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PSOs: Essential to ACO Success

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As health care responds to the imperative to improve quality and efficiency, a variety of business models featuring a clinically integrated approach to care and alternate payment methods are under consideration. Even before passage of the Patient Protection and Affordable Care Act (“PPACA”) in March 2010, there was increased interest in the development of different care delivery and payment models as mechanisms to transform health care through better alignment of financial incentives for providers with quality and cost goals. Prior legislation had already moved the Centers for Medicare and Medicaid Services (CMS) from a passive purchaser of volume-based health care to an active purchaser of value-based, high quality health care, targeting quality and efficiency improvements through payment reform.ⁱ

Although PPACA authorizes an assortment of programs and demonstration projects designed to control costs and improve the quality of care provided to Medicare, Medicaid, and CHIP beneficiariesⁱⁱ, the “Medicare Shared Savings Program”, which provides the framework for Accountable Care Organizations (ACOs)ⁱⁱⁱ, is the only payment reform to be established in statute. Fragmentation and discontinuities in health care services are key factors contributing to poor health outcomes, decreased quality and safety, and

escalating health care costs.^{iv} Since PPACA’s passage, ACOs have generated increased interest in both the public and private sectors as a means to shift the health care service delivery paradigm to a value-based, coordinated system of care.

ACOs require providers across the spectrum of health care services to work together within a comprehensive, integrated care delivery system. Providers in both Medicare and non-Medicare ACOs are accountable for the cost, quality and overall health of a designated population. They also share in savings generated by meeting quality and efficiency goals.^v In order to meet quality and cost targets, ACOs will need to form seamless provider networks that are collectively responsible for providing safe, high-quality care across the continuum of health care services, from primary care to long term-care.^{vi} Participation in a Patient Safety Organization (PSO) benefits ACO Providers by making available:

- A way to systematically identify emerging vulnerabilities and near misses that have the potential to create risk across the integrated clinical environment;
- A means of analyzing medical errors in a protected environment in order to improve patient safety in all segments of the ACO; and,

- A forum for learning about patient safety issues and best practices to support patient safety and quality improvement efforts across the ACO.

This paper will describe the key features of ACOs and PSOs, discuss how ACO objectives align with PSO patient safety activities, and consider likely benefits of PSO participation to ACO Providers.

Understanding ACOs and PSOs

The Accountable Care Model

ACOs are networks of providers that accept responsibility for the cost and quality of care delivered to a specific population of patients cared for by the groups' clinicians. The model provides a framework for a comprehensive, integrated care delivery system in which providers across the spectrum of health care services agree to be accountable for the cost, quality and overall health of a designated population, and share in savings generated through meeting quality and efficiency targets.^{vii} Data is used to assess performance and drive cost and quality improvement.^{viii}

Since introduction of the ACO concept, a variety of accountable care or "clinical integration" models have emerged, defined by their provider composition, priorities, strategies and incentive mechanisms. Today's ACOs differ from the early Health Maintenance Organizations (HMOs) or Managed Care Organizations (MCOs) in that care management is assigned to a group of health care providers instead of payers. The ACO focus is on measurable outcomes, and the use of technology for risk adjustment, advanced analysis, and population and individual health data management.^{ix} Rather than focusing on cost containment, the ACO is premised on health management that generates improved

patient outcomes, which in turn result in decreased cost. The most common models to date include small physician group ACOs, Hospital-led ACOs, Hospital-Physician Group ACOs and Medicaid ACOs. As the accountable care model grows, non-Medicare models are slightly outpacing the Medicare ACOs, with physician sponsored arrangements outnumbering hospital or insurance led ACOs.^x Despite variation in organizational structures, the core concept of joint accountability for patient safety, quality and cost improvement remains constant.

Understanding PSOs

Patient Safety Organizations (PSOs) are entities where health care providers may voluntarily report information regarding adverse events, medical errors, near misses, and other patient safety activities on a privileged and confidential basis, in order to learn from such events to improve health care quality and safety.^{xi} Information that is "assembled or developed by a provider for the purpose of reporting to a PSO and is reported to a PSO; developed by a PSO for the conduct of patient safety activities; or constitutes the deliberation or analysis of, or identifies the fact of reporting to a PSO" is considered Patient Safety Work Product (PSWP).^{xii} PSOs utilize PSWP to conduct their patient safety activities, including: collection and analysis of PSWP; development and dissemination of patient safety information, such as recommendations, protocols and best practices; and, providing feedback to PSO participants to assist in minimizing patient risk and harm.

