Physician-Focused Payment Model Technical Advisory Committee

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August 19, 2026

Robert F. Kennedy Jr., Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Kennedy:

On behalf of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), we are pleased to submit PTAC's report on Targeting Improvements in Patient Safety Through Alternative Payment Models. Section 1868(c) of the Social Security Act directs PTAC to: 1) review physician-focused payment models (PFPMs) submitted to PTAC by individuals and stakeholder entities; 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (HHS); and 3) submit these comments and recommendations to the Secretary.

PTAC's June 2026 public meeting focused on targeting improvements in patient safety through Alternative Payment Models (APMs). The information that PTAC has gleaned from a review of previous PFPM proposals, other literature that addressed this important topic, as well as input received from the subject matter experts who participated in the public meeting, has informed the Committee members' comments, which are summarized in the following broad topic areas in this report:

- Current State: Challenges With the Delivery of Safe Health Care;
- Future State: Striving for Zero Preventable Harm; and
- Action: Options to Improve Patient Safety.

Key highlights include:

- The current state of patient safety in the United States is unacceptable; immediate action is needed.
    - Although isolated pockets of safety improvements have been observed in the past 20 years (e.g., for hospital-acquired infections), the current volume of medical errors, near misses, and undetected patient harm is unacceptably high.
    - Safety improvement efforts have been limited to the inpatient setting, largely ignoring errors in the ambulatory/outpatient setting. Likewise, efforts have focused on commission errors (where an incorrect action occurred), overlooking the far more common errors of omission (where a correct action was needed but not taken).
    - A culture of blame and punishment exists in the current health care system, impeding progress to improve patient safety.
    - The current strategy for addressing patient safety tends to be retroactive—identifying medical errors after they have occurred—rather than prospective—identifying areas of risk and implementing preventive system-level changes before errors occur.
- The goal for patient safety must be zero preventable harm.
    - A culture that rigorously prioritizes patient safety should be fostered throughout the health care system.
    - Patient safety should be proactive, preventive, and risk-focused, aimed at preventing medical errors before they occur (rather than monitoring for and reacting to errors after they happen).
    - Patient safety should emphasize broad system improvement rather than target isolated types of adverse events.
    - Data should be collected across a patient's care journey and from a variety of data sources—importantly, including patients themselves—to fully identify safety issues.
- The Department of Health and Human Services (HHS) through the Centers for Medicare & Medicaid Services (CMS) and other relevant organizational components should drive rapid patient safety improvement.
    - HHS should implement all possible approaches to improve patient safety, emphasizing safety in developing and implementing its performance measures (for example, developing patient-reported safety measures), data infrastructure and standardization efforts, and value-based care programs and models. CMS' Meaningful Use programs can serve as a roadmap to achieving large-scale transformation.

- CMS should consider adopting three possible approaches to promote patient safety:
    1. Incorporate a specific emphasis on patient safety in all existing APMs. All CMS programs and models should emphasize patient safety as a minimum core requirement.
    2. Offer innovation awards to stakeholders to develop and test new patient safety solutions. HHS should consider implementing a patient safety innovation awards program, similar to its 2011 Health Care Innovation awards, open to a wide range of stakeholders to propose and test innovative approaches to improve patient safety.
    3. Develop new APMs focused specifically on improving patient safety. CMS should consider new models that explicitly target patient safety, with an emphasis on real-time proactive risk assessment, system improvement, technical assistance and continuous learning, rewards for improvements, use of appropriate artificial intelligence (AI) and technology for measurement and improvement efforts, and infrastructure support.

The members of PTAC appreciate your support of our shared goal of improving the Medicare program for both beneficiaries and the physicians who care for them. PTAC members would be happy to discuss any of these observations with you. However, the Committee appreciates that there is no statutory requirement for the Secretary to respond to these comments.

Sincerely,

//Terry Mills//

Terry L. Mills Jr., MD, MMM
Co-Chair

//Soujanya Pulluru//

Soujanya R. Pulluru, MD
Co-Chair

Attachment

Physician-Focused Payment Model Technical Advisory Committee

REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

Targeting Improvements in Patient Safety Through Alternative Payment Models

August 19, 2026

About This Report

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to: 1) review physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities; 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (HHS); and 3) submit these comments and recommendations to the Secretary. PTAC reviews submitted proposals using criteria established by the Secretary in regulations at 42 CFR §414.1465.

Within this context, from time to time, it may be beneficial for PTAC to reflect on proposed PFPMs that have been submitted to the Committee to provide further advisement on pertinent issues regarding effective payment model innovation in Alternative Payment Models (APMs) and PFPMs. Given that, in the past, at least 23 of the proposals that have been submitted to PTAC address issues related to patient safety, PTAC now sees value in reviewing these elements in previously submitted proposals related to this topic, along with current information on targeting improvements in patient safety through APMs. To ensure that the Committee was fully informed, PTAC's June 2026 public meeting included a theme-based discussion on targeting improvements in patient safety through APMs.

This report summarizes PTAC's findings and comments regarding targeting improvements in patient safety through APMs. This report also includes: 1) a summary of the characteristics related to targeting improvements in patient safety through APMs from proposals that have previously been submitted to PTAC; 2) an overview of key issues relating to targeting improvements in patient safety through APMs and value-based care transformation; and 3) a list of additional resources related to this theme-based discussion that are available on the Assistant Secretary for Planning and Evaluation (ASPE) PTAC website.

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SUMMARY STATEMENT

On June 15–16, 2026, the Physician-Focused Payment Model Technical Advisory Committee's (PTAC's) public meeting focused on targeting improvements in patient safety through Alternative Payment Models (APMs). This report provides PTAC's findings and valuable information on best practices for targeting improvements in patient safety through APMs. The information that PTAC has gleaned from a review of previous physician-focused payment model (PFPM) proposals and other literature that addressed this important topic, as well as input received during the theme-based discussion, will help to inform PTAC in its review of future proposals. This material has informed the Committee's comments, which are summarized in the following broad topic areas in this report:

- Current State: Challenges With the Delivery of Safe Health Care;
- Future State: Striving for Zero Preventable Harm; and
- Action: Options to Improve Patient Safety.

Key highlights include:

- The current state of patient safety in the United States is unacceptable; immediate action is needed.
    - Although isolated pockets of safety improvements have been observed in the past 20 years (e.g., for hospital-acquired infections), the current volume of medical errors, near misses, and undetected patient harm is unacceptably high.
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    - A culture of blame and punishment exists in the current health care system, impeding progress to improve patient safety.
    - The current strategy for addressing patient safety tends to be retroactive—identifying medical errors after they have occurred—rather than prospective —identifying areas of risk and implementing preventive system-level changes before errors occur.
- The goal for patient safety must be zero preventable harm.
    - A culture that rigorously prioritizes patient safety should be fostered throughout the health care system.
    - Patient safety should be proactive, preventive, and risk-focused, aimed at preventing medical errors before they occur (rather than monitoring for and reacting to errors after they happen).

- Patient safety should emphasize broad system improvement rather than target isolated types of adverse events.
- Data should be collected across a patient's care journey and from a variety of data sources—importantly, including patients themselves—to fully identify safety issues.

- The Department of Health and Human Services (HHS) through the Centers for Medicare & Medicaid Services (CMS) and other relevant organizational components should drive rapid patient safety improvement.
  - HHS should implement all possible approaches to improve patient safety, emphasizing safety in developing and implementing its performance measures (for example, developing patient-reported safety measures), data infrastructure and standardization efforts, and value-based care programs and models. CMS' Meaningful Use programs can serve as a roadmap to achieving large-scale transformation.
  - CMS should consider adopting three possible approaches to promote patient safety:
    1. Incorporate a specific emphasis on patient safety in all existing APMs. All CMS programs and models should emphasize patient safety as a minimum core requirement.
    2. Offer innovation awards to stakeholders to develop and test new patient safety solutions. HHS should consider implementing a patient safety innovation awards program, similar to its 2011 Health Care Innovation Awards, open to a wide range of stakeholders to propose and test innovative approaches to improve patient safety.
    3. Develop new APMs focused specifically on improving patient safety. CMS should consider new models that explicitly target patient safety, with an emphasis on real-time proactive risk assessment, system improvement, technical assistance and continuous learning, rewards for improvements, use of appropriate artificial intelligence (AI) and technology for measurement and improvement efforts, and infrastructure support.

I. PTAC REVIEW OF TARGETING IMPROVEMENTS IN PATIENT SAFETY THROUGH ALTERNATIVE PAYMENT MODELS (APMs)

In developing the comments in this report, PTAC considered information from the theme-based discussion during the June 2026 public meeting, an environmental scan developed to provide information on targeting improvements in patient safety through APMs, and three responses

from external stakeholders[i] to a Request for Input (RFI) on targeting improvements in patient safety through APMs.

PTAC formed a Preliminary Comments Development Team (PCDT) for the June 2026 theme-based discussion, which was comprised of Soujanya (Chinni) Pulluru, MD (Lead); and Terry (Lee) Mills, MD, MMM (see Appendix 1 for a list of all Committee members). The PCDT reviewed the environmental scan and delivered a summary presentation to the full Committee during the theme-based discussion. The theme-based discussion featured perspectives from a diverse group of subject matter experts (SMEs) and provided an opportunity for public comments. At the end of the theme-based discussion, Committee members identified comments to be included in this report to the Secretary (RTS).[ii]

The Committee members synthesized information from PTAC proposals, the environmental scan, RFI responses, and sessions with SMEs during the June 2026 public meeting on targeting improvements in patient safety through APMs. This RTS summarizes PTAC's comments from its findings, which are organized in three topics:

- Current State: Challenges With the Delivery of Safe Health Care;
- Future State: Striving for Zero Preventable Harm; and
- Action: Options to Improve Patient Safety.

For each topic, relevant issues are highlighted. Appendix 2 includes information about proposals that were previously submitted to PTAC which addressed issues related to patient safety. Appendix 3 provides a list of additional resources related to PTAC's patient safety theme-based discussion that are available on the Assistant Secretary for Planning and Evaluation (ASPE) PTAC website. Appendix 4 includes a summary of the Committee members' comments.

II. BACKGROUND: DEFINITIONS AND CONTEXT RELATED TO TARGETING IMPROVEMENTS IN PATIENT SAFETY THROUGH APMs

Patient safety errors are a prevalent and costly challenge in the U.S. health care system. The landmark report from the Institute of Medicine (IOM), *To Err Is Human: Building a Safer Health System,* published in 1999, spearheaded the focus on patient safety and helped establish dedicated research funding to improvement efforts.[1] The report focused attention on the significant mortality (as many as 98,000 deaths annually) resulting from preventable medical errors occurring in U.S. hospitals and outlined a national agenda for prioritizing a safer health

[i] External stakeholders who submitted responses to the RFI were Rubrum Advising; William Padula, PhD and Peter Pronovist, MD, PhD; and RTI International.

[ii] Henish Bhansali, MD, FACP and Joshua Liao, MD, MSc were not in attendance at the June 15–16, 2026, public meeting.

care system. Many strategies and interventions to prevent patient safety errors have been developed and adopted since the report's publication.[2] Despite this, progress in preventing medical errors has been slow and, in some cases, has stalled.[3,4]

PTAC has developed the following working definition for patient safety:

- *Freedom from errors that could cause patient harm during the delivery of or associated with health care. Errors may be either errors of commission, in which an incorrect action was taken, or errors of omission, in which a correct action was not taken.*

Patient safety errors can be broadly classified as either errors of commission (i.e., errors that occur when an incorrect action was taken) or errors of omission (i.e., errors that occur when a correct action was not taken). Errors of commission occur when the wrong action was taken—for example, a physician ordering a medication for a patient who has a documented allergy to the medication. A large proportion of the research on patient safety has focused on errors of commission, particularly those that occur within hospital settings. However, errors of commission represent only about 4 percent of all medical errors. Errors of omission represent a far larger proportion—approximately 96 percent—of medical errors and occur across both inpatient and outpatient settings.[5] Errors of omission involve failure to take the correct action, such as failing to prescribe a medication for a patient who would likely benefit from it. Despite their prevalence, errors of omission and their consequences tend to be more difficult to identify and track compared with errors of commission, contributing to the limited amount of research on omission errors.[6]

Several categories of patient safety errors exist, and each category includes both errors of commission and errors of omission:

- Medication errors, such as administering the wrong medication or incorrect dose of medication (commission), failing to document a patient's drug allergy (omission), or failing to prescribe a needed medication (omission);
- Diagnostic, laboratory, or test errors, such as misdiagnosing a health condition (commission), delaying diagnosis of a health condition (omission), or failing to follow up regarding abnormal test results (omission);
- Surgery and procedure errors, such as wrong-site surgeries (commission), wrong-procedure surgeries (commission), or postoperative complications related to poor preparation (omission);
- Hospital-acquired infections (HAIs), such as infections acquired through improper hand hygiene (omission), catheter-associated urinary tract infections (CAUTIs; commission), or central line-associated bloodstream infections (CLABSIs; commission);
- Patient handling errors, such as falls due to inadequate monitoring (omission) or environmental hazards (e.g., wet floors; commission); and pressure injuries due to

placing the patient in an improper position (commission) or failure to reposition immobile patients (omission);

- Equipment, device, and technology errors, such as malfunctioning medical equipment (commission) or not acting on a critical test because the electronic health record (EHR) system failed to alert the clinician (omission); and
- Communication, handoff, and follow-through errors, such as taking incorrect actions due to misunderstood verbal orders (commission) or not following up with patients in need of screening tests (omission).[7,8]

Research demonstrates that patients can experience significant injury or harm resulting directly from medical procedures, treatment, or care.[9] This type of harm is called an adverse event and may be permanent or temporary, vary in degree of severity, and, in extreme cases, result in death. Some adverse events are controllable and result from medical error, meaning that the patient harm could have been prevented if appropriate medical care—following established standards and practices—had been delivered. However, in other cases, adverse events are not under the control of the health care system. Examples of non-controllable adverse events include patient biology (e.g., a patient has a previously unknown drug reaction), environmental factors (e.g., an earthquake that causes a patient to fall and be injured), or inherent risks with medical care (e.g., sudden cardiac arrest during surgery for a patient with no prior cardiac disease).

