-risk patient/resident groups and formulating targeted interventions. • **Help providers manage risk** by tracking their performance on shared-risk contracts, and reporting findings to them on a regular basis.

The healthcare industry is making major changes to improve efficiency, flexibility and market scope. The evolving models of care being spearheaded by new technology and data analytics, are a step in the right direction. However, these innovative delivery systems present certain liability implications, which must be addressed by leadership in the course of forming partnerships and revising policy and procedure. The various strategies suggested in this publication serve as a reminder of the need to prioritize safety and quality, irrespective of how healthcare services are delivered or reimbursed.

Alternative Payment Models

Several value-based payment methodologies are currently in use to help achieve high-quality and cost efficient care, including the following:

- **Accountable care organizations,** in which networks of healthcare providers assume joint responsibility for improving clinical outcomes and reducing spending for a given patient/resident population.
- **Patient-centered medical homes,** in which primary care is delivered via a care team comprised of primary care providers, nurses, case managers and others.
- **Clinically integrated networks,** in which hospitals and health systems are organized around service lines designed to treat specific conditions, such as cancer, heart disease or vascular disorders.
- **Program of All-Inclusive Care for the Elderly (PACE),** which is a Medicare and Medicaid program that helps elderly people meet their health care needs in the community setting.

Quick Links

- Burgstahler, L. "Will AI Replace Humans in Health Care? Not Likely, But Here's How to Talk to Your Staff About It." Posted on *Healthcare Innovation Blog*, December 5, 2019.
- "Evolving Care Models: Aligning Care Delivery to Emerging Payment Models," a report issued by the American Hospital Association Center for Health Innovation.
- Harrer, S. "Commercializing Digital Health: Trading On A Dynamic Data Marketplace." *Forbes*, June 1, 2021.
- "Shaping the Physician of the Future," a report issued by Deloitte Consulting, LLP, 2019.
- *Vantage Point*® 2022-Issue 2, "Mergers and Acquisitions: Enhancing Clinical Integration, Reducing Risk."
- *Vantage Point*® 2022-Issue 1, "Scope of Practice Changes: Ten Keys to Safer Delegation."
- *Vantage Point*® 2021-Issue 2, "Telemedicine: A Brief Guide to the Emerging Risks of Remote Care."
- *Vantage Point*® 2021-Issue 1, "Provider Burnout: A Root Cause Approach to Reducing Stress."
- *Vantage Point*® 2020-Issue 1, "Artificial Intelligence: Examining Five Key Liability Exposures."

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