A broad range of privilege and confidentiality protections are triggered when health care providers and PSOs define, manage, and maintain patient safety related information according to specific statutory and regulatory requirements enumerated in

the Patient Safety and Quality Improvement Act of 2005^{xiii} and its implementing regulations^{xiv}. For PSO participants, information that qualifies as Patient Safety Work Product (“PSWP”), with limited exceptions, may not be disclosed, and is not subject to subpoena, discovery or admission into evidence in federal, state or local civil, criminal or administrative proceedings, including disciplinary proceedings against a provider. Further, recommendations developed by the PSO for a specific PSO participant are considered to be PSWP and remain confidential until such time as the participant selects and implements a recommendation.

PSOs are charged to engage in “efforts to improve patient safety and the quality of health care delivery”^{xv}. This core patient safety activity aligns well with the ACO mission to improve the quality and efficiency of health care service delivery. The broad range of Federal peer review protections available to PSO participants engaged in patient safety activities facilitates better reporting of adverse events, leading to a better understanding of near misses, provider and system errors, and never events experienced by ACO providers for evaluation against aggregated data from the larger PSO data set. Such information can inform ACOs understanding of factors contributing to challenges in meeting quality and efficiency targets and highlights possible improvement solutions, thus supporting ACOs in meeting quality and efficiency benchmarks.

ACO Provider Access to PSO Protections

An ACO is a legal entity formed under applicable State, Federal, or Tribal law and authorized to conduct the business of the ACO in each state where it operates for the purpose of receiving and distributing shared savings, repaying shared losses, establishing reporting and ensuring provider compliance with health care quality criteria, and

otherwise fulfilling ACO functions.^{xvi} It is comprised of individuals or groups of ACO providers and suppliers that have established a mechanism for shared governance, including hospitals, skilled nursing facilities, outpatient rehabilitation facilities, home health agencies, hospices, physicians and other practitioners. Providers and suppliers eligible to form ACOs include ACO professionals^{xvii} in group practice arrangements, networks of individual ACO professionals, and hospitals that either employ health care providers, or form partnerships or joint ventures with other health care providers.^{xviii}

The PSO confidentiality and privilege protections are available to health care providers who appropriately assemble or develop PSWP for reporting to a PSO. Likewise, disclosure of PSWP between the PSO and provider is protected. Within the context of the PSO, the term “provider” means an “individual or entity licensed or otherwise authorized under State law to provide health care services.”^{xix} In most states the ACO itself is not licensed under state law to provide health care services. Under this regulatory structure, the ACO does not meet the PSO definition of a provider. It is the business model under which the providers function as a clinically integrated entity within a shared risk financial model. But, the ACO providers, suppliers and professionals that make up the ACO are, most likely, “individuals or entities licensed or otherwise authorized under State law to provide health care services”, and would be eligible to participate in a PSO.

As ACO models continue to develop it is likely that states will consider a means, including licensure, to regulate ACOs. Until that time, the ability to share PSWP and to conduct patient safety activities within

the ACO will vary based on the business relationship between the ACO and its constituent participants. Mechanisms to allow for data sharing by ACO participants, within the context of the PSO regulations, should be considered with the respective ACO and PSO staff and legal counsel to determine their best method for PSO participation.

Patient Safety is Essential to ACO Success

The ACO concept is built on an integrated set of providers who are “jointly held accountable for achieving measured quality improvements in care and reductions in spending growth for a defined population”.^{xx} Outside of a clinically integrated structure, such as an ACO, most care is delivered by sets of local physicians, hospitals and other entities that are not necessarily aligned in any way. As such, care is conducted within silos, leading to the discontinuities and fragmentation that contribute to patient safety events. While bringing providers together within an accountable care model is intended to address this fragmentation, different risks for patient safety events exist as providers grapple with new systems of care. Further, most state peer review protection acts define peer review narrowly and may not include private physician practices, or entities outside of the hospital setting.^{xxi} The patchwork of state peer review protections can be cause for concern as ACOs engage in data driven activities to support clinical integration. As physicians, hospitals, and other health care professionals and entities come together to form ACOs, PSO participation provides a protected pathway to better understanding of contributors to risk, opportunities for improvement, and reduction of patient harm across the ACO’s continuum.

Effects of a Changing Clinical Paradigm

To date, most patient safety efforts have centered on hospital metrics, while patient safety research in the primary and ambulatory care settings remain deficient.^{xxii} Yet the majority of health care visits occur in the primary or ambulatory care setting. Of those ambulatory care visits related to injury, approximately 14% were a result of the adverse effect of medical or surgical care, or medications.^{xxiii} The outpatient setting is a potentially high risk environment due to the complexity of care provided and dysfunctional interfaces between inpatient and outpatient care.^{xxiv} Contributing factors identified in an analysis of 49,345 malpractice claims suggest that seemingly trivial system problems in primary care, such as “problems with records” and “communication between providers”, can lead to poor health outcomes for patients.^{xxv} Family physicians report a spectrum of medical errors that differ from those reported in hospital-based care, with most errors arising from system issues, such as mishandling of communications and administrative functions.^{xxvi}

Medication errors are one of the most common types of medical errors across settings. Injuries related to adverse drug events (ADEs) are a significant cause of morbidity, and associated increased costs, in primary care. Of the estimated 1.5 million annual ADEs in the U.S., approximately 530,000 occur in ambulatory care among Medicare patients alone.^{xxvii} Individuals age 65 or older are estimated to have more than 175,000 emergency department visits related to ADE annually.^{xxviii} The high cost of inefficient prescribing, the disease burden associated with ADEs, and the likelihood of successful intervention, makes understanding medication errors and prescribing inefficiencies a priority.