Controllable adverse events are of particular interest because they result from medical errors and could be avoided. However, near misses (also called potential adverse events or "close calls") also are important because they represent instances where patients were exposed to unsafe situations and only by chance or early detection avoided harm.[10] Near misses are indistinguishable from controllable adverse events except for the outcome.[11]

Sentinel events are adverse events that lead to severe temporary harm, permanent harm, or death. Depending on the outcome to the patient, sentinel events can include falls, wrong surgery (i.e., wrong implant, procedure, patient, or site), delay in treatment (e.g., misdiagnosis, missed diagnosis, delay in care), unintended retention of a foreign object (e.g., sponge, fragments, needle), fire/burns, or severe maternal morbidity. Although some sentinel events may be noncontrollable adverse events, they often are controllable and rooted in preventable causes.

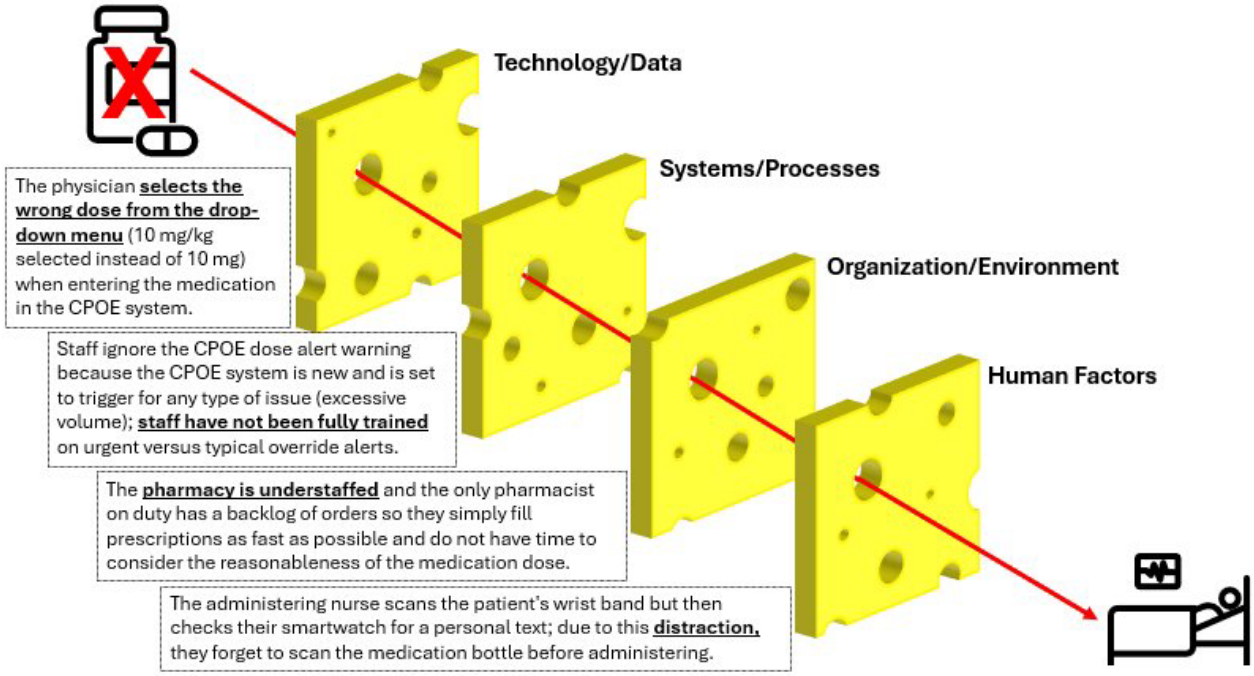
Some sentinel events are never events. Never events are very serious preventable events that should never happen in health care. The most common types of never events are performing a surgery on the wrong body part, performing the wrong surgical procedure, leaving a foreign object in a patient after surgery, and performing surgery on the wrong patient.[12] Never events are less common than other sentinel events.

Patient safety errors can occur for many reasons that fall into four general categories: system and process-related factors, human factors, organizational and environmental factors, and technology and data-related factors. System and process-related factors contribute to the

greatest number of patient safety errors.[13] However, safety errors are often the result of more than one contributory factor.[14]

The Swiss cheese model of patient harm illustrates how different types of errors can lead to patient harm. While barriers (cheese slices) prevent errors from occurring, gaps in those barriers (holes in the cheese) allow mistakes to slip through.[15,16] When a series of gaps occurs across barriers, the result is a patient safety error. Exhibit 1 provides an example of how multiple mistakes in an inpatient setting can lead to the administration of the wrong dose of medication.

Exhibit 1. Swiss Cheese Model of Patient Harm for an Inpatient Medication Error



Abbreviation: CPOE, Computerized Provider Order Entry

The main causes of patient safety errors differ by health care setting. Within hospital settings, human factors, system and process factors (e.g., communication failures), and organizational and environmental factors (e.g., equipment and supply errors, issues with management of staff, and staffing levels) are among the most frequently reported factors that contribute to patient safety errors.[17] Within primary care settings, system and process factors (e.g., communication errors) and human factors are among the most frequently reported factors that contribute to patient safety errors.[18]

Patient safety is commonly considered a component of health care quality—the degree to which health services increase the likelihood of the desired outcome—which includes six domains: Safe, Timely, Effective, Efficient, Equitable, Patient-Centered (STEEEP) care. However, safety is also fundamentally different than the broader concept of quality in that safety focuses

on preventing avoidable harm, irrespective of outcomes. While true high-quality health care cannot exist if that care is not safe, it is still important to examine patient safety independent of other components of quality. Patient safety requires understanding human factors, such as psychological safety, team training, and the design of the systems with which humans interact.

Patient safety measures include structure, process, and outcome measures. Structural measures focus on the health system or culture around patient safety and include measures such as staffing ratios, attitudes regarding patient safety, and use of technology to promote safety. Process measures focus on how care is delivered and include use of checklists and other processes. Outcome measures include occurrence of adverse events and failure to rescue, as well as never events.

Patient safety can be measured in multiple ways, such as by examining clinical information in retrospective chart review, using voluntary error reporting systems to identify errors that providers perceive as important, using surveillance monitoring to identify patients at risk for adverse events, analyzing administrative data to identify and track adverse events over time, analyzing EHR data to assess the quality of care delivered, and collecting patient-reported data, which may capture certain types of errors that are not easily collected using other strategies.[19]

III. CHARACTERISTICS OF PTAC PROPOSALS RELEVANT TO TARGETING IMPROVEMENTS IN PATIENT SAFETY THROUGH APMs

Between 2016 and 2025, PTAC received 36 proposed PFPMs submitted by stakeholders and voted on the extent to which 28 of these proposals meet the Secretary's 10 regulatory criteria, including Patient Safety.[iii] The goal of this criterion is to "aim to maintain or improve standards of patient safety." Twenty-three of the 28 proposals met the Patient Safety criterion.

The clinical focus of these 23 proposals varied. More than half (13 proposals) focused on episode-based care (e.g., oncology, chronic obstructive pulmonary disease, Crohn's disease). For the remaining 10 proposals:

- Two proposals focused on primary care;
- Two proposals addressed inpatient services in the home setting;
- Two proposals focused on serious illness and palliative care;
- Two proposals focused on emergency medicine;
- One proposal addressed coordination across primary and specialty care services; and
- One proposal focused on frequently hospitalized patients.

[iii] The remaining eight proposals were withdrawn prior to the Committee's deliberation.

Proposals also varied in their approaches to address patient safety. Several proposals included quality measures specific to patient safety. For example, common patient safety measures for these proposals were surgery complications, hospital-acquired infections, pressure ulcers, falls with injury, adverse drug events, and potentially avoidable adverse events. However, nine proposals did not mention specific patient safety measures and only referenced other quality measures, such as advance care plans, hospital admissions/readmissions, and patient experience measures. Beyond including or not including specific patient safety measures, some proposals suggested additional approaches. For example, two proposals planned to regularly review organization safety standards to ensure participant adherence. One proposal described a compliance hotline where patients could formally report safety concerns and issues.

See **Appendix 2** for additional information on the 23 proposals.

IV. COMMENTS FOR CONSIDERATION BY THE SECRETARY

Based on findings from the Committee members' analysis of PTAC proposals, information in the literature, RFI responses, and information from sessions involving SMEs during the June 2026 public meeting, this section summarizes Committee members' comments regarding targeting improvements in patient safety through APMs. Committee members' comments are organized in three topics:

- Current State: Challenges With the Delivery of Safe Health Care;
- Future State: Striving for Zero Preventable Harm; and
- Action: Options to Improve Patient Safety.

For each topic, relevant issues are highlighted. **Appendix 4** includes a summary of the Committee's comments.

The Committee notes that the strong consensus of the SMEs as well as the public responders to the RFI was that the current status quo is unacceptable and that strong and immediate action is needed. Maintaining the current status quo of patient safety will put patients, and their trust in the health care system, at unnecessary risk of significant harm. Current APMs, other payment policies, and quality measurement activities do not place enough emphasis on patient safety. As a result, many presenters stated that these policies do not create a sufficient business case for substantial change at the provider level. Significant and immediate policy change and courage is required to alter the trajectory of patient safety.

IV.A. Current State: Challenges With the Delivery of Safe Health Care

Following the publication of the 1999 *To Err is Human* report, a considerable amount of policy and measurement attention was placed on patient safety, particularly in the hospital setting. Over time, there were quantifiable improvements in select measures of patient safety such as

hospital-acquired conditions (HACs), better infection control practices, stronger reporting systems, safer surgical protocols, and improved awareness of health care harms. In recent years, however, progress seems to have stalled, and many of the poorest performing hospitals have not improved over time (e.g., 44 percent of hospitals in the bottom decile on the PSI 90 patient safety and adverse events composite measure in 2014–2017 remained in the bottom three deciles in 2021–2024).[20]

Perhaps more importantly, what has been measured is considered to be the "tip of the iceberg." That is, unreported errors such as diagnostic and communication errors, as well as near misses, represent a much greater patient safety problem. Moreover, current measures focus on inpatient care while many procedures are now provided in ambulatory settings.

Currently, safety-related operations are geared to either making retrospective quick fixes or hiding errors when they occur. Providers lack the data and IT infrastructure to prospectively identify potential errors. In addition, current culture does not support a learning system in which identifying potential errors and implementing system fixes to address them are valued. Indeed, it appears that current policy does not foster an adequate business case for providers to address these challenges, as opposed to less substantially dealing with errors when they occur.

Issues associated with the current state of patient safety— focused on what is wrong with the current system and what has been learned over the past 25 years—are discussed in more detail in this section:

- Safety improvement efforts have been too narrowly focused on hospitals;
- Many medical errors and near misses are going undetected; and
- The current health system infrastructure and operations do not optimally support patient safety.

PTAC's specific comments on the current state of patient safety are listed in **Appendix 4**.

Preventable harm remains persistent in the U.S. health care system and is estimated to cost over $600 billion annually across Organisation for Economic Co-operation and Development (OECD) countries.[21] In the United States, direct medical costs exceed billions of dollars each year.[22] Indirect and societal costs of patient harm affect productivity, family stability, caregiver burden, workforce participation, disability, and overall quality of life. Moreover, the societal costs of patient harm often exceed the direct medical costs.[23] Globally, more than one in 10 patients experience medical harm, half of which may be preventable.[24] Approximately one in four hospitalized Medicare beneficiaries experience a harm event.[25]

CMS has attempted to promote improvements in patient safety through its programs and Innovation Center models, although no value-based care models have been implemented to

date that focus specifically on patient safety. Rather, patient safety has been subsumed among other quality measures in these models. While some CMS programs and models have shown select improvements, most initiatives have demonstrated limited or no improvements in patient safety.

One program that has shown measurable improvement is the Hospital Readmissions Reduction Program (HRRP) (2012–present) in which CMS applies a payment reduction for hospitals with excess readmissions for select conditions (acute myocardial infarction [AMI], coronary artery bypass graft [CABG] surgery, chronic obstructive pulmonary disease [COPD], heart failure, pneumonia, and hip/knee surgery). The program has shown decreases in readmission rates, especially for AMI, heart failure, and pneumonia.[26]

The CMS Innovation Center model, Transforming Episode Accountability Model (TEAM), launched at the beginning of 2026, shows promise to improve patient safety; however, it is too early to measure results. Under TEAM, acute care hospitals will coordinate care for certain surgical procedures, and participants will report on select patient safety measures.

Many CMS programs that directly focus on patient safety have introduced complex measure sets and substantial penalties but have not shown improvements in safety. The HAC Reduction Program (2014–present), where CMS reduces payments to hospitals in the worst-performing quartile on HAC measures, has not improved patient outcomes.[27] Furthermore, results revealed that hospitals that had more complex patient case mixes, were safety-net hospitals, and/or were accredited by the Joint Commission were more likely to receive reduced payments (i.e., be penalized) compared with hospitals that did not possess these three characteristics.[28] The Surgical Care Improvement Program (SCIP) (2005–2015), where CMS and the Centers for Disease Control and Prevention (CDC) partnered to improve surgical infection complication rates, also did not show improved clinical outcomes.

Other CMS programs that have included patient safety as part of broader quality measures also have not demonstrated improvements in patient safety. The Hospital Value-Based Purchasing (VBP) Program (2012–present), where CMS redistributes 2 percent Medicare payment withholds as value-based incentives to hospitals based on performance (including specific patient safety measures) and includes incentives for reducing adverse events and adopting evidence-based care standards and protocols, has shown no impact on safety-related outcomes.[29] The Merit-based Incentive Payment System (MIPS) Program (2017–present) has a complex and burdensome measure system in place and has produced limited evidence of improved safety-related outcomes.[30] In general, these programs and models have historically focused more on measuring individual components of safety rather than on the whole system change that is needed to prevent harm. Additionally, these programs have revealed challenges associated with the burden that penalties and complex measure sets have on safety-net providers and hospitals treating disadvantaged patients.

To date, the CMS Innovation Center has not implemented any value-based care models that specifically target improving patient safety. One CMS model—the Bundled Payments for Care Improvement Advanced (BPCI-A) Model (2018–2025), which focused on coordinating care across all providers—included select patient safety measures, but the model was not primarily focused on patient safety. BPCI-A did not show improvements in safety-related outcomes.

Safety improvement efforts have been too narrowly focused on hospitals. Patient safety efforts have historically focused on inpatient care; however, much of the health care that was previously delivered only in hospitals, such as surgeries, has shifted in the last 10 to 15 years to ambulatory (outpatient) settings. Medical errors are common in the outpatient environment. In one study of Massachusetts outpatient sites, 7 percent of patients experienced at least one adverse event and, of these events, one-quarter were preventable and over 17 percent were considered serious events.[31] The focus on inpatient safety may stem in part from the health care system traditionally being hospital-centric. Moreover, patient safety errors may be more readily visible in hospitals compared with ambulatory settings, which do not directly care for or monitor patients for an extended period of time, or home settings where providers are not present to observe patient outcomes.

Common patient safety errors in the ambulatory setting include medication errors, diagnostic and laboratory errors, and communication errors.[32] Diagnostic safety errors—incorrect, delayed, or missed diagnoses—are a significant threat to safety and the most common type of error involved in malpractice suits.[33,34] Some efforts in recent years have been made to promote diagnostic excellence, which emphasizes ensuring accurate and timely diagnoses. For example, CDC released the *Core Elements of Hospital Diagnostic Excellence* in 2024, but notably the focus of this report was on the inpatient setting. Relatively little progress has been made to improve diagnostic safety in ambulatory settings.

Many medical errors and near misses are going undetected. A 2025 report from the HHS Office of Inspector General (OIG) estimated that half of harm events that occur among hospitalized Medicare patients are not captured.[35] The amount of patient harm not captured in ambulatory settings may be even higher given the more limited focus on measurement and reporting in this setting. Safety has historically been defined by what is easily observable. Errors of commission—errors that occur when an incorrect action was taken—are more easily identifiable and, therefore, have received more attention than errors of omission—errors that occur when a correct action was not taken. However, errors of omission may happen more frequently, may be more harmful compared with errors of commission, and are going undetected. Any gap in care could be viewed as a potential error of omission.

Many patient safety errors are not detected by existing performance or quality measures. As succinctly stated by one of PTAC's public meeting experts, "The absence of measurable harm is not necessarily the presence of safety." The feasibility and reliability of current patient safety measures may be limited because these measures often rely on data in unstructured fields or

external systems beyond clinical information reported in the EHR (e.g., laboratory, pathology, radiology), and some errors may be too rare at the organization level to support consistent performance measurement. Additionally, measurement strategies may be misaligned in scope, scale, and timing to produce meaningful results. There also are attribution challenges to measuring patient safety, such as care being delivered by multiple providers and outcomes potentially occurring outside the measured episode, which can complicate attributing outcomes and assigning accountability to providers.

One of the most common hospital patient safety measure sets is the Agency for Healthcare Research and Quality's (AHRQ's) Patient Safety Indicators (PSIs) which focus on identifying potentially preventable adverse events, such as hospital complications following surgeries. The PSIs have some gaps, which AHRQ is working to address, by not measuring some of the most common types of patient safety errors. In particular, the PSIs do not include diagnostic safety errors, such as missed laboratory tests, imaging results, and follow-up care, or adverse drug events, largely due to the lack of clinical detail in claims data needed to capture medication reconciliation errors and/or adverse reactions.

Some efforts have been made to improve detection of patient safety errors. The Institute for Healthcare Improvement (IHI) Global Trigger Tool measures all-cause harm and may capture about 10 times more safety events than traditional reporting systems.[36] In one sample, over 350 adverse events were identified through the Global Trigger Tool, compared with 35 adverse events identified through the AHRQ PSIs, and only four adverse events identified through hospital reporting systems. This finding illustrates how traditional patient safety measurement approaches are capturing only a small fraction of patient harm and emphasizes the need to improve patient safety detection methods.[37]

The current health system infrastructure and operations do not optimally support patient safety. Three health system organizational factors impede improvements in patient safety: the current patient safety infrastructure, safety culture, and financial motivations.

- *Health systems have a current infrastructure around safety measurement that does not optimally detect harm events.* Current measurement systems are largely retrospective, designed to identify harm after it occurs, and do not account for near misses. To date, measurement has focused on what can be counted or captured in claims data, rather than what will lead to improved patient safety outcomes. For example, care coordination and transitions of care are not typically measured because they are not easily captured in claims data.
- *Organizations perpetuate a culture of blame and punishment for reporting adverse events.* Assigning blame and punishing providers or hospitals for reporting adverse events manifests a "deny and defend" culture that discourages reporting and encourages hiding errors. Some organizations also have shown a reluctance to adopt

new methods of detecting patient safety errors, in part because they may not have the infrastructure in place to address those errors.

- *Health system business and financial considerations may favor taking penalties for patient safety errors rather than investing in the systems to address and prevent those errors.* Incentives provided in many APMs are not large enough for some organizations to justify investing in the technological, systemic, and personnel changes that may be needed to improve patient safety. Financial performance can take priority over the delivery of high-quality and safe health care.

IV.B. Future State: Striving for Zero Preventable Harm

The future state of patient safety should be one in which the health delivery culture values the identification of potential safety errors and modifies operations as needed to prevent those errors. Data and information technology should be readily available to support that culture through timely and actionable information. As part of reporting and developing appropriate patient safety performance measures, patients and families should have a voice. Indeed, developing a set of patient-reported experience and outcome measures may be an effective way of identifying errors and system problems that might otherwise not be visible.

Issues associated with the future state of patient safety—focused on striving for zero preventable harm—are discussed in more detail in this section:

- Ensure that there is a culture of patient safety throughout the health care system;
- Patient safety should be proactive and preventive rather than retrospective and reactive;
- Collect patient safety information directly from patients;
- Adopt a comprehensive, longitudinal approach to measuring patient safety; and
- Patient safety improvement should focus on building systems that promote patient safety.

PTAC's specific comments on the future state of patient safety are listed in **Appendix 4**.

Ensure that there is a culture of patient safety throughout the health care system. PTAC believes that, with the right health care structure and systems, achieving zero patient harm is possible. Indeed, CMS' 2024 National Quality Strategy included a patient safety goal to achieve zero preventable harm.[38] Underlying this vision is the need for a pervasive culture of patient safety. The preconditions for patient safety—such as technology and policy tools—already exist. However, not all health care organizations are utilizing them. Ultimately, improving patient safety will require providers, provider organizations, health IT vendors, payers, and other health care entities to have the will to rigorously prioritize patient safety.

One expert shared that their integrated health system is committed to principles of a high reliability organization (HRO)—an organization that operates in a high-risk and complex environment for an extended period without serious failures.[39] HROs have a culture that prioritizes safety above other concerns (such as revenue). Staff have the authority to make real-time decisions to ensure that safety is the dominant focus in the moment. HROs are common in commercial aviation, nuclear power, and aerospace, among other industries. Health care organizations that subscribe to HRO principles have a preoccupation with patient safety and operate with a failure mindset. The organization emphasizes anticipating safety threats; individuals are encouraged to report safety issues in a safe, no-blame environment; and safety investigations focus on a root-cause analysis.

The culture of patient safety needs to shift from outcomes-focused—responding to errors after they have occurred by seeking out, blaming, and punishing an individual—to systems-focused—organizations and individuals sharing accountability to develop systems that keep patients safe, transparently reporting errors and systems issues, and focusing on system improvement and staff learning and training. This type of "just culture" promotes transparency in the reporting of errors and near misses without fear of blame for honest human errors. Focus is on how systems and processes can be improved to prevent errors, with a learning orientation around continuous improvement.

A patient safety culture requires participation and accountability at all levels of the organization, both top down and bottom up. An active leadership with a fundamental commitment to patient safety—ensuring that safety receives the attention and resources needed—is essential. Safety concerns in health care organizations should not be relegated to risk management groups but should be the focus of an organization's Chief Executive Officer (CEO), Chief Financial Officer (CFO), and Chief Counsel, among other C-Suite executives. A patient safety culture also must be driven by the staff who directly deliver health care services, such as the providers who interact with and deliver medical care to patients. Both accountability and actionability are critical, ensuring that staff feel not only accountable for patient safety but also empowered to take action to ensure it.

Patient safety should be proactive and preventive rather than retrospective and reactive. Patient safety improvement efforts must shift away from a focus on retrospective compliance—monitoring for errors after they have occurred and reacting to them—to proactive risk surveillance—identifying risk areas that could lead to safety errors and preventing them. Reliance on months-old administrative claims data and voluntary error reporting systems promotes reaction after an error occurs. Although there is still value in retrospective error identification to help inform areas for safety improvement, there is a critical need to focus on preventing patient harm from occurring in the first place. Success in moving to zero preventable harm will depend on risk assessment upstream rather than error measurement downstream.

Significant advances in technology and AI mean that risk detection and error prevention are achievable health care objectives. Technological advancement enables detection of risks that previously were difficult to identify, such as diagnostic delays and communication failures. Electronically captured data, such as through an EHR, enable near real-time surveillance that can be used to identify risk areas and prevent potential errors. Automated safety monitoring through electronic clinical quality measures (eCQMs) can increase error detection by 20 to 25 times, increase the timeliness with which errors are detected, enable continuous risk monitoring, and reduce provider reporting burden. Recent advancements with digital quality measures and the use of large language models offer significant opportunity to facilitate patient safety measurement.

Risk detection also can focus on identifying safety signals that prompt intervention before an error occurs. Rules engines can apply clinical logic to EHR data to detect potential risks, such as medication interaction alerts, infection precursors, or fall risk indicators. Clinical decision-support—evidence-based medical information aligned with patient-specific data—can enhance a provider's ability to prevent medical errors, such as by setting reminders for recommended screenings or highlighting abnormal lab values that require follow-up. AI also can be used to develop predictive risk models that use patient medical histories, symptoms, lab results, and other data to predict risk (e.g., risk of sepsis, surgical complications, hospital readmission).

Technology also can be useful to support improvements in retrospective error detection, such as through natural language processing (NLP) applied to provider notes and documentation to identify safety signals, or batch analysis of integrated claims, clinical, pharmacy, and other data to identify patterns across patients and providers that may indicate patient safety issues. Trigger tools, such as the IHI Global Trigger Tool, involve automated screens of medical records for cases of possible patient safety errors, such as medication issues and surgical complications.

One challenge that arises with the use of technology and AI to improve error detection is that these methods can dramatically increase the volume of information produced. Some organizations that have initially implemented these systems have then abandoned them due to the large volume of safety errors generated due to the organization's inability to manage the information. AI can be valuable to help decipher, synthesize, and prioritize the vast volume of information generated.

The use of technology, such as predictive risk models or provider performance dashboards, should be embedded in provider workflows. The information produced should be understandable, timely, and actionable. Training should be provided so providers know how to use the technology, interpret the information, and understand the limitations and safeguards of the technology (e.g., what data were used to train a predictive model). Moreover, technical assistance and resources should be available, particularly for small and rural practices, to facilitate adoption of safety-enhancing technologies.

Although the technology exists to support proactive error prevention, optimizing its use to promote patient safety would be facilitated by two factors: a common data infrastructure and inclusion of all care settings. First, despite near universal adoption of EHRs, data infrastructure remains fragmented and siloed, impeding the use of technology. A national data infrastructure is needed, including Fast Healthcare Interoperability Resources (FHIR) standards (how data is structured) and FHIR Application Programming Interface (API) standards (how those data are exchanged electronically), to promote seamless integration and exchange of data. Second, use of safety-enhancing technologies must extend beyond the inpatient and outpatient settings to other care settings such as behavioral health and long-term care facilities. This would enable a truly longitudinal view of patient care that would best enable early risk detection and error prevention.