Likewise, little is known about medical errors and near misses in home health, skilled nursing facilities and long term care. The home health care setting provides unique patient safety challenges in that homes present environmental hazards, fall risks, medication errors and exposure to infection.^{xxxix} With regards to long-term care, it is estimated that approximately 800,000 medication-related injuries occur in these facilities annually, making long-term care patients more at risk for such errors than patients in acute care hospitals.^{xxx}

Providers entering into ACO arrangements will need to shift their thinking from a single purpose to an integrated approach that considers the risk for near misses and patient safety events across the continuum of care. Likewise, evaluation of the type of errors occurring in each segment of the ACO, and the implications for contributing to patient safety events across sectors, is critical to patient safety and quality improvement activities. Efficient, cost effective care delivery requires access to patient information, decision support, and timely access to benchmarking data. The ACO serves as the information and data center for its population, using information technologies (IT) and analytical resources to achieve the level of clinical integration necessary to improve quality, reduce costs,^{xxxi} and track performance against explicit quantitative benchmarking targets. Similarly, the PSO provides data collection and analytical resources that enable participants to improve patient safety performance and reduce provider risk.

PSO Alignment with ACO Quality Targets

To qualify for shared savings or other risk-based incentive payments, ACOs must meet both the minimum savings rate requirement and the minimum

quality performance standards.^{xxxii} For ACOs participating in the Medicare Shared Savings Program, the required Quality Performance Standard contains 33 measures organized within four domains: Patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk population.^{xxxiii} All domains are weighted equally in scoring, regardless of how many measures they contain, so as not to create a preference for any one domain.^{xxxiv} Patient safety factors can significantly affect ACO success in optimizing all domain scores.

Patient/Caregiver Experience. This domain contains seven measures reflecting the standardized Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey criteria, including timeliness of access to appointments and information, communication patterns, patient education and shared decision-making.^{xxxv} Standardized CAHPS modules, considered together as one measure, will allow for better comparisons of ACOs and benchmarking over time. The access to a specialist measure is expected to promote care coordination and provides a surrogate to monitor avoidance of high risk patients and underutilization of care. Patient dissatisfaction is strongly related to increased risk of litigation and has implications for patient safety. Review of over 49,000 medical malpractice claims in primary care found that only 23% resulted from negligence^{xxxvi}. A Harvard Medical Practices study revealed that for every individual who filed a valid malpractice claim, 4 to 5 individuals filed a suit where an adverse outcome occurred in the absence of medical negligence.^{xxxvii}

The volume and complexity of off-site provider-patient communication can leave patients vulnerable to medical errors, raising concerns regarding delayed responses, compromised access, and patient

perception of declining interpersonal relationship with their health care provider.^{xxxviii} Communication failures resulting from individual, interpersonal or system factors within the health care setting are a leading cause of patient harm.^{xxxix} Patients transitioning between health care settings encounter difficulty in scheduling, lapses of information, duplicative testing, and confusion about the respective providers' responsibilities in their care.^{xi}

Delivery of health care across the continuum of an ACO adds layers of complexity, requiring communication and coordination among primary care, specialty care, acute care and other health care entities, their providers and staff, patients and families. PSO participation can provide a valuable tool for identifying areas of patient dissatisfaction with direct implications for opportunities to improve patient safety and reduce provider risk.

Care Coordination/Patient Safety. Three of the six care coordination/patient safety measures address all cause readmissions, and admissions for ambulatory sensitive conditions, specifically congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD). One metric is directly related to electronic health record (EHR) use and achieving meaningful use standards. The two remaining measures focus on direct patient safety measures: Medication reconciliation after discharge from an inpatient facility, and screening for fall risk.^{xli} The hospital-ambulatory care interface is particularly vulnerable to patient safety events, and such events may impact readmission rates. About one in five patients experience an adverse event within three weeks of discharge, most frequently related to medication errors.