Collect patient safety information directly from patients. Patients and their families/caregivers can detect and report harm, and they are a crucial but underutilized source of patient safety information. U.S. results from the 2023 Patient-Reported Indicators Survey (PaRIS) and Medicare Current Beneficiary Survey (MCBS) revealed that 13 percent of primary care patients reported that something went wrong with their medical care within the past 12 months. Securing patient safety information directly from patients also is an important step in the journey to empower patients and ensure that patient voices are prominent in the health care system.

Patients are in a unique position to report patient safety events and near misses in real time. Patients inherently know when something is wrong with them or that their concerns have not been adequately addressed. Patients also can report on safety concerns such as diagnostic delays, care coordination issues, communication failures, and at-home recovery issues that are not readily detectible through other data collection mechanisms such as chart review or claims data. Patient-reported information can help fill a gap to provide a more longitudinal view of the patient's care journey and where safety issues occur.

A standard mechanism is needed to systematically collect and respond to patient-reported safety information. Patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs) can be used to capture safety data directly from patients. These measures should be aligned with AHRQ Common Formats—standard definitions and formats for collecting patient safety information, including incidents, near misses, and unsafe conditions—so patient-reported measures and data can be integrated and compared with other sources of patient safety information (e.g., clinical data, provider reports). Patient-reported data collection should encompass multiple modalities (e.g., digital, paper, phone, in-person), as needed, to ensure that information is obtained from a full spectrum of patients (e.g., patients residing in rural areas who may have limited digital connectivity). There also is an opportunity to use AI to support patient-reported data collection, including to survey patients about safety, provide automated safety-related alerts and messages to patients (e.g., upon hospital discharge), and extract safety themes from patients' comments. One Committee member reported their experience with an organization that collected patient safety data via

phone and patient surveys. Information regarding near misses, for example, was investigated, led to safety improvements, and helped promote a safety culture at the organization.

Acknowledging and responding to patient-reported events are critical. Patients must have the assurance not only that their concerns will be heard but also that they will be followed up and addressed. Patients also need to know that they will not be negatively labeled or that they will not be dropped as a patient for reporting a patient safety concern. Additionally, there must be clear data use agreements in place to assure patients that their self-reported data are private and secure.

Patients should also be included as part of patient safety improvement efforts beyond simply reporting their safety-related concerns. For true transparency, safety reports across sources and investigative findings should be shared with patients. Patients should be integrated directly as part of safety improvement efforts, including being part of organizational safety committees, being involved in development of patient safety measures, and being included in the design of new safety initiatives and payment models.

Adopt a comprehensive, longitudinal approach to measuring patient safety. Fully capturing patient safety information requires a patient-centered, longitudinal approach with a comprehensive, parsimonious, and balanced set of measures. Measurement should focus on driving system-level change that will meaningfully improve patient outcomes and minimize data collection and reporting burden.

Patient safety measures should capture the full range of adverse events and near misses, including high-severity incidents such as never events, high-frequency events such as medication administration errors, and temporary harm events such as minor falls. It is critical that patient safety measurement move beyond errors of commission to include omission errors, such as delayed and missed diagnoses, and delayed or poorly communicated diagnoses and abnormal test results.

Safety measurement also must move beyond the hospital setting to capture information across the patient's full care trajectory, including ambulatory, post-acute, and long-term care, and community-based settings. Patient errors may manifest in one setting (e.g., a hospital) but have originated in another setting (e.g., a missed diagnosis in a physician's office weeks before the hospital admission) and should be captured at the point of origin. Moreover, risk may be highest in the transition and hand-off between settings and must be part of safety measurement.

To ensure a balanced measure set, patient safety measures should encompass structural, process, and outcome measures. Measures must include access to care and timeliness to capture the full range of the patient safety experience. Measures should rely on a variety of data sources, including claims, electronic, patient-reported, and surveillance data, and cross-validation or triangulation across data types should be built into the analysis and interpretation

of patient safety information. However, duplicative and burdensome measures should be eliminated.

Finally, patient safety measurement must be done across a broad population to ensure that information from different types of patients is obtained and potential safety differences among them can be addressed.

Patient safety improvement should focus on building systems that promote safety. Achieving the goal of zero preventable harm will require a shift away from individual harm events and toward health care systems. Patient safety improvement must focus on building the infrastructure and systems that support safe care. That is, there must be movement away from compliance-based activities and toward systems redesign.

Patient safety measurement must move beyond simply counting and targeting improvements of isolated adverse events such as falls, infections, and medication errors. This approach fragments harm prevention efforts and dilutes resources. Instead, emphasis needs to be placed on measuring the underlying health care systems and developing integrated prevention strategies that address shared risk factors across multiple forms of harm. CMS' Patient Safety Structural Measure (PSSM)—a self-attestation measure that assesses a hospital's leadership, culture, and policies around patient safety—is an important move in the direction of measuring whether an organization possesses the capabilities to prevent patient safety errors. Improving patient safety will require meaningful investment in health care infrastructure and systems.

The health care environment and tools must be designed in a way that mitigates risks. Applying principles of human factors engineering—optimizing the design of systems and products based on how humans interact with them—can produce safer systems. Advances in aviation safety are attributed not to direct reductions in human errors but rather to understanding where and how human errors occur and designing systems that mitigate those errors. Attention is needed to implement systems and processes in areas where risk is found, such as diagnosis and care transitions. The types of providers who will be using the systems should be engaged to ensure user-centered system design. The systems and culture of an organization must promote comfort in talking about risks and near misses in health care—where there is psychological safety for people to report near misses or safety errors without fear of repercussions. Only then can proper systems be designed to mitigate these risks. Finally, continuous improvement and learning systems should be part of safer system design.

IV.C. Action: Options to Improve Patient Safety

The statutory responsibility of PTAC is to make recommendations to the Secretary concerning PFPMs. Through expert presentations and public comments at its public meetings, as well as responses to its public RFI, PTAC also is informed about a variety of other potential policy

alternatives to address a given issue. In this report, the Committee members inform the Secretary of these policy alternatives and then provide recommendations on APM policies.

Issues associated with action—focused on options to improve patient safety—are discussed in more detail in this section:

- HHS should use all available levers to improve patient safety; and
- Three possible approaches should be considered to promote patient safety through APMs.
    1. Incorporate a direct focus on patient safety in existing APMs.
    2. Offer innovation awards to develop patient safety solutions.
    3. Develop new APMs focused specifically on improving patient safety.

PTAC's specific comments on actions needed to improve patient safety are listed in **Appendix 4**.

HHS should use all available levers to improve patient safety. As the largest health care payer in the United States, CMS has tremendous opportunity to drive changes in patient safety across the health care system. PTAC believes that CMS should use all of its available policy levers to ensure that patient safety is prioritized.

First, CMS should continue to leverage its existing regulatory interventions to prioritize patient safety. CMS can use its conditions of participation (CoPs), coverage and payment determinations, and auditing and compliance assessments to update minimal acceptable safety standards and push for continued patient safety improvements. CMS could also explore how to optimally utilize its Quality Improvement Organizations (QIOs) to promote patient safety, such as partnering with the lowest performing providers to address patient safety.

Second, CMS should expand its safety measures and tools to further promote patient safety. Currently 122 of CMS' 400 existing quality measures focus on patient safety. However, the measures focus extensively on isolated adverse events (e.g., medication safety, complications, and HAIs). CMS has developed a new PSSM to assess hospitals' structure, processes, and culture for prioritizing patient safety. CMS is also introducing two diagnostic measures focused on the timeliness of mammograms and colonoscopies. Additionally, CMS is transitioning to digital measures (eCQMs) to promote real-time measurement for continuous improvement. PTAC encourages CMS to broaden its measure portfolio to focus on measures of patient safety systems, omission errors (e.g., diagnostic safety), and error prevention. Most importantly, patient-reported safety measures should be developed, tested and implemented for reporting and as a key component of value-based payment.

CMS can also further promote patient safety through measurement-related tools such as Care Compare and Star. Publishing patient safety data is important to promote transparency and

empower patients. CMS is updating its approach for assigning its 5-star hospital quality ratings: hospitals in the lowest quartile of the Safety-of-Care measure group will be capped at a 4-star maximum (starting in 2026) and will receive a blanket 1-star reduction (starting in 2027).

Third, CMS should continue to drive efforts for data infrastructure and standardization, which are needed to support patient safety improvements efforts. Longitudinal patient data across care settings must be more accessible. CMS has been helping to promote standardization through its shift to digital quality measures. CMS also has been assessing whether AI—specifically, large language models—can assist with extracting information from text-based documents such as clinical notes and laboratory reports. Ultimately, to enable rapid transformation nationwide, CMS should lead efforts to promote standardized health data, infrastructure, and interoperability to support patient safety.

CMS' Meaningful Use programs provide a roadmap for CMS to drive large-scale changes in health care. Signed into law in 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act was designed to support adoption of EHRs. CMS conducted Medicare and Medicaid EHR Incentive Programs (commonly referred to as "Meaningful Use"), established as part of the HITECH Act, for providers to adopt and meaningfully use certified EHR technology (CEHRT).[40] The percentage of physicians and hospitals adopting CEHRT increased dramatically between 2008 and 2024, from 17 percent to 91 percent for physicians and from 9 percent to 99 percent for hospitals.[41] CMS adopted a staged approach to promoting Meaningful Use, moving from initial data capture and sharing to improved outcomes.[42] CMS offered significant financial incentives for the adoption and use of CEHRT, ranging from tens of thousands of dollars for individual Medicare providers to millions of dollars for hospitals.[43] In later years, CMS reduced Medicare reimbursements for providers who failed to meet certain CEHRT benchmarks.[44] Through the Office of the National Coordinator for Health IT (ONC), HHS also promoted a national health IT infrastructure by providing funding for Regional Extension Centers (RECs) to offer technical assistance to CEHRT implementation for small providers, and for states to establish Health Information Exchanges (HIEs).[45] CMS and HHS could draw upon these same strategies—coordinated efforts among Medicare and Medicaid, significant financial incentives, and a national support infrastructure—to drive patient safety improvements.

As CMS continues and extends its policy levers to promote patient safety, several significant concerns require attention. These efforts should not increase the administrative burden that providers already face in their safety compliance efforts. Special consideration is needed for how to finance and implement patient safety improvements among under-resourced small and rural practices, as well as those treating highly complex patients. Finally, patient safety improvement efforts must be implemented in a way to ensure that providers do not simply drop out of Medicare, particularly in locations where patients do not have alternative providers available. While the physician opt-out rate for Medicare overall currently is low (1.2 percent), the rate is higher for certain specialties (e.g., 8.1 percent of psychiatrists).[46]

Three approaches should be considered to promote patient safety through APMs. To rapidly address the existing problem of unacceptably high levels of patient safety errors, PTAC recommends that CMS consider adopting three approaches to promote patient safety: 1) incorporate a direct focus on patient safety in all existing APMs; 2) offer innovation awards to stakeholders to develop and test patient safety solutions; and 3) develop new APMs focused specifically on improving patient safety.

Because patient safety improvement is largely about culture change, a multi-year, sustained, and incremental process is needed. CMS can quickly take advantage of opportunities to incorporate a more direct focus on patient safety in existing models. Concurrently, CMS can solicit applications from stakeholders to propose and test innovative approaches to improving patient safety. The experience and evidence from these innovative approaches can then be used to fully develop and test a patient safety-specific APM. Alternatively, CMS can consider developing a stand-alone patient safety model simultaneous with updating existing models and offering innovation awards.

Incorporate a direct focus on patient safety in existing APMs. To date, most CMS programs and models have had limited emphasis on patient safety, and those that have included patient safety have demonstrated either limited or no safety improvements. CMS instead has focused on driving care coordination and communication, which are a fundamental part of patient safety. Where safety has been incorporated, CMS has seen some evidence of improvement; however, more work needs to be done.

Patient safety should be required, expected, and integral to every CMS initiative. CMS should ensure that patient safety is prominent and fundamental in all of its value-based care programs and APMs. CMS can draw clear attention to patient safety by making safety risks and errors more visible consistently across its programs, as part of the drive to culture change.

A core set of high-impact safety measures should be included in all models. Measures should be broadened beyond standard measures of commission that focus on isolated adverse events; measures of omission, such as missed or delayed diagnoses, or timely follow-up on imaging or lab results, are essential to include. Patient-reported measures and AI-enabled tools to identify safety issues also should be incorporated wherever feasible into existing models. CMS has committed to incorporating patient safety measures in all 27 of its current value-based care programs and models, extending into all types of care facilities.

Patient safety should be raised to the forefront by expecting that all model participants meet minimum safety standards as a core, foundational requirement. Meeting safety standards should be a minimum condition to receive incentive payments. Transparency should also be incorporated; transparency of safety results, at least in the short term, may be more motivating for patient safety improvements than financial incentives. Being transparent about patient safety helps build patient trust, appeals to providers' intrinsic motivation and professionalism

to provide the best possible care, and promotes the shift to a just culture. Separate funding dedicated specifically to safety infrastructure also could promote patient safety improvements within existing models.

Offer innovation awards to develop patient safety solutions. Similar to the design-and-test approach of APMs, health care innovation awards from HHS offer another method to improve the current patient safety environment. Through these awards, stakeholder entities would be awarded upfront funds to build and test innovative solutions to improve patient safety. Innovative awards could help promote an environment that is both evidence-based and collaborative to develop innovative solutions to improve patient safety.

HHS used this approach in 2011 through its Health Care Innovation Awards, which awarded three-year grants ranging from $1 million to $30 million to entities to develop and test new payment and service delivery models.[47] For example, one awardee collaborated with three other hospital systems and organizations to pool their EHR data, along with CMS, which contributed longitudinal claims history to the pooled data. The combined data allowed for better clinical protocols to be established. Similar to the Health Care Innovation Awards, HHS could fund patient safety innovation awards, which could provide grants to applicants to improve patient safety through innovative and collaborative approaches. Any cost savings that awardees achieve by implementing patient safety system improvements could be invested or used to generate additional patient safety improvements. Moreover, the results of these innovative projects could yield patient safety improvement ideas that warrant widespread promotion and adoption.

Develop new APMs focused specifically on improving patient safety. To prioritize, drive, and test generalizable approaches to significant patient safety improvements, CMS should develop new models that specifically target patient safety. These models should focus on measuring and improving patient safety systems and patient safety culture rather than isolated adverse events. While improvements in patient safety outcomes are clearly the end goal, true safety improvements will happen through process and system change. Rewarding improvements in reported performance on select adverse event measures does not equate with true improvements in the delivery of safer care. A patient safety model should focus on supporting and promoting building and implementation of robust safety systems. Linking of processes to outcomes can be assessed through assurance cases that evaluate the safety logic in the system with supporting evidence that the system yields safe outcomes.

In addition to safety system and culture measures, such as CMS' PSSM, emphasis should be placed on real-time, proactive risk assessment, including patient-reported measures. New technologies and AI should be used wherever possible to facilitate participation and reduce administrative burden. Program emphasis should be on learning and continuous improvement, not fear that could induce hiding harm. Consistent with this, transparency in safety should be

encouraged, and emphasis should be on rewarding improvement rather than penalizing failure to perform.

In embarking on designing a patient safety model, CMS should consider and collaborate with other organizations that are promoting patient safety. For example, Patients for Patient Safety US (PFPS US), as part of its Project PIVOT (Patients Involved in deVeloping Outcomes Together), has proposed an earn-back model whereby payment is withheld for failure to meet benchmarks but can then be earned back by demonstrating improvement. The PIVOT Model emphasizes patient-reported measures. CMS also could collaborate with medical societies that actively develop standards, measures, and certification programs focused on patient safety for their members. Drawing upon work done with such certification programs, for example, could facilitate adoption of patient safety practices through strategic coordination with existing programs and workflows, reduced administrative burden, and increased multi-payer alignment.

Goals/strategies. A patient-safety-focused APM should be designed with the goal of proactive, upstream harm prevention rather than downstream identification of complications and errors after they have occurred. Patient safety improvement efforts should start with the most significant harm areas (e.g., those with the highest harm rates, largest number of impacted patients, greatest morbidity/mortality, highest cost). Safety improvement must extend beyond the inpatient environment to ambulatory care.

A primary consideration in model design should involve addressing infrastructure and helping practices overcome barriers to changing their infrastructure to improve patient safety. In addition to data and data sharing capabilities (discussed below), technology and AI should also be part of providers' infrastructure. APMs should support use of appropriate technology to advance patient safety, such as testing how best to integrate AI tools in patient safety system development. Cooperative federal grant programs, such as with ONC, may be a useful avenue to help fund the infrastructure to support technology adoption. Demonstrating the financial return on technology investment can also encourage providers to develop the necessary infrastructure to support patient safety.

A core strategy when developing a patient safety APM should focus on building a robust technical assistance program that will assist providers with the design of the systems and processes needed to promote patient safety. This may include providing training, access to resources, and learning support collaboratives. Building the concept of learning as a core component of the model is also important to convey that patient safety improvement should be grounded in continuous learning and not shrouded in fear of punishment. Additionally, careful consideration of the special needs of small practices and hospitals, as well as providers with highly complex patients, should be part of the development of a technical assistance plan for a patient safety APM.

One substantive goal of a patient safety APM should be decreasing the variability in safety performance between the top performing providers and the bottom performing providers. Different approaches may be needed to ensure that high performers remain high, while still bringing about further incremental improvements, versus addressing issues with low performers to quickly bring them up to minimum standards and implement a path of significant and accelerated improvement.

Design of a patient safety model must be done with special attention to avoid unintended consequences, such as selection bias (e.g., cherry-picking) or premature hospital discharge. For example, the model could be designed to include a broad population (e.g., all of a practice's patients) to prevent selection bias. CMS can build in routine monitoring of a practice's case mix to ensure that providers are not systematically avoiding highly complex patients. Safety measurement should focus on the patient longitudinally (e.g., episodes of care) to capture issues that could result from premature discharge. Finally, model design should be sensitive to factors likely to impede practices, including administrative burden and cognitive overload.

Care delivery. Patient safety models should focus on the design and testing of systems that promote the safe delivery of health care, shifting the focus from reactive to proactive health care. Safer systems will prevent the occurrence of medical errors.

Care coordination and care transitions are two critical areas that should be examined for safe systems design. Poor communication is a significant contributor to patient safety errors, and approximately 60 percent of medication errors happen during care transitions.[48] Behavioral health should also be studied, as patients with behavioral health conditions are at greater risk of preventable harm than those without these conditions.[49]

Human factors and systems engineering (HFSE) principles—focused on designing systems, tools, and processes based on an understanding of human capabilities—should be applied to the design of safer care delivery systems. This approach involves careful consideration of the interaction among technology, people, and work environments. AHRQ has funded more than 125 projects to apply HFSE principles to improving clinical processes and patient safety.[50] For example, one project analyzed videos of chest tube insertions to identify where disruptions in the sterile field occurred, and subsequently developed a best practices training module for staff. After receiving training on the new processes, post-operative complications (empyema) decreased from 15 percent to 4 percent.

Engaging providers. Provider engagement is critical to the success of any APM. Shared accountability is needed across the organization, with all types of providers involved—including physicians, nurses, and advanced practice providers—to be reflective of care teams with shared decision-making.

APMs can employ numerous methods to maximize provider engagement to ensure optimal success implementing patient safety improvements:

- Where possible, APMs should be multi-payer, striving to include as much of a provider's patient population as possible.
- Clear, clinically meaningful program goals should be established and communicated with providers.
- Measures should be parsimonious, generate real-time actionable data, and ensure that timely feedback is shared with providers. Providers should be empowered to act upon data. Seeing evidence of how their patient safety improvement efforts translate to patient harm reductions will further reinforce provider engagement.
- Safety improvements should be integrated into existing workflows, where possible, rather than introducing additional requirements.
- APMs should focus on partnering with providers to drive meaningful safety improvements rather than relying on compliance with external mandates. Emphasis should be on learning and improvement, not on surveillance and enforcement.
- A range of technical assistance (TA) options should be available to all participants, allowing flexibility to choose the TA resources that best support their needs. Peer-to-peer learning and national patient safety collaboratives should be supported to promote knowledge sharing. Providers and organizations should incorporate case reviews, safety huddles, and conferences focused on safety improvement processes.
- Providers should serve as safety leaders within their organizations, including presenting to senior leadership.

CMS should consider making patient safety models mandatory. Mandatory models may be needed to ensure operational redesign and promote broader accountability around patient safety. Health system providers and organizations that are well resourced and well positioned to succeed and earn financial incentives will be more inclined to participate in voluntary models; participation will be least likely among those who view the models as too challenging, too costly, or too long to realize improvements. Mandatory models would ensure that the providers most in need of improvement do not opt out. Related, it may not be necessary to make model participation mandatory for all providers. For example, mandatory participation could be concentrated among those providers who fall in the bottom quartile on patient safety systems and outcomes; an incentive bonus could be provided to those performing at or above the median to encourage their voluntary participation.

Data infrastructure. Patient safety improvement hinges on having a strong data infrastructure that relies on EHRs and HIEs. Strong infrastructure enables improved patient tracking and issue

identification. Three components of a strong data infrastructure to support patient safety are data quality and standardization, data sharing, and data interoperability.

- *Data Quality and Standardization.* The data which feed into the integrated data infrastructure need to be of high quality, standardized, consistent, and complete. CMS should continue to promote data standardization, such as using standard health care terminology (e.g., Systemized Nomenclature of Medicine – Clinical Terms [SNOMED CT], Logical Observation Identifiers Names and Codes [LOINC]), to encourage wide adoption of standardized, consistent, and high-quality data.
- *Data Sharing.* Challenges exist with sharing multiple data sources across different organizations, including ensuring that data sharing agreements are in place, standardizing different data sources collected across organizations, and ensuring that clear guidance is provided on the permissible uses of patient safety data. One mechanism that could be explored is the statutory protections provided under the Patient Safety and Quality Improvement Act of 2005 (PSQIA), which created Patient Safety Organizations (PSOs) that collect and analyze confidential health care data. The PSO data provide harm events and near misses and could be used by APMs.
- *Data Interoperability.* Improved interoperability across EHRs, payers, and health care systems requires broad adoption of HL7 FHIR standards. Many organizations do not have the financial resources necessary to invest in interoperability and data infrastructure improvements. A patient safety model should support investment in technology through upfront payments or other financial incentives so that these standards can be implemented.

Performance measures and reporting. Performance measurement for patient safety should focus on structure, process, and outcome measures that matter to patients and clinicians. Specifically, a patient safety measurement portfolio should include structural measures (e.g., organizational culture of safety), evidence-based process measures (e.g., checklists, monitoring), patient-reported and patient experience measures (e.g., perceptions of care received, ability to contact providers), and a focused set of outcome measures (e.g., serious preventable harm events, preventable readmissions). Measurement of team-based performance, such as coordination efforts across specialties and settings, also should be conducted.

It is vital to measure patient safety structures to ensure that organizations are promoting a culture of safety with participation and accountability at all levels. Structural measures, such as CMS' PSSM, should be included in a patient safety model. The PSSM measures an organization's ability to implement approaches that strengthen infrastructure and safety culture across five domains: leadership commitment to eliminating preventable harm, strategic planning and organizational policy, culture of safety and learning health system, accountability and transparency, and patient and family engagement.

Patient-reported experience and outcome measures have not been broadly used, but they are critically important, providing value by measuring what matters to patients, transparency by revealing potentially hidden harms, and accountability by making patient experiences measurable. It is important to include patients and their caregivers in the creation of patient-reported measures to ensure that what matters most to patients is being measured and identified. Recently, PFPS US, through its Project PIVOT, has focused on creating patient-reported experience and outcome measures, such as asking patients about whether they experienced unexpected harm, were treated differently due to personal characteristics, felt their concerns were dismissed, were informed of how to report a concern about patient safety, were informed of how to escalate care or obtain a second opinion, and were provided test results. These questions were developed for use in hospitals but are being refined to also apply to ambulatory care.

To increase the number of errors detected and decrease provider burden, patient safety models should rely heavily on the use of electronic and digital measures. Electronic measures enable organizations to monitor patient safety using data that are already part of the patient EHR. Electronic measures should be flexible in their design and allow for identification of areas where practices are not adhering to evidence-based protocols.

Payment methodology and financial incentives. Payment methodology and incentives should be structured to reward patient harm reporting, learning, and measurable improvements. Incentives should be based on patient safety process improvements rather than penalties for failures and mistakes. A desirable payment approach is one that incentivizes entities to identify and correct errors. On the other hand, penalizing when errors occur leads to organizations hiding and failing to report their errors.

Beyond incentives, APMs also should provide upfront funding to participating organizations and providers to support investment in patient safety system improvements. Many organizations need glide paths and upfront payments to invest in data infrastructure, technology, and other capabilities that can lead to improvements in patient safety. For example, it is important to provide meaningful incentives for organizations to adopt FHIR-compliant HIEs and electronic-based quality reporting. These types of investments help improve the timeliness and reliability of safety performance information. It is also important for organizations to invest in team-based care and systematic identification of communication and coordination failures across settings to prevent harm events. Upfront payments often are needed to help organizations make the necessary investment and implementation that yields real system transformation before incentives based on outcomes can play a role. Incentives that focus on system transformation and improvements, rather than end outcomes, also can facilitate the necessary changes.

Once upfront funding and glide paths have been established to allow APMs to invest in the needed data infrastructure and technology, potential options to structure ongoing APM payment methodology include shared savings and earn-back (or withhold) models. Shared

savings can serve as an important mechanism for patient safety payment models because implementing high-quality and safe practices will reduce the cost of care and decrease hospital admissions and readmissions, creating savings to circulate to organizations that demonstrate improvements in patient safety. The earn-back approach is where a portion of the provider's baseline payment for medical services is withheld. Providers can earn back their withheld funds by showing improvements in patient safety.

Incentives for providers to improve patient safety should be proactive rather than retrospective. Current payment mechanisms are designed retrospectively and punitively. Typically, harm is detected once it has already occurred, accountability is assigned, and a financial consequence is imposed on the accountable entity. It is more effective to design incentives that reward safety processes and capabilities rather than penalize for safety failures.

Providing upfront funding and strong, proactive incentives creates the willingness for organizations to invest in and adopt a culture of patient safety. However, caution is needed in using incentives in a way that could reduce or inhibit reporting of errors. Organizations must instill a culture that encourages sharing patient harms and near misses without fearing the consequences of reporting these errors.