In any given patient encounter information is located in multiple places, some of which are not available at the site where care is being provided. While EHRs may reduce the problem of information scatter, they can also contribute differently to data issues.^{xlii} Upon hospital discharge, almost 40 percent of patients have pending test results and no follow-up plan.^{xliii}

Medicare claims data show that almost one-fifth of Medicare beneficiaries discharged from a hospital were readmitted within 30 days at an estimated cost of \$17.4 billion, with heart failure identified as a key reason for readmissions. In more than half of the rehospitalizations, there was no evidence of a visit to a physician's office during the time between discharge and readmission.^{xliiv}

As noted earlier, fall risk and medication errors are among the top concerns in home health and long-term care facilities as well. The PSO Common Formats, report guides provided to PSOs by the Agency for Healthcare Research and Quality to facilitate standardized PSO reporting for patient safety activities, contain specific templates for fall risk and medication reconciliation.^{xliv}

Preventive Health. The eight measures in the Preventive Health domain target improvement in adherence to interventions proven to impact health outcomes, such as immunizations, preventive health screenings and lifestyle modification.^{xlvi} Patients in the U.S. receive slightly more than half (54.9 percent) of recommended preventive care services.^{xlvii} Deficits in adherence to recommended screenings and preventive health care pose significant threats to public health. Population outcome projections suggest that compliance with evidence-based guidelines, such as obtaining pneumococcal vaccines and breast and colon cancer screenings, could save 4,000 to 10,000 lives

annually.^{xlviii} Even when screening tests are completed per evidence-based guidelines, system failures can result in adverse patient outcomes. The screening process requires multiple steps from the time the order is written to test completion and incorporation of findings into the plan of care.^{xlix} With each step in the process, there is potential for a missed or delayed diagnosis that could result in patient harm.

Attention to lifestyle modifiers has the potential to influence health and decrease overall health care costs. As an example, the annual mortality burden associated with smoking in the United States is estimated to be about 480,000, with millions more living with smoking-related diseases, at an estimated cost of between \$289 billion and \$333 billion.¹ Evaluation of patient safety events, particularly those related to missed or delayed diagnoses, can provide information to lead system improvements with direct effect on preventive services metrics.

At Risk Population. The remaining twelve items listed in the At Risk Population domain focus on Diabetes, Hypertension, Ischemic Vascular Disease, Heart Failure, and Coronary Artery Disease. The Diabetes and Coronary Artery Disease scores are reported as composite, or “all or nothing” scores, meaning that if one element is missing, no credit is given. The At Risk Population metrics are composed of measures related to recommended diagnostic tests and medication regimens.^{li} A study of Medicare costs over two decades confirmed the impact of chronic conditions on Medicare spending, with heart disease ranked first in terms of attributable share. Diabetes, arthritis, hyperlipidemia, kidney disease, hypertension and mental disorders accounted for over one-third of the increase in health spending.^{lii}

Although inpatient care remains the largest spending category, the percentage of spending for physician visits related to heart disease grew by 21 percent during the study period, and spending for outpatient care of other chronic conditions increased as well.^{liii} Further, regional variations in health care spending are associated with variability in primary care provider’s discretionary decision-making. While providers in both high and low spending regions are equally likely to recommend evidence-based interventions, providers practicing in high spending regions are more likely to recommend more resource intensive interventions and screening tests of uncertain benefit.^{liv}

Failures in care coordination, communication, and standardization are linked to increased hospitalizations and readmission rates, contributing to large health care expenditures.^{lv} The overall metrics in this domain cue ACOs to the importance of utilizing evidence-based guidelines and care management to monitor and treat chronic conditions associated with costly morbidities. PSO evaluation of patient safety events can help to identify trends in system and process design impacting quality scores and cost metrics within the At Risk Population domain.

Conclusion

The hospital centric approach to patient safety has led to an unbalanced view, emphasizing only one segment of the health care continuum, while information about the bulk of the health care enterprise remains elusive. Because patient safety is directly related to quality improvement, understanding the drivers of near misses and patient safety events across all segments of the health care enterprise, from the home to provider practices through long term care, is increasingly important to

ACOs. Opportunity to share in the savings resulting from decreased expenditures provides the incentive for ACOs. The percentage of savings that an ACO can access is directly tied to performance on the established quality metrics. Initial evaluation indicates that ACOs participating in the Medicare Shared Savings Program, and the Pioneer ACOs funded by the Center for Medicare and Medicaid Innovation (CMMI) are garnering significant savings while improving the quality of health care service delivery.^{lvi} The PSO's overall objective; to improve patient safety and the quality of health care service delivery is well aligned with the ACO charge to improve health outcomes cost and quality. PSO participation by ACO providers from all segments of the clinically integrated environment, by establishing

a culture that encourages reporting or adverse events and collaboration to identify solutions, provides the opportunity to:

- Understand the types of errors that occur in different parts of the health care system;
- Identify if and how errors that occur in one segment of the clinically integrated system can affect the occurrence of errors in other parts of the system;
- Understand how activities in one segment of the clinically integrated system can serve to prevent, mitigate or exacerbate errors in other parts of the system; and
- Potentially reduce the number of errors and improve quality throughout the ACO.

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