APPENDIX 1. COMMITTEE MEMBERS AND TERMS

Terry L. Mills Jr., MD, MMM, *Co-Chair*
Soujanya R. Pulluru, MD, *Co-Chair*

Term Expires October 2026

Lauran Hardin, MSN, FAAN
HC² Strategies
Maysville, KY

Joshua M. Liao, MD, MSc
Ascension
Dallas, TX

Walter Lin, MD, MBA
Generation Clinical Partners
Saint Louis, MO

Terry L. Mills Jr., MD, MMM
Aetna Better Health of Oklahoma,
Strategic Health, LLC
Tulsa, OK

Term Expires October 2027

Henish Bhansali, MD, FACP
Independent Consultant
Chicago, IL

Lawrence R. Kosinski, MD, MBA
VOCnomics, LLC
Scottsdale, AZ

Soujanya R. Pulluru, MD
CP Advisory Services, My Precious Genes
Sarasota, FL

Krishna Ramachandran, MBA, MS
UnitedHealth Group
Piedmont, CA

Term Expires November 2028

Lindsay K. Botsford, MD, MBA
One Medical
Houston, TX

David Tyson, MA
Novant Health
Winston-Salem, NC

APPENDIX 2. CHARACTERISTICS OF SELECTED PTAC PFPM PROPOSALS IDENTIFIED AS BEING RELEVANT TO PATIENT SAFETY

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American Academy of Family Physicians (AAFP) *(Provider association and specialty society)* **Advanced Primary Care: A Foundational Alternative Payment Model (APC-APM) for Delivering Patient-Centered, Longitudinal, and Coordinated Care** Recommended for limited-scale testing, 12/19/2017	**Clinical Focus**: Primary Care **Providers**: Physicians with a primary specialty in family medicine, general practice, geriatric medicine, pediatric medicine, or internal medicine **Setting**: Primary care practices **Patient Population:** Medicare fee-for-service (FFS) beneficiaries	**Overall Model Design Features**: APC-APM builds on concepts tested through Comprehensive Primary Care (CPC) and CPC+ models. Primary care medical homes (PCMHs) work closely with patients' other health care providers to coordinate and manage care transitions, referrals, and information exchange. **Financial Methodology**: Capitated per-beneficiary-per-month (PBPM) with shared risk options for accountability **How Payment is Adjusted for Performance**: Participants assume performance risk. APMs that meet or exceed agreed-upon benchmarks retain incentive payment. Failure to meet benchmarks would involve repaying all or part of the incentive payment. **Approaches to Address Patient Safety**: Entities would be required to report on selected quality measures from the Core Quality Measures Collaborative's PCMH/Accountable Care Organization (ACO)/Primary Care Core Set that are tied to payment. However, the proposal does not mention specific patient safety measures. The authors also state that the model would support patient safety by making the primary attribution method be patient choice. Patients may leave the model at any time.
American Academy of Hospice and Palliative Medicine (AAHPM) *(Provider association/specialty society)* **Patient and Caregiver Support for Serious Illness (PACSSI)** Recommended for limited-scale testing, 3/26/2018	**Clinical Focus:** Serious illness and palliative care **Providers:** Palliative care teams (PCTs) **Setting:** Inpatient; outpatient; other palliative care settings **Patient Population:** Patients with serious illness	**Overall Model Design Features:** PACSSI proposes palliative care medical home services for high-need patients not yet eligible or not wanting hospice care. **Financial Methodology:** Monthly care management payments adjusted based on geographic location and site of care. There are two tracks: Track 1 – payment incentives and Track 2 – shared savings and shared risk. **How Payment is Adjusted for Performance:** Payments would be adjusted based on performance on quality and spending. **Approaches to Address Patient Safety:** Participants would be required to report on two quality measures regarding hospice election rates, patient-reported surveys, and certain processes of care. These measures would be linked to payment.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American College of Allergy, Asthma & Immunology (ACAAI) *(Provider association/specialty society)* **Patient-Centered Asthma Care Payment (PCACP)** Referred for other attention by HHS, 6/22/2020	**Clinical Focus:** Asthma care **Providers:** Allergists, immunologists, pulmonologists, primary care providers (PCPs), other providers **Setting:** Emergency department **Patient Population:** Patients with asthma and asthma-like symptoms	**Overall Model Design Features:** Supports asthma specialists, PCPs, and other providers to coordinate treatment of patients with asthma **Financial Methodology:** Bundled payments based on the severity of patient symptoms **How Payment is Adjusted for Performance:** Asthma Care Teams receive the default payment level for each patient if the team scored "good" on all performance measures; payments are increased or decreased (up to +/-5% to increase over time to +/-9%) if team scored "high" or "low" on some performance measures. **Approaches to Address Patient Safety:** Quality standards must be met to receive full bundled payments. However, the proposal does not list specific patient safety measures. The authors also mention providing patient education about proper use of medications.
American College of Emergency Physicians (ACEP) (*Provider association/specialty society*) **Acute Unscheduled Care Model (AUCM): Enhancing Appropriate Admissions** Recommended for implementation, 9/6/2018	**Clinical Focus**: Emergency medicine **Providers**: Emergency medicine physicians and advanced practice professionals **Setting**: Hospital emergency departments (EDs) **Patient Population**: Medicare FFS beneficiaries presenting in the ED	**Overall Model Design Features**: AUCM aims to coordinate care post-discharge from the ED. Several elements are adapted from the Comprehensive Care for Joint Replacement (CJR) and the BPCI Advanced Models. **Financial Methodology**: Episode-based, bundled payment; if spending for eligible and attributed episodes is less than the bundled payment target price, the participant is eligible for a positive reconciliation payment; if it is more, the participant will have to reimburse CMS. Also includes payment waivers for ED acute care transition services, telehealth services, and post-discharge home visits. **How Payment is Adjusted for Performance**: A composite quality score, including post-ED event rates and patient safety measures, determines whether participants are eligible for a reconciliation payment or if repayment to Medicare is warranted. **Approaches to Address Patient Safety:** Specific patient safety measures will be required, such as for post-discharge falls, adverse drug events, and post-surgery complications, and will be tied directly to payment.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American College of Physicians-National Committee for Quality Assurance (ACP-NCQA) *(Provider association and specialty society/other*) **The "Medical Neighborhood" Advanced Alternative Payment Model (AAPM) (Revised Version)** Recommended for testing to inform payment model development, 9/15/2020	**Clinical Focus**: Improved coordination in primary and specialty care practices **Providers**: Primary and specialty care practitioners **Setting**: Primary and specialty care practices **Patient Population**: Medicare FFS beneficiaries with multiple chronic conditions	**Overall Model Design Features**: The model builds on the CPC+, PCMHs, and patient-centered specialty practice (PCSP) concepts. **Financial Methodology**: Participants receive a monthly PBPM care coordination fee and a retrospective positive or negative payment adjustment. Track 1 includes fee-for-service payments, while Track 2 has a reduced fee-for-service payment and a comprehensive specialty care payment (CSCP). **How Payment is Adjusted for Performance**: Performance-based payment adjustment is based on spending relative to a financial benchmark, adjusted for performance on quality and utilization metrics. **Approaches to Address Patient Safety:** NCQA would regularly review PCSP standards and rescind PCSP status if the review identified a patient safety threat. The model would include various patient experience measures, as well as National Healthcare Safety Network measures to detect if patients acquired methicillin-resistant Staphylococcus aureus **(**MRSA) bacteria and/or other HAIs when in the hospital.
The American College of Surgeons (ACS) *(Provider association/specialty society)* **The ACS–Brandeis Advanced Alternative Payment Model** Recommended for limited-scale testing, 4/11/2017	**Clinical Focus**: Cross-clinical focus with sets of procedural episodes of care **Providers**: Single or multispecialty practices and groups of small provider practices **Setting**: Inpatient, outpatient, ambulatory **Patient Population**: Medicare FFS beneficiaries from over 100+ conditions or procedures	**Overall Model Design Features**: Focused on procedural episodes, leveraging the Episode Grouper for Medicare (EGM) software developed by CMS and Brandeis University, the model is based on shared accountability, integration, and care coordination. **Financial Methodology**: Retrospective payment that compares episode target prices to the actual cost of the care provided **How Payment is Adjusted for Performance**: Performance (e.g., unacceptable, acceptable, good, excellent) determines the shared savings retained by the APM entity or the amount to repay CMS for losses. **Approaches to Address Patient Safety:** ACS proposed to monitor and compare care levels and outcomes across participants to identify participants with potential gaps in care that may be indicative of delayed or missed care. The authors also suggested creating a potentially avoidable adverse event measure.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
American Society of Clinical Oncology (ASCO) *(Provider association/specialty society)* **Patient-Centered Oncology Payment Model (PCOP)** Recommended for testing to inform payment model development, 9/15/2020	**Clinical Focus:** Oncology **Providers:** Clinicians, including hematologists and oncologists **Setting:** Oncology specialty practices **Patient Population:** Oncology practice patients	**Overall Model Design Features**: The model proposes to create PCOP communities that include several providers, payers, and other entities to provide high-quality, coordinated care. **Financial Methodology**: Providers receive three payments: monthly care management payments (CMPs), performance incentive payments (PIPs), and adjustments to FFS reimbursement. A portion of the CMP will be allocated to a PIP. PIPs will be positively or negatively adjusted based on provider success in adherence to clinical treatment pathways, quality metrics, and cost reduction. There are two tracks: Track 1 participants continue to receive FFS reimbursement in addition to the CMPs; Track 2 participants participate in the Consolidated Payments for Oncology Care (CPOC) where practices can bundle 50% or 100% of the value of specified services. 10% of the amount bundled will be subject to the same performance adjustment as PIPs times a 1.4 multiplier. **How Payment is Adjusted for Performance**: If providers do not meet minimum expectations, CMP and PIP amounts may be suspended, and providers will need to develop an improvement plan. **Approaches to Address Patient Safety:** Entities would be required to follow ASCO's Quality Oncology Practice Initiative (QOPI) safety standards for chemotherapy administration. Entities must also have a process for implementing follow-up visits and tests as the authors cite failure to follow up as an important patient safety issue.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Avera Health (*Regional/local multispecialty practice or health system*) **Intensive Care Management in Skilled Nursing Facility Alternative Payment Model (ICM SNF APM)** Recommended for implementation, 3/27/2018	**Clinical Focus**: Geriatric primary care for residents in long-term care **Providers**: Geriatric care teams that include geriatricians, PCPs, nurses, social workers, pharmacists **Setting:** Skilled nursing homes and long-term care facilities **Patient Population**: Medicare FFS beneficiaries in skilled nursing homes or long-term care facilities	**Overall Model Design Features**: Provides access to a geriatrician-led care team through telemedicine; provides geriatric care management and management of care transitions; and mentors and trains long-term care staff **Financial Methodology**: One-time payment for new admission care and a PBPM payment for post-admission care. Two payment method options are proposed for the model: 1) a *performance-based payment* adjusted on quality performance; and 2) a *shared savings model* with an annual financial reconciliation. **How Payment is Adjusted for Performance**: In the *performance-based payment* option, payments are adjusted positively or negatively by the ability to meet performance criteria. **Approaches to Address Patient Safety:** The model would require patient safety metrics, such as percentage of patients who had a catheter left in their bladder, who were physically restrained, who fell and sustained a major injury, or who have pressure ulcers. Entities must be above the 50th percentile or not decrease more than 5% per year for at least eight of the 13 required measures or they will be removed from the model.
Coalition to Transform Advanced Care (C-TAC) (*Coalition*) **Advanced Care Model (ACM) Service Delivery and Advanced Alternative Payment Model** Recommended for limited-scale testing, 3/26/2018	**Clinical Focus**: Advanced illness, palliative care, end-of-life care **Providers**: PCPs, specialists **Setting**: Hospitals, health systems, hospices, home health **Patient Population**: Medicare FFS beneficiaries with advanced illness in the last year of life	**Overall Model Design Features**: An interdisciplinary care team implements the ACM care delivery services. **Financial Methodology**: A non-tiered PMPM payment with downside risk for total cost of care (TCOC) and an upside bonus for quality, subject to maximum payment and loss amounts **How Payment is Adjusted for Performance**: Pay-for-quality structure, where participants are eligible for a quality-based bonus funded by shared savings and determined by performance measure performance **Approaches to Address Patient Safety:** The model proposes to address patient safety by offering care coordination approaches and monitoring quality measures. However, the proposal does not include specific patient safety measures.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Dialyze Direct *(Regional/local single specialty practice)* **APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities** Recommended for attention, 9/6/2018	**Clinical Focus:** End-stage renal disease (ESRD) **Providers:** Nephrologists **Setting:** Skilled nursing facilities (SNFs) **Patient Population:** Geriatric dialysis patients residing in SNFs	**Overall Model Design Features:** Nephrologists provide ESRD beneficiaries who reside in SNFs with home hemodialysis services. **Financial Methodology:** Bundled payment model with ability to receive shared savings, as well as a one-time additional payment for efforts related to educating patients on the benefits of on-site staff-assisted home dialysis in the nursing home **How Payment is Adjusted for Performance:** N/A **Approaches to Address Patient Safety:** Complications of transportation, such as falls or fractures that occur, would be a measure. The authors mention that they would perform a study to accurately develop other measures that pertain specifically to the ESRD population that resides in SNFs, which is known to have a higher prevalence of comorbidities, be older, and be more frail.
Hackensack Meridian Health and Cota, Inc. (HMH/Cota) *(Regional/local multispecialty practice or health system; Device/technology company)* **Oncology Bundled Payment Program Using CNA-Guided Care** Recommended for limited-scale testing, 9/8/2017	**Clinical Focus:** Oncology **Providers:** Clinicians with admitting privileges in the Hackensack Meridian Health (HMH) health system **Setting:** HMH health system that includes hospitals, home health, rehabilitation clinics, skilled nursing facilities, and mental health facilities **Patient Population:** Medicare patients with breast, colon, rectal, or lung cancer attributed to clinicians in the HMH health system	**Overall Model Design Features:** This is an oncology bundled payment model in which care choices are modulated by the prior outcomes of similar patients from real-world data. This process is called Cota Nodal Address (CNA) guided care. **Financial Methodology:** Prospective payment is provided to HMH for patients participating in the model. HMH bears the risk of bundled payments and distributes payments to physicians. **How Payment is Adjusted for Performance:** Compensation is, in part, incentive-based and determined by the achievement of clinical quality and patient satisfaction outcomes. **Approaches to Address Patient Safety:** HMH performed analysis and learned that patients who see their doctors before starting chemotherapy treatment have fewer occurrences of toxicity compared to those patients who do not see their provider or see their provider not right before starting chemotherapy. There are also several patient safety measures included, such as biopsy review completed within 48 hours, documentation of post-operation vomiting and pain scores, presence of pressure sores, monitoring for infections, and falls/falls with injury.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Johns Hopkins School of Nursing and the Stanford Clinical Excellence Research Center (Hopkins/Stanford) *(Academic institution)* **CAPABLE Provider Focused Payment Model** Recommended for testing as specified in PTAC comments, 9/6/19	**Clinical Focus:** Chronic conditions and functional limitations **Providers:** Interdisciplinary team of an occupational therapist, registered nurses, and a handy worker **Setting:** Home and community-based settings **Patient Population:** Medicare FFS beneficiaries with at least two chronic conditions and difficulty with at least one activity of daily living	**Overall Model Design Features**: A time-limited intervention performed by an interdisciplinary team to target specific functional goals, perform limited home repairs and modifications, and address common geriatric concerns **Financial Methodology:** Partial bundled payment with partial upside, moving toward a fully capitated model of care **How Payment is Adjusted for Performance:** A bonus for meeting quality metrics would be awarded. **Approaches to Address Patient Safety:** The authors highlighted that the CAPABLE Model is a patient safety approach because it aims to improve the ability for older adults to take care of themselves at home. It has been approved by the National Council on Aging as a fall prevention program. The model would include metrics such as home hazard or fall risk.
Illinois Gastroenterology Group and SonarMD, LLC (IGG/SonarMD) *(Regional/local single specialty practice; Device/technology company)* **Project Sonar** Recommended for limited-scale testing, 4/10/2017	**Clinical Focus**: Chronic disease (Crohn's disease) **Providers**: Specialty physicians **Setting**: Outpatient settings and specialty care practices **Patient Population**: Medicare FFS beneficiaries	**Overall Model Design Features**: The model integrates evidence-based medicine with proactive patient engagement. It allows physicians to participate in chronic disease management that is not triggered by a surgical procedure or on an inpatient or outpatient basis. **Financial Methodology**: Add-on PBPM payment with two-sided risk, plus a payment to support remote monitoring **How Payment is Adjusted for Performance**: Payments would be adjusted based on quality and financial performance. **Approaches to Address Patient Safety:** Project Sonar references patient engagement to aid in decreasing patient safety concerns.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Innovative Oncology Business Solutions, Inc. **(IOBS)** *(For-profit corporation)* **Making Accountable Sustainable Oncology Networks (MASON)** Referred for further development and Implementation, 12/10/2018	**Clinical Focus**: Oncology **Providers**: Oncologists, surgeons, PCPs, pathologists, radiologists **Setting**: Oncology practices **Patient Population**: Medicare FFS beneficiaries	**Overall Model Design Features**: Builds off the Community Oncology Medical Home (COME HOME) CMS Innovation Center project **Financial Methodology**: Determined by the oncology payment category (OPC), consisting of FFS payments for physician visits, imaging, lab, radiation therapy, surgery; infusion with a facility fee; ambulatory payment classifications (APCs) for hospital outpatient care; diagnosis-related groups (DRGs) for inpatient care; and the PCOP for medical home infrastructure **How Payment is Adjusted for Performance**: 2% of the OPC, which includes all expenses related to cancer care except drugs, is reserved for a quality pool. If quality measures are not met, the 2% is not rewarded. **Approaches to Address Patient Safety:** COME HOME, the program this model builds from, measured patients who went to different care sites than expected (e.g., office instead of ED) and found that patients experienced no harm when visiting the doctor's office versus the ED.
Large Urology Group Practice Association (LUGPA) *(Provider association and specialty society)* **LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer** Not recommended, 2/28/18	**Clinical Focus:** Urology/Oncology (treatment of prostate cancer) **Providers:** Eligible professionals (including urologists) at large and small urology and multispecialty practices **Setting:** Large and small urology and multispecialty practices **Patient population:** Newly diagnosed prostate cancer patients with localized disease	**Overall Model Design Features**: The model aims to identify those newly diagnosed prostate cancer patients with low-risk localized disease to receive active surveillance rather than active intervention. **Financial Methodology**: An episode-based payment that would retrospectively compare actual initial episode spending against a target amount **How Payment is Adjusted for Performance**: Participants earn performance-based payments or owe performance-based repayments based on the number of quality performance targets achieved/exceeded. **Approaches to Address Patient Safety:** LUGPA proposes several quality measures, such as biopsy follow-up and avoidance of overuse of bone scan. However, the proposal does not list specific patient safety measures.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Icahn School of Medicine at Mount Sinai (Mount Sinai) (*Academic institution*) **"HaH-Plus" (Hospital at Home-Plus): Provider-Focused Payment Model** Recommended for implementation, 9/17/2017	**Clinical Focus**: Inpatient services in the home setting **Providers**: Physicians and HaH-Plus providers, including nurse practitioners, registered nurses, social workers, and physical, occupational, and speech therapists **Setting**: Patient homes **Patient Population**: Medicare FFS beneficiaries who have one of the 44 acute conditions	**Overall Model Design Features**: Multidisciplinary care around an acute care event to reduce complications and readmissions **Financial Methodology**: Bundled payment covering the acute episode and an additional 30 days of transition services. Two components are in the payment model: 1) a new DRG-like HaH-Plus payment to substitute for the acute inpatient payment to the hospital and attending physician; and 2) the potential for a performance-based payment linked to the total Medicare spend for the entire HaH-Plus episode and the APM performance on quality metrics. **How Payment is Adjusted for Performance**: The APM entity's performance on quality metrics influences payment. **Approaches to Address Patient Safety:** The authors propose to track adverse events metrics, such as occurrence of various infections, pressure ulcers, falls, and adverse drug reactions. Furthermore, all adverse events must be reported within 24 hours of occurrence for review by a medical director, as well as an independent provider.
New York City Department of Health and Mental Hygiene (NYC DOHMH) *(Public health department)* **Multi-provider, bundled episode of care payment model for treatment of chronic hepatitis C virus (HCV) using care coordination by employed physicians in hospital outpatient clinics** Not recommended, 12/18/2018	**Clinical Focus**: Hepatitis C virus (HCV) **Providers**: Primary care and internal medicine physicians (infectious disease specialists, gastroenterologists) **Setting**: Hospital-based outpatient clinics **Patient Population**: Patients with HCV	**Overall Model Design Features**: The Project INSPIRE Model proposes integrated medical, behavioral, and social services for patients with HCV. **Financial Methodology**: Bundled payment with the opportunity for shared savings **How Payment is Adjusted for Performance**: Additional shared savings are awarded for being a "high-performing facility" based on their sustained virological response (SVR) score. **Approaches to Address Patient Safety:** The proposal references that patient safety is addressed through the use of a care coordinator, as well as the ability to modify shared savings rates to incentivize provider behavior and decrease potential care stinting. The proposed model does not list specific patient safety measures. It also does not include patient-reported outcome measures.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group Inc. (PMA) (*Regional/local single specialty practice*) **The COPD and Asthma Monitoring Project (CAMP)** Not recommended, 4/11/2017	**Clinical Focus:** COPD and/or asthma **Providers:** Pulmonary physicians **Setting:** Patient home **Patient Population:** COPD and asthma patients	**Overall Model Design Features**: The model proposes remote interactive monitoring for patients with COPD, asthma, and other chronic lung diseases. **Financial Methodology**: Two-sided risk arrangement that would permit CMS to recoup up-front costs first and then allow participants to share in remaining savings or losses up to a stop loss percentage amount **How Payment is Adjusted for Performance**: The proposal does not specify how quality measures would affect payment. **Approaches to Address Patient Safety:** The proposal mentions that there will be several checks in place to ensure that patients are not neglected; however, specific details are not provided. The proposal also does not include specific patient safety measures.
Personalized Recovery Care (PRC) (*Regional/local single specialty practice*) **Home Hospitalization: An Alternative Payment Model for Delivering Acute Care in the Home** Recommended for implementation, 3/26/2018	**Clinical Focus**: Inpatient services in the home setting or skilled nursing facility **Providers**: Admitting physicians at facilities receiving personalized recovery care (PRC) payments; on-call physicians; recovery care coordinators **Setting**: Patient home or skilled nursing facility **Patient Population**: Commercial and Medicare Advantage patients with one of 150 acute conditions	**Overall Model Design Features**: This is a home hospitalization care model that proposes to provide inpatient hospitalization-level care and PRC at home or a skilled nursing facility for patients with certain conditions through an episodic payment arrangement. **Financial Methodology**: Bundled episode-based payment not tied to an anchor admission, replacing FFS with shared risk. Bundled payment has two components: 1) risk payment for delivering care compared to the targeted cost of care; and 2) a per-episode payment made for care provided instead of an acute care hospitalization. **How Payment is Adjusted for Performance**: To be eligible for shared savings, providers must meet or exceed benchmarks for performance measures. Participants are eligible to receive 20% of savings for each measure that meets or exceeds the benchmark. Participants receive 100% of savings if all five performance measures are met (0% if none are met). **Approaches to Address Patient Safety:** The authors cite that because the care takes place at home and not in a hospital, hospital-acquired infections and other conditions are avoided. Care coordinators would have substantial involvement and engagement with patients to ensure patient safety. The proposed model would also offer a compliance hotline number where patients can formally report patient safety concerns and issues. Specific patient safety measures are also included, such as the percentage of episodes with adverse events (e.g., pressure ulcers, falls with injury) and medication reconciliation.

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
Renal Physicians Association (RPA) (*Provider association and specialty society*) **Incident ESRD Clinical Episode Payment Model** Recommended for implementation, 12/18/2017	**Clinical Focus**: ESRD **Providers**: Nephrologists, PCPs **Setting**: Dialysis centers **Patient Population**: Medicare patients with ESRD	**Overall Model Design Features**: Condition-specific, episode-of-care payment model for ESRD patients during the first six months of dialysis therapy that promotes coordination, patient choice for treatment, chronic kidney disease (CKD) patient education, quality of life, and advanced care planning **Financial Methodology**: Episode of care payment model with shared savings achieved over the entire six-month episode of care. There is also a one-time bonus payment for nephrologists to facilitate a patient receiving a kidney transplant preemptively or during the episode of care. **How Payment is Adjusted for Performance**: Physicians' quality scores based on performance on patient-centered quality measures determine the percentage of overall shared savings the physician receives. The higher the quality score, the higher amount of shared savings received. **Approaches to Address Patient Safety:** The proposal describes that interventions, such as this proposed model, that keep patients out of the hospital improve patient safety because there is decreased risk of hospital-acquired infections. Additionally, avoiding use of hemodialysis catheters decreases risk of catheter infections. RPA also developed a kidney patient safety resource for nephrologists. The proposal references quality measures specific to the care of ESRD patients, including home dialysis percentage and patient experience measures, but does not list specific patient safety measures.
University of Chicago Medicine (UChicago) *(Academic Institution)* **The Comprehensive Care Physician Payment Model (CCP-PM)** Recommended for limited-scale testing, 9/7/2018	**Clinical Focus**: Frequently hospitalized patients **Providers**: Inpatient and outpatient providers **Setting**: Home care and rehabilitation **Patient Population**: Medicare beneficiaries who are at high risk for hospitalization	**Overall Model Design Features**: The model seeks to coordinate care for patients at risk for hospitalization by having one physician to provide inpatient and outpatient care. **Financial Methodology**: Add-on PBPM payment with shared risk **How Payment is Adjusted for Performance**: Providers will continue to be incentivized or penalized for quality outcome measures based on their APM or MIPS participation. **Approaches to Address Patient Safety:** The proposal describes that it ensures patient safety by reducing the transitions of care between inpatient and outpatient settings and providing coordination (e.g., one provider responsible for both inpatient and outpatient care).

Proposal Name	Clinical Focus, Providers, Setting, Patient Population	Value-Based Care Components
The University of New Mexico Health Sciences Center (UNMHSC) (*Academic institution*) **ACCESS Telemedicine: An Alternative Healthcare Delivery Model for Rural Emergencies** Recommended for implementation, 9/16/2019	**Clinical Focus**: Cerebral emergency care; telemedicine **Providers**: Neurologists, neurosurgeons, and providers in rural and community systems **Setting**: Inpatient, outpatient, or emergency department **Patient Population**: Patients with neurological emergencies	**Overall Model Design Features**: Rural EDs can consult neurologists via teleconsultation and assess patients' condition when they present at the hospital ED. The model aims to reduce costs in hospital transfers and ambulatory medicine. **Financial Methodology**: Additional one-time payment without shared risk **How Payment is Adjusted for Performance**: Performance is monitored but does not impact payment. **Approaches to Address Patient Safety:** The authors propose that there would be a process in place to verify patient identification and to obtain written consent for telemedicine. Additionally, education and resources, such as neuroscience workshops and technology education, would be provided to all clinical staff to ensure competency of staff. Model leaders would perform a systematic review to ensure that clinical guidelines are being followed.
Upstream Rehabilitation (Regional/local single specialty practice) **CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients** Not recommended, 5/11/2019	**Clinical Focus:** Chronic wound care **Providers:** Physical and operational therapists **Setting:** Physical and occupational therapy centers **Patient Population:** Medicare patients with chronic wounds	**Overall Model Design Features:** Physical and occupational therapists will provide chronic wound care services in outpatient therapy clinics. **Financial Methodology:** Providers would track the total cost of and time in treatment for each patient, to include wound care supplies. CMS would allow providers to be reimbursed $250 per patient for wound care supplies and to bill for advanced therapeutics (e.g., bioengineered dressings). **How Payment is Adjusted for Performance:** Claim refunded to CMS if minimum standards of improvement are not met. Clinicians can receive a 3% savings bonus for achieving average reimbursement costs below risk-adjusted thresholds. **Approaches to Address Patient Safety:** The proposal would measure rates of infection, patient level of pain, and patient satisfaction.

APPENDIX 3. ADDITIONAL RESOURCES RELATED TO PTAC'S THEME-BASED DISCUSSION ON TARGETING IMPROVEMENTS IN PATIENT SAFETY THROUGH ALTERNATIVE PAYMENT MODELS

The following is a summary of additional resources related to PTAC's theme-based discussion on targeting improvements in patient safety through Alternative Payment Models. These resources are publicly available on the ASPE PTAC website:

Environmental Scan

Environmental Scan on Targeting Improvements in Patient Safety Through Alternative Payment Models

Request for Input (RFI)

Targeting Improvements in Patient Safety Through Alternative Payment Models — Request for Input (RFI)

Materials from the Public Meetings

Materials from the Public Meeting on June 15, 2026

Presentation: Targeting Improvements in Patient Safety Through Alternative Payment Models — Preliminary Comments Development Team Findings

Presentation: Session 1 Slides

Presentation: Session 2 Slides

Presentation: Session 3 Slides

Session Participants' Biographies

Session 1 Discussion Guide

Session 2 Discussion Guide

Session 3 Discussion Guide

Materials from the Public Meeting on June 16, 2026

Presentation: Session 4 Slides

Session Participants' Biographies

Session 4 Discussion Guide

Other Materials Related to the Public Meeting

Public Meeting Minutes

Public Meeting Transcripts

APPENDIX 4. SUMMARY OF PTAC COMMENTS ON TARGETING IMPROVEMENTS IN PATIENT SAFETY THROUGH ALTERNATIVE PAYMENT MODELS

The Committee's comments have been summarized in the following broad topic areas:

- Current State: Challenges With the Delivery of Safe Health Care;
- Future State: Striving for Zero Preventable Harm; and
- Action: Options to Improve Patient Safety.

Current State: Challenges With the Delivery of Safe Health Care	
1A	While there is risk in trying something new to improve patient safety, there is equal or greater risk in not trying something new.
1B	Current measures of patient safety show improvement. However, in the aggregate, patient safety is not improving. Only a percentage of what should be measured is actually measured.
1C	Errors of omission may be more significant than errors of commission.
1D	An idea shared by one of the SMEs is noteworthy – the absence of measurable harm is not necessarily the presence of safety.
1E	Practicing clinicians may not consider patient safety a part of clinical quality. Making a distinction between quality and safety may be more useful for clinicians compared with wider audiences.

Future State: Striving for Zero Preventable Harm	
2A	A strong safety culture depends on transparency, psychological safety, and encouraging clinicians and organizations to report harm, adverse events, near misses, and unsafe conditions without fear of blame.
2B	The policy tools and the legal framework needed to improve patient safety already exist.
2C	To improve patient safety, culture needs to change on an individual- and team-level basis.
2D	The preconditions to improve patient safety, such as technology, information, and regulatory framework policies, already exist. What is needed to improve patient safety is willpower.
2E	An idea shared by one of the SMEs is noteworthy – where safety is a non-revenue generating cost center. Changing culture across multiple services, including hospitals, primary care, and ambulatory settings, is needed to improve patient safety.
2F	Provider experience should be addressed. A more positive term, such as a "safety quotient," should be used in place of the term "error." A negative focus on errors may delay improvement in safety culture.
2G	There are potential benefits of collaborating with CEOs and CFOs to encourage patient safety. These individuals run large health systems and employ physicians across the country. Safety issues that occur in integrated delivery systems are often subsumed into risk management. Chief counsels, compliance officers, and the risk safety community should be included in efforts to improve patient safety.

Future State: Striving for Zero Preventable Harm	
2H	Lessons on patient safety can be learned from other industries, such as the airline industry, law enforcement, and athletics.
2I	One organization improved its reliability, enabling the organization to provide a warranty for heart surgeries.
2J	Real-time patient reporting provides an opportunity to improve patient safety. The integration of AI and the expansion of technology provide an opportunity to use prospective systems and continuous risk assessment.
2K	Patients and families observe safety risks that the system often misses. PROMs and PREMs can serve as important safety signals for providers.
2L	Patients should have a role in safety reporting structures. The current infrastructure does not have a standard mechanism to capture, measure, respond to, or assign accountability to patients' safety reports.
2M	PROMs and PREMs should be a standard part of the data set for patient experience, monitoring, and quality data reporting. There are opportunities to increase the use of standardized questions for different domains of patient safety.
2N	There are opportunities to design systems that capture patients' and families' voices at the point of care to identify risk in real time. It is important to make identifying and elevating risk safe for patients and families so that they do not fear abandonment or being labeled by the system.
2O	Shifting the focus of patient safety away from the hospital environment and toward the ambulatory environment will support a more longitudinal view of patient safety. Understanding patient safety can be difficult in the ambulatory environment because of small sample sizes. Capturing some types of patient safety errors requires longitudinal assessment because the results of some errors can take time to appear.
2P	AI should be used responsibly to advance patient safety, such as by increasing reporting and supporting follow-up. AI should be incorporated into model features.
2Q	The evolution of an automated trigger tool to identify and measure patient safety is interesting. There may be opportunities to incorporate these types of trigger tools into model features.
2R	Safety is broader than avoiding adverse events; patient safety includes errors of omission, diagnostic errors, communication failures, and unsafe transitions of care across settings.
2S	AI can improve patient safety by decreasing cognitive burden, identifying risk earlier, and increasing the predictability of safety issues before they become harm events.
2T	The technology necessary for improving patient safety already exists. It is important to improve safety culture, integrate AI, and monitor errors.
2U	Improving patient safety will require attention, payment, and innovation. AI can materially change patient safety, specifically by supporting early detection and warning systems.
2V	Collaboration and coordination are needed to improve patient safety.
2W	It is important to address challenges in the workforce, such as administrative burden, stress, and having the right information at the point of care to inform decisions.

Future State: Striving for Zero Preventable Harm	
2X	The core components of improving patient safety include longitudinal care coordination, interdisciplinary team engagement, and integration of behavioral health. The core components of design that result in change are learning systems and a focus on safe system design.
2Y	Patient safety is not a standalone issue; harm often results from system failures.

Action: Options to Improve Patient Safety	
3A	An incremental approach may be needed to improve patient safety. Providers would benefit from having tools, not more regulations. There is a need to convene EHR vendors, as well as those who will implement and pay for EHRs. Doing so could help develop a solution to incrementally employ and build a culture of change.
3B	There is a need to standardize data and infrastructure. Data should be more easily accessible. CMS could drive standardization efforts.
3C	EHRs should be provider- and patient-centric and not contribute to provider burden. Cognitive burden from documentation can increase safety risks.
3D	An incentive structure is needed to support individuals being trained in patient safety.
3E	Overall, a mandatory approach may be needed to improve patient safety; however, the source of the payment remains unclear.
3F	The use of prospective payments and a regulatory intervention may be two strategies to improve patient safety.
3G	A mandatory approach may be needed to improve patient safety. Providers will opt out if a model is too challenging or if their journey to improve will be too long. As an example, a new APM could be mandatory for hospitals in the bottom quartile of patient safety mechanisms, and then a bonus incentive could be provided for those already performing at or above the median. These levers could be used independently; mandatory participation does not have to be implemented for all providers.
3H	Rewards rather than penalties may motivate systems change. Evidence shows that investments in Meaningful Use resulted in a large-scale transformation and integration of EHRs. There are opportunities to assess the types of investments that will motivate change.
3I	Patient safety should be embedded into APMs either as a core objective or as the primary focus of a model.
3J	Value-based care and APMs have a unique opportunity to make patient safety risks visible and actionable. Historically, however, payment models have not improved patient safety. Improvements in patient safety depend on professionalism, continuous quality improvement, a culture of safety, and learning.
3K	Patient safety should be integrated into all CMS models and programs. There is also merit in developing a specific patient safety model.
3L	Payment models align incentives to shape different areas of focus in the health care delivery system. It is time to reinvigorate a focus on patient safety. Patient safety can first be introduced parsimoniously into existing models. If this approach does not work well or does not reach the intended scale, then efforts should focus on creating a dedicated patient safety model with high intensity, such as using mandates or withholds.

Action: Options to Improve Patient Safety	
3M	There were six actionable steps described by Dr. Patrick Romano during the public comment period: safety should be part of all APMs; there should be a balanced approach across multiple measures; there should be a graded approach to the money at stake; innovation in infrastructure and measurement should be promoted; providers should be engaged from the bottom up with alignment in actionability and accountability; and unintended consequences should always be considered).
3N	Improving patient safety is about changing culture. Culture change is slow, measured in years, and incremental. This multi-year, incremental process should be considered when incorporating patient safety into existing models as well as developing a specific model. Incentives, either upside or downside, will need to gradually increase in bonus or severity over the multi-year period.
3O	Payment models must be structured correctly. Patient safety needs to be part of every value-based care model in addition to EHR integration, patient engagement, and care coordination.
3P	Improving patient safety nationally may require both a bottom-up and top-down approach. ○ Working from the bottom up, it is important to ensure that the right measurement is used. Interoperable, real-time, predictive, and prospective data should be used. Additionally, patient-report data should be used. The power of AI should be leveraged to synthesize and syndicate data to make data actionable. Current certification mechanisms can be used to train providers and physicians in various specialties. Patient safety can be embedded into current APMs to some degree. ○ Working from the top down, it is important to have a top-down initiative that is led by CMS, the director, and leadership to ensure national attention on patient safety. Using a top-down approach can involve developing a framework to both embed patient safety in existing models and programs and create a new model focused on patient safety. There may be a way to embed patient safety into multiple levels by using a bottom-up approach that leverages what already exists as the chassis while also developing a new model.
3Q	There may be ways to emphasize patient safety in existing models, potentially by using existing quality measures that assess safety. For example, some medication reconciliation measures promote the avoidance of errors.
3R	There are opportunities to align APMs with existing certification programs as opposed to designing entirely new models or programs. This could be a place to start the process of improving patient safety.
3S	A concrete payment model focused on patient safety has not been described, potentially indicating that more work is needed before developing a model.
3T	There may be opportunities to use waivers to create a model.
3U	Models should also align with what matters most to patients, families, and purchasers without encouraging underreporting, risk avoidance, or stinting on care.
3V	It is important to consider administrative burden, cognitive overload, and operational fragility of the system when considering adding new expectations.
3W	Health care is in a technological revolution. Advances in AI may provide an inflection point in the implementation of care redesign.

Action: Options to Improve Patient Safety	
3X	Process measures and systems may be more important than outcome measures to drive a culture of safety.
3Y	Care coordination and transitions of care are not typically built in as required or mandatory metrics in CMS and CMS Innovation Center models, despite a large body of evidence supporting care coordination and transitions of care. These measures could be prominently featured in models.
3Z	Payment models should reward reporting, learning, corrective action, and measurable improvement.
3AA	Linking payment to patient safety may hinder improvement in patient safety, as some payments can incentivize the wrong action and encourage gaming the system. Although payment models have historically not substantially improved patient safety, funding or payment is still needed to improve patient safety. This funding or payment could be provided through a payment model or through a different type of investment, such as investment in tools and systems that support a culture of safety. For example, AI, EHR investment, and human factors designs could potentially lead to more improvements in patient safety relative to payment models.
3AB	Shared savings could be used for patient safety rather than financially penalizing providers.
3AC	Approaches to incentivize tactical, on-the-ground full-time equivalents (FTEs) and how to include safety officers as part of an incentive structure should be considered.
3AD	Shared savings may serve as a mechanism to improve patient safety.
3AE	There may be a need for initial investment in patient safety to increase process and capability performance.
3AF	Incentive structures should not make penalties less expensive than implementing safety programs. It should be difficult to take the wrong action and easy to take the right action. It is currently too easy for CFOs to take penalties without building the system to support patient safety.
3AG	As opposed to penalties for unsafe environments, payment to invest in infrastructure—including data, technology, and the capability for safety—may help improve patient safety.
3AH	When considering approaches beyond penalties, it is important to understand that delays in payment or withholds can be a penalty for many systems.
3AI	A two-tailed model could be used where there is an upside bonus for providers already performing at or above the median, and there is a downside risk loss prevention mechanism for providers performing at the bottom.
3AJ	A patient safety model would need to ensure that the magnitude of the fee or penalty for poor performance is worse than not trying to improve patient safety.